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Medicare Lab Fees Under Threat From All Sides

Clinical lab groups are aggressively lobbying Congress to head off any cost sharing for Medicare-covered lab services and further cuts in reimbursement for those services.

With roughly three months left before Congress wraps for the year, clinical laboratories are facing multiple potential threats to how they bill and get paid for Medicare-covered services.

Of immediate concern is a series of saving proposals that could be tapped by the Joint Select Committee on Deficit Reduction. The 12-member bipartisan panel, composed of House and Senate members, is charged with recommending cuts of up to $1.5 trillion in federal spending by Thanksgiving.

If a majority on the panel agrees, the recommendations go to the House and the Senate for an up-or-down vote, with no amendments or filibusters, by Dec. 23. Failure to enact at least that level of savings would trigger automatic across-the-board cuts as of Jan. 1, 2013, including reductions in Medicare reimbursement.

Among the savings ideas circulating around Washington are several strongly opposed by the clinical lab industry, including:

❑ Introducing lab coinsurance as part of a uniform 20 percent coinsurance requirement for all Medicare services. Beneficiaries currently

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CMS to Give Patients Direct Access to Lab Test Results Under Proposed New Rule

Citing a need to further individualized medicine and empower patients to participate in medical care decisions, the U.S. Department of Health and Human Services (HHS) has proposed giving patients (and their authorized representatives) direct access to their own laboratory test results.

The proposed rule, published in the Sept. 14 *Federal Register*, would modify regulations under two statutes that restrict such access: the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA).

CLIA currently allows disclosure of laboratory test results only to "authorized persons" unless state law decrees otherwise. "Authorized persons" include the individual who orders and/or receives the test results, the person responsible for using the results for treatment, and the referring lab. A laboratory may release patient test results directly to the patient only if (1) the ordering provider expressly authorizes the lab to do so at the time the test is ordered or (2) state law expressly allows for it.

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CMS to Give Patients Direct Access, *from p. 1*

Removing CLIA restrictions would impact 39 states and territories, encompassing some 22,671 laboratories that provide approximately 6.1 billion tests annually, HHS noted. The proposed rule would override such restrictions in these jurisdictions (*see table*).

States, Territories Affected by Direct Access Proposed Rule

NO STATE LAW AUTHORIZING ACCESS		*ALLOWS TEST REPORTS ONLY TO PROVIDER*
Alabama	Nebraska	Arkansas
Alaska	New Mexico	Georgia
Arizona	North Carolina	Hawaii
Colorado	North Dakota	Illinois
Guam	N. Mariana Islands	Kansas
Idaho	Ohio	Maine
Indiana	Oklahoma	Missouri
Iowa	South Carolina	Pennsylvania
Kentucky	South Dakota	Rhode Island
Louisiana	Texas	Tennessee
Minnesota	Utah	Washington
Mississippi	Vermont	Wisconsin
Montana	Virgin Islands	Wyoming

Source: CMS

The proposal also would modify the HIPAA privacy rule to provide individuals the right to receive their test results directly from the laboratory by removing the exceptions for labs subject to CLIA. "There is no longer a need for the exceptions," HHS said. "Unless removed, they would serve as a barrier to individuals' right of access to test reports."

'Information Is Power'

"When it comes to health care, information is power," HHS Secretary Kathleen Sebelius said in a statement. "When patients have their lab results, they are more likely to ask the right questions, make better decisions, and receive better care."

The proposed rule was issued jointly by HHS, the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and the HHS Office for Civil Rights at the start of National Health IT Week.

HHS said removing current restrictions stems from a review by the Health Information Technology Policy Committee, which concluded that current CLIA and HIPAA regulations prevent patients from taking a more active role in their personal health decisions.

Handling Request From Patients

Under the proposed rule, HHS said labs have flexibility in how they choose to handle patients' requests for their test report. Where direct access would apply for the first time, labs in these locales will have to establish processes and procedures for responding to patients. HHS expects that in many cases labs can furnish reports electronically in machine-readable formats (Microsoft Word or Excel, HTML, or PDF, among other formats); however, patients always have the right to request a paper copy.

Processing requests, either manually or electronically, would require completion of the following steps, according to the proposed rule:

- ❏ Receipt of the request from the patient;
- ❏ Authentication of the identification of the patient;
- ❏ Retrieval of the test reports;
- ❏ Verification of how and where the patient wants the test report to be delivered and provision of the report by mail, fax, e-mail, or other electronic means; and
- ❏ Documentation that the test report was issued.

In instances where anonymous testing is performed, the lab is not required to furnish these patients with their test reports.

Compliance Costs

If implemented in 2011, the rule would impose compliance costs of $3 million to $56 million, HHS estimates. First-year costs would include the start-up costs of developing internal processes and procedures for handling requests from patients. These would range from $2.2 million to $10.2 million, HHS estimates. Because the start-up costs would not be needed in subsequent years, HHS said it expected that compliance costs would diminish over time.

Comments on the proposed change are due Nov. 17. If it's finalized, labs would have to comply with it within 180 days after its effective date, which would be 60 days after its publication in the Federal Register, *HHS said.*

To help offset compliance costs, labs may charge a reasonable, cost-based fee. If the patient requests that the copy be mailed, the fee may include only the cost of copying (including supplies and labor) and postage. If the patient asks for a summary or explanation of the information, the fee may be charged for preparing the summary or explanation, but not any costs associated with searching for and retrieving the information requested.

Pathology 'Grandfather' Protection 'On the Ropes' Again

At year's end the Centers for Medicare and Medicaid Services (CMS) plans a knockout punch to eliminate certain pathology technical component (TC) billings, but pathology and clinical lab groups strongly oppose the move and are lobbying Congress to block it. In formal comments on the proposed change, the groups also urged CMS to reconsider.

At issue is the "grandfather" protection that allows independent clinical laboratories to bill Medicare separately for the 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 CMS first proposed to end such billings.

This protection is one of a series of so-called Medicare extenders that expire at year's end. Legislation to make the protection permanent has been introduced in the House (H.R. 2461) by Rep. Geoff Davis (R-Ky.). Meantime, the House Ways and Means health subcommittee held a Sept. 21 hearing on the extenders, including the grandfather provision.

CMS has since repeatedly sought to eliminate this billing practice, but Congress has time and again thwarted this effort by approving a series of extensions of the protection. The current extension expires Dec. 31 of this year. The College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association want the protection made permanent or at least have it further extended.

CMS estimates that the savings from ending the protection are approximately $80 million for 2012. The agency contends that payment for the TC (the preparation of the slide involving tissue or cells that a pathologist interprets) is included in the hospital's prospective payment, and labs should seek reimbursement from the hospital, not the Part B program.

Critics say the protection is vital for hospitals in rural and underserved areas that lack the resources to furnish the pathology work in-house and must rely on outside labs to provide this component of patient care.

focus on: Lab Payment Policy

CMS Releases Preliminary Payment Rates for New, Reconsidered Lab Codes in 2012

The Centers for Medicare and Medicaid Services (CMS) has posted its preliminary payment determinations for two new CPT codes to be added to the 2012 Medicare lab fee schedule, effective Jan. 1. It also has released its decisions on requests to reconsider the crosswalk and payment in 2012 for five codes on the current fee schedule.

The new codes include:

- ❏ One in immunology used to detect human bladder cancer; and
- ❏ One in microbiology used to detect HIV-1 antigen and HIV-1 and HIV-2 antibodies.

For each, CMS used the crosswalk method to make its preliminary payment determinations, matching the new code to a similar code on the lab fee schedule and payable at that rate. Payment is the lower of the local fee schedule amount or the national fee cap. Most lab codes are paid at the cap.

New CPT Lab Codes on the 2012 Medicare Fee Schedule: Preliminary Payment Determinations

*Code/Descriptor**	*Recommended Payment Method*	*Current National Fee Cap*
IMMUNOLOGY		
863XX Nuclear Matrix Protein 22 (NMP22), qualitative	Crosswalk to 82487, Chromatography, qualitative, paper, 1-dimensional, analyte not elsewhere specified	$22.47
	Industry recommendations: **AACC:** Crosswalk to 83499, 20-hydroxyprogesterone, $35.48 **ASCP, CAP:** Crosswalk to 86294, Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen), $27.61	
MICROBIOLOGY		
873XX Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result	Crosswalk to 50 percent of 87390, Infectious agent antigen detection by EIA technique, qualitative or semiquantitative, multiple-step method; HIV-1 plus 50 percent of 86703, HIV-1/HIV-2 antibodies, single assay	$22.06
	Industry recommendations: **AACC, ACLA, ASCP:** Crosswalk to 87391, HIV-2 antigen assay plus 50 percent of 86703, for a total of $34.48 **CAP:** Crosswalk to 87390 plus 50 percent of 86703, for a total of $34.48	

*Last two digits to be finalized.
CPT codes © American Medical Association.

The table on page 4 compares the preliminary crosswalk decisions for the new codes with pricing recommended by selected national groups: the American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society for Clinical Pathology (ASCP), and the College of American Pathologists (CAP).

In its rationale for the initial decision on new immunology code 863XX, CMS noted, "[It] does not have as much methodological similarity to the industry recommended crosswalk. Comments presented at the annual public meeting on July 18 indicated that this test is performed using a lateral flow immunochromatographic strip, which is how 82487 is performed."

With regard to new microbiology code 873XX, CMS said, "[It] yields a single positive result if HIV-1 p24 antigen, HIV-1 antibody, and/or HIV-2 antibody are present in detectable amounts. It does not test for the three analytes separately. By crosswalking to the two codes which include the same three analytes, which were also recommended by other commenters, but at 50% of each code, there is a reduction for the duplication of effort and resources eliminated by performing a single test as opposed to two separate tests."

Reconsideration Requests

CMS responded to requests to reconsider five code crosswalks and payment rates for the 2012 Medicare lab fee schedule. In three of the five cases, the agency recommended no change. In one case, the preliminary determination would amount to a higher fee for the code at issue.

Below are the preliminary payment determinations for the five codes and the CMS rationale for each.

G0434, Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter. Retain the current descriptor and payment, $20.47 (current fee cap).

AACC and ACLA recommended creating a new code, G043X, to describe instrumented moderate-complexity systems and revising code G0434 to clearly describe single-test systems (*NIR 11, 14/July 14, p. 2*).

CMS Rationale: The agency recommends keeping the current descriptor and not adding G043X. "Although commenters recommended that G043X be priced at four times G0434 ($81.88), the cost data did not justify this. The commenters also acknowledged that the moderate-complexity instrument is used to perform other testing such as cardiac disease testing. Further, other commenters provided input that the payment of about $20 for this test is reasonable."

G0435, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening. Retain the current descriptor and payment but consider changing the descriptor to: "Infectious agent antibody detection by rapid antibody test, HIV-1/HIV-2, oral screening." Current cap, $16.88

AACC, ACLA, ASCP, and CAP had no comment on this request.

CMS Rationale: This reconsideration request concerns instructions on how users of the test should bill. If the product is utilized for an oral specimen, it should be billed with G0435. If used for a blood specimen, which commenters state is common, it

should be billed with G0433. Since G0435 predominantly reflects oral screening, it has been assigned an appropriate payment crosswalk, CMS said.

83861, Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity. Retain current crosswalk and payment to molecular diagnostics code 83909, currently capped at $23.58.

AACC, ASCP, and CAP had no comment.

CMS Rationale: "The objection to the crosswalk is based on the mapping to local contractors for some states where the state payment amount is less than the national fee cap. Thus, commenters want to select a different crosswalk code that will result in a similar payment amount in all states. However, the logic for crosswalking to 83909 as one of the codes recommended by the manufacturer last year is much stronger than the logic to crosswalk to the newly proposed code, 84081. In last year's presentation the manufacturer listed seven methodological similarities between 83861 and 83909."

The initial payment decisions are open to further public comment. Final fee determinations will be published later this year in the 2012 Medicare lab fee schedule.

86481, Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension (current national fee cap, $87.22). Crosswalk to 86480 plus 83520. Current cap is a total of $105.44.

AACC recommended a crosswalk to 86480, TB test, cell mediated immunity antigen response measurement; gamma interferon, plus 86332, immune complex assay (total current cap: $121.15).

CMS Rationale: "This test is similar to 86480 except that it enumerates gamma interferon producing T cells. According to the commenters, in order to perform 86481, it is necessary to perform at least 14 additional steps versus performing 86480. CMS believes that 1X 83520 rather than 2X 83520 as suggested by the commenters is a more appropriate reflection of the additional clinical resources and complexity required by 86481 as opposed to 86480."

87906 Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion). Cap, $181.14. Retain the same crosswalk and payment at 50 percent of the cap for 87901 ($362.28), or $181.14.

AACC recommended a crosswalk to 87901, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease (current cap: $362.28).

CMS Rationale: The agency recommends retaining the crosswalk to 50 percent of the national fee cap for 87901 as determined last year. Based on the information presented by commenters at the annual public meeting, CMS said it does not believe there is sufficient evidence to justify changing the payment level.

Next Steps in the Fee-Setting Process

The initial payment decisions are open for additional public comment and can be found at *www.cms.gov/ClinicalLabFeeSched/*. Final determinations on the new CPT lab codes and the five reconsidered codes will be published later this year in the 2012 Medicare lab fee schedule. It typically has been released in late October or in November via a program transmittal to local Medicare contractors.

Medicare Lab Fees Under Threat, *from p. 1*

have no copay, and labs are paid at 100 percent of the applicable fee. Opponents say a coinsurance requirement would increase the out-of-pocket expenses of beneficiaries for needed and recommended testing and burden labs with the added costs of billing and collecting the coinsurance. In many cases, this is a money-loser, costing labs more to collect than the amount owed (*NIR 11, 16/Sept. 8, p. 1*).

❑ Requiring both coinsurance and a deductible for Medicare lab services. This proposal appeared in a summary of health care savings options that could come before the joint select committee. Prepared by House Democratic staff, it detailed proposals previously advanced by various commissions and lawmakers, including the Congressional Budget Office. In its savings options book, CBO estimated that requiring full cost sharing would save Medicare $24 billion over 10 years. No cost sharing has been required since 1984 in the switch to the lab fee schedule.

Latest Potential Threat

This comes from the Medicare Payment Advisory Commission (MedPAC) in a proposed fix to the sustainable growth rate (SGR) formula used to annually update the physician fee schedule.

The proposal, which would require congressional approval, was discussed at the commission's Sept. 15 meeting. It would offset the cost of repealing the SGR (an estimated $235 billion over 10 years) with payment cuts to other Medicare providers, of which 9 percent would be carved out of Part B lab spending, or $21 billion. This option also would cut payments for lab services on the physician fee schedule.

In a Sept. 16 letter to MedPAC chairman Glenn M. Hackbarth, J.D., the American Clinical Laboratory Association (ACLA) said it was "particularly concerned about the prospect of the commission making recommendations to Congress for fixing the SGR through cuts in providers' payments, including clinical lab fees and payments to pathologists."

While agreeing with MedPAC that the SGR payment system should be replaced with one that is stable and predictable, ACLA took issue with how to pay for the change by "sharing the cost of repealing the SGR across physicians, other health professionals, providers in other sectors, and beneficiaries."

Additional lab cuts are "unsustainable," said ACLA President Alan Mertz in the letter. "Clinical lab services inform 70 percent of health care providers' decisions, while accounting for only 1.6 percent of Medicare spending. Yet, payments for lab services have been reduced by about 40 percent in real (inflation-adjusted) terms over the past 20 years. They are scheduled to decline an additional 19 percent over the next 10 years under changes mandated by the health care reform law. And more cuts are reportedly on the table for the joint select committee."

Pathology and other medical groups are looking to the joint select committee to repeal the SGR system. Under the SGR, physician fees are scheduled to be cut by 29.5 percent as of Jan. 1, 2012, and even deeper cuts are forecast for subsequent years.

Under the MedPAC plan, the 2012 cut would be blocked, but payments for primary care physicians would be frozen for 10 years and pathologists would see a reduction in payments for three years, followed by a seven-year freeze. *Continued on p. 8*

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The American Medical Association wants the committee to block the impending cut and replace the SGR with stable fee increases over the next five years in the transition to a system based on payment and delivery alternatives to traditional fee-for-service.

Automatic Triggers on the Horizon

If a deficit-reduction deal is not reached, this would trigger automatic cuts of up to $1.5 trillion split between defense and nondefense spending beginning in 2013.

Cuts in Medicare provider payments would be limited to 2 percent of total program spending. This, however, would not involve any cut in Medicare benefits or added cost sharing or any cuts in Medicaid, Social Security, or veterans' benefits.

While labs are designated as "suppliers" under Medicare, not providers, industry sources tell *NIR* they are operating under the assumption that labs could be ensnared in the provider payment reductions.

Said one Washington source, "I think there is no practical difference for these purposes between providers and suppliers, and labs would be vulnerable to payment reductions in the sequestration process."

