WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 10, Iss. 20, November 4, 2010

CMS to Require Physician Signature on Lab Test Requisitions

This reverses longstanding Medicare policy, established by a congressionally mandated lab-negotiated rulemaking, that while a signature is one way to document who ordered the test, it is not the only permissible way as long as the documentation exists in an alternate format, such as the beneficiary's medical record.

The Centers for Medicare and Medicaid Services (CMS) is finalizing, without modification, its controversial proposed policy to require the signature of a physician or nonphysician practitioner (NPP) on requisitions for clinical diagnostic laboratory tests paid under the Medicare Part B lab fee schedule.

The proposal drew strong opposition from the Clinical Laboratory Coalition, representing 10 major lab associations (*NIR 10, 15/August, p. 1*). While CMS said it "carefully considered comments received," it decided to adopt the proposal without change. This prompted a swift objection from the American Clinical Laboratory Association, a coalition member: "Although this would require a major change in the way that labs and physicians handle lab testing, CMS apparently intends to impose the requirement as soon as it can amend the underlying manuals. As a result, unnecessary burdens will be imposed on physicians and labs, and patients' access to lab services could be limited."

The new policy does not require physicians or NPPs to use a requisition to request Part B-covered clinical lab services, CMS emphasized. Those who choose not to can continue to request such tests by other means, such as annotated medical records, documented telephonic requests, or electronically.

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CMS Announces End to Pathology 'Grandfather' Protection

The Centers for Medicare and Medicaid Services (CMS) has announced that after Dec. 31 it will bar an independent laboratory from billing Medicare for the technical component (TC) of physician pathology services furnished to a hospital inpatient or outpatient.

The agency stated this reimbursement policy change in the final 2011 Medicare physician fee schedule rule (with comment period), released Nov. 2 and set for publication in the Nov. 29 *Federal Register*.

The new policy would end the current pathology "grandfather" protection that allows an independent lab to bill Medicare directly for the TC. CMS has long advocated elimination of these billings, contending that the TC is reimbursed through the hospital's prospective payment and the lab should seek payment for the service from the hospital, not Medicare Part B.

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CMS Announces End, *from p. 1*

Congress has repeatedly blocked the agency from moving ahead by enacting a series of short-term extensions of the "grandfather" protection, most recently last year by approving a one-year extension, through Dec. 31, 2010. Clinical lab and pathology groups have urged Congress to extend it again, noting it is of special benefit to rural hospitals that cannot afford to perform the pathology work in-house but must send it to an outside clinical lab.

Unless Congress steps in again, the CMS policy is on track to take effect Jan. 1, 2011. There is little time to get another extension of the protection on the legislative fast track. The calendar for the upcoming lame-duck session of Congress is already tight and little time is left to pass an extension of the protection. The session is set to begin Nov. 15 and break for the Thanksgiving holidays, leaving only a scant few weeks to act on a host of more high-profile items, such as expiring tax breaks and a Medicare physician payment fix, before adjourning.

The likely legislative vehicle to save the protection, industry sources speculate, would be an extenders bill that would encompass the grandfather protection along with other expiring Medicare payment and policy changes.

If not extended during the lame-duck session, the protection could be revived retroactively when the new Congress opens in January. But this would be an uphill battle, industry sources say. Given the Republican gains in the House and the Senate in the midterm elections, the prism through which all proposals will be reviewed will be their effect on the budget and deficit reduction.

The grandfather protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to eliminate such billings. Further, it 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. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

CMS Proposes Tougher Screening of All Providers, Suppliers

The Centers for Medicare and Medicaid Services (CMS) has proposed a new rule that would tighten the screening requirements for all providers and suppliers enrolling or participating in federal health care programs, adding fingerprinting and criminal background checks of those providers and suppliers rated high risk for fraud, waste, and abuse.

The new rule is part of the switch from pay-and-chase enforcement to enforcement based on preventing the possible payment of fraudulent claims, said CMS Administrator Donald Berwick, M.D.

The proposal would implement provisions in the Patient Protection and Affordable Care Act (PPACA), giving the secretary of health and human services new discretionary authority to increase the level of screening for providers and suppliers operating within Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). It would apply to all those newly enrolled on March 23, 2011, as well as all those currently enrolled and revalidating their status.

Under the proposal, all providers and suppliers in these programs would be ranked in one of three risk levels—limited, moderate, or high—based on an assessment of their overall risk for fraud, waste, and abuse. Screening procedures would differ for every risk level, with those ranked high risk getting the most attention (*see table*).

Three-Tiered Model for Screening

RISK LEVEL	*ENTITIES AFFECTED*	*SCREENING CHECKS*
Limited	Physicians, nonphysician practitioners, group practices, medical clinics	Verify any provider/supplier requirements set forth by Medicare; verify his or her licensing; and undergo database checks before and after enrollment to verify Social Security numbers, tax delinquency, and any exclusions by the OIG
Moderate	Independent clinical labs, non-publicly traded ambulance service providers, community mental health centers, comprehensive outpatient rehabilitation facilities	Same as Level 1, plus subject to unscheduled site visits
High	Home health agencies, DMEPOS suppliers	Same as Levels 1 and 2, plus criminal background checks and fingerprint checks

Fingerprint checks have never been used in the screening process, but CMS said this would verify an individual's identity and prevent any identity theft. Criminal background checks have been used sparingly, but CMS said they would help stop fraud from happening in the first place by weeding out criminals attempting to enroll in the programs.

Independent Labs Rated Moderate Risk

CMS would place independent clinical labs in the moderate-risk category, meaning they would be subject to unscheduled site visits. While these labs are subject to survey requirements, such as those under the Clinical Laboratory Improvement Amendments (CLIA), the agency said these labs' "sheer volume of services and associated billings" warrants ranking them in this category.

Physicians, nonphysician practitioners, group practices, and medical clinics would be considered limited risk because they are state-licensed and CMS is aware of no recent research warning of an elevated fraud risk from these providers.

Home health agencies and durable medical equipment, prosthetics, and orthotics suppliers (DMEPOS) are regarded as high risk, CMS said, based on numerous reports from the Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office.

New Fee for Providers, Suppliers

A new fee would be imposed to pay for the tougher screening rules. It would apply to all providers and suppliers billing Medicare, Medicaid, and CHIP for services, except for Part B medical groups or clinics and physicians and nonphysician practitioners submitting a CMS application for enrollment in Medicare.

The fee, to be set initially at $500, would apply to all enrolled for the first time as well as all currently enrolled and revalidating their status. It would take effect March 23, 2011. For each subsequent year, the fee would be the same as the previous year, adjusted for the consumer price index.

Temporary Suspension

Under the proposed rule, CMS also could temporarily suspend enrollment of new providers and suppliers in the programs, either individually or on a category basis, if this would prevent fraud, waste, and abuse.

The rule, published in the Sept. 23 *Federal Register*, is open for comment by Nov. 16.

N.Y. Prohibits Labs From Donating EHRs to Referring Physicians

The New York Department of Health is prohibiting laboratories operating in the state from providing electronic health record (EHR) systems and software packages to referring physicians even though federal law allows labs to donate or cost-share up to 85 percent of the cost of EHR software.

In a Sept. 27 letter to clinical labs operating in New York state, the department said that state rules "do not allow cost sharing; therefore, provision of EHR, software, and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in the state." The letter noted that the preamble to the federal EHR regulations, published in the *Federal Register* Aug. 8, 2006, makes it clear that the EHR-related federal payment allowance does not preempt state laws and regulations.

To clarify the policy and assist compliance, the department plans to issue frequently asked questions "hopefully in a month, probably mid-December," Deidre Astin, MS, MT(ASCP), director of regulatory affairs, told G-2 Reports in a Nov. 3 e-mail reply to a G-2 inquiry.

Between 2011 and 2015, it is predicted that nationally 350,000 or more physicians will implement EHR systems for use in their daily practices, according to the letter. The rapid and widespread adoption of EHRs by both hospitals and physician practices is unprecedented and creates several challenges for labs, including being asked by health care providers to pay for or contribute to the cost of the interface to client EHRs or being asked to donate or cost-share up to 85 percent of the cost of new EHR software.

While the federal and state governments are involved in a variety of efforts to encourage the use of health information technology, the department said it has become aware of abusive business practices—"specifically, that clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner."

But labs operating in New York state may provide limited types of software and hardware that facilitate test ordering and the transfer and storage of laboratory-generated data, the letter noted. For example, labs may:

1 Interface their laboratory information system to the client's existing EHR to enable seamless test ordering and results reporting and facilitate other lab-related functions (see No. 2 below) and may assume, as a cost of doing business, the cost of a such a limited interface.

2 Provide a practitioner with computer hardware, software, and information technology training and supplies that are restricted to lab-related functions that enable a practitioner to (a) order tests from the lab, including access to a directory of services (i.e., specimen type, collection container, and test information); (b) receive, access, print, and store test results received from the lab, including storing cumulative results for individual patients; (c) transmit data necessary for the lab to prepare requisitions and generate bills, invoices, or claims for reimbursement; and (d) transfer lab data received from the lab to any computer system maintained by the practitioner.

3 Provide computer hardware and software as noted above that also contains functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals.

4 Provide to a Regional Health Information Organization (RHIO) or health information exchange (HIE) computer equipment and supplies, information technology, and software in accordance with the requirement in No. 2 above. Labs may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's costs of participation unless in accordance with the requirements in No. 2 above. Nothing in No. 2 requires a lab to provide such EHR components to a RHIO or HIE for its participants.

The health department also said that labs operating in New York state must retrieve all computer equipment placed with the health services provider and related unused supplies and discontinue paying for an interface upon termination of a lab services agreement or arrange for a one-time purchase at fair market value that transfers ownership of hardware and software to the practitioner.

Potential Problems for Labs, Pathologists

Several health care attorneys contacted by G-2 Reports say the letter could create significant problems for labs and pathologists who thought they were covered by the federal exception. Enforcement of this policy could require them to undo current contracts with referral sources and possibly even seek reimbursement for the share of the cost they have paid.

Rob Mazer, an attorney with Ober Kaler (Baltimore), notes that physicians may try to enforce any contracts they have with labs covering EHR software, technology, and training, particularly since the physicians likely have signed an agreement with the EHR vendor. This may not be possible, however, he added, because a court may refuse to enforce an agreement that it believes is illegal. Mazer says he hopes the department will allow a reasonable amount of time for labs to unwind existing agreements.

The policy stated in the letter presumably would apply to pathologists as well, says Jane Pine Wood, an attorney with McDonald Hopkins (Boston), who advises pathology groups. While this is not necessarily a new policy, she notes, it has never been widely publicized or enforced, and many labs and pathologists may have been unaware of the state prohibition. For now, Wood advises waiting for further clarification from the department before starting the process of undoing agreements. "I would advise my clients to take a wait-and-see approach until we have more answers."

Independent Payment Advisory Board Under New Fire

The American Hospital Association (AHA) has come out in favor of scrapping a provision in the health care reform law that establishes the Independent Payment Advisory Board whose proposals for controlling Medicare spending growth would become law unless Congress intervenes. The AHA is supporting repeal legislation introduced in the Senate last July by John Cornyn (R-Texas).

In an Oct. 26 letter to Cornyn, AHA said the board's existence "permanently removes Congress from the decisionmaking process and threatens the long-time, open, and important dialogue between hospitals and their elected officials about the needs of local hospitals and how to provide the highest quality care. Already, America's hospitals are paid less than the cost of treating Medicare patients, and although hospitals will not be subject to IPAB decisions until 2020, *Continued on p.8*

CMS to Require Physician Signature, *from p. 1*

In setting forth the details, CMS reinforced the distinction it is making between a written test "order" and a test "requisition." These are two different documents, the agency said, although a requisition that is signed may serve as an order.

A Test Order

This is defined in the *Internet Only Manual* (100-02, Chapter 15, Section 80.6.1) as a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial test ordered yields to a certain value determined by the treating physician/practitioner (for example, if test X is negative, then perform test Y).

An order may be delivered via any of the following forms of communication:

- ❏ A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility.
- ❏ A telephone call by the treating physician/practitioner or his or her office to the testing facility.
- ❏ Electronic mail, or other electronic means, by the treating physician/practitioner or his or her office to the testing facility.

The new policy is contained in the final 2011 Medicare physician fee schedule rule, released Nov. 2 and scheduled for publication in the Nov. 29 Federal Register. *Acknowledging that clinical labs need time to educate physicians and NPPs on the change, CMS said that for its part, in addition to updating its manuals, it will direct Medicare contractors to furnish educational materials on this issue to affected providers.*

If the order is communicated via telephone, both the treating physician/practitioner, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

A Test Requisition

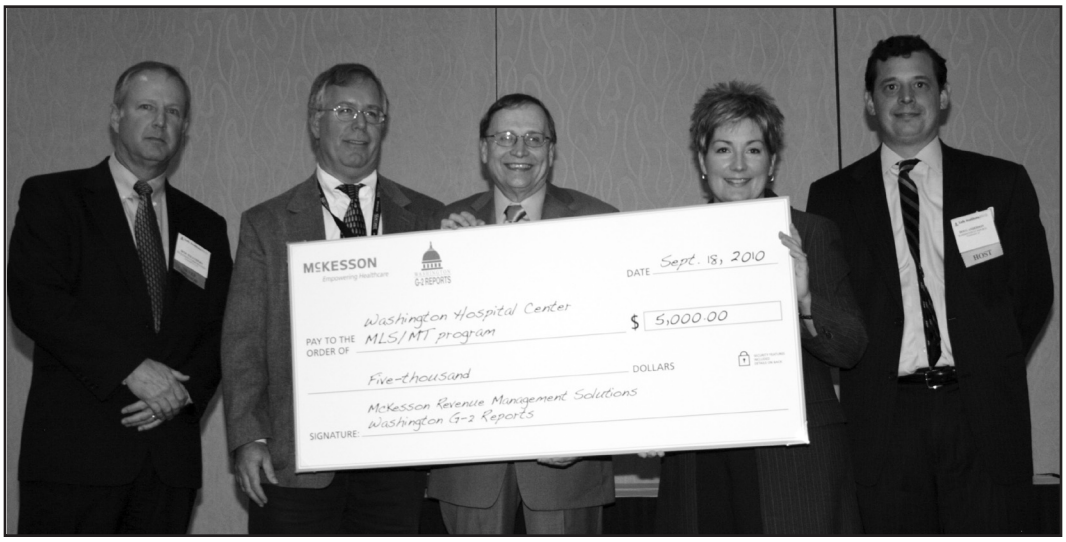
This is defined as "the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient." It may contain information on the patient, the ordering physician, the referring institution, where to send reports, billing, specimen collection, shipping addresses for specimens or tissue samples, and checkboxes for test selection.

Sticking to Its Guns

In finalizing its proposal, CMS stuck to its original argument that the new policy provides a straightforward directive for labs to meet. Requiring a physician's signature for all requisitions and orders eliminates uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature.

Nor will the policy increase the burden on physicians, CMS reiterated, because, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the "order"), as well as a signature on the paperwork provided to the lab that identifies the test or tests to be performed for a patient (the "requisition") as a matter of course. It also makes it easier for reference lab technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized in subsequent Medicare audits because a signature would be consistently required.

Scholarship Award for 2010 Presented at Lab Institute



The seventh annual Dennis Weissman/Washington G-2 Reports Scholarship, sponsored by McKesson and Washington G-2 Reports, was presented to the Washington Hospital Center CLS/MT Program (Washington, D.C.) at a special ceremony held during G-2's Lab Institute in October.

Pictured at the award ceremony are, from left to right, Bob Weathers (McKesson), Tom Godwin (chairman of the CLS/MT program), Dr. John Rees (outgoing program director), Amy McCarty (incoming program director), and Doug Anderson (publisher, Washington G-2 Reports).

The $5,000 scholarship, given annually for excellence in clinical laboratory science, is intended to help develop future leaders and qualified medical technology professionals.

Interest Rate Drops for Medicare Overpayments, Underpayments

Effective Oct. 22, 2010, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has dropped to 10.75 percent from the rate of 11 percent in effect since July 21.

RATE CHANGES THIS YEAR	*PERCENT*
Jan. 1 – Jan. 24	10.875
Jan. 25 – April 22	11.25
April 23 – July 20	10.875
July 21 – Oct. 21	11

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar year 2010) or the private consumer rate fixed by the Treasury. Upon notification from the Treasury of the new private consumer rate at 11 percent, the Centers for Medicare and Medicaid Services announced the quarterly update to the Medicare interest rate in Transmittal 174, Change Request 7155 (Oct. 18, 2010).

The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent.

Independent Payment Advisory Board, *from p. 5*

we are deeply concerned that removing elected officials from the decisionmaking process could result in even deeper cuts to Medicare in the future."

The IPAB is charged with monitoring Medicare's fiscal health and recommending payment policy revisions to contain the program's cost growth. Its 15-member board, appointed by the president, is set to begin its work in 2012. Then, starting in 2014, in any year in which the Medicare per capita growth rate exceeds certain growth targets, the IPAB would be required to recommend Medicare spending reductions. Its proposals are binding unless Congress passes an alternative to reduce an equivalent amount of Medicare spending. Most providers would be affected by IPAB actions in 2014 (clinical labs in 2015, while hospitals are exempt until 2020).

The Congressional Budget Office has estimated the IPAB would save Medicare $15.5 billion between 2015 and 2019, the years in which its recommendations would be implemented.

The College of American Pathologists, the American Clinical Laboratory Association, the American Medical Association, and a host of others have raised concerns about the IPAB, because it shifts responsibility for Medicare coverage and payment decisions historically made by Congress to an unelected body in the executive branch. The groups say the current process provides an open and transparent legislative means to air important policies on health care services.

• Upcoming G-2 Events •

Webinar *2:00 p.m.–3:30 p.m. (Eastern)*

Nov. 16

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Conference

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NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com.

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