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# NATIONAL INTELLIGENCE REPORT®

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## Down to the Wire Again for Key Pathology, Lab Goals

*Congress has little time to block resumption of deep cuts in Medicare physician fees and to extend the pathology grandfather protection for independent clinical labs serving hospital patients.*

Congress returned to work this week for a session that pundits say will be more about campaigning than legislating in the run-up to the volatile midterm elections as Democrats and Republicans jockey for electoral advantage over jobs and the economy, tax breaks, and deficit spending.

In this climate, legislative consideration of two key pathology and clinical laboratory priorities could be pushed off to a lame-duck session after the elections, it is widely speculated.

These key priorities are:

- ❑ Blocking a 21 percent cut in Medicare physician payments scheduled for Dec. 1 as well as a further 27 percent cut on Jan. 1, and persuading lawmakers to replace the sustainable growth rate (SGR) formula that has triggered ever deeper fee cuts over the past decade with a new payment update system.
- ❑ Extending beyond Dec. 31 the grandfather protection that allows independent labs to bill Part B for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients.

*Continued on p. 2*

## CMS Considers Withdrawing Proposed Cytology Proficiency Testing Rule

The Centers for Medicare and Medicaid Services (CMS) is considering withdrawal of its proposal to revise requirements for gynecologic cytology proficiency testing (PT) under the Clinical Laboratory Improvement Amendments (CLIA), the agency said at the Sept. 1-2 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC).

That proposal, issued in 2009, was based on most of the recommendations from a CLIAC work group and endorsed by the committee. The changes included lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies, for example, digital images, as they become available (*NIR, 09, 2/Jan. 26, p. 1*).

In explaining the CMS change of mind, Judy Yost, the top CLIA official, told *NIR*, "Unfortunately, the current CLIAC members were not members at the time that CLIAC made the original recommendations to CMS for these proposed changes. Therefore, they were unable to

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**Down to the Wire,** *from p. 1*
Congressional and voter concern over federal deficit spending clouds the prospects for fundamental reform of Medicare's physician payment system as well as a permanent extension of the grandfather protection. Deficit anxiety combined with the short time left on the legislative calendar, make it doubtful that lawmakers will do little more than fall back on more temporary fixes to these issues.

*The grandfather provision is especially important to rural hospitals that often cannot afford to do the pathology work in-house and must send it out. They are expected to have a sympathetic ear from two influential senators from rural states, Max Baucus (D-Mont.), chairman of the Finance Committee, and ranking Republican Charles Grassley (Iowa).*

## Pathology Payments

Congress this year has repeatedly blocked a 21 percent cut in Medicare physician fees required under the SGR formula, most recently when it approved a six-month increase of 2.2 percent from June 1 through Nov. 30 (the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, Pub. L. No. 111-192).

This ended months of wrangling over how extensive a fee fix should be and how to pay for it. Partisan differences on the question in the House and the Senate resulted only in repeated compromises to block the scheduled SGR cut and freeze fees at their 2009 levels before Congress finally granted the six-month 2.2 percent increase, paying for it by cuts elsewhere in the Medicare budget. The estimated cost: $6.3 billion, according to the Congressional Budget Office (CBO).

Unless lawmakers step in again, the 21 percent SGR cut is due to be implemented Dec. 1, followed by a further cut of an estimated 27 percent on Jan. 1.

Adopting a 10-year Medicare physician payment fix would cost an estimated $330 billion, CBO said in a letter to Sen. Mike Crapo (R-Idaho), released Aug. 25. Prior to the 2.2 percent pay hike, the cost of freezing Medicare physician fees at the 2009 level for six months during the second half of calendar year 2010 and allowing for an inflation update for 2011 through 2019 would carry a price tag of $278 billion. But this estimate, CBO noted, did not include the 2.2 percent payment rate increase, with an estimated cost of $6.3 billion over the 2010-2011 period. "The net cost of providing December 2010 payments at the 2009 level and allowing for an inflation update for 2011 through 2019 would be $272 billion," CBO stated.

However, legislation enacted during the remainder of this Congress would be assessed over the 2011 to 2020 period, rather than through 2019, CBO told Crapo. As a result, the estimated cost would be $330 billion.

## Pathology 'Grandfather' Protection

With this protection due to expire Dec. 31, absent congressional action, CMS intends to end independent lab billings for the TC of anatomic pathology services to hospital inpatients and outpatients. The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed eliminating these billings. The agency contends that payment for the TC is included in the hospital's inpatient DRG payment, so labs should seek reimbursement from the hospital, not Part B. The cost of extending the protection is estimated at around $100 million a year.

At this point, the likely legislative vehicle appears to be a bill with Medicare and other extenders, sources tell *NIR*, similar to last year when the grandfather protection was renewed for 2010 as part of a broader bill.

# Opposition Grows Against Physician Signature Proposal

Clinical laboratory, hospital, and health care organizations have come out strongly against a proposed new Medicare payment policy that would require the signature of a physician or a nonphysician practitioner (NPP) on all requisitions for tests reimbursed via the Part B lab fee schedule.

*CMS proposed requiring a physician's signature on all lab test requisitions in its July 13 proposal for the 2011 physician fee schedule and said it would address all related comments in a final fee schedule rule that the agency expects to publish in November.*

This would reverse longstanding Medicare policy agreed to in 2001, following a negotiated rulemaking that involved 18 laboratory and health care organizations, including the American Medical Association, as well as the Centers for Medicare and Medicaid Services (CMS).

The change would lead to confusion, a complicated and unnecessary administrative process, and potential harm to patients forced to wait too long for lab tests, 13 organizations said in a letter to Donald Berwick, M.D., head of CMS.

Currently, a physician's signature is one way to document that the treating doctor ordered a service for a Medicare beneficiary, but not the only permissible way and it is not required as long as documentation exists in an alternate form. For example, the physician may document the ordering of specific services and their medical necessity in the patient's medical record.

### Signatories to Letter to CMS Chief

American Association of Bioanalysts
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Clinical Laboratory Management Association
College of American Pathologists
National Independent Laboratory Association
American Hospital Association
Laboratory Corporation of America Holdings
Quest Diagnostics Incorporated

CMS said the new policy would create less confusion by eliminating any uncertainty over whether the documentation is a requisition or an order, since signatures would be required on both. But the organizations countered that any uncertainty is rooted in confusing language in CMS manuals and can be resolved "without adding the extra and repetitive step of requiring a physician's signature on all requisitions." They then presented Berwick, head of CMS, with examples of the new administrative burdens and the potential harm to patients:

- There will be duplication of recordkeeping since the physician would need to sign the requisition and the patient's chart. Many labs cite a situation in which either of these two is not signed or differ in some way. The decision as to which is the final order would then be at the lab's discretion.

- There is no incentive for physicians to comply with the proposed requirement or any consequences for not complying. Many physicians collect lab specimens in their offices, and in this case, requiring a signature for specimens collected by office staff, based on the doctor's order, adds another redundant process to the implied consent found in the use of preprinted requisitions and office collections.

- Medicare will be one of the few programs with a physician signature rule. Only three state Medicaid programs and no private insurance companies require signatures on clinical lab requisitions.

- What should a lab do if a signature is missing? Standard practice is to perform

the test when the specimen arrives because this is in the best interest of the patient. Is it the lab's function to hold all tests until the physician complies with the regulations? Timely testing is often essential to patient care. In the skilled nursing home environment, obtaining a physician signature for daily lab orders and stat requests creates additional documentation requirements without any improvement in the order validation process.

# CMS Pressed to End Pathology Self-Referral Arrangements

*The pathology and lab groups say specialty practices are abusing the Stark exception for in-office ancillary services (IOAS) as well as the Medicare anti-markup rule. The proposed 2011 physician fee schedule rule is silent on these issues, and the groups want CMS to address them in the final rule expected in November.*

Pathology and clinical laboratory groups are again urging the Centers for Medicare and Medicaid Services (CMS) to close regulatory loopholes they say an increasing number of medical specialty groups are exploiting to boost Medicare revenue by insourcing anatomic pathology work.

Specialty practices defend such arrangements, saying it enables them to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with diagnostic and treatment recommendations.

The Stark law prohibits Medicare and Medicaid referrals of beneficiaries for designated health services to entities with which the physician has a financial relationship (either by ownership interest or compensation arrangements or both) unless it fits within an exception. The anti-markup rule does not bar a billing physician from marking up the payment for the professional component and the technical component of a pathology service as long as the performing physician shares a practice with the billing physician.

In a letter to CMS administrator Donald Berwick, M.D., the IOAS coalition asked that anatomic pathology and certain radiology services be removed from the in-office exception. Coalition members include the College of American Pathology (CAP), the American Clinical Laboratory Association (ACLA), the American Society for Clinical Pathology, and the American College of Radiology.

In separate comments, ACLA said CMS's reluctance to tackle the issues has given the green light for physician specialties to capture more pathology work. "Physician specialists are increasingly taking advantage of gaps in the anti-markup and self-referral rules and entering into business arrangements that permit them to order, bill, and be paid the full fee schedule rate for anatomic pathology, even though the services are actually furnished by physicians who have little or no relationship with the ordering physician and his or her group." At a minimum, CMS should "emphasize its concerns about these arrangements in the final rule" to deter their proliferation in 2011.

Both ACLA and CAP called on CMS to reinstate the requirements governing "purchased" diagnostic tests that were dropped in 2009. This previous policy prevented physicians from marking up diagnostic tests purchased from an outside supplier.

The Medicare Payment Advisory Commission (MedPAC) has also voiced its concern over volume growth and increased Part B spending associated with physician investment in ancillary services in its June 2010 report to Congress (*NIR, 10, 13/ July 12, p. 2*).

# HHS to Destroy Data From Lab Bidding Demo

The long-running litigation over Medicare's competitive bidding demonstration for independent clinical lab services has come to an end. The Department of Health and Human Services (HHS) has agreed to destroy the bidding data that labs in the San Diego area submitted during the project.

*The demonstration project was intended to test the use of competitive bidding in paying for Part B lab services in place of the existing lab fee schedule.*

HHS consented to destroy the documents by Aug. 20. The lab plaintiffs had asked that the bids be returned and that they not be used for any Medicare payment determinations, including reimbursement cuts.

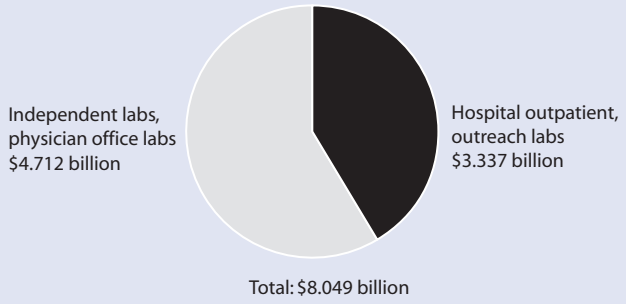
The Centers for Medicare and Medicaid Services (CMS) had planned to launch the demo in the San Diego area on July 1, 2008, but earlier that year lab plaintiffs obtained a preliminary injunction to stop the project. The court also ordered CMS not to announce any winners or disclose any bid information that labs had submitted (*NIR, 29, 12/April 14, pp. 1, 4-6*). Subsequently, following vigorous lobbying by the clinical laboratory industry, Congress repealed CMS's authority to conduct the lab bidding demo (*NIR, 29, 20/Aug. 13, p. 2*).

But CMS refused to return the data to the lab plaintiffs (*NIR, 10, 6, March 25, p. 3*). This prompted them to pursue the issue further, culminating in the signing of the settlement agreement and dismissal of the case Aug. 3.

# Part B Lab Spending Reaches $8 Billion in 2009

Medicare spending on Part B clinical laboratory services soared 11.2 percent to reach $8.049 billion in calendar year 2009, according to data from the 2010 Medicare Trustees Report. The jump is significant compared to the anemic 2 percent increase between 2007 and 2008.

**Part B Lab Outlays, 2009**




Carrier labs (i.e., independent labs and physician office labs) accounted for $4.712 billion, up 10.5 percent from $4.265 billion in 2008. Intermediary labs (i.e., hospital lab outpatient and outreach) provided $3.337 billion of this spending, an increase of 12.3 percent compared with $2.971 billion in 2008.

Total Medicare spending in 2009 was $508 billion, up 8.5 percent from $468.1 billion in 2008. The number of beneficiaries increased by 2.4 percent to approximately 46.3 million, a slight increase over 45.2 million in 2008.

Part B lab services represented 1.6 percent of overall Medicare expenditures in 2009. Over the past five years, Part B lab expenditures have risen an average 5.9 percent per year, compared with an average rate of growth of 10.5 percent for total Medicare spending over the same time frame.

Over the next 10 years, 2010-2019, Part B spending on lab services is projected to increase 8.6 percent annually. However, the Medicare trustees predict that the annual growth in total Medicare spending will slow to an average of 5.8 percent per year. This is based in part on scheduled physician payment cuts, which lawmakers are not likely to allow.

# FDA, CDC Issue Warning on Fingerstick Device Use

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have issued a new alert for laboratory personnel, phlebotomists, and all who perform blood testing about the use of fingerstick devices on more than one person and the risk this poses for transmitting bloodborne pathogens.

*The warning targets reusable fingerstick (blood lancing) devices and point-of-care blood testing devices (for example, blood glucose meters, PT/INR anticoagulation meters, cholesterol testing devices, etc.).*

In an Aug. 26 initial communication, the FDA and the CDC noted a progressive increase in reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of fingerstick and point-of-care (POC) blood testing devices.

While the infections occur in a variety of health care settings, the agencies noted "a significant increase in hepatitis B virus infection outbreaks related to the shared use of multiuse fingerstick devices and POC blood testing devices in long term care and assisted living settings. Unclear labeling and ineffective cleaning and disinfection instructions may have contributed to these outbreaks."

## Precautions Advised

The FDA and the CDC recommend that health care professionals and patients take the following immediate precautions:

- ❏ Fingerstick devices should never be used for more than one person.
- ❏ Auto-disabling, single-use fingerstick devices should be used for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped, or otherwise made unusable. These may also be called "safety" lancets.
- ❏ Whenever possible, POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, should be used only on one patient and not shared. If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.
- ❏ Change gloves between patients, even when patient-dedicated POC blood testing devices and single-use, self-disabling fingerstick devices are used by health care personnel.

## Policy Change Planned

"Improper use or device malfunction can lead to the use of the contaminated lancet blade on more than one patient. Furthermore, it is difficult for health care staff to ensure that all blood has been removed from POC blood testing devices and the reusable portions of the fingerstick device. If POC blood testing devices are used on multiple patients and are not cleaned and disinfected correctly and thoroughly between each patient, contaminated blood left on them could result in bloodborne pathogen transmission among patients."

Some legally marketed fingerstick devices have been cleared for use on more than one patient. Shortly, the FDA said, it will issue a separate communication describing the actions it will take to ensure that these devices are labeled for use on only one patient to reduce the risk of bloodborne infection transmission.

# First Review Bodies Named to Certify E-Health Records

The Certification Commission for Health Information Technology (CCHIT, Chicago) and the Drummond Group Inc. (DGI, Austin, Texas), have been selected by the HHS Office of the National Coordinator for Health Information Technology as the first technology review bodies authorized to test and certify electronic health record (EHR) systems.

EHR vendors can now begin to have their products certified as meeting the criteria to support "meaningful use," the first stage of which was detailed in a final rule published in July (*NIR, 10, 14/July 23, p. 4*).

*More information about the first certifying bodies is available at* http://www.cchit.org/ *and* http://www.drummondgroup.com.

In announcing the first certifying bodies, David Blumenthal, national coordinator for health IT, said, "This is a crucial step because it ensures that certified EHR products will be available to support the achievement of the required meaningful use objectives, that these products will be aligned with one another on key standards, and that doctors and hospitals can invest with confidence in these certified systems," he said. Applications from other organizations are under review.

Demonstration of meaningful use of EHRs by physicians and other eligible professionals as well as hospitals is required in order to qualify for new incentive payment programs to help providers switch from paper-based medical records to electronic ones. Individual physicians and other eligible professionals can receive up to $44,000 through Medicare and almost $64,000 through Medicaid.

The certification of e-health records and the financial incentives to adopt and use them effectively is part of a national initiative undertaken by Congress and the Obama administration under the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act (ARRA) of 2009.

# New Billing Modifier for Non-ESRD Related Lab Tests

In the transition to Medicare's new prospective payment system for services to end-stage renal disease (ESRD) beneficiaries, clinical laboratory services paid under the composite rate and those separately billable to Part B will be rolled into a single bundled payment (*NIR, 10, 15/Aug., p. 3*).

*Medicare preventive services, telehealth services billed with HCPCS code Q3014, and blood and blood services remain separately payable.*

As of Jan. 1, 2011, certain lab services and limited drugs and supplies for beneficiaries will be subject to Part B consolidated billing and will no longer be separately payable when provided to ESRD beneficiaries by providers other than the renal dialysis facility. However, when these lab services and limited drug and supplies are furnished to an ESRD beneficiary but are *not* related to the treatment for ESRD, they are separately payable but must be billed with a new modifier, the Centers for Medicare and Medicaid Services announced in a recent transmittal (Change Request 7064, Aug. 20, 2010).

The claim lines submitted by the laboratory or other supplier should include the new AY modifier to allow for separate payment outside the ESRD prospective payment system. ESRD facilities billing for any labs or drugs should take note that these services will be considered part of the bundled ESRD payment unless billed with the modifier AY.

**Cytology PT Proposed Rule,** *from p. 1*

come to agreement about it, even though 77 percent of the comments we received expressed dislike for the rule." CLIAC has urged CMS to take another look at the comments received on the PT proposal before deciding whether to move forward or not. Nationwide cytology PT testing began in 2005. Approved providers are CAP and the American Society for Clinical Pathology.

The proposal to revise the PT requirements would impact 2,142 cytology laboratories and 12,831 individuals who screen or interpret 65 million gynecologic cytology preparations in the U.S. each year, CMS noted. The agency said the program has been successful, based on PT results from the first three years of nationwide testing.

"For example, failure rates on the initial test of each annual testing cycle dropped from 33 percent in 2005 to 11 percent in 2007 for pathologists reading slides without the assistance of a cytotechnologist. Nonetheless, given the consequences of false Pap test results, the current level of failure is still of great concern to CMS. During the same period, the failure rates dropped from 10 percent to 3 percent for pathologists reading slides with the assistance of a cytotechnologist, and from 7 percent to 3 percent for cytotechnologists reading slides alone under the supervision of a pathologist."

## • Upcoming G-2 Events •

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

**Sept. 14**
**The Central Role of the Sample: Principles and Case Studies in Reducing Laboratory Errors**

**Sept. 29**
**Health Care Reform: Implications and Opportunities for the Lab Industry**
*Discussing key drivers for success in this new environment, including the electronic medical record, global payment structures, and the aggregation of health care provider organizations and physicians into large integrated networks*

***Conferences***

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*Come for the Summit and Stay for Lab Institute*
Crystal Gateway Marriott
Arlington, Va.

**Oct. 13-15**
**28th Annual Lab Institute**
**Making Change Work for You**
Crystal Gateway Marriott
Arlington, Va.

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

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