G2 INTELLIGENCE

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ACLA Calls on Congress for Relief From Medicare Lab Fee Cuts

Medicare lab reimbursement has been cut by 62 percent in real (inflation-adjusted) dollars since the Part B lab fee schedule debuted in 1984, ACLA said. A test reimbursed at $10 then is paid at $8.32 today but would have been paid at $21.72 if adjusted for inflation using the original update formula.

In a March 6 letter to House Majority Leader John Boehner (R-Ohio) and Senate Majority Leader Harry Reid (D-Nev.), the American Clinical Laboratory Association (ACLA) asks that the current level of cuts to Medicare lab fees be revisited and relief provided.

Under current law clinical labs face a reduction in Medicare payments approaching 23 percent over the next 10 years.

ACLA warns that the cumulative effect of cuts on the books threatens the ability of clinical labs to continue serving beneficiaries, especially those that are the sole provider in rural areas and to nursing home and homebound populations.

The causes are threefold:

- ❑ The revised annual update formula for the Part B lab fee schedule, enacted by the Patient Protection and Affordable Care Act of 2010 (PPACA) and effective in 2011;
- ❑ The 2 percent cut in 2013 to help pay for a physician fee fix, enacted in the Middle Class Tax Relief and Job Creation Act of 2012; and
- ❑ The 2 percent automatic cut (or sequestration) over the next 10 years required by the Budget Control Act of 2011.

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INSIDE *NIR*

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CAP to Congress: 'Restore Pathology TC Grandfather Protection'

It is a long shot, Washington sources tell *NIR*, but nonetheless the College of American Pathologists (CAP) wants Congress to reverse itself and restore the pathology grandfather protection, which under current law is to expire June 30 this year.

Though slated to lapse Feb. 29, Congress gave it a four-month lease on life as part of the Middle Class Tax Relief and Job Creation Act of 2012, which the president signed into law Feb. 22.

The grandfather protection allows certain independent clinical laboratories to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when Medicare officials first proposed to eliminate the direct billing, saying this amounts to duplicate payment.

Under the new law, affected labs must turn to the hospital, not Part B, for reimbursement. The hospital will get no additional reimbursement since the TC is considered part of the hospital's prospective payment.

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ACLA Calls on Congress for Relief, *from p. 1*

Under PPACA, the annual update to the lab fee schedule is the consumer price index for all urban consumers (CPI-U, determined by the rate published June 30 of the previous year by the Bureau of Labor Statistics); minus a productivity adjustment (though the law guarantees that this adjustment, currently an estimated 1.3 percent, will never result in an update below 0 percent); minus an additional cut of 1.75 percent from 2011 through 2015, which can cause the update to fall below 0 percent.

The Middle Class Tax Relief and Job Creation Act of 2012 targeted clinical labs for a fee reduction of 2 percent in 2013, or a savings of $2.7 billion over 10 years, to help pay for canceling a 27.4 percent cut in Medicare physician fees, due March 1 under the sustainable growth rate formula, and freezing these fees at current levels through Dec. 31, 2012. The cost of the short-term physician fee fix is $18 billion, ACLA noted, and labs shoulder a "disproportionate share of the offsets in the bill, a full 15 percent though labs represent only 1.6 percent of Medicare spending."

This 2 percent cut is on top of the PPACA-mandated cuts. "As [this 2 percent] reduction is applied after the update is calculated, the resulting 2013 update amount becomes the new reset base" for 2014 and subsequent years, according to a summary prepared by staff of the House committees on Ways and Means and Energy and Commerce.

The big unknown is whether the 2 percent sequestration will take effect in 2013. This automatic cut would be triggered unless Congress enacts a broad deficit-reduction package of at least $1.2 trillion or up to $1.5 trillion in federal spending, split equally between defense and nondefense spending.

Below is a sequence of calculations, prepared by ACLA, on how cuts in current law affect the Part B clinical lab fee schedule (CLFS) from 2013 through 2021.

2013

1. 2012 CLFS plus June-June CPI-U Update minus Productivity Adjustment (cannot adjust below zero) minus 1.75% (can adjust below zero) = "first base"
2. "first base" rebased by minus 2% across the board = "2013 second base" (and base for 2014 calculations)
3. "2013 second base" minus 2% sequestration

2014

1. "2013 second base" plus June-June CPI-U Update minus Productivity Adjustment minus 1.75% = 2014 base
2. 2014 base minus 2% sequestration

2015

1. 2014 base plus June-June CPI-U Update minus Productivity Adjustment minus 1.75% = 2015 base
2. 2015 base minus 2% sequestration

2016

1. 2015 base plus June-June CPI-U Update minus Productivity Adjustment = 2016 base
2. 2016 base minus 2% sequestration

2017–2021

Prior year base plus June-June CPI-U Update minus Productivity Adjustment (new base) minus 2% sequestration

IPAB Repeal Advances in the House

The House Energy and Commerce Committee March 6 approved the Medicare Decisions Accountability Act (H.R. 452), which repeals the controversial Independent Payment Advisory Board (IPAB) established by the health care reform law.

The legislation, introduced by Rep. Phil Roe (R-Tenn.), has 232 co-sponsors, including 20 Democrats, and passed the committee by voice vote without any recorded opposition. It cleared the panel's health subcommittee Feb. 29 by a vote of 17-5.

If the legislation passes the House, it faces an uncertain future in the Senate where similar legislation (S. 2118) has been introduced by John Cornyn (R-Texas) to repeal the IPAB and pay for it by cutting premium subsidies in the reform law.

Under terms of the Patient Protection and Affordable Care Act, beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the 15-member board—appointed by the president and subject to Senate confirmation— must recommend program spending reductions that would become law unless Congress passes an alternative. But the law also sets boundaries for the board. It cannot make recommendations that would ration care, increase Medicare beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

The IPAB has drawn widespread opposition in Congress and strong objections from a host of health care providers, including pathology and clinical laboratory organizations. Its power over Medicare payment policy would be difficult for legislators to override. Under the law, Congress cannot consider any amendment to the IPAB cost-cutting proposal that does not meet the same cost-reduction goals unless both houses of Congress and three-fifths of the Senate vote to waive this requirement. Critics also note the board is not required to obtain public comment on its proposal and its actions are not subject to judicial review.

Hundreds of business and provider groups, including pathology and clinical lab organizations, have called for repeal of the IPAB (*NIR 11, 18/Oct. 6, p. 4*), objecting to its role in setting Medicare payment rates and short-circuiting the time frame for an open legislative airing of important health care policies historically within the purview of Congress. Provider groups also note that much of Medicare spending is exempt from the board's oversight until 2020 (hospital spending, for example), so those most affected by any cuts that must be made are physicians, clinical labs, drug companies, medical device makers, Medicare Advantage plans, prescription drug plans, and beneficiaries.

Proponents say the IPAB is intended as a "backstop" to other Medicare reforms by ensuring that the program's spending growth does not outstrip the ability to pay for it over the long run. It would help control Medicare costs and remove politics from program reimbursement decisions.

Democratic supporters say the GOP drive to scrap the board is another assault on the health care reform law. IPAB recommendations may not be needed, they argue, if the reform law is successful in holding down health care cost increases, as expected. "But in either case, beneficiary benefits and access to care will be protected," said Henry A. Waxman (D-Calif.), the ranking member on the Energy and Commerce Committee.

Deadlines Proposed to Report, Return Overpayments

Under a rule proposed by the Centers for Medicare and Medicaid Services (CMS), Medicare Part A and Part B providers and suppliers must report and return self-identified overpayments either within 60 days of the incorrect payment being identified or on the date when a corresponding cost report is due—whichever is later.

Comments on the proposed rule, published in the Feb. 16 Federal Register*, are due to CMS by April 16.*

The proposed rule would implement a provision of the health care reform law, the Patient Protection and Affordable Care Act of 2010, which established, for the first time, an explicit deadline for reporting and returning overpayments. Any failure to do so within the applicable time frame could be a violation of the False Claims Act and could also subject providers and suppliers to civil monetary penalties or exclusion from federal health care programs.

Key Terms

The proposed rule adopts the statutory definition of "Medicare overpayment" as "any funds that a person receives or retains under Medicare to which the person is not entitled." Examples could include all of the following, CMS said:

- ❑ Medicare payments for noncovered services;
- ❑ Medicare payments in excess of the allowable amount for an identified covered service;
- ❑ Errors and nonreimbursable expenditures in cost reports;
- ❑ Duplicate payments; and
- ❑ Receipt of Medicare payment when another payer had the primary responsibility to pay.

An overpayment is "identified," CMS proposes, if the provider or supplier has actual knowledge of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. This standard, the agency said, would require providers and suppliers to use due diligence through self-audits, compliance checks, or other research to determine if there is any overpayment.

An overpayment must be reported and returned only if a person identifies it within 10 years of the date it was received, CMS proposes. The 10-year lookback period was selected, the agency said, to coincide with the outer limit of the statute of limitations under the False Claims Act. "We believe that providers and suppliers should have certainty after a reasonable period that they can close their books and not have ongoing liability associated with an overpayment. We also believe the length of the lookback period is sufficient to ensure that overpayments are timely returned."

Overpayments would be returned through the existing voluntary refund program on forms available from local Medicare contractors.

Compliance Issues for Labs

"Compliance with the proposed rule could be extraordinarily difficult for clinical laboratories because of the sheer number of similar tests they perform and Medicare claims that they file," said attorney Robert E. Mazer, a principal with the law firm of Ober/Kaler (Baltimore), in comments to *NIR*.

"If there is evidence to suggest that a lab has been overpaid for a particular test or even for tests ordered by a particular physician, the process of identifying and quantifying any overpayments could be overwhelming."

Under the proposed rule, health care providers are required to make a "reasonable inquiry" when there is evidence of a possible overpayment, Mazer noted. "A lab, however, may be unable to determine whether a previously received Medicare payment was an overpayment based on its own records. The treating physician's medical records would generally control medical necessity issues, for example. These records may be extremely difficult or impossible for a lab to obtain, particularly when tests could have been performed up to 10 years earlier. It would appear reasonable that if the lab cannot access records required to determine whether tests were not medically necessary, then it has not identified an overpayment that must be reported and repaid. The proposed rule, however, is silent on this issue."

The Medicare statute prevents labs and other providers from being required to return overpayments when they were "without fault" in causing the overpayment, Mazer pointed out. "This provides substantial protection to labs when they had no reason to know that a physician had not properly documented a test's medical necessity in the patient's record. The proposed rule does not specifically acknowledge this principle. If the 60-day refund requirement were permitted to override Medicare's 'without fault' provisions, labs would lose an important financial protection."

The proposed rule provides uniform requirements for all providers and suppliers, so "it is up to clinical laboratories to make CMS aware of their special circumstances that require accommodation," he concluded.

Physicians Cautioned When Reassigning Medicare Benefits

Pathologists and other physicians who reassign their right to bill the Medicare program and receive Medicare payments by executing the CMS-855R application may be liable for false claims submitted by entities to which they reassigned their Medicare benefits.

This warning comes in an alert from the Health and Human Services Office of Inspector General (OIG) encouraging physicians to "use heightened scrutiny of entities prior to reassigning their Medicare payments" and "ensure that the entities are legitimate providers or suppliers of health care items and services."

The OIG recently reached settlements with eight physicians who violated the civil monetary penalties statute by causing the submission of false claims to Medicare from physical medicine companies. "Specifically, these physicians reassigned their Medicare payments to various physical medicine companies in exchange for medical directorship positions. While serving as medical directors, the physicians did not personally render or directly supervise any services," the OIG noted. "There was evidence that the services the companies claimed the physicians performed were not actually performed or were not performed as billed."

Many of the owners and operators of the physical medicine companies were criminally prosecuted, and the OIG determined that the physicians were an integral part of the scheme and pursued their liability under the civil monetary penalty statute.

"Physicians have unrestricted access to claims submitted by an entity for services that the entity billed using the physicians' reassigned provider numbers to provide added assurances that the services for which the entity billed Medicare were, in fact, performed and were performed as billed," the OIG noted.

NIH Launches Online Genetic Testing Registry

The National Institutes of Health (NIH, located in Bethesda, Md.) announced Feb. 29 that it has launched a free online resource, the Genetic Testing Registry (GTR), to make it easier for health care providers, researchers, and consumers to navigate the rapidly changing landscape of genetic tests.

The new registry is available at *www.ncbi.nlm.nih.gov/gtr*. Its unveiling comes two years after NIH announced its intention to create this single public resource about the availability, validity, and usefulness of genetic tests.

"Our new registry features a versatile search interface that allows users to search by tests, conditions, genes, genetic mutations, and laboratories," said Wendy Rubinstein, M.D., Ph.D., director of the GTR. "What's more, we designed this tool as a portal to other medical genetics information, with context-specific links to practice guidelines and a variety of genetic, scientific, and literature resources available through the National Library of Medicine at NIH."

"Genetic tests currently exist for about 2,500 diseases," NIH noted, "and the field continues to grow at an astonishing rate." To keep pace, the GTR will be updated frequently, using data voluntarily submitted by genetic test providers. Such information will include the purpose of each genetic test and its limitations, the name and location of the test provider, whether it is a clinical or research test, what methods are used, and what is measured. The GTR will contain no confidential information about people who receive genetic tests or individual test results.

In addition to basic facts, the registry will offer detailed information on analytic validity, which assesses how accurately and reliably the test measures the genetic target; clinical validity, which assesses how consistently and accurately the test detects or predicts the outcome of interest; and information relating to the test's clinical utility, or how likely the test is to improve patient outcomes.

"The GTR will be developed in a phased manner," according to a GTR fact sheet, "and Phase I will focus on tests for heritable mutations, including pharmacogenomic tests and tests using complex arrays and multiplex panels. Future phases will incorporate tests for somatic mutations and whole exome or whole genome sequencing assays."

While NIH is not verifying the information submitted to the GTR, submitters are required to agree to a code of conduct that stipulates that the information they provide is accurate and updated on an annual basis. The GTR Web site also posts the following disclaimer: "Patients and consumers with specific questions about a genetic test should contact a health care provider or a genetics professional."

The GTR was developed by the National Center for Biotechnology Information, which is part of NIH's National Library of Medicine. It was built on data pulled from the laboratory directory of GeneTests, an NIH-funded resource that will be phased out over the coming year.

The new registry is designed to contain more detailed information than its predecessor, as well as to encompass a much broader range of testing approaches, such as complex tests for genetic variations associated with common diseases and with differing responses to drugs. GeneReviews, which is the section of GeneTests that contains peer-reviewed, clinical descriptions of more than 500 conditions, is also now available through the GTR.

CAP: Restore Grandfather Protection, *from p. 1*

CAP has registered its opposition to the policy change and says it is "exploring all options, including congressional action, for extending the protection." There is still support for the protection within Congress, CAP notes, and the college is consulting its allies on Capitol Hill "to chart next steps and assess the willingness of Congress to revisit the issue."

CAP also is urging its affected members to take several steps. One is to let their members of Congress know how the change will impact their communities and the beneficiaries served. Another is to contact their hospitals and ask them to advocate for restoration of the pathology TC protection.

In a model letter for its members, CAP explains that without this protection, "costs would suddenly shift to hospitals. Hospitals would not receive additional funding to pay for these services. Letting this provision expire will seriously threaten the operation of small and rural hospitals, as well as independent laboratories, many of which are small businesses."

The grandfather provision, which costs Medicare an estimated $80 million per year, was one of a number of cuts enacted to offset the $18 billion needed to pay for a freeze on Medicare physician fees through 2012, canceling a cut of 27.4 percent under the sustainable growth rate formula.

Currently, there are two bills that, if passed, would permanently extend the TC protection, CAP notes in the letter. One is a stand-alone measure, H.R 2461, the Physician Pathology Services Continuity Act of 2011. The other is a rural health care package, H.R. 3859, the Rural Hospital and Provider Equity Act of 2012. Passage of either of these two bills would provide much needed stability in the delivery of important diagnostic services, CAP says.

However, Washington sources speculate that a more likely vehicle for approval of an extension would be a broader piece of legislation, but that would not come up, if at all, until a lame-duck session after the elections when Congress must again address a Medicare physician fee cut of an estimated 30 percent starting Jan. 1, 2013.

In comments to *NIR*, Barry Portugal, president of Health Care Development Services (Highland Park, Ill.), observed, "The American Hospital Association counts about 1,650 hospitals in their small and rural constituency. About 1,300 are critical-access hospitals and are not impacted by the sunset of the TC protection. They are reimbursed at their costs plus 1 percent.

"This means that about 350 small and rural hospitals, plus other hospitals that do not have an in-house histology lab to process surgical pathology specimens (some of these are over 200 beds), will need to negotiate pricing arrangements for purchasing the TC services from independent labs or other hospitals."

For the lab owner, the end of TC direct billing means, "We must now bill you for the work we do for you." For the hospital owner, it is a question of "How much will you charge and what is reasonable?"

The lab owner's incentive is to retain at least as much as possible of the rates previously paid by Medicare. For the hospital, since the end of the protection is an unanticipated budget item, the incentive is to negotiate rates as low as possible.

"Based on a national survey we conducted a few years ago," Portugal said, "we found that hospitals pay from 40 percent to 55 percent of the Medicare physician fee schedule rates for TC services they purchase from independent labs."

How much the hospital may be willing to pay will vary, he cautioned, because size does not equate to the number of diagnostic cases or specimens that need to be factored in to arrive at what the parties agree is fair and reasonable.

How to Avoid Paying Interest on Medicare Overpayments

Currently, Medicare contractors begin recoupment of an overpayment on Day 41 from the date of the initial demand letter. Interest accrues and assesses on an overpayment if not paid in full by Day 30.

By choosing immediate recoupment, providers waive their rights to interest should the overpayment be reversed at the administrative law judge level or subsequent higher levels.

Under the immediate recoupment process implemented by the Centers for Medicare and Medicaid Services (CMS) and effective July 1, 2012 (Change Request 7688 revised), providers may request that recoupment begin prior to Day 41. Those who elect this option may avoid paying interest if the overpayment is recouped in full prior to Day 31.

Key to understanding this change, said CMS, is that providers who request an immediate recoupment must realize it is considered a voluntary repayment. Also, these providers must make the request in writing to their Medicare contractor. They may submit a one-time request for a specific demanded overpayment (the total amount of the demanded overpayment) or a permanent request for the specific demanded overpayment and all future overpayments. Providers also may terminate the immediate recoupment process at any time with written notice.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

March 27

Lab Cuts and Expiring TC Grandfather Policy: What the Middle Class Tax Relief and Job Creation Act of 2012 Means for Your Laboratory

Conferences

April 17-19

MDx *Next*
Molecular Diagnostics Spring 2012
Gaining the MDxEdge
Fairmont Copley Plaza
Boston
www.mdxconference.com/Home

June 6-8

Lab Outreach 2012
Paris Las Vegas
Las Vegas
www.G2Outreach.com

Oct. 10-12

30th Anniversary Lab Institute
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