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Senate Approves One-Year Medicare Physician Fee Fix

The fix would be paid for by modifying provisions in the health care reform law to correct overpayments of federal subsidies to help people buy health insurance, starting in 2014. Recipients would have to return a portion of the tax credit if they earned more money than expected in a given year. The payback amount would be on a sliding scale, based on the recipient's income.

Having blocked a Dec. 1 steep cut in Medicare physician payments, Congress is facing a Jan. 1 deadline to avert another cut estimated at 25 percent.

The Senate late Dec. 8 approved by unanimous consent a bipartisan deal that would block this cut and freeze the physician fee update through 2011 at an estimated cost of $14.9 billion (H.R. 4994). The bill now goes to the House for consideration.

The bill also would extend the pathology grandfather protection that expires Dec. 31 through all of 2011. The protection allows certain independent labs to bill Medicare Part B for the technical component of anatomic pathology services to hospital patients. Reasonable cost reimbursement for Part B lab services to hospital patients in certain rural areas would be continued to July 1, 2011.

Meanwhile, for December, Congress approved a 2.2 percent physician fee update in legislation signed into law Nov. 30 (Public Law No. 111-286, the Physician Payment and Therapy Relief Act of 2010). Estimated cost: $1 billion, paid for by cuts in multiple physical therapy services.

Forum Sheds More Light on New FDA Oversight of Lab-Developed Tests

Officials of the Food and Drug Administration (FDA) met with lab industry stakeholders late last month to discuss the agency's plan to use its enforcement discretion to expand regulation of laboratory-developed tests (LDTs) and what it portends for stakeholder operations.

The public forum, held Nov. 22 in Washington, D.C., was sponsored by eight organizations and drew more than 250 attendees representing lab interests of all stripes: clinical, hospital, and public health labs; professional laboratory organizations; and diagnostic manufacturers.

LDTs are in vitro diagnostics manufactured by and offered in the same laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). The tests number in the thousands and include genetic tests and others used to prevent, diagnose, and treat patients with a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions.

The FDA announced in July that it plans to expand its regulatory reach to include LDTs based on the level of risk *Continued on p. 2*

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Forum Sheds More Light, *from p. 1*

associated with the test and solicited comments from stakeholders on how it should proceed (*NIR 10,14/July 23, p. 1*). Currently, the agency has limited its enforcement discretion to analyte-specific reagents and in vitro diagnostic multivariate index assays (IVDMIAs) using a proprietary algorithm to produce patient-specific results.

But the agency's new policy on LDTs has raised anxiety within the laboratory community that lengthy approval procedures would delay the introduction of new tests, stifle innovation, raise development costs, and, as a result, limit patients' access to potentially beneficial assays.

At the recent forum, FDA official Alberto Gutierrez, Ph.D., sought to allay some of those concerns. "We are in a process to develop a draft regulatory framework" on the policy change and how and when it will play out. Meetings with stakeholders are part of that process to craft draft guidance, he said. "We're not coming after LDTs tomorrow."

In remarks at the LDT forum, FDA official Alberto Gutierrez said, "In this era of personalized medicine where test results are dictating the therapy, greater FDA involvement is especially important to ensure patient safety."

Gutierrez, who is director of the FDA Office of In Vitro Diagnostic Device Evaluation and Safety, and other participating officials from his office, were restricted in discussing details of the draft guidance because it has not yet been released.

While the forum did not tackle concerns over a risk-based classification scheme and evidence requirements for ranking risk, it did spark give-and-take between the FDA participants and attendees over how the FDA should proceed.

In devising an enforcement framework, Gutierrez noted there are very different types of tests to look at, but the initial scrutiny will be on those that pose high risk to patients, and "we want the lab community to help us identify those tests." He suggested that one way would be to have panels of experts from stakeholders to help the FDA decide the level of risk and oversight for particular tests.

It is important to "get the lay of the land," he said, "how many LDTs are out there, what they are, and what claims are made for them." On this point, several participants said this information is already available from the CLIA program which certifies some 10,000 clinical labs that provide LDTs as well as the genetic testing registry at the National Institutes of Health.

The draft guidance will be coming soon, Gutierrez said, but he could not specify a date certain since the document is subject to review above his office. But "there will be plenty of time to comply," he assured the audience, and there likely will be another meeting with stakeholders after the guidance is released to solicit further feedback.

One participant questioned why the FDA was using the guidance approach rather than the formal rulemaking process, which is more interactive, more clear-cut, and binding as to the rights and responsibilities of all parties. Gutierrez replied, "We will respond in the same way under the guidance route

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Sponsors of Stakeholder-FDA Meeting

- ❑ American Clinical Laboratory Association
- ❑ American College of Medical Genetics
- ❑ Association for Molecular Pathology
- ❑ American Medical Technologists
- ❑ American Society for Clinical Laboratory Science
- ❑ Clinical Laboratory Management Association
- ❑ Coalition for 21st Century Medicine
- ❑ Mayo Clinic

focus on: Lab Payment Policy

Quick Guide to the 2011 Medicare Lab Fee Schedule

Annual Update Triggers Cut of 1.75 Percent

Starting Jan. 1, the reimbursement rates for clinical laboratory tests covered under the 2011 Medicare lab fee schedule are cut by 1.75 percent, the Centers for Medicare and Medicaid Services (CMS) announced in publishing the final schedule for next year.

This marks the second time that the annual update to the lab fee schedule has fallen into negative territory since the schedule debuted in 1984. The first time was this year, when fees were reduced by 1.9 percent. The last increase in the update was in 2009, when fees rose 4.5 percent, following a five-year freeze from 2004 through 2008.

CMS instructions to local Medicare contractors on implementing the 2011 Part B lab fee schedule are found in Transmittal 2106 (Nov. 24, 2010) at cms.hhs.gov/transmittals.

The cut coming in 2011 results from the new formula, enacted in the health care reform law, to calculate the fee update: the consumer price index (CPI-U), minus a productivity adjustment (PA) and an additional 1.75 percent cut for a limited time (2011 through 2015). The PA, however, can never reduce the update below zero. For 2011, the CPI update is 1.1 percent, but the PA is minus 1.3 percent. Thus, only the 1.75 percent reduction is applied to clinical lab fees in 2011.

Clinical lab tests are payable under local fee schedules and the national limitation amounts (fee caps) for these tests. Payment for a clinical lab test is the lesser of the actual charge billed, the local fee, or the national fee cap. The Part B deductible and coinsurance do not apply to services payable under the lab fee schedule.

The 2011 update to payments made on a reasonable charge basis for all other laboratory services (blood products, transfusion medicine, and reproductive medicine procedures) is 1.1 percent. The annual update is based on the CPI for the 12-month period ending June 30 of each year (1.1 percent as of June 30, 2010). "The reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update," CMS noted.

Pap Smear Minimum Payment

The update for 2011 reduces the minimum national payment for cervical and vaginal smears to $14.87, down from $15.13 in 2010 and from $15.42 in 2009. The payment was frozen at $14.76 from 2004 through 2008. These tests are paid at the lesser of the local fee or the national fee cap, but never below the national payment floor and never more than the actual charge. Affected codes include:

88142	88150	88164	88174	G0123	G0148
88143	88152	88165	88175	G0144	P3000
88147	88153	88166		G0145	
88148	88154	88167		G0147	

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Medicare Pricing for New 2011 Lab Fee Schedule Codes: *Final CMS Crosswalks and National Fee Caps*

Code/Descriptor	*Final Crosswalk Decision*	*2011 National Fee Cap*
DRUG TESTING		
80104, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure (this CPT code takes the place of the HCPCS code G0430)	No recommendation	N/A
CHEMISTRY		
82930, Gastric acid analysis, includes pH if performed, each specimen	82926, Gastric acid, free and total, each specimen	$7.67
83861, Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity	83909, Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation	$23.58
84112, Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative	82731, Fetal fibronectin, cervicovaginal secretions, semiquantitative	$90.64
IMMUNOLOGY		
86481, Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension	86480, Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response	$87.22
MICROBIOLOGY		
87501, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or subtype	87521, Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique PLUS 83902, Molecular diagnostics; reverse transcription	$72.22
87502, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, reverse transcription and amplified probe technique, first two types or subtypes	87801, Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique PLUS 83902, Molecular diagnostics; reverse transcription	$119.75
87503, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or subtype beyond two (List separately in addition to code for primary procedure)	83901, Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond two (List separately in addition to code for primary procedure) PLUS 83896, Molecular diagnostics; nucleic acid probe, each	$29.22
87906, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)	87901, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease, at half the payment rate	$181.14

Medicare Pricing for New 2011 Lab Fee Schedule Codes: *Final CMS Crosswalks and National Fee Caps*

Code/Descriptor	*Final Crosswalk Decision*	*2011 National Fee Cap*
HEMATOLOGY AND COAGULATION		
85598, Phospholipid neutralization; hexagonal phospholipid	85597, Platelet neutralization	$25.30
TRANSFUSION MEDICINE		
86902, Blood typing; antigen testing of donor blood using reagent serum, each antigen test	86905, Blood typing; RBC antigens, other than ABO or Rh(D), each	$5.38
HCPCS CODES		
G0432, Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: EIA HIV-1/HIV-2 screen	86703, Antibody, HIV-1 and HIV-2, single assay	$19.30
G0433, Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: ELISA HIV-1/HIV-2 screen	86703, Antibody, HIV-1 and HIV-2, single assay	$19.30
G0435, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening. Short descriptor: Oral HIV-1/HIV-2 screen	87804, Infectious agent antigen detection by immunoassay with direct optical observation; Influenza	$16.88
G0434, Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived test or moderate-complexity test, per patient encounter	G0430, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure	$20.47
G9143, Pharmacogenomic testing for Warfarin response	83891, Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA) PLUS 3 x 83896, Molecular diagnostics; nucleic acid probe, each PLUS 83900, Molecular diagnostics; amplification, target, multiplex, first two nucleic acid sequences PLUS 83901, Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond two (List separately in addition to code for primary procedure) PLUS 3 x 83908, Molecular diagnostics; amplification, signal, each nucleic acid sequence PLUS 83912, Molecular diagnostics; interpretation and reportt	$169.87
CPT codes © American Medical Association.		

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No Change in How Fee Caps Are Set

Medicare's national fee caps remain set at 74 percent of the national median for those tests on the lab fee schedule that were capped prior to Jan. 1, 2001. For tests whose fee caps were first established on or after Jan. 1, 2001, the caps are to be set at 100 percent of the national median, in accord with the Benefits Improvement and Protection Act of 2000 (BIPA).

This BIPA provision has been applied by CMS, since April 1, 2001, to 12 diagnostic/screening Pap smear codes involving thin-layer preparation and manual or automated screening or rescreening:

88142/G0123	88143/G0143
88147/G0147	88148/G0148
88174/G0144	88175/G0145

Final Fees Established for New CPT, G Lab Codes

In setting fees for CPT codes and G codes new to the Part B lab fee schedule in 2011, CMS used the crosswalk method in all cases; no new test codes were gap-filled (*see table, p. 4*). The agency adopted as final its preliminary fee decisions released earlier this year (*NIR 10, 18/Oct. 8, p. 3*).

Under the crosswalk method, a new test code is matched to a similar code on the fee schedule and paid 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. The gap-fill alternative is used to set a fee when there is no comparable test and is based on local pricing patterns.

New Set of Drug Screening Codes

CMS made no recommendation for pricing the new drug screening code 80104, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure. Instead, the agency created a new set of HCPCS G codes for drug screening, depending on the complexity of the test method assigned under the Clinical Laboratory Improvement Amendments (CLIA)—waived, moderate, or high.

While acknowledging that the new code 80104 was created by the CPT committee to take the place of G0430, CMS said that neither of these codes is properly described in order to control improper payment, billing, and utilization. Accordingly, neither should be priced under Medicare, the agency said, "because the descriptor does not accurately reflect the types of tests that need to be captured for accurate billing and payment."

The agency has deleted G0430, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure. Instead, to account for the CLIA complexity of the test method used, the descriptor for G0431 has been edited and a new test code G0434 has been created.

- ❏ G0431, Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter. Crosswalked to G0430 x 5. $102.33 (National fee cap).

- ❏ G0434, Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived or moderate-complexity test, per patient encounter. $20.47 (fee cap).

Contractors have been notified that 80100, Drug screen, qualitative; multiple drug

classes chromatographic method, each procedure, and 80104 are "not valid for Medicare purposes," effective Jan. 1, 2011.

Reconsideration Requests

CMS accepted requests to reconsider the pricing of five codes currently on the lab fee schedule. It has decided to crosswalk four and delete one, G0430, as part of the switch to a new set of drug screening codes, based on the CLIA complexity of the test method.

CPT Code	Final Crosswalk Decision	2011 National Fee Cap
84145, Procalcitonin (PCT)	82308, Calcitonin	$37.69
84431 Thromboxane metabolites, including thromboxane if performed, urine	84443, Thyroid stimulating hormone (TSH)	$23.64
86352 Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP)	2 X 86353, Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis PLUS 2 X 82397, Chemiluminescent assay	$191.19
G0431Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter	5 X G0430, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure	$102.33

Specimen Collection

There is no change in 2011 in the fee for specimen collection. It remains at $3 for the following codes:

- ❏ 36415, collection of venous blood by venipuncture
- ❏ P9612, catheterization for collection of specimen, single patient, all places of service
- ❏ P9615, catheterization for collection of specimen(s) (multiple patients)

Travel Allowance

In a separate instruction to Medicare contractors (Transmittal 2110, Dec. 3, 2010) CMS announced the pay rates in 2011 for travel allowance codes P9603 and P9604. The rates remain the same as in 2010. These codes are billable only for traveling to collect a specimen from a nursing home or homebound beneficiary.

Effective Jan. 1, the rates are

- ❏ P9603, 95 cents per mile travel allowance. This code is used when the average trip is longer than 20 miles round trip and is prorated in situations where specimens are drawn from non-Medicare patients in the same trip.
- ❏ P9604, $9.50 per flat rate trip basis.

Contractors have the option of establishing a higher per mile rate in excess of the minimum $0.95 per mile if local conditions warrant it. The minimum mileage rate will be reviewed and updated throughout the year, as needed, CMS said.

No grace period for adopting 2011 coding changes: Medicare no longer allows a three-month grace period (Jan. 1-March 31) for processing lab claims with CPT/HCPCS codes active in 2010 but deleted or not payable in 2011. As of Jan. 1, 2011, only active codes will be accepted.

Forum Sheds More Light, *from p. 2*

as under rulemaking. We will address all comments as possible as if it were a rulemaking." The guidance will be a draft, subject to change, he emphasized.

Others urged the FDA to consider whether adding regulatory processes adds value to the service or is this better achieved through existing mechanisms such as strengthened oversight under CLIA and FDA postmarket surveillance rules.

Does the FDA have the resources to expand oversight at a time of budget cuts and other restraints and avoid lengthy registration and approval delays over LDTs subject to review, one participant asked. Gutierrez replied, "It depends on how big a bite we want to take." Well established tests and low-volume tests for rare diseases or health conditions are not at the top of the list for FDA scrutiny, he said. That spot is reserved for tests the agency considers high risk.

Would the FDA consider outside involvement in any expanded LDT regulation? Answering that question, Gutierrez said the agency is open to the idea of using third-party reviewers and inspectors but "fuzzy" on how to do it. This approach has not proved productive with IVDMIAs. But if the agency goes this route, it would train the inspectors and reviewers in medical device review and have the final sign-off on their reports.

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