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Down to the Wire Again on Medicare Physician Fee Fix

At press time it was unclear whether there are enough votes or enough time on the congressional calendar to pass H.R. 4213, which blocks SGR cuts to Medicare physician fees through 2014. Three times this year, Congress has let a 21 percent cut take effect, then canceled it and frozen fees at their 2009 level.

Heading into the Memorial Day recess, Congress is scrambling to avert a scheduled June 1 cut of 21 percent in Medicare payments to pathologists and other physicians under the Sustainable Growth Rate (SGR) fee update formula.

At press time, Democratic health leaders have unveiled a revamped version of H.R. 4213 that would cancel the cut and replace it with a 1.3 percent increase for the rest of 2010 and a 1 percent pay increase for 2011. In 2012 and 2013, the fee update would be based on a target growth rate in legislation the House passed last year to repeal the SGR. But that bill, with a net cost of around $210 billion, has faltered because of objections by conservatives that it was not paid for and would add to the federal deficit.

The fix proposed in H.R. 4213 by Senate Finance Committee chairman Max Baucus (D-Mont.) and House Ways *Continued on p. 8*

Going Retail With Genetic Tests: Furor Heats Up as Congress Joins the Fray

The Food and Drug Administration (FDA) squelched the plan by San Diego-based Pathway Genomics to sell its over-the-counter genetic test kit at Walgreens drugstores nationwide, starting in mid-May. And now, health lawmakers have escalated the issue to include two other California companies that make and market genetic tests online.

In a May 10 warning letter, the FDA said the product "appears to meet the definition of a medical device" in federal law and gave Pathway Genomics until May 25 to explain why it believes the product does not require FDA clearance or approval.

On May 19, leaders of the House Energy and Commerce Committee gave Pathway Genomics, 23andMe, and Navigenics until June 4 to respond to concerns by the scientific community about the accuracy and proper consumer use of the test results.

Pathway Genomics' product was developed in-house and is performed by its CLIA-certified lab. Consumers collect the sample, send it to the lab for use in a series of personalized genetic test reports for drug response, prepregnancy planning, and other disease conditions. For more on the controversy, see the *Focus*, pp. 4-5.

INSIDE *NIR*

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NPI Required for Enrollment, Claims in Medicare, Medicaid

To enroll or change an existing Medicare enrollment record, use the Internet-based PECOS on the CMS Web site or submit a paper application (CMS-855) to your Medicare contractor. The CMS-855 form is available at cms.hhs.gov/cmsforms.

All providers and suppliers who qualify for a National Provider Identifier (NPI) will be required to include the NPI on any enrollment application to Medicare and Medicaid, as well as on any reimbursement claims to these programs, under an interim final rule issued by the Centers for Medicare and Medicaid Services (CMS). Compliance is required by Jan. 1, 2011.

In addition, providers and suppliers who participate in Medicare must maintain documentation of any referrals for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); home health services; or other programs deemed high risk by the secretary of Health and Human Services.

The documentation requirement includes written or electronic records, including the NPI of the physician or nonphysician practitioner who ordered or referred the services, and must be kept for seven years.

Failure to comply with the requirement may result in CMS revoking their enrollment in federal health care programs for up to a year.

The rule, published in the May 5 *Federal Register* and open for comment until July 2, takes effect July 6, 2010. It implements various provisions in the health care reform law, the Patient Protection and Affordable Care Act (Pub. L. No. 111-148), that aim to weed out fraudulent entities from legitimate health care providers and suppliers, making it harder for the former to bill the federal programs.

For Medicare Part B claims for a covered service furnished by clinical laboratories, imaging suppliers, and specialists that require identification of who ordered the service or made the referral, the rule stipulates that the one ordering or referring "must be a physician or nonphysician practitioner with an approved enrollment record (or a valid opt-out record) in the Provider Enrollment, Chain, and Ownership System (PECOS) and be identified by his or her legal name and by his or her own NPI (that is, the NPI assigned by the National Plan and Provider Enumeration System as an Entity Type 1, an individual)."

Reminder: Ordering/referring providers who are enrolled in Medicare but have not updated their record since November 2003 should update it now, CMS has advised. Even if there are no changes to their enrollment data, providers need to submit an initial enrollment application to establish a current enrollment record in PECOS. Also, those who have not billed Medicare in 12 months need to submit an application to reactivate their enrollment.

As of Jan. 3, 2011, claims from Part B providers and suppliers will be rejected when the ordering/referring physician or nonphysician practitioner does not have a current enrollment record in PECOS (*NIR, 10, 5/March 15, p. 3*).

Organizations must be enrolled before individuals. Before a physician or nonphysician practitioner can reassign their benefits to a medical group or clinic other than the one they solely own, the medical group or clinic must have an approved enrollment record in PECOS.

CDC to Labs: Be on Alert for Vancomycin-Resistant Staph

Following recent confirmation of the 11th case of vancomycin resistant Staphylococcus aureus (VRSA) infection since 2002 in the United States, the Centers for Disease Control and Prevention (CDC) is calling on clinical laboratories to review their procedure or algorithm to detect and help contain VRSA infection.

A sample algorithm at *cdc.gov/ncidod/dhqp/ar_visavrsa_algo.html* highlights the recommended testing methodologies for detecting VRSA and actions to take based on testing results.

Also, because of the exchange of genetic material from vancomycin-resistant enterococci (VRE) to methicillin-resistant Staphylococcus aureus (MRSA) in the emergence of VRSA, CDC is asking that when patients are identified with suspected or confirmed VRSA, clinical labs take steps to ensure that all VRE, MRSA, and VRSA isolates from these patients are saved. Following confirmation of VRSA, the agency recommends that all three isolate types be shared with public health partners, including CDC.

Lab Resource on VRSA

- Frequently asked questions: Laboratory Detection of Vancomycin-Intermediate/ Resistant Staphylococcus aureus, lab for testing.
  cdc.gov/ncidod/dhqp/ar_visavrsa_labFAQ.html

CDC advises that "immediately, while performing confirmatory susceptibility tests, labs should notify the patient's primary caregiver, patient care personnel, and infection control personnel regarding the presumptive identification of VRSA so that appropriate infection control precautions can be initiated promptly. It is also important to notify local and state public health departments."

Coordination with public health authorities is critical, CDC says. It has issued specific infection control recommendations intended to reduce the transmission of VRSA, but these may need to be customized to specific health care settings, for example, dialysis facilities and home health care. Infection control precautions should remain in place until a defined end point has been determined in consultation with public health authorities.

VRSA infection continues to be a rare occurrence, CDC notes, but a few existing factors seem to predispose case patients to it, including:

- Prior MRSA and enterococcal infections or colonization
- Underlying conditions (such as chronic skin ulcers and diabetes)
- Previous treatment with vancomycin

The latest confirmed case was found in Delaware in a 64-year-old patient undergoing wound drainage for prosthetic joint infection. The underlying conditions were diabetes, end-stage renal disease, and dialysis. Eight confirmed cases emerged in Michigan (one in 2002 and seven between 2005 and 2009), one in Pennsylvania in 2002, and one in New York in 2004.

focus on: Genetic Testing

Congress Expands Scrutiny of Direct-to-Consumer Genetic Tests

The Food and Drug Administration (FDA) fired the first shot in the controversy over direct-to-consumer marketing of genetic tests in a May 10 letter, questioning Pathway Genomics' plan to offer an over-the-counter testing product for sale through the Walgreens pharmacy chain nationwide. Upon learning of the letter, Walgreens put the deal on hold, pending further clarification.

Stepping into the controversy, leaders of the House Energy and Commerce Committee have upped the ante, seeking extensive documentation from San Diego-based Pathway Genomics and two other manufacturers in California that market personal genetic tests online.

Pathway Genomics Genetic Test at Issue

The Insight Saliva Collection Kit was expected to retail in most Walgreens pharmacies for $20 to $30 per kit. Customers would collect a sample and return it to the company's CLIA-certified lab for testing. They then could order from a tier of personalized Genetic Test Reports at increasing costs:

$79: Customers can get their DNA tested for how their bodies are likely to respond to 10 substances, including caffeine, cholesterol-lowering statins, the blood thinner warfarin, and the breast cancer drug tamoxifen.

$179: Prospective parents can be tested to see whether they carry 23 genetic conditions, including the blood disorder beta thalassemia, diabetes, and polycystic kidney disease. For the same price, they can be tested for their own risk for 23 conditions, including heart attack, high blood pressure, leukemia, lung cancer, and multiple sclerosis.

$249: Customers can get all of the tests.

The results, although not definitive, could encourage people to adopt more healthful lifestyles if they find they might be at increased risk, company officials said. They further note that customers are offered genetic counseling by phone, both before and after getting the test results, to make sure they are interpreted properly.

They sent their request to Pathway Genomics, 23andMe in Mountain View, and Navigenics in Foster City for information on why they are marketing their products to consumers "despite concern from the scientific community regarding the accuracy of test results."

The May 19 letters were signed by Energy and Commerce chairman Henry A. Waxman (D-Calif.), the ranking member Joe Barton (R-Texas), subcommittee on oversight and investigations chairman Bart Stupak (D-Mich.), and the ranking subcommittee member Michael C. Burgess (R-Texas).

They set a June 4 deadline for receiving documentation from Jan. 1, 2007, to the present on how the companies link certain genetic markers to risks for diseases and adverse drug reactions, how they handle genetic samples collected from customers, how they ensure testing accuracy, and whether FDA approval rules have been met. The companies have all indicated they will cooperate fully with the requests of the committee and the FDA.

FDA Wants Clarification

In its warning to Pathway Genomics, the FDA said the retail kit "appears to meet the definition of a medical device" in current law and has not been submitted for review. The agency gave the company until May 25 to explain its position to the contrary. "If you do not believe you are required

A CDC survey found that 22 percent of Americans were aware of genomic testing, and a sampling of consumers interviewed by the Associated Press found they have real concerns about the cost and potential misuses of such information.

to obtain FDA clearance or approval for the Genetic Health Report, please provide us with the basis for that determination," wrote James Woods, deputy director of patient safety and product quality in FDA's Office of In Vitro Diagnostic Device Evaluation and Safety.

In its initial response, Pathway Genomics said its understanding is that "under current rules, the test does not require FDA approval per se" and "we do not claim that it does." It is a lab-developed test performed only in its CLIA-certified laboratory, company officials noted. The company said the test would help more people get access to potentially invaluable genetic information.

But FDA officials are skeptical, saying the company breached currently sanctioned boundaries for lab-developed tests by going retail. They contend the test is being sold as a tool to make decisions about medical treatments, yet it has not been reviewed by the FDA for accuracy. Alberto Gutierrez, director of the FDA's office of in vitro diagnostics, said, "They are making medical claims. We don't know whether the test works. We think this would be an illegally marketed device if they proceed." The agency is evaluating similar tests, he added.

ACLA Supports Physician Guidance

The American Clinical Laboratory Association (ACLA), responding to the Pathway Genomics plan, issued a statement supporting physician involvement and guidance in ordering genetic tests and using those results to diagnose conditions.

"When genetic services are marketed and delivered directly to the consumer—without important input before and after testing from a personal health care provider and genetic counselors—gaps in understanding can result in serious negative consequences," ACLA said. "In using or interpreting tests that are important for disease prevention, diagnosis, and monitoring, consumers should rely upon an ordering physician with whom they have a personal relationship, and results should not be communicated via long-distance consultations." This would ensure that meaningful action to reduce the chance of developing disease can be taken and unnecessary services avoided.

While other companies have been selling genetic tests online and some tests for paternity and ancestry are sold in stores, the retail plan by Pathway Genomics was hailed by some advocates as a further advance for personalized medicine, breaking down barriers to individuals' access to their genetic makeup and learning about their propensity for certain critical risk factors. But critics say the biology of DNA variations and actual disease is poorly understood and patients could easily misconstrue results, putting them in jeopardy in some cases, based on the test.

Meanwhile, the Federal Trade Commission has warned consumers about the claims made by some genetic testing companies that market their services online. For its part, the FDA, while asserting its jurisdiction over all medical devices (including lab-developed tests), has thus far limited its enforcement actions to analyte-specific reagents (the ingredients used for these tests) and to a category of tests known as in vitro diagnostic multivariate index assays (IVDMIAs) that use a proprietary algorithm to produce results. But the Pathway Genomics incident, coupled with the new congressional inquiry into the mass marketing of genetic tests, may prompt the agency to increase its regulatory clout over similar lab-developed tests.

Lab National Coverage Policies: Coding Changes in July 2010

The next quarterly update to contractor edits of claims for tests subject to Medicare's clinical laboratory national coverage determinations (NCDs), effective July 1, 2010, makes several deletions and additions to the list of noncovered diagnosis codes for all 23 NCDs (see box).

Lab NCDs

Alpha-fetoprotein
Blood Counts
Blood Glucose Testing
Carcinoembryonic Antigen (CEA)
Collagen Crosslinks
Culture, Bacterial, Urine
Digoxin Therapeutic Drug Assay
Fecal Occult Blood
Gamma Glutamyl Transferase (GGT)
Glycated Hemoglobin/Glycated Protein
Hepatitis Panel
HIV Testing (Diagnosis)
HIV Testing (Prognosis including monitoring)
Human Chorionic Gonadotropin (hCG)
Lipids
Partial Thromboplastin Time
Prostate-Specific Antigen (PSA)
Prothrombin Time
Serum Iron Studies
Thyroid Testing
Tumor Antigen by Immunoassay CA 125
Tumor Antigen by Immunoassay CA 15-3/CA 27.29
Tumor Antigen by Immunoassay CA 19-9

Details for each NCD are posted at *www. cms.hhs.gov/CoverageGenInfo*

The deleted ICD-9-CM codes are:

— V17.4, Family history of other cardiovascular diseases

— V18.1, Family history of other endocrine and metabolic diseases

The added ICD-9-CM codes are:

— V17.41, Family history of sudden cardiac death

— V17.49, Family history of other cardiovascular diseases

— V18.11, Family history of multiple endocrine neoplasia syndrome

— V18.19, Family history of other endocrine and metabolic diseases

The changes result from coding analysis decisions and biannual updates to the diagnosis codes, said the Centers for Medicare and Medicaid Services (Change Request 6964, April 30, 2010).

The NCDs affect frequently ordered clinical laboratory procedures and stipulate requirements for uniform coverage, claims processing, and medical necessity documentation. They specify the circumstances under which Medicare will pay for a test, the appropriate CPT and ICD-9-CM codes to use, coverage limitations (such as frequency limits), and other guidelines.

The one exception to this format is the NCD for blood counts. Because there are so many diagnosis codes that could support the medical necessity of blood counts, the NCD lists only those ICD-9 codes that would not support medical necessity.

The NCDs were developed by a laboratory negotiated rulemaking required by the 1997 Balanced Budget Act and were published in a final rule on Nov. 23, 2001. Lab claims for each of the NCDs have been processed uniformly nationwide since April 1, 2003.

Medicare Claims Advisory

Medicare Appeals: CMS Raises the Bar for Dollars in Dispute

New monetary thresholds apply this year if you disagree with your Medicare contractor's decision on paying claims for covered services and you opt to escalate the dispute up the Medicare appeals ladder, the Centers for Medicare and Medicaid Services announced in Change Request 6894 (May 7, 2010).

For requests for an administrative law judge (ALJ) hearing filed on and after Jan. 1, 2010, the amount in controversy is $130, up from $120 required for requests filed prior to that date. The amount required for review by a federal district court on or after Jan. 1, 2010, is $1,260, up from $1,220 for requests filed before then.

Each calendar year since 2005, the dollar threshold for the amount in controversy requirement for an ALJ hearing or judicial review is adjusted to "reflect the percentage increase in the medical care component of the consumer price index for all urban consumers for July 2003 to the July preceding the year involved," according to revised text in the Medicare claims processing manual.

Two or more claims may be aggregated to meet the dollar thresholds as long as they involve the delivery of similar or related services or involve issues of law and fact. Part A and Part B claims may be combined to meet the requirements.

The amount in controversy is computed as the actual amount charged for the items or services in question, reduced by any Medicare payments already made or awarded for the items or services or any deductible and coinsurance applicable to the particular case (the latter does not apply to Part B lab services since they are never subject to an annual deductible or to coinsurance).

The Medicare appeals process consists of five levels and begins after receipt of an initial determination of a Part A or Part B claim by the local Medicare contractor. Each level thereafter has procedural steps that must be completed for each claim at issue prior to moving to the next level of appeal. An appellant has the right to appeal any determination up the ladder until appeal rights are exhausted.

Medicare Fee-for-Service Appeals Process

Appeal Level	Time Limit to File Request	Monetary Threshold to be Met
Redetermination by local contractor	120 days from date of receipt of the initial determination (presumed to be five days from date of the notice)	None
Reconsideration by Qualified Independent Contractors (QICs)	180 days from date of receipt of the redetermination	None
Administrative Law Judge (ALJ) Hearing	60 days from the date of receipt of the reconsideration	For requests filed on or after Jan. 1, 2010, at least $130 remains in controversy.
Departmental Appeals Board (DAB) Review/Appeals Council	60 days from the date of receipt of the ALJ hearing decision	None
Federal Court Review	60 days from date of receipt of the Appeals Council decision or declination of review by DAB	For requests filed on or after Jan. 1, 2010, at least $1,260 remains in controversy.
	Source: CMS Change Request 6894, cms.hhs.gov/Transmittals/downloads/R1965CP.pdf.	

H.R. 4213 also provides that during 2012 and 2013, physicians in accountable care organizations can be subject to their own specific spending targets in lieu of national targets tied to growth in the gross domestic product.

Medicare Physician Fee Fix, *from p. 1*

and Means Committee chairman Sander Levin (D-Mich.) would cost nearly $65 billion over five years, according to the Congressional Budget Office (CBO). When the payment system reverts to current law in 2014, physician fees would be cut 35 percent, the CBO said.

Pathology and other physician groups favor scrapping the SGR system, but acknowledge that only a temporary fix may be politically possible. Even so, it would bring short-term stability to Medicare payment updates, they say.

H.R. 4213 also would clarify the three-day payment window for hospitals under Medicare. Under current law, all services related to an inpatient admission are bundled into the inpatient DRG rate.

The bill "would conform the law with recent practice by preventing future unbundling of services and submission of adjustment claims seeking separate and additional Medicare payments," according to a Democratic summary. Hospitals say this would cut their payments by about $4.5 billion.

• Upcoming G-2 Events •

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June 2-4
Lab Outreach 2010: Building the Value Equation for Your Program
Hyatt Regency Baltimore on the Inner Harbor, Baltimore

Oct. 13-15
Lab Institute 2010
Crystal Gateway Marriott
Arlington, Va.

Dec. 8-10
Laboratory Sales and Marketing 2010
The Venetian Las Vegas
Las Vegas

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