



# NATIONAL INTELLIGENCE REPORT®

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## Push Is on to Overhaul Medicare Physician, Lab Payments

*Pathology and other physician groups want Congress to repeal the SGR system for physician fee updates, while some lab groups back development of a resource-based alternative to the lab fee schedule*

**W**hile Congress just enacted Medicare legislation canceling a physician fee cut and repealing lab competitive bidding, lawmakers have already been put on notice that physician and clinical laboratory groups will be pushing next year for fundamental changes in the methods that Medicare uses to pay for their services.

The Medicare law enacted July 15 approved a short-term fix that cancels any cuts in physician fee schedule payments under the update formula and grants a 0.5 percent fee increase through 2009. But the medical community is united in urging Congress to devote next year to devising a permanent solution before more cuts kick in again in 2010.

The College of American Pathology, the American Society for Clinical Pathology, and other physician groups advocate repeal of the Sustainable Growth Rate (SGR) update system that has triggered fee cuts for most of this decade and want to be involved in developing a legislative alternative.

Overhaul of the Part B lab payment method is also on the table, with the recent introduction of legislation, backed by the American Society for Clinical Laboratory Science and the Clinical Laboratory Management Association, to revamp the lab fee schedule based on value, resources required, and geographic cost variations. For details on the lab bill, see the *Focus*, pp. 4-6. 🏛️

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## Delay Seen in Switch to New Single ABN

**T**he Centers for Medicare and Medicaid Services earlier this year announced plans to issue a revised Advance Beneficiary Notice (ABN) that clinical laboratories and other providers billing Medicare Part B must use by no later than Sept. 1. But since CMS has yet to release final instructions implementing the change, this deadline will not likely be met.

Though CMS had yet to respond to a *NIR* inquiry on the issue at press time, industry sources said they have been told by agency officials that a delay of six to seven months is more on the mark, with March as a likely time for the transition to be effected.

The ABN alerts beneficiaries that Medicare is not likely to cover a particular item or service and they are financially liable if the claim is denied. CMS has proposed replacing the two approved forms required since 2003 (the general-use ABN-G, Form CMS-R-131G, and the lab-specific ABN-L, Form CMS-R-131L) with a revised *Continued on p. 2*



### **New Single ABN**, *from p. 1*

single-page ABN, CMS Form CMS-R-131 (*see the April 28 2008 issue of NIR, p. 3*). Combining the two into a single all-provider form was first proposed by CMS last year (*NIR, 28, 10/Mar 12 2007, pp. 4-5*).

Lab organizations across the board have urged CMS to grant more time for the transition—at least one year from the date that the agency issues final instructions to Medicare contractors on use of the revised ABN and what is required to make it valid. More time is needed, the American Clinical Laboratory Association has told the agency, since the switch will require major changes to computer systems, both internal and with third-party vendors, plus the re-education of ordering physicians and staff. This work cannot begin in earnest until CMS has finalized the instructions.

Most controversial in the revised single ABN is a new requirement that, to be valid, the form must provide an estimated cost for the particular item or service in question. ACLA continues to oppose requiring a cost estimate as a condition of validity.

“The options CMS is proposing in this section of the [draft] instructions will be very confusing to beneficiaries and are highly unlikely to permit them to make informed decisions,” said ACLA. “For example, asking a beneficiary to sign a ‘routine’ ABN for a blood glucose test based on frequency limitations and giving an estimate of \$100 provides no real information to the beneficiary as to his or her actual liability. If labs choose to preprint a menu of tests on the form and include a cost estimate for each test, would the range for a valid ABN be by test?”

CMS is not expected to budge on requiring a cost estimate and has said the ABN would be valid if a good-faith effort were made to calculate the cost. “We will be flexible in defining ‘good faith’, particularly in cases where the ordering and rendering providers may be different.” ACLA and other lab groups see this as problematic, particularly for labs that are often the rendering provider and must rely on the physician or other ordering provider to complete the ABN form appropriately. For this reason, the groups urge CMS to set clear standards in the instructions for what is and is not permissible. 🏛️

## **CMS Seeks Dismissal of Lab Bidding Demo Lawsuit**

**T**he Centers for Medicare and Medicaid Services has asked a federal district court in San Diego to dismiss the lawsuit filed by local labs to stop the agency from implementing the launch of a Medicare competitive bidding demonstration for independent clinical laboratory services. The court granted a preliminary injunction earlier this year blocking CMS from proceeding with the demo and gave the agency until Aug. 8 to respond.

CMS says the suit is now beside the point because Congress, in approving the new Medicare law July 15, repealed the agency’s authority to conduct the demo. But attorney Patric Hooper, who represents the local labs in the case, told *NIR* he is not so sure the lawsuit is over yet, noting that the plaintiffs are still awaiting return of the bid applications submitted to CMS before the court issued the preliminary injunction. The injunction barred CMS from disclosing or using information on the bid applications. “We have been negotiating with CMS on this precise point,” said Hooper, who is with Hooper, Lundy & Bookman in Los Angeles. At press time, he added, “We are analyzing next steps,” following the government’s motion to dismiss. Each side in the case will bear its own fees and expenses, he noted. 🏛️

## OIG Assures Providers on Waivers of Beneficiary Cost Sharing

*The waivers are allowed in circumstances occasioned by the new Medicare physician fee schedule payment increases and are subject to certain conditions, the OIG noted. However, providers are not required to waive retroactive beneficiary liability.*

Physicians and other Medicare providers will not risk administrative sanctions if they waive retroactive beneficiary cost sharing amounts attributable to increases in the Part B physician fee schedule payments enacted in the new Medicare law, the HHS Office of Inspector General said in a July 23 policy announcement.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P. L. 110-275, enacted July 15, 2008) cancelled a 10.6 percent cut in physician fees that took effect July 1 and granted a 0.5 percent increase retroactive to that date and continuing through 2009.

The OIG issued the policy statement after being informed by the Centers for Medicare and Medicaid Services that beneficiaries who already paid or were billed for cost sharing amounts based on lower pay rates temporarily in effect since July 1 are liable for additional cost sharing under the increased MIPPA rates (Retroactive Beneficiary Liability or RBL).

“We have been asked whether providers affected by the payment increases are required to bill for or collect the RBL in order to comply with the OIG’s fraud and abuse authorities,” said Inspector General Daniel R. Levinson in the statement. “Ordinarily, routine waivers potentially implicate the federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibiting inducements to beneficiaries.

“Notwithstanding, in these limited circumstances, providers will not be subject to OIG administrative sanctions if they waive RBL, subject to these conditions,” Levinson noted:

- ❑ The policy applies to these waivers only for the period from July 1 until the date on which CMS (or the relevant contractor) implements the higher payment rates applicable to the particular provider. Once the new rates are implemented, providers are expected to calculate the beneficiary’s financial responsibility based on these rates.
- ❑ The policy applies only to RBL, that is, the increase in the beneficiary’s financial obligation attributable to the increase in MIPPA payment rates. The policy does not apply to waivers calculated using the lower payment rates temporarily in effect since July 1.
- ❑ The policy does not apply to waivers if they are conditioned in any manner on the provision of future items, supplies, or services.

The OIG emphasized that nothing in the policy statement affects the ability of a provider to waive any cost sharing amount on the basis of a good-faith determination of a beneficiary’s financial need or when reasonable collection efforts have failed. 

## Medicare Nixes Stamped Physician Signatures

Stamped physician signatures are not acceptable on any medical record, the Centers for Medicare and Medicaid Services has emphasized in new guidance to providers and Medicare contractors. CMS acted in response to problems of noncompliance with requirements for a valid physician signature on medical documents. The new guidance (Change Request 5971) prohibits use of stamped signatures. Medicare does accept handwritten or electronic signatures or facsimiles of the original written or electronic signatures. 



## focuson: Lab Payment Policy

### New Bill Aims to Modernize Medicare Lab Fee Schedule

Coming fast on the heels of the clinical laboratory industry's victory in beating down the competitive bidding demonstration and securing a CPI update to Medicare fees in 2009 after a five-year freeze, legislation was unveiled in the House that calls for a radical change in the Part B lab reimbursement methodology.

Repeal of the lab bidding demonstration authority and a 4.5 percent CPI increase in the 2009 lab fee schedule were approved in the Medicare bill that became law on July 15. The Centers for Medicare and Medicare Services had planned to launch the bidding demo in San Diego on July 1, but was blocked by court order earlier this year in a lawsuit filed by labs in the area. CMS has since moved to dismiss the case, saying repeal has made the issue moot (*related story, p. 2*).

With an end to the threat of competitive bidding as a fee schedule alternative, the American Society for Clinical Laboratory Science (ASCLS) and the Clinical Laboratory Management Association (CLMA) want Congress to turn its attention to reform of the current Part B lab fee schedule, using negotiated rulemaking to rebase payment rates in line with advances in clinical practice and changes in market factors. (Negotiated rulemaking has been required in the past, at the urging of the lab industry, to establish national Medicare coverage decisions for 23 frequently performed clinical lab tests, eliminating payment differences among carriers.)

#### Alternative to Present Payment Method

Through the efforts of ASCLS and CLMA, the Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008 (H.R. 6761) was introduced July 31 to reform the present lab fee system. The goal is to develop a single national Part B lab fee schedule for use in all lab settings, based on the value of the testing and the resources required, plus an adjustment for geographic cost differences.

While lab industry groups generally acknowledge that the current lab fee schedule is inadequate and inefficient, especially in pricing new tests such as molecular diagnostics and other gene- or protein-based procedures, some caution that switching to a different payment method could "open a can of worms."

The industry was united against competitive bidding, one source told *NIR*, but regarding replacement of the current fee system, "it would likely speak with a variety of voices."

But lab lobbyist Don Lavanty told *NIR* it was "important politically to get the issue introduced and on the table" so it can be pushed next year as part of broader health care reform that Congress is expected to consider, including a Medicare physician fee overhaul.

Lavanty does not foresee further action on H.R. 6761 this year, given the tight legislative calendar before Congress adjourns for the October election campaigns. But advocates of the bill “will go full bore next year” to get it passed, he said.

H.R. 6761 is sponsored by Reps. Bart Stupak (D-Mich.) and Michael Burgess (R-Tex.), both serving on the Energy and Commerce Committee. The bill has been referred to that committee and to Ways and Means.

CLMA and ASCLS are urging their members to get their representatives to sign on as cosponsors and are working to secure support from other members of the Clinical Laboratory Coalition. In citing the need for reform, the legislation notes that clinical labs provide vital information that influences 70 percent of all patient care decisions.

In a statement supporting the bill, CLMA said, “The Medicare lab fee schedule was adopted in 1984 and has not been subject to a fundamental review and updating since then to reflect changes in the delivery of clinical lab medicine, resulting in real reductions in reimbursement. Today, clinical labs are paid only 75 percent of the 1984 level when adjusted for inflation ... CLMA and ASCLS believe the time has come for a new fee schedule to be developed with legislated goals and guidance based on the Institute of Medicine (IOM) report and ensuring full industry input.”

### Problems with the Current Lab Fee Schedule

The Medicare Part B lab fee schedule was adopted in 1984, based on 1983 prevailing charges. Fee schedules vary by region, though most tests are paid at the national limitation amount (NLA) set by CMS.

Mechanisms to keep lab payments up to date are inadequate. The inflation update factor and the NLAs raise or lower fees across the board, but the current system does not readily accommodate changes in payment rates for specific tests, in particular, new molecular diagnostics.

The annual CPI update is no sure thing. Congress has blocked it in 12 of the years from 1994 to the present. For 2009, lawmakers have whittled down the full update by 0.5 percent.

The NLAs have been in place since 1986 for most tests on the lab fee schedule, but Congress has steadily reduced them. Initially, the cap was set at 115 percent of the median amount of all carriers’ fee schedules for that particular test, but by 1998, the cap had been reduced to 74 percent of the national median, where it remains today for most tests.

Fees for new and revised tests are set using one of two methods: a crosswalk to an existing code on the fee schedule or the gap-fill method that establishes a fee based on local pricing patterns.

CMS can adjust a fee up or down by 15 percent under its Part B inherent reasonableness authority if the payment is grossly excessive or deficient, but the agency has not yet applied this authority to lab services.

The IOM report, “Medicare Laboratory Payment Policy: Now and in the Future,” released in 2000, recommended a single national fee schedule developed through a data-driven consensus process and adjusted for geographic location. Congress requested the study to assess current Medicare lab payment policy and evaluate alternatives. The report said existing mechanisms for keeping payments up to date were inadequate, noting that the inflation update factor and the national fee caps raise or lower fees across the board but do not accommodate changes in payment levels for specific tests, in particular, new technologies.

### Key Provisions

In accord with H.R. 6761, the Health and Human Services secretary is to appoint a negotiated rulemaking committee comprised of 15 voting members and two nonvoting members who are representative of lab industry groups, test manufacturers, private payers, and beneficiary organizations.



The committee is charged with developing a proposal for modernizing the lab fee schedule. No later than two years from enactment, the committee is to submit a report to Congress on the proposal, and if there are no objections, HHS is to move to finalize regulations creating the new fee schedule.

Reimbursement under the new fee schedule would be developed as follows:

- ❑ A primary base pay rate would be established to account for the value of lab testing in patient care management, the potential for Medicare cost savings, and industry wide clinical lab practice expenses, including liability costs and the costs of specimen collection and transportation.
- ❑ An adjustment would be made to the base rate to account for variations in the cost of furnishing such services among various geographic areas, among various types of lab settings for comparable purposes, and to special beneficiary populations served by skilled nursing facilities, hospital outpatient departments, and physician offices.
- ❑ The fee schedule shall include a mechanism to periodically revise fees, with input from stakeholders, to reflect the changing costs, value, and utilization of tests. There would be no arbitrary cap, and revisions would be made at least once every five years, but not more frequently than once a year.

To phase in the new fee schedule, CMS would utilize payment rates that reflect a blend of rates under the new schedule and those under the old one until the new schedule is fully implemented. Also, to achieve greater administrative simplicity and efficiency, the new fee schedule will eliminate or reduce the number of differential pay rates under the present fee system.

H.R. 6761 further stipulates that the new payment method would not require beneficiary cost sharing.

### **AdvaMed Takes a Different Tack**

The leading medical device manufacturers' group, AdvaMed, is backing a separate measure pending in the House that also calls for changes in Medicare lab payment policy. The bipartisan bill (H.R. 1321) would require a consensus-driven approach to determining fees for molecular diagnostics, starting with the gap-fill method that relies on local pricing patterns. The legislation was introduced March 5, 2007, by Rep. Bobby Rush (D-Ill.) and has 13 cosponsors. It has been referred to the Energy and Commerce health subcommittee.

Relying on the crosswalk method in setting fees for these tests is flawed, AdvaMed argues, because the fee schedule lags behind new technologies and does not reward their value, raising barriers to innovation and beneficiary access. Also, when considered in light of fee limits enacted by Congress since the current fee schedule was introduced in 1984, it is way out of date, says AdvaMed.

AdvaMed favors a demonstration to test a new payment scheme for molecular diagnostics. It would reflect value in patient care management, resource use, stakeholder involvement, administrative efficiency and overall cost savings, and would have no geographic or site-of-service limits. 🏛️



## ◆ Medicare Coverage *Advisory*

### Prothrombin Time Home Monitoring

On Aug. 25, Medicare will begin to implement its new national coverage decision (NCD) that expands coverage of prothrombin time monitoring for home anti-coagulation management to encompass more beneficiaries on warfarin therapy.

The NCD previously was limited to home PT/INR (Prothrombin Time/International Normalized Ratio) monitoring by beneficiaries with mechanical heart valves who are on warfarin. Under the expanded policy, coverage will include home monitoring by beneficiaries with chronic atrial fibrillation or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) who are on warfarin.

Coverage requirements under the new national policy also specify that the treating physician must prescribe the monitor and the home testing, and all of the following must be met:

- ❑ The patient must have been anticoagulated for at least three months prior to use of the home device;
- ❑ The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated correct use of the device prior to its use in the home;
- ❑ The patient continues to correctly use the device in managing anticoagulation therapy after home monitoring has begun; and
- ❑ Self-testing with the device should not be done more than once a week.

Porcine valves are not included in this NCD, so Medicare will not pay for beneficiaries with them unless covered by local contractors.

The new NCD applies to claims with dates of service on or after March 19, 2008, (CMS Change Request 6138, July 25, 2008). Applicable HCPCS codes will continue to be used for claims processing:

G0248	Demonstrate use home INR mon
G0249	Provide INR test meter and equipment
G0250	MD INR test review and management

This NCD is distinct from, and makes no changes to, the prothrombin time clinical laboratory NCD at Pub. 100-03, section 190.17 of the NCD Manual. 🏛️

### DNA Stool Screening Test for Colorectal Cancer

The Centers for Medicare and Medicare Services has declined to expand the Medicare Part B colorectal cancer screening benefit to include coverage of Pre-Gen-Plus™, a commercially available screening DNA stool test, as an alternative to a screening colonoscopy or a screening flexible sigmoidoscopy.

The Food and Drug Administration has determined that this test is a medical device requiring premarket review and approval which, to date, has not been obtained, CMS said (Change Request 6145, July 25, 2008).

CMS acted in response to an external request for reconsideration of the current NCD at Pub. 100-03 for colorectal cancer screening. Once FDA approval is obtained, another request for reconsideration will be considered, CMS said. 🏛️



# CMS Finalizes Stark ‘Stand in the Shoes’ Provisions

The Centers for Medicare and Medicaid Services has put the finishing touches on new requirements that physicians who own physician organizations will be treated as “standing in the shoes” of those entities for purposes of complying with the Stark self-referral law. Under the ‘stand in the shoes’ analysis, physicians referring Medicare or Medicaid patients to an entity for clinical lab and other designated health services are considered to have the same compensation arrangements with the entity as the physician organization in which they have ownership interest.

Physicians with only titular ownership interests in their organizations are not subject to the requirement, nor are financial arrangements that meet the self-referral exception for academic medical centers. Titular ownership interests are defined by CMS as cases where physicians do not reap the financial benefits of ownership, such as profit distributions, sale proceeds, and investment returns, from their physician organizations. However, CMS noted, titular owners and nonowners have the discretion to “stand in the shoes” of their organizations. 🏛️

*CMS finalized the provisions, which take effect Oct. 1, in Medicare’s fiscal 2009 inpatient prospective payment rule scheduled to appear in the Aug. 19 Federal Register.*

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

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