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Labs Get Short Reprieve on New Physician Signature Policy

The policy change applies to test requests made on paper forms, not to tests requested electronically or by telephone.

The Centers for Medicare and Medicaid Services (CMS) has delayed implementing a controversial new policy, effective Jan. 1, requiring the signature of a physician or nonphysician practitioner (NPP) on clinical laboratory test requisitions.

Citing concern about lack of awareness or understanding of the new policy, the agency said it would devote the first three months of this year to educating providers about the change via its Web site and other channels of communications.

But "once our first quarter educational campaign is fully underway, [we] expect requisitions to be signed," CMS said.

A requisition is the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient.

In adopting the new policy in the 2011 Medicare physician fee schedule rule, CMS exempted test requests made electronically or by telephone, stating that it "does not consider these to be requisitions." If the request is made by telephone, both the treating physician or practitioner, or

Continued on p. 2

Revised Conversion Factor Released for 2011 Medicare Physician Fees

In the waning days of the lame-duck session in December, Congress approved, and the president signed, legislation (H.R. 4994) canceling the 25 percent cut in Medicare physician payments scheduled for Jan. 1 and freezing the fee update for one year, through 2011.

As a result, the Centers for Medicare and Medicaid Services (CMS) has released a revised conversion factor to be used to translate the relative value units (RVUs) of a Part B physician service—work, practice expense, and malpractice expense—into a dollar amount.

The conversion factor for 2011 is $33.9764, the agency announced in a Dec. 29, 2010, transmittal. "While the physician fee schedule update will be zero percent, other changes to the RVUs (e.g., misvalued code initiative and rescaling of the RVUs to match the revised Medicare Economic Index weights) are budget-neutral. To make them so, CMS must adjust the conversion factor." As a result, it drops from $36.8729 in the second half of 2010 to $33.9764 as of Jan. 1, 2011.

Continued on p. 6

INSIDE NIR

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Labs Get Short Reprieve, *from p. 1*

his or her office, and the testing facility must document the call in their respective copies of the beneficiary's medical records.

Physicians are not required to use a requisition. They can use an "order," which CMS defines as "a communication from the treating physician or practitioner requesting that a diagnostic test be performed." This can be an annotated medical record or a documented telephone request.

While the clinical laboratory community had hoped to persuade CMS not to go ahead with the change—or at least delay its implementation for one year, through 2011—groups representing labs say they are grateful for a three-month reprieve.

"Implementation on Jan. 1, 2011, would have resulted in a crisis in access to laboratory services for the nation's seniors," said the American Clinical Laboratory Association (ACLA) in a statement issued Dec. 21, 2010. "ACLA maintains that the policy is unworkable and is committed to working with CMS to examine a feasible alternative approach to meeting CMS's objective of ensuring that laboratory requisitions are appropriately documented."

In a Dec. 3, 2010, letter signed by 29 groups, the Clinical Laboratory Coalition urged CMS not to alter longstanding policy that while a signature is one way to document who ordered the test, it is not the only permissible way so long as the documentation exists in an alternate format, such as the beneficiary's medical record. This was agreed to in a final 2001 rule developed by a congressionally mandated negotiated rulemaking committee and had been reiterated in CMS issuances as late as March 2010.

CMS argues that the new requirement eliminates uncertainty about whether documentation was required, will not increase the burden on physicians because "it is our understanding that physicians are already annotating the medical record or signing the paperwork provided to the laboratory," and would minimize compliance problems for labs during audits.

But the abrupt turnabout, critics say, increases the burden not only on physicians but also on labs, which have no way of enforcing the requirement and are the only provider at financial risk if the requisitions are not signed.

In a policy statement, ACLA said that "physicians simply do not sign requisitions today; rather, the requisition is handed off to nonphysician staff, who are expected to fill out the requisition pursuant to the physician's direction." Someone must then track down the physician or NPP for the sign-off. The new policy "will add a new, and unnecessary, step to the patient encounter, disrupt the work and paper flow in the physician's office, and could cause the patient to wait before being able to leave."

The policy applies to clinical laboratory services payable under the Part B lab fee schedule. It does not apply to pathology services payable under the Part B physician fee schedule. Nonetheless, Peter Kazon, an attorney with Alston & Bird (Washington, D.C.), advises that once the policy goes into effect, labs should plan on getting a signature on all written orders for laboratory services, regardless of whether they

If You Use a Requisition . . .

Prepare to invest time and money in reformatting forms and client education.

- ❒ On printed forms make the fields for "physician signature" and "date" prominent to the eye and flag them as "required."
- ❒ Train laboratory staff, including phlebotomists and data-entry personnel, on standard operating policies in handling requisitions that don't comply with the new CMS policy.
- ❒ Educate your referral client base on the new policy, calling attention to the new requirements for paper forms.

are paid via the clinical lab or physician fee schedule.

During a Dec. 16, 2010, webinar sponsored by Washington G-2 Reports, Kazon discussed several key issues.

What happens if a lab bills without a signed requisition?

CMS says you need a physician signature to have a valid order. If you don't have a valid order, then it raises the very substantial question about whether a laboratory should bill for the service.

Can a laboratory go back to a physician to obtain a signature if the requisition comes in unsigned?

It appears likely. In certain circumstances, CMS has permitted labs to obtain an "attestation statement" signed by the physician to support that he or she ordered certain testing (see Transmittal 327, issued March 10, 2010). However, this is a key issue that CMS will have to clear up prior to implementation.

What will the likely impact of this rule be on nursing homes?

It seems likely that this rule could have a significant impact on labs that specialize in servicing nursing home patients. In many instances, nursing homes order tests after a telephone consultation with the patient's physician. Because this physician is usually not on site, it will make it difficult for the nursing home to obtain a signature prior to ordering the test. Also, this difficulty is magnified because often testing is ordered based on a standing order, which may cover a plan of care for the patient. If the standing order is otherwise valid, and signed by the physician, then it is possible that that could serve as the order, although CMS has not spoken to that issue.

Are stamped signatures permissible on requisitions?

No. In transmittal 327, CMS states that a signature must be handwritten or electronic. Stamped signatures are not permissible

Pathology 'Grandfather' Protection Extended for 2011

Congress approved a one-year extension, through 2011, of the statutory moratorium protecting certain pathology billings by independent clinical laboratories, which expired Dec. 31, 2010. The extension was part of H.R. 4994, the Medicare and Medicaid Extenders Act, signed Dec. 15, 2010.

The "grandfather" protection allows an independent clinical laboratory to bill Medicare directly for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, when the Medicare program first proposed to end such billings. Congress has repeatedly stepped in to block this policy change. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

The cost of extending the grandfather protection is pegged at $100 million over 10 years.

CMS has repeatedly sought to end the "grandfathered" pathology TC billings, contending that the TC is paid through the hospital's perspective payment and labs should seek reimbursement from the hospital, not the Part B program.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected.

GOP Takes Control of Key House Health-Related Committees

With the Republicans taking control of the House as the 112th Congress opened this month, the chairman's gavel passed into the hands of new leaders on several key health-related committees that have broad powers over tax and spending measures, including Medicare coverage and payment policy.

The new leadership lineup is as follows. All the new GOP chairmen have insisted that their priority is to cut the federal deficit and to repeal the health care reform law or at least cut off or curb the Obama administration's funding requests to carry out the law's numerous provisions.

Appropriations
Harold Rogers of Kentucky, 73, member of Congress since 1981. Charged with cutting billions from the president's budget for the current fiscal year.

Budget
Paul D. Ryan of Wisconsin, 40, first elected to Congress in 1998. Regarded as a budget hawk. Last year he drew up a blueprint for entitlement reform that involved partially privatizing Social Security and doing away with Medicare in its current form. Under new House rules, he has the authority to set spending limits for the rest of the year, which could not be exceeded by any bill unless a majority of the House agreed to waive the limits.

Ways and Means
Dave Camp of Michigan, 57, has served in Congress since 1991. Former chairman Sander Levin of Michigan becomes the ranking minority member. At the health subcommittee level, Wally Herger of California assumes the chair; former head Pete Stark of California becomes the ranking Democrat.

Energy and Commerce
Fred Upton of Michigan, 57, has served in the House since 1987. His committee has the most sweeping jurisdictions in the House. Former chairman Henry Waxman of California becomes the ranking minority member. At the health subcommittee level, Rep. Joseph R. Pitts of Pennsylvania assumes the chair.

Oversight and Government Reform
Darrell Issa of California, 57, elected to Congress in 2000. Has cited health care reform as a potential target for heightened investigation and oversight.

Medicare to Begin Coverage of Annual Wellness Visits

Effective Jan. 1, 2011, Medicare will expand its Part B preventive services benefit to cover and pay for annual wellness visits for beneficiaries that include a risk assessment and personalized preventive service plan. All cost sharing is waived.

One key element of the added benefit is to provide a written schedule for screening tests for the individual, such as a checklist for the next five to 10 years, for age-appropriate preventive services covered by Medicare as well as recommendations for screening and immunizations from other federal bodies.

Medicare already covers and pays for a one-time-only "Welcome to Medicare"

baseline physical exam furnished to a beneficiary within 12 months of his or her enrollment in Part B. This initial preventive physical exam also includes education, counseling, and referrals for clinical laboratory screenings and physician services included in the Part B benefit.

Key Elements of the Wellness Visit

The annual wellness visit includes the establishment of, or update to, the beneficiary's medical and family history; measurement of height, weight, body-mass index or waist circumference, and blood pressure; a list of current providers and suppliers that are regularly involved in providing medical care to the individual; detection of any cognitive impairment; risk for depression; and functional ability and level of safety.

New Billing Codes

G0438—Annual wellness visit, includes a personalized prevention plan of service (PPPS), first visit (Short descriptor—Annual wellness first)

G0439—Annual wellness visit, includes a personalized prevention plan of service (PPPS), subsequent visit (Short descriptor—Annual wellnesssubseq)

Another element of the visit—voluntary advance care planning—was defined in the 2011 final physician fee schedule rule to include end-of-life planning. But such planning was removed from the rule Jan. 5 by the White House. End-of-life planning was not contained in the proposed physician rule, and press secretary Robert Gibbs said pulling it from the final was a procedural matter to give stakeholders more time to comment.

Key Eligibility Requirements

To be covered, the annual visit must be:

—Performed by a health professional: a doctor of medicine or osteopathy, qualified nonphysician practitioner (nurse practitioner, physician assistant, or clinical nurse specialist), or a medical professional (including a health educator, registered dietitian, nutrition professional, or other licensed practitioner), or a team of such medical professionals who are working under the direct supervision of a physician.

—Furnished to an eligible beneficiary who is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period, and he or she has not received either the baseline exam or an annual wellness visit within the past 12 months.

Most Cost Sharing Waived for Medicare Preventive Services

Covered clinical laboratory tests are not affected. They are paid under the Medicare lab fee schedule, and beneficiary cost sharing has never applied.

As of Jan. 1, 2011, under terms of the health care reform law, out-of-pocket costs for Medicare beneficiaries—the annual deductible and 20 percent copay—are scrapped for most preventive services.

In a transmittal to local contractors (Change Request 7012), the Centers for Medicare and Medicaid Services notes that the law waives both the deductible and coinsurance for the initial preventive physical exam and the annual wellness visit and for Medicare-covered preventive services that have been recommended with a grade of A ("strongly recommends") or B ("recommends") from the U.S. Preventive Services Task Force *(NIR 10, 9/May 5, p.* 5). Also waived: the Part B deductible for tests that begin as colorectal cancer screening but, based on findings during the test, become diagnostic or therapeutic services.

Revised Conversion Factor, *from p. 1*

CMS illustrated the calculation of the calendar year 2011 conversion factor (CF) in the following table.

December 2010 CF	$36.8729
MMEA "Zero Percent Update"	0.0 percent (1.000)
RVU Budget Neutrality Adjustment	0.4 percent (1.0043)
Rescaling to Match MEI Weights Budget Neutrality Adjustment	-8.3 percent (0.9175)
CY 2011 CF	$33.9764

The cost of the physician fee fix is $14.9 million over 10 years. The fix, along with other extenders in H.R. 4994, are 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.

Physician groups and the Obama administration are urging the new Congress to use this year to tackle a fundamental reform of physician payment as an alternative to the Sustainable Growth Rate Formula (SGR) that has triggered negative updates for most of the past decade, prompting lawmakers to intervene with a series of short-term patches. But cost is a major obstacle—upward of $300 billion over 10 years, according to a Congressional Budget Office estimate.

Reminder: New Deadline for Filing Medicare Claims

As of the first of this year, all Medicare fee-for-service claims for services furnished on or after Jan. 1, 2010, must be filed within one calendar year (12 months) of the date of service or they will be automatically denied. The new timely filing deadline was required by the health care reform law, the Patient Protection and Affordable Care Act of 2010.

The Centers for Medicare and Medicaid Services (CMS) is handling claims from institutional providers and professional and supplier claims differently with respect to span date claims (Change Request 7080 at *cms.hhs.gov/transmittals*).

- ❏ For institutional claims that include span dates of service (a "From" and "Through" date span), the "Through" date will be used to determine the date of service in accord with the new timely filing deadline.
- ❏ For professional claims (CMS-1500 Form and 837P) submitted by physicians, clinical laboratories, and other providers that include span dates of service, the line item "From" date will be used to determine the date of service and the timely filing deadline. (This includes supplies and rental items.)
- ❏ If a line item "From" date is not timely, but the "To" date is, Medicare contractors will split the line item and deny untimely services as not timely filed.
- ❏ Claims with a date of service of Feb. 29 must be filed by Feb. 28 of the following year to be considered as timely filed. If the date of service is Feb. 29 of any year

and is received on or after March 1 of the following year, the claim will be denied as having failed to meet the timely filing requirement.

CMS has the authority to exempt providers from the one-year limit in cases where there is an error or misrepresentation by an employee, Medicare contractor, or agent of the U.S. Department of Health and Human Services.

CMS Announces New Waived Tests, Billing Codes

The Jan. 1, 2011, update by the Centers for Medicare and Medicaid Services (CMS) to the list of test devices waived under the Clinical Laboratory Improvement Amendments (CLIA) includes the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

The list of CLIA-waived tests and billing codes is updated quarterly. For the Jan. 1 update, which includes a complete list of all currently waived tests, see the official instruction at http://www.cms.gov/Transmittals/downloads/R2084CP.pdf.

When billing for the tests below, use the QW modifier so your local Medicare contractor can recognize the code as CLIA waived. Prior to approval for payment, your claims are checked to see whether you are certified for waived testing.

The latest tests approved by the FDA as waived under CLIA are valid as soon as they are approved. They are:

CPT Code	Effective Date	Description
G0430QW	Jan. 1, 2010	American Screening Corp. OneScreen Drug Test Cups
84443QW	March 2, 2010	Aventir Biotech LLC, Forsure TSH Test {Whole Blood}
84443QW	March 4, 2010	BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette
G0430QW	April 21, 2010	CLIAwaived, Inc. Rapid Drug Test Cup {OTC}
G0430QW	April 21, 2010	Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup
G0430QW	May 10, 2010	US Diagnostics ProScreen Drugs of Abuse Cup {OTC}
G0430QW	July 1, 2010	Ameditech, Inc ImmuTest Drug Screen Cup
G0430QW	July 4, 2010	Quik Test USA, Inc. Multi-Drug of Abuse Urine Test
G0430QW	July 4, 2010	Screen Tox Multi-Drug of Abuse Urine Test
82274QW, G0328QW	July 8, 2010	Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT)
G0430QW	July 19, 2010	Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test
G0430QW	July 19, 2010	Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test
G0430QW	Aug. 18, 2010	American Screening Corp. Reveal Multi-Drug Testing Cups
87880QW	Aug. 18, 2010	PSS Consult Diagnostics Strep A Dipstick

Contractors are not required to search their files to either retract payment or retroactively pay claims, but they are to adjust claims brought to their attention.

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