WASHINGTON G–2 REPORTS

# NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 29th Year of Publication

Vol. 29, No. 13, April 28, 2008

## CMS Mandates Switch to Single Medicare ABN by Sept. 1

*Lab groups are seeking more time to make the transition and resolve a host of implementation issues, including the new cost estimate requirement.*

The Centers for Medicare & Medicaid Services has issued a revised Advance Beneficiary Notice (ABN) that clinical laboratories and other providers billing Part B must use by no later than Sept. 1 of this year. The ABN alerts beneficiaries that Medicare is not likely to cover a particular item/service and they are financially liable if the claim is denied.

The revised single-page ABN (Form CMS-R-131) replaces the general-use ABN-G (CMS-R-131G) and the lab-specific ABN-L (CMS-R-131L) that CMS has required since 2003. Combining the two into a single all-provider form was proposed by CMS last year (*NIR, 28, 10/Mar 12 '07, pp. 4-5*).

Lab organizations have responded that the time period to make the switch to the new form is too short and want CMS to grant a longer extension—at least one year from the date that CMS issues final instructions to Medicare contractors on use of the revised ABN and what is required to make it valid.

At press time, the Clinical Laboratory Coalition was preparing a formal request to CMS for a one-year transition. The American Clinical Laboratory Association and the Clinical Laboratory Management Association have already sent letters to CMS asking for a delay. More time is needed, ACLA noted, since the switch will require major changes to computer systems, both internally *Continued on p. 2*

## Senate Prepares to Tackle Physician Fee Fix

Congress is expected to prevent a scheduled July 1 cut in Medicare fees to pathologists and other physicians but has yet to decide how to finance it under pay-as-you-go rules. On the table are cost offsets from other providers, potentially even clinical laboratories, which are due to get a fee increase in 2009 after a five-year freeze.

The Senate will soon consider the issue in Medicare spending legislation, said Finance Committee chairman Max Baucus (D-Mont.). Medicare managed care won't be spared, he noted, nor will other providers, though he did not specify which providers would take a hit.

Absent congressional action, a 10.6 percent reduction in Medicare physician fees is set to take effect July 1 under the statutory SGR update formula. Congress previously blocked a fee cut set for Jan. 1 of this year and approved a 0.5 percent increase through June 30. *Continued on p. 7*

INSIDE *NIR*



www.g2reports.com

**Switch to Single Medicare ABN,** *from p. 1*

and with third-party vendors, plus the re-education of ordering physicians and staff. This work cannot begin in earnest now since CMS has yet to finalize the instructions to contractors.

Industry sources say there appears to be some "wiggle room" with CMS on the issue of allowing more time, but the agency is not likely to budge on one big change in the revised ABN: a new requirement that to be valid, the form must provide an estimated cost for the particular item/service in question.

CMS has said, in preliminary instructions accompanying the revised ABN, that "there is flexibility in listing individual or total cost. The revised ABN will not be considered valid absent a good-faith attempt to estimate cost. CMS will be flexible in defining what a good-faith estimate is, particularly in consideration of cases where the ordering and rendering providers may be different."

In its letter to CMS, ACLA said its members "find this type of flexibility to be extremely problematic … particularly for clinical labs that are often the rendering provider and are forced to rely on the physician, or other ordering provider, to complete the ABN form appropriately. Therefore, contractors need to be instructed clearly that an ABN is not invalidated merely because it does not contain the estimated cost … It is very important that there be clear standards for what is and what is not permissible, particularly with respect to cost. Otherwise, there will be repeated disputes about whether or not the lab or other provider can bill for the service."

### Other Key Features of the Revised ABN

The final version (CMS-R-131) is written in more beneficiary-friendly language, CMS says, and meets both general and lab-specific needs. Along with replacing the general-use and lab-specific forms and requiring inclusion of a cost estimate, the new form:

- ❑ Has a changed title, the "Advance Beneficiary Notice of Noncoverage," to convey more clearly the purpose of the notice.
- ❑ May also be used for voluntary notifications in place of the Notice of Exclusion From Medicare Benefits (NEMB).
- ❑ Offers a new option whereby a beneficiary may choose to receive an item/service and pay for it out-of-pocket, rather than have a claim submitted to Medicare.

The ABN must be signed and dated by the beneficiary (or representative) before the item/service is furnished. The form is never required in emergency or urgent care cases.

ACLA also noted that the decision to make a cost estimate mandatory represents a substantial change in written notice requirements. Though providing a cost estimate is a good practice, it has not been specifically mandated under current law, regulations, and CMS's own guidance. Adding the cost-estimate requirement is more than a modification to the utility of the form and sets forth a new mandate for users, ACLA said, contending that CMS should at the very least vet the change through public notice and comment rulemaking under the Administrative Procedures Act.

The revised ABN, preliminary instructions, and frequently asked questions are posted at *www.cms.hhs.gov/bni*. Medicare inpatient hospitals, skilled nursing facilities (SNFs), and home health agencies use other OMB-approved notices to inform beneficiaries of potential financial liability. A revised SNF ABN covering all Part B items/services delivered in a SNF will be available before Sept. 1, CMS said. Until it is implemented, SNFs may continue to use the current ABN-G.

***(A) Notifier(s):***

***(B)* Patient Name:** ***(C)* Identification Number:**

# ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

***NOTE:*** If Medicare doesn't pay for ***(D)*_____** below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the ***(D)*_____** below.

| ***(D)*_____** | ***(E)* Reason Medicare May Not Pay:** | ***(F)* Estimated Cost:** |
|---|---|---|
| | | |

**WHAT YOU NEED TO DO NOW:**

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the ***(D)*_____** listed above.

  **Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

***(G)* OPTIONS:** **Check only one box. We cannot choose a box for you.**

❑ **OPTION 1.** I want the ***(D)*_____** listed above. You may ask to be paid now, but I also I want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

❑ **OPTION 2.** I want the ***(D)*_____** listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed**.

❑ **OPTION 3.** I don't want the ***(D)*_____** listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

***(H)* Additional Information:**

**This notice gives our opinion, not an official Medicare decision.** If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

| ***(I)* Signature:** | ***(J)* Date:** |
|---|---|
| | |



Form CMS-R-131 (03/08) Form Approved OMB No. 0938-0566

focus on: Competitive Bidding

# With Medicare Demo on Hold, Labs Step Up Legislative Repeal Drive

*Get the latest on the lab bidding lawsuit and the legislative outlook for demo repeal in our May 8 audio conference, featuring Patric Hooper, lead counsel for labs in the San Diego case, and Alan Mertz, ACLA president. Time: 2:00 – 3:30 p.m. (Eastern). Sign up at* www.g2reports.com

Now that a federal court has slammed the brakes on Medicare's competitive bidding demonstration for independent clinical laboratory services, it is up to the government to decide how to proceed. The demo, required by the Medicare Modernization Act of 2003, is intended to see if competitive bidding can be used to pay for lab services at rates below the current Part B lab fee schedule.

Opponents of the demo throughout the lab industry emphasize, however, that the court order is temporary, not final, and the push is still on to get Congress to kill the demo. The court's ruling "has not stopped us in our drive to repeal competitive bidding," said Alan Mertz, president of the American Clinical Laboratory Association. "We think Congress needs to finish the job."

In fact, he said, the court's findings boost the industry's case against the project. The main criticisms are that the demo as designed is seriously flawed and will result in severe harm to small business labs and their patients, less competition, and reduced beneficiary access to quality services.

## San Diego Labs Win Reprieve

On April 8, a federal court in San Diego granted a preliminary injunction sought by three clinical laboratories—Sharp Healthcare, Scripps Health, and Internist Laboratory—to halt implementation of the bidding demo in the San Diego-Carlsbad-San Marcos metro area, the first site selected for the project.

The court ordered the Health & Human Services Secretary, and his agent, the Centers for Medicare & Medicaid Services, to stop work on the project until further notice and barred the government from announcing winning bidders on April 11 as planned and from disclosing any information in the bid applications submitted.

Judge Thomas J. Whelan agreed with key complaints raised by the labs. He said the project, as designed, poses a real threat of irreparable injury to the labs' business and their patients that could not be compensated by monetary damages. He faulted CMS for not following public notice and comment procedures in developing the demo, for misreading congressional intent on the face-to-face exception, and for expanding the scope of the demo to include not just specific tests, but also specimen collection and handling (*NIR, 29, 12/Apr 14 '08, pp. 4-6*).

## CMS Ponders Next Steps

In follow-up to the court ruling, *NIR* contacted CMS for comment on how the agency would respond. Would it seek reconsideration, appeal, or retool the demo design to meet the court's objections?

In an April 16 e-mail reply, CMS said its official word for now is: "We are disappointed by the court's injunction because we believe we followed Congress' direction in implementing the laboratory competitive bidding demonstration … The project is currently on hold. We are reviewing the decision and will get back to you when the project continues."

In its defense, CMS said it "was careful in designing the demonstration to ensure the quality of lab services to beneficiaries, particularly the most vulnerable who reside in nursing homes and underserved areas. Throughout development of the demonstration, CMS has communicated with and sought input from the laboratory industry and other stakeholders to address the issues outlined in the suit."

The agency has a range of responses to consider regarding the injunction, said CMS acting head Kerry Weems the day after the April 8 ruling. "I will have to confer with our general counsel, but I am anxious to start this project," he told reporters from the Bureau of National Affairs. Asked if there is a chance of appeal, he replied, "Few judges are the final decision-makers, so there are requests for reconsideration, appeals, a whole range of options that are open to us which [we'll] consider at this junction."

Meantime, the lab plaintiffs are awaiting the government's response, said their lead counsel, Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles. The government has until May 8 to file a response or it can appeal within 60 days of the date the injunction was ordered.

### Industry Pitches in to Help San Diego Labs

The three San Diego-area labs suing to stop the demo are shouldering the legal expenses, but nine national associations and two national companies have contributed to the legal fund supporting the lawsuit.

- American Association of Bioanalysts
- American Association for Clinical Chemistry
- American Clinical Laboratory Association
- American Medical Technologists
- American Society for Clinical Pathology
- American Society for Clinical Laboratory Science
- American Society for Microbiology
- Clinical Laboratory Management Association
- National Independent Laboratory Association
- Roche Diagnostics
- Sonic Healthcare, USA

### Demo Repeal Drive Intensifies

The industry's lobbying campaign to get Congress to terminate the project is concentrating on adding more co-sponsors to demo repeal bills pending in the House and the Senate and to get repeal language attached to Medicare legislation the Senate is expected to take up soon, including action on the physician payment cut scheduled for July 1 and other issues.

The Senate repeal legislation—S. 2099, introduced by Ken Salazar (D-Colo.)—currently has eight co-sponsors (six Democrats and two Republicans). Four sit on the influential Finance Committee. They are, in addition to Salazar, Maria Cantwell (D-Wash.), Pat Roberts (R-Kan.), and Charles Schumer (D-N.Y.). The House companion bill, H.R. 3453, introduced by Nydia Velazquez (D-N.Y.), chairwoman of the Committee on Small Business, currently has 40 bipartisan co-sponsors.

Getting more co-sponsors is critical in getting Congress to act on demo repeal, Sen. Roberts said April 17 in remarks at the ACLA annual meeting in Washington, D.C. He said he supports repeal because he has seen the harm that the demonstration may have on the market. Kansas City is one of the sites impacted by competitive bidding for durable medical equipment, he noted, and 60 percent of DME providers were eliminated from the project.

Meantime, the fear early on that the court-ordered halt to the lab demo might tempt Congress to take a hands-off approach while the issue is tied up in litigation has dissipated, said Mark Birenbaum, administrator of the American Association of Bioanalysts and the National Independent Laboratory Association.

The bigger issue, he told *NIR*, is the manner in which repeal legislation will have to be maneuvered, outside usual procedures, to get it incorporated in a final Medicare spending bill.

# Medicare's Financial Health Seriously Strained, Trustees Warn

As Congress prepares to consider Medicare spending legislation—including preventing a physician payment cut with offsets from other providers to pay for it—lawmakers have at hand for their consideration an outlook on the program's current and future financial health from its Board of Trustees.

In their 2008 annual report, released March 25, the trustees said the Part A hospital fund will become insolvent earlier in 2019 than projected last year. Moreover, expected congressional overrides of scheduled physician fee cuts in coming years will require ever-higher beneficiary premiums and general revenue financing to keep Part B in balance.

Spending growth for Part A and the Supplementary Medical Insurance (SMI) Trust Fund, that includes Part B medical services and the Part D drug benefit, is due largely to rising health care costs, but continued growth in the volume and medical intensity of services is also a factor, the trustees said, recommending a series of reforms, including more competitive bidding.

Overall, expenditures for Part A and Part B are growing faster than the rest of the economy, the trustees reported. Spending reached $432 billion in 2007, or 3.2 percent of the gross domestic product (GDP), and is projected to rise to nearly 11 percent of GDP in 75 years. The Part A hospital fund will continue to spend more than its income this year and will become insolvent in 2019. Spending growth for Part A is estimated to average 7.4 percent each year from 2008 to 2017, a rate higher than either the GDP or the Consumer Price Index.

The SMI Trust Fund is automatically in financial balance because beneficiary premiums and general revenue financing are reset each year to match the expected costs of the program for the following year. Nevertheless, general revenue financing for SMI is expected to increase from about 1.3 percent of GDP in 2007 to more than 4 percent in 2082. The monthly premium for Part B, set at $96.40 for 2008, is expected to reach $126.40 by 2017.

Continued growth in Part B benefit payments—up an average of 9.6 percent for each of the past five years—remains a concern, the trustees noted. Further, actual Part B costs will likely exceed current-law projections, they concluded, because Congress is expected to continue to block substantial reductions in Medicare physician fees over the next 10 years. Of the $178.9 billion in total Part B expenditures in 2007, $176.4 billion represented net benefits paid from the health services account, up 6.3 percent over the amount paid the previous year, reflecting in part increased payments to physicians.

In comparison to Part A and Part B, expenditures for the Part D drug benefit have consistently been lower than projected, the trustees noted. They continue to project lower spending, primarily due to a reduction in bids from private plans. Still, costs over time are expected to increase at an average annual rate of about 11.1 percent through 2017, down from the 12.6 percent estimated last year.

"These projections demonstrate the need for timely and effective action to address Medicare's financial challenges. The sooner the solutions are enacted, the more flexible and gradual they can be," said the trustees. They include Treasury Secretary Henry M. Paulson Jr., Labor Secretary Elaine L. Chao, Social Security Commissioner Michael J. Astrue, and HHS Secretary Michael Leavitt. The seats of the two public trustees are vacant.

**Senate Prepares,** *from p. 1*

*A physician fee fix could move through Congress as part of an omnibus budget reconciliation bill or as part of a Medicare bill stripped down to a short-term fix and possibly other non controversial policy reforms.*

As to the type and term of a fee fix, the consensus appears to be that it should be short-term, for 18 months (through 2009), according to legislative sources. But even if the fix were held to a zero update, it would be expensive. Granting a zero update followed by a 20 percent cut in 2010 to pay for the earlier increases would cost slightly more than an estimated $8.4 billion over five years.

Baucus has floated the prospect of an increase around 1.1 percent. Sen. Debbie Stabenow (D-Mich.), a member of the Finance panel, has introduced a bill (S. 2785) to replace the July 1 cut with a 0.5 percent pay hike for the remainder of 2008 and a 1.8 percent pay raise in 2009. Stabenow acknowledged that a 1.8 percent pay hike would be an "uphill" battle to achieve for 2009, due to costs.

The American Medical Association supports the Stabenow bill and says the 18-month fix should be used to come up with a permanent replacement to the SGR formula that has triggered a cascade of cuts for most of this decade, a remedy also backed by national pathology organizations.

But getting the physician fee fix money from other providers is highly sensitive politically. The Medicare managed care program, Medicare Advantage (MA), has long been a target for payment reductions by the congressional Democratic leadership, and the White House has consistently threatened a veto of any cuts in MA payments. Last year, Congress, unable to resolve the issue, settled for a six-month physician fee increase with only a modest MA cut. As part of the compromise, it dropped House-passed provisions to reduce MA payments to 100 percent of traditional fee-for-service levels.

Medicare managed care is definitely not off the table this year, Baucus has said in briefings of reporters this month. CMS announced April 7 that the MA growth percentage used to calculate payments to private health plans will increase by an average 4.24 percent in 2009, a little below the preliminary estimate of 4.8 percent. Although rates vary by county, the growth percentage is a factor used to calculate an average 3.6 percent hike in MA rates for 2009, slightly lower than the estimated 3.7 percent growth trend for 2009, CMS said. "Individual counties may see different increases," CMS cautioned, "because we rebased the fee-for-service rates using the most recent FFS spending data and recalibrated the risk adjustment model."

## ♦ Medicare Coding *Advisory*

# Payment Rate Change for Blood Glucose Home Tests

Effective April 1, 2008, Medicare is paying for hemoglobin A1c tests using a device approved by the FDA at the same rate as other glycated hemoglobin tests. The national Medicare fee cap for home-use A1c tests (CPT 83037) had been $21.06. Now, the cap is reduced to $13.56, the maximum allowable for other A1c tests billed under CPT 83036.

For dates of service on or after April 1, claims for 83037 and 83037QW are priced by a crosswalk to code 83036, the Centers for Medicare & Medicaid Services announced in Change Request 5987 (April 11, 2008). Congress eliminated the higher payment for home-use tests in Section 113 of the Medicare, Medicaid & SCHIP Extension Act of 2007, passed late last December.

# Snapshot of Growth in Medicare Part B Lab Spending

Growth in Medicare Part B lab spending slowed in calendar-year 2007, the program's trustees noted in their recent annual report, increasing by only 1.6 percent, to $6.8 billion, well below the growth in 2006, when this spending rose 3.7 percent over the 2005 total. The slowdown was attributed in part to beneficiaries' shift toward Medicare managed care, up from 7.1 million in 2006 to 8.5 million in 2007. Managed care expenditures rose 24 percent in 2007, to $38.9 billion. Overall, Medicare had 44.1 million beneficiaries in 2007, up 1.7 percent from 2006.

Independent labs and physician office labs got the lion's share of the Part B lab spending pie in 2007—59 percent, or slightly more than $4 billion (a rise of about 9.5 percent over 2006). Intermediary labs (hospital outpatient and outreach facilities) accounted for 40 percent, or $2.74 billion (a drop of about 8 percent from 2006).

From 2002 to 2007, Part B lab spending rose close to 8 percent per year on average. Over this same time period, total Part B expenditures increased an average of 9.6 percent, the trustees noted, reflecting continued growth in the volume and intensity of medical services. Total Medicare spending in 2007 was $432 billion; for the Part B account, the total net figure was $178.9 billion.

## G-2 Conference Calendar

**Apr. 30-May 2:**
**Molecular Diagnostics: Making $ & Sense in Operating an MDx Lab**
Hyatt Regency, Cambridge, Mass. Get the lowdown on different business models, plus financial and technical trends driving this fastest-growing area of the U.S. lab industry.

**June 18-20:**
**Laboratory Outreach 2008, Winning With the Right Numbers**
The Bellagio, Las Vegas, Nev. Profit from expert know-how on building state-of-the-art group, hospital, and health system outreach programs.

**Sept. 17-19:**
**26th Annual Lab Institute**
Crystal Gateway Marriott Hotel, Arlington, Va. Join us for this premier event for the lab and pathology industry, your early-warning venue for objective, accurate information and forecasts on legislative, policy, business, and technological challenges impacting your "bottom line." Sign up now to enjoy special "early bird" savings.

For registration and other information on the above, go to *www.g2reports.com*.



 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 Washington Park, Suite 1300, Newark, NJ 07102-3130. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com. Order Line: (212) 629-3679.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President.

*Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.*