G2 INTELLIGENCE

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Covering Government Policy For Diagnostic Testing & Related Medical Services

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Medicare Lab Fees to Rise 0.65 Percent in 2012

While no fees are set for the new CPT molecular pathology codes developed by the American Medical Association, labs are asked to report these codes on claims that use Medicare-recognized 'stacked' codes to capture the entire performance of a test (details on p. 6).

The payment rates for clinical laboratory tests on the Medicare Part B fee schedule will increase 0.65 percent as of Jan. 1, 2012, welcome news after a cut of 1.75 percent in 2011 and a 1.9 cut in 2010. The last increase was in 2009 (4.5 percent) following an update freeze from 2004 to 2008.

The fee increase for calendar year 2012 is based on the revised update formula enacted in the health care reform law. It is calculated using the consumer price index minus a productivity adjustment and an additional 1.75 percent reduction.

The increase also boosts the national minimum payment amount for a cervical or vaginal Pap smear in 2012—$14.97, up from $14.87 this year. The affected codes are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

For payments made on a reasonable-charge basis for laboratory services the annual inflation-indexed update is 3.6 percent. This includes codes for blood products, transfusion medicine, and reproductive medicine.

Continued on p. 6

Time Is Short to Block Physician Fee Cut, Keep 'Grandfather' Protection Alive

At press time, Congress was working toward averting the 27.5 percent reduction in Medicare physician payments as of Jan. 1 and devising another short-term fix. The GOP-controlled House passed tax legislation (H.R. 3630) on Dec. 13 that included an increase in physician fees of 1 percent for 2012 and 2013 at an estimated cost of $39 billion. To help pay for it, other Medicare changes would be made, including a $17 billion cut in hospital reimbursement.

The House bill is not expected to move in the Senate primarily because of partisan differences over extending the payroll tax cut and unemployment benefits due to expire at the end of this year. But since all sides agree that a Medicare physician fee fix is a priority, the House version could be a compromise and advance in a separate legislative vehicle.

Also in need of rescue: the pathology grandfather protection that allows independent labs to bill Medicare directly for the technical component of pathology services to hospital inpatients and outpatients. It expires Dec. 31. Legislation to extend it is pending in the House and the Senate.

INSIDE *NIR*

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CMS Grants 90-Day Grace Period for Version 5010 Compliance

While Jan. 1, 2012, remains the effective date when all entities covered under the Health Insurance Portability and Accountability Act (HIPAA) must comply with use of the new Version 5010 and other electronic health care transaction standards, no enforcement action will be initiated for those not in compliance until March 31, 2012, the Centers for Medicare and Medicaid Services (CMS) has announced.

CMS urges all covered entities to work with their trading partners to be ready to accept the new HIPAA standards as of Jan. 1, 2012. Noncompliance could result in disruptions in claims processing and reimbursement. Links to a Version 5010 Testing Readiness Fact Sheet and other information on the above are available at www.cms.gov/ICD10.

CMS said it is responding to feedback from the health care industry that many HIPAA-covered entities are not ready to make the required conversions by Jan. 1, with many waiting for software upgrades.

During this period, however, the CMS Office of E-Health Standards and Services, the component that enforces compliance with HIPAA transactions and code sets, will investigate complaints for noncompliance. If requested by this office, covered entities that are the subject of complaints (known as "filed-against entities") must produce evidence of either compliance or a good-faith effort to become compliant during the 90-day period.

The new versions of standards for electronic health care transactions are:

- ASC X12 Version 5010, which allows more functionality for transactions such as eligibility requests and claims status. It also is a prerequisite for using the ICD-10 diagnosis and procedural code sets effective Oct. 1, 2013.
- NCPDP Telecom D.0 (NCPDP D.0), which addresses certain pharmacy industry needs.
- NCPDP Medicaid Subrogation 3.0 (NCPDP 3.0), which allows state Medicaid programs to recoup payment for pharmacy services in cases where a third-party payer has primary financial responsibility. (For small health plans, the deadline to comply with this standard is Jan. 1, 2013).

CMS Extends Medicare Revalidation Timeline to 2015

The timeline to revalidate the Medicare enrollment of every provider and supplier under new risk-screening procedures will be extended for two more years, from March 2013 through March 2015, the Centers for Medicare and Medicaid Services (CMS) has announced.

This effort applies to clinical laboratories, pathologists, and others who enrolled in the program prior to March 25, 2011, an estimated 1.4 million in all. Those newly enrolled that submitted applications to CMS on or after March 25 generally are not affected since they have been screened under the new risk criteria.

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.

The new timeline, CMS said, "will allow a smoother process for providers, suppliers, and Medicare Administrative Contractors (MACs). Therefore, between now and

Continued on p. 7

Marilyn Tavenner Is President's Pick to Head CMS

Marilyn Tavenner

President Obama has nominated Marilyn Tavenner to become administrator of the Centers for Medicare and Medicaid Services (CMS), a post that requires Senate confirmation. She will serve as acting CMS administrator while her nomination is considered.

If confirmed, Tavenner, a former nurse and hospital executive and currently CMS's second-highest-ranking official, would succeed Donald M. Berwick, M.D., who resigned Dec. 2, a month before his recess appointment expires.

Berwick, who garnered broad support from health care provider and consumer groups, never got a formal hearing before the Finance Committee. He ran into strong opposition from Senate Republicans, already irate over enactment of the health care reform law, who challenged his views on "rationing" of health care and his qualifications to implement the law, charges he rejected. But earlier this year, Utah Sen. Orrin Hatch, the panel's ranking Republican, got 42 of 47 GOP senators to sign a letter vowing to block Berwick's confirmation, effectively ending any chance of him serving beyond 2011.

Tavenner has been the CMS principal deputy administrator since the agency's reorganization in February 2010. She also served as acting administrator from February to July 2010, when Obama installed Berwick using the recess appointment to bypass Senate confirmation. Previously, Tavenner was the Commonwealth of Virginia's secretary of health and human resources in the administration of former Gov. Tim Kaine (D).

In announcing her nomination, the White House highlighted Tavenner's nearly 35-year career in health care, "including almost 20 years in nursing, 3 years as a hospital CEO, and 10 years in various senior executive level positions for Hospital Corporation of America." She also has served as a board member of the American Hospital Association and as president of the Virginia Hospital Association. She holds a bachelor of science in nursing and a master of arts in health administration, both from Virginia Commonwealth University.

Goodbye to Berwick

Despite the partisan opposition, Berwick, a Harvard-educated pediatrician, got good marks from major health care groups and Obama administration officials for his energetic handling of the rollout of major provisions of the health care reform law that alter the landscape of the private insurance market and Medicare.

One of these key provisions calls for coordinated care demonstrations that seek to shift payment to physicians and other providers based on the volume of their services toward reimbursements based on improved quality of care and the patient's experience at lower cost. Programs launched under Berwick's aegis include the Medicare shared savings program for accountable care organizations and a Medicare bundled payment initiative through the CMS Innovations Center.

Berwick's 18-month tenure at the top of CMS also saw the issuance of regulations for new health insurance exchanges where, starting in 2014, Americans can shop, compare, and purchase health care coverage.

Payment to Begin Under Medicare Lab Test Demo

As of Jan. 1, 2012, Medicare will begin paying a set national rate for certain complex clinical laboratory tests selected for a new demonstration project on separate payment for these tests.

Participation is voluntary and open to clinical laboratories, both hospital-based and independent.

The project, authorized under Section 3113 of the health care reform law, will run for two years or until a total payment limit of $100 million is reached. Dates of service must be between Jan. 1, 2012, and Dec. 31, 2013.

The demo applies to a diagnostic lab test ordered by the beneficiary's physician less than 14 days following the date of the patient's discharge from the hospital.

Under standard Medicare "date of service" rules, such testing is considered bundled into payment to the hospital, and the lab must seek reimbursement from the hospital, not directly from Part B. Under the demo, the payment (inpatient and outpatient) to the hospital or critical-access hospital is unbundled.

Participants in the demo will be paid directly under a separate fee schedule at national payment amounts that the Centers for Medicare and Medicaid Services (CMS) has established for covered tests (*see table*). CMS has identified 36 CPT codes that meet the statutory criteria, including molecular diagnostics and genetic testing codes: 23 in the chemistry series, 10 in immunology, one in microbiology, and two in anatomic pathology.

For tests on the fee schedule list, labs directly billing Medicare must submit claims with a project identifier 56 or an approved temporary G code, CMS said in a previous program transmittal (*NIR 11, 13/July 14, p. 4*).

Tests Defined

For purposes of the demonstration, the health care reform law defines a complex diagnostic laboratory test as a diagnostic laboratory test that is:

1. an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;
2. determined by the Health and Human Services secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics;
3. billed using a code from the Healthcare Common Procedure Coding System (HCPCS) other than a not otherwise classified (NOC) code under HCPCS;
4. approved or cleared by the Food and Drug Administration or covered under Medicare; and
5. described in Section 1861(s)(3) of the act, which defines "medical and other health services," including diagnostic laboratory tests.

Details on the project implementation are posted on the CMS Web site at *http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611*.

Questions may be sent to ACA3113labdemo@cms.hhs.gov.

Section 3113 Demonstration Test List (as of December 2011)

HCPCS CODE	CODE DESCRIPTION	DEMO PAYMENT RATE
83890	Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (ie, DNA or RNA)	$5.68
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (ie, DNA or RNA)	$5.66
83892	Molecular diagnostics; enzymatic digestion, each enzyme treatment	$5.70
83893	Molecular diagnostics; dot/slot blot production, each nucleic acid preparation	$5.74
83894	Molecular diagnostics; separation by gel electrophoresis (eg, agarose, polyacrylamide), each nucleic acid preparation	$5.69
83896	Molecular diagnostics; nucleic acid probe, each	$5.67
83897	Molecular diagnostics; nucleic acid transfer (eg, Southern, Northern), each nucleic acid preparation	$5.74
83898	Molecular diagnostics; amplification, target, each nucleic acid sequence	$23.40
83900	Molecular diagnostics; amplification, target, multiplex, first 2 nucleic acid sequences	$45.66
83901	Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2	$21.52
83902	Molecular diagnostics; reverse transcription	$19.97
83903	Molecular diagnostics; mutation scanning, by physical properties (eg, single strand conformational polymorphisms [SSCP], heteroduplex, denaturing gradient gel electrophoresis	$23.87
83904	Molecular diagnostics; mutation identification by sequencing, single segment, each segment	$23.44
83905	Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment	$24.01
83906	Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment	$24.01
83907	Molecular diagnostics; lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue), each specimen	$19.12
83908	Molecular diagnostics; amplification, signal, each nucleic acid sequence	$23.91
83909	Molecular diagnostics; separation and identification by high resolution technique (eg, capilary electrophoresis), each nucleic acid preparation	$23.12
83912	Molecular diagnostics; interpretation and report	$5.71
83913	Molecular diagnostics; RNA stabilization	$19.13
83914	Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay, single base chain extension, or allele-specific primer extension)	$21.52
83950	Oncoprotein; HER-2/neu	$92.26
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)	$92.26
86215	Deoxyribonuclease, antibody	$18.98
86225	Deoxyribonuclease acid (DNA) antibody; native or double stranded	$19.61
86226	Deoxyribonuclease acid (DNA) antibody; single stranded	$17.35
86235	Extractable nuclear antigen, antibody to, any method (eg, nRNP, SS-A, SS-B, Sm, RNP, Sc170, J01), each antibody	$25.44
86294	Immunoassay for tumor antigen, qualitative or semiquantitative (eg, bladder tumor antigen)	$28.10
86300	Immunoassay for tumor antigen, quantitative; CA 15-3	$29.73
86301	Immunoassay for tumor antigen, quantitative; CA 19-9	$29.78
86304	Immunoassay for tumor antigen, quantitative; CA 125	$29.74
86305	Human epididymis protein 4 (HE4)	$29.81
86316	Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each	$29.81
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed	$28.72
88371	Protein analysis of tissue by Western Blot, with interpretation and report	$28.42
88372	Protein analysis of tissue by Western Blot, with interpretation and report; immunological probe for band identification, each	$27.89

Source: CMS. CPT codes © American Medical Association

Medicare Lab Fees to Rise, *from p. 1*

There is no change in the $3 specimen collection fee nor in the amount of the travel allowance. It remains at $1.005 per mile (P9603) and $10.50 on a flat-rate basis (P9604). These codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for 2012, CMS said, the agency will issue a separate instruction on the lab travel fees.

The surprise in the Dec. 9 transmittal to contractors on the 2012 lab fee schedule is how the Centers for Medicare and Medicaid Services (CMS) intends to address payment and claims processing issues connected with the Jan. 1, 2012, rollout of 101 new CPT molecular pathology test codes by the American Medical Association.

Molecular Pathology Procedure Test Codes

CMS had previously indicated that it wanted more input on these new codes before recognizing any or all of them. Now, it has given them a status "B" indicator and is asking clinical labs to report this on claims along with "stacked" molecular diagnostic and genetic testing codes.

"For payment purposes under the Medicare lab fee schedule," CMS said in the Dec. 9 transmittal, "these test codes will be assigned a B indicator—Payment for covered services are always bundled into payment for other services not specified." There will be no relative value units or payment amounts for these codes and no separate payment is ever made. "When these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient)."

Each of these new test codes represents a test that is currently being utilized and which may be billed to Medicare, CMS noted. "When billed to Medicare, we understand that existing CPT codes are 'stacked' to represent a given test. For example, Laboratory A has a genetic test that is generally billed in the following manner—83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time)—in order to represent the performance of the entire test. If the new CPT test coding structure were active, Laboratory A would bill Medicare the new, single CPT test code that corresponds to the test represented by the 'stacked' codes in the example above rather than billing each component of the test separately."

As of Jan. 1, 2012, CMS is asking labs to submit Medicare claims for these molecular pathology procedures that "reflect both the existing CPT stacked test codes that are required for payment and the new, single CPT test code that would be used for payment purposes if the new CPT test codes were active."

Referring to the example above, CMS said, "Laboratory A would report the existing stacked set of codes that are required to receive payment [*i.e.*, 83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time)] along with the new, single CPT test code that corresponds to the test represented by the stacked test codes. While the allowed charge amount will be $0.00 for the new molecular pathology procedure test codes that carry the 'B' indicator, Medicare requests that claims also reflect a charge for the non-payable service."

Medicare Fees for New and Reconsidered Lab Test Codes in 2012

CODE/DESCRIPTOR	CROSSWALK	2012 NATIONAL FEE CAP
NEW CPT CODES		
IMMUNOLOGY		
86386 Nuclear Matrix Protein 22 (NMP22), qualitative	**82487**	**$22.61**
MICROBIOLOGY		
87389 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	**86703 + 50 percent of 87390**	**$34.12**
RECONSIDERED CODES		
G0434 Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived test or moderate-complexity test, per patient encounter	**82487**	**$20.60**
G0435 Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening	**87804**	**$16.99**
83861 Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity	**84081**	**$23.40**
86481 Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension	**86480 + 83520**	**$87.79**
87906 Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion) (current national fee cap, $181.14)	**50 percent of 87901**	**$182.32**

Source: Mapping information, CMS Transmittal 2365, Change Request 7654, Dec. 9, 2011. CPT codes © American Medical Association.

CMS Extends Timeline, *from p. 2*

2015, MACs will send revalidation notices on an intermittent, but regular basis to begin the process for each provider and supplier."

The agency reiterated that providers and suppliers must submit the revalidation application only after being asked by their MAC to do so.

The revalidation effort does not change other aspects of the Medicare enrollment process. You should continue to submit routine changes—address updates, reassignments, addition to practices, changes in authorized officials, and other information updates—CMS says.

If you receive a revalidation notice from your MAC, "respond by completing the application either through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) or by completing the appropriate 855 form," CMS said. Upon receipt of the notice, providers and suppliers have 60 days from the date of the letter to submit complete enrollment forms. Those failing to revalidate within the set time frame risk deactivation of Medicare billing privileges.

Institutional providers (*i.e.*, all providers except physicians, nonphysician practitioners, physician group practices, and nonphysician practitioner group practices) must submit an application fee or hardship exception when initially enrolling, revalidating their enrollment, or adding a new Medicare practice location. The fee is $505 for calendar year 2011 and $523 for 2012.

In answer to problems providers have raised in the past when using PECOS, CMS announced certain changes expected to be in place by the end of 2012. These include e-signatures, electronic document upload, batch upload capability, and seamless password reset, among other improvements.

Medicare Streamlines Overpayment Notification Process

If you have received a Medicare overpayment for a covered service and have not returned it, you can expect to get one, not two, demand letters from your Medicare Administrative Contractor (MAC) seeking to recoup the amount at issue.

This change, effective Nov. 1, 2011, streamlines the Medicare overpayment notification process. Providers previously got three notices—an initial demand letter, a follow-up letter, and an intent to refer letter. The second letter would be sent to providers 30 days after the initial notice. The Centers for Medicare and Medicaid Services (CMS) is eliminating the second demand letter, determining that "this is not efficient since the majority of providers respond to the initial demand letter and pay the debt."

Recoupment action currently happens 41 days after the initial letter. If an overpayment is not paid within 90 days of the initial letter, providers will receive a letter explaining CMS's intention to refer the debt for collection. The remittance advice which describes this action is another notice to providers of the overpayment. Provider appeal rights remain unchanged.

Happy Holidays from all of us at G2 Intelligence!

Reminder: December is a one-issue month for *NIR*.

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NIR 12/11AB

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