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CMS Mandates March '09 Switch to New Medicare ABN

The revised single-page ABN (CMS-R-131) replaces the general-use ABN-G and the lab-specific ABN-L required since 2003 to notify beneficiaries that they may be financially liable if Medicare denies a claim for a particular item/service.

The Centers for Medicare and Medicaid Services on Sept. 5 issued final instructions on the new single Advance Beneficiary Notice (ABN) that clinical laboratories and other providers billing Part B must use by no later than March 1, 2009.

The ABN alerts beneficiaries that Medicare is not likely to cover a particular item or service and that they are financially liable if the claim is denied. Without a validly executed ABN, the provider cannot bill the beneficiary when a claim is denied.

CMS had intended to make use of the new ABN mandatory as of Sept. 1 of this year, but final instructions were not completed in time (*NIR, 29, 20/Aug 13 '08, p. 1*).

Completing the "Estimated Cost" blank on the form has been controversial for labs and other providers, and CMS has offered more specific guidance on how to comply with this requirement. While allowing for certain exceptional cases, the general rule is that the cost should be within $100 or 25 percent of the actual cost of the service. For more on the new ABN requirements, see the *Focus*, pp. 4-6.

HHS Proposes Transition to ICD-10 Diagnosis Codes by October 2011

In a sweeping change affecting both public and private sectors of the nation's health care industry, the U.S. Department of Health and Human Services has proposed replacing the current ICD-9 diagnosis coding system used in HIPAA transactions with ICD-10 code sets by Oct. 1, 2011.

To accommodate the conversion to ICD-10, HHS has proposed a separate rule to adopt the updated X12 standard, Version 5010, for health care transactions and the Prescription Drug Programs standard, Version D.0, for pharmacy transactions, effective April 1, 2010.

The proposed rules impact all entities, public and private, that are covered under HIPAA (the Health Insurance Portability and Accountability Act of 1996). These include health plans, health care clearinghouses, clinical laboratories, and other health care providers that transmit any electronic health information in a transaction for which HHS has adopted a standard. *Continued on p. 2*

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The proposed rules for ICD-10 code sets and the Version 5010 electronic transaction standards were published in the Aug. 22 Federal Register*, with a comment deadline of Oct. 21.*

ICD-10 Diagnosis Codes, *from p. 1*

HHS says the changeover will improve disease tracking and speed the shift to an electronic health care environment. The ICD-9 system is outdated, the agency notes, and cannot handle new diagnoses and procedures.

"The greatly expanded ICD-10 code sets will enable us to fully support quality reporting, pay-for-performance, biosurveillance, and other critical activities," said HHS secretary Michael Leavitt. Developed almost 30 years ago, ICD-9 contains only 17,000 codes and will run out of available codes next year. The ICD-10 code sets contain more than 155,000 codes and accommodate a host of new diagnoses and procedures. The additional codes will provide more granularity in electronic transactions, Leavitt said, that will help identify emerging health threats such as Methicillin-Resistant Staphylococcus aureus (MRSA).

CMS acting administrator Kerry Weems acknowledged that "the transitions will require up-front costs, but each year of delay would create additional costs, both because of the limitations of ICD-9 and because of the need to employ the greater precision that ICD-10 codes provide to support value-based purchasing of health care." He pledged that CMS will "work collaboratively to ensure a smooth transition."

Under the proposed rule for ICD-10 code sets, HHS would concurrently adopt the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding. The new codes would replace the ICD-9-CM, Volumes 1 and 2, and the ICD-9-CM, Volume 3, for diagnosis and procedure codes, respectively. The ICD-10-CM is maintained by the National Center for Health Statistics at the Centers for Disease Control and Prevention. The ICD-10-PCS is maintained by CMS.

The International Classification of Diseases (ICD), Version 10, was endorsed by the 43rd World Health Assembly in May 1990 and came into use in WHO member states beginning in 1994.

The ICD system is the international standard diagnostic classification for all general epidemiological and many health management purposes. It is used to classify diseases and other health problems recorded on many types of health and vital records, including death certificates and hospital records.

In addition to enabling the storage and retrieval of diagnostic information for clinical and epidemiological purposes, these records provide the basis for compilation of national mortality and morbidity statistics by WHO member states.

The proposed rule on updated transaction standards also calls for adoption of a standard for the Medicaid pharmacy subrogation transaction. This is the process by which state Medicaid agencies recoup funds for payments they have made for pharmacy services for Medicaid recipients in cases where another third-party payer has primary financial responsibility.

Initial reaction to the rules from the health care industry took sharp issue with the proposed conversion timetable. While agreeing with the need to move to ICD-10, the Blue Cross and Blue Shield Association warned that if the government acts too quickly, this could trigger a "major meltdown in the health care industry." The group, whose members process 85 percent of Medicare claims annually, favors a five-year transition to ICD-10, a time frame also recommended by the HHS National Committee on Vital and Health Statistics.

Moreover, said the Blues vice president Alissa Fox, under the HHS proposal, the shift to ICD-10 would begin before the 5010 switch was completed. The timetable preferred by the industry, she noted, is to achieve compliance with the 5010 standards before implementation of the ICD-10 code sets.

The American Clinical Laboratory Association, which along with the Blues is part of the 33-member ICD-10 coalition, agrees that the transitions should not overlap. They involve a vastly expanded number of codes and different nomenclatures, ACLA senior vice president JoAnne Glisson told *NIR*, and this poses a host of administrative and educational complexities to surmount. "You can't make the switch to both during the same time span. This would require you to simultaneously support two systems for payers, Versions 4010 and 5010, and two systems for diagnosis codes, ICD-9 and ICD-10, during the turnover. And at the same time, you would be dealing with physicians and other trading partners at various stages of readiness for the transitions."

Clinical labs and other providers dodged the ICD-10 bullet in 2006 when legislative proposals to mandate the switch from ICD-9 by 2009 failed to clear Congress (*NIR, 28, 4/Nov 20 '06, p. 5; 27, 16/Jun 12 '06, p. 1, 4-5*). HHS did indicate at the time, however, that it could require the switch administratively. Earlier this year, the president's Medicare budget request for fiscal 2009 asked for new spending of $40.3 million to make the transition to ICD-10 by 2011 (*NIR, 29, 9/Feb 25 '08, p. 3*).

Is It Time to Consider Overhauling the Lab Fee Schedule?

The American Society for Clinical Laboratory Science (ASCLS) and the Clinical Laboratory Management Association (CLMA) think so and last month secured the introduction in the House of a bill (H.R. 6761) that would require a negotiated rulemaking process to revamp the Medicare lab fee schedule based on the value of the testing, the resources required, and geographic cost differences *(NIR, 29, 20/Aug 13 '08, pp. 4-6)*.

CLMA's director of legislative and regulatory affairs, Katharine Ayres, told *NIR* in a recent interview that it was important to get the measure introduced for political reasons—"to get the idea out there and gain ground to push hard for it next year when the new Congress is expected to take up health care reform." The groups had put off getting it introduced earlier because the industry was fighting to defeat lab competitive bidding and get an inflation update in lab fees next year, both goals achieved in the Medicare law that was passed in July.

H.R. 6761 is intended to start a process, Ayres said. It does contain provisions to guide the rulemaking (such as tapping the Institute of Medicine report on lab payment alternatives), but does not prescribe the outcome, she noted, emphasizing that "we want all stakeholders' input."

CLMA is resuming advocacy this month to get a counterpart bill introduced in the Senate this year, Ayres said. Meantime, CLMA and ASCLS are holding various exchanges with other groups in the 10-member Clinical Laboratory Coalition to muster support for the legislation, she said.

Mark Birenbaum, head of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), told *NIR* that AAB is still looking at H.R. 6761 and could not comment on specifics. The bottom-line response for most people involved, he thinks, will be to look at the overall reimbursement outcome—will this legislation result in better payment?

He expressed concern that the measure was not a coalition bill and that it contains some provisions that some members may not agree with. "We have to work together as a united front in our advocacy," he said. "That was the lesson we learned this year from our successful effort to defeat lab competitive bidding." *Continued on p. 7*

focuson: *New Medicare ABN*

Quick Guide to New Advance Beneficiary Notice Requirements

Clinical laboratories and other providers billing Part B may switch to the revised single-page ABN at any time but must start using it as of March 1, 2009.

Starting in March 2009, the revised single-page Advance Beneficiary Notice (CMS-R-131) will be the only written notice recognized by Medicare as satisfying the requirement that Part B fee-for-service beneficiaries be alerted when they may be financially liable for an item or service that Medicare is likely to deny. The Centers for Medicare and Medicaid Services has released final manual instructions to guide providers on its proper use (Transmittal 1587, Sept. 5, 2008).

What does the ABN (CMS-R-131) replace?
Three notices: the general use ABN-G (CMS-R-131-G), the ABN-L (CMS-R-131-L) specific to lab services, and the Notice of Exclusion from Medicare Benefits.

When must it be used?
When the provider knows that Medicare will deny a service as noncovered or has genuine doubt that Medicare will pay for the service. The ABN must be signed and dated by the beneficiary (or representative) before the service is furnished. An ABN is never required in emergency or urgent care cases.

Who is responsible for effective delivery of the ABN?
The "notifier," typically the provider of the service. When multiple entities are involved, it is not necessary to give separate ABNs. Any party involved can be the "notifier" when:

- ❑ There are separate ordering and rendering providers (for example, a physician orders a lab test and an independent lab delivers the ordered tests);
- ❑ One provider delivers the technical and another the professional component of the same service (for example, an independent diagnostic testing facility renders a radiological test and a physician interprets it); or
- ❑ The entity that obtains the beneficiary's signature on the ABN is different from the entity that bills for the service (for example, one lab refers a specimen to another lab that then bills Medicare for the test).

Regardless of who gives the notice, CMS says, the billing entity will always be held responsible for effective ABN delivery.

Can the new ABN be customized?
Yes, some customization is allowed, such as preprinting information in certain blanks to promote efficiency and ensure clarity for beneficiaries, including the name and logo of your facility. Multiple versions may be specialized for common treatment scenarios, using the required language and general formatting of the ABN. Letterings of blanks A-J should be removed prior to issuance of an ABN.

If preprinted information is used to describe services or common reasons for non-coverage, clearly indicate on the ABN which portions apply to the beneficiary (for example, preprinted services that do not apply may be crossed out or applicable items or services may be checked off).

What restrictions are there on customizing or modifying the ABN?
This is allowed only when specified in the instructions, and the changes must be

(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:**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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

approved by the provider's CMS Regional Office. CMS advises caution on customizing beyond the manual guidelines, since this could result in an invalid ABN and the provider is liable for noncovered charges.

Who has the final say on what constitutes a valid ABN?
In general, Medicare contractors. They usually make this determination as part of their review of ABN-related claims.

Must I complete the Identification Number section?
No, use of this field is optional. You may enter an ID for the beneficiary that helps to link the notice to a related claim, but absence of an ID does not invalidate the ABN. An internal filing number you create, such as a medical record number, may be used; however, Medicare numbers or Social Security numbers must not appear on the notice.

How should I complete the 'Reason Medicare May Not Pay' section?
This must explain, in beneficiary friendly language, why you believe the services described may not be covered by Medicare. Three commonly used reasons are:
- ❑ Medicare does not pay for this test for your condition;
- ❑ Medicare does not pay for this test as often as this (denied as too frequent); and
- ❑ Medicare does not pay for experimental or research use tests.

To be a valid ABN, there must be at least one reason applicable to each item or service listed. The same reason for noncoverage may be applied to multiple items.

Providers must make a good-faith effort to include a reasonable cost estimate for all the items or services listed. What is a reasonable estimate?
As a general rule, CMS says, "We would expect [it] to be within $100 or 25 percent of the actual costs, whichever is greater; however, an estimate that exceeds the actual cost substantially would generally still be acceptable, since the beneficiary would not be harmed if the actual costs were less than predicted."

Some examples of acceptable estimates include, CMS says, but are not limited to:
- ❑ *For a service that costs $250*
  - —Any dollar estimate equal to or greater than $150
  - —Between $150 and $300
  - —No more than $500
- ❑ *For a service that costs $500*
  - —Any dollar estimate equal to or greater than $375
  - —Between $400 and $600
  - —No more than $700

Can multiple items or services that are routinely grouped be bundled into a single cost estimate?
Yes, for example, when the service involves a group of laboratory tests, such as a basic metabolic panel. Average daily cost estimates are also permissible for long-term or complex projections. If there is a possibility of additional tests (such as reflex testing) and the associated costs cannot be reasonably estimated at the time of ABN delivery, you may enter the initial cost estimate and indicate the possibility of further testing. Finally, if for some reason you are unable to provide a good-faith estimate at the time of ABN delivery, you may indicate that no cost estimate is available. "We would not expect either of these last two scenarios to be routine or frequent practices," CMS warns, "but the beneficiary would have the option of signing the ABN and accepting liability in these situations."

♦ Medicare Payment *Advisory*

CMS Increases Per-Mile Travel Allowance

The Centers for Medicare and Medicaid Services has announced an increase of 80 cents in the per-mile travel allowance when collecting specimens from nursing home and homebound Medicare beneficiaries. Effective July 1, payment on a per-mile basis (billing code P9603) will rise to $1.035. This includes the federal mileage rate of $0.585 per mile, plus an additional $0.45 per-mile to cover personnel time and travel costs. Payment on a flat-rate basis (P9604) remains unchanged at a minimum of $9.55.

CMS announced the per-mile update in Change Request 6195 (Sept. 5, 2008). The implementation date is Oct. 6. Contractors are not required "to search and adjust claims that have been already processed unless brought to their attention," CMS said.

The per-mile travel allowance is used when the average trip to patients' homes is *longer than 20 miles round trip* and is to be prorated when specimens are drawn or picked up from non-Medicare patients during the same trip.

Example 1: In calendar 2008, a laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location and back to the lab after drawing a single Medicare patient's blood. The total reimbursement would be $62.10 (60 miles x $1.035 cents a mile), plus the specimen collection fee.

Example 2: In calendar 2008, a laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, then travels an additional 10 miles to a non-Medicare patient's home, and in returning to the lab, travels 30 miles. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled (because only one of the two patients was a Medicare beneficiary) or a total of $41.40 (40 miles x $1.035), plus the specimen collection fee.

Lab Fee Schedule, *from p. 3*

Maintaining a united front is especially important, Birenbaum pointed out, given the legislative fix required next year to avert a Medicare physician fee cut in 2010. Congress will be searching for budget offsets to help pay for a physician fee fix, and labs historically have been a favorite target, he said.

Alan Mertz, president of the American Clinical Laboratory Association, told *NIR* that ACLA is reviewing H.R. 6761 and talking to proponents. But it is clear that there is not a consensus within the lab industry on key questions, he said. Should there be an overhaul of the current lab fee schedule? If there is a need to do it, how should it be done? Is this the approach we should ask Congress to take?

As the competitive bidding battle demonstrated, Mertz said, "We need to focus and set our priorities for lobbying our cause on Capitol Hill. We need to emphasize the upside of laboratory testing, its vital role in treatment and prevention, while making sure lawmakers see the downside of cutting lab spending. We also need to lobby for better reimbursement for prevention and genetic testing." Labs need to remain vigilant that we are not tapped to pay for other priorities. We are getting a healthy fee update in 2009, so we could again become a target as has happened often in the past."

Competitive Bidding Lawsuit Not Over Yet

The lab plaintiffs in the San Diego lawsuit against the Medicare competitive bidding demonstration "are formally opposing the government's motion to dismiss," attorney Patric Hooper, with Hooper, Lundy and Bookman (Los Angeles) told *NIR*. The Centers for Medicare and Medicaid Services last month asked the federal district court in San Diego to dismiss the case, saying the matter is moot because Congress, in approving the new Medicare law July 15, repealed the agency's authority to conduct the demo (*NIR, 29, 20/Aug 13 '08, p. 2*).

The lab plaintiffs want CMS to return the bid applications submitted and want the Health and Human Services secretary to agree to make no further use of the bid information, attorney Jordan Keville told *NIR*. There is concern that the bid information be kept confidential because it includes items such as bank statements, audits, and other proprietary items. Also, there is concern over what the government might do with the bid prices it has obtained.

Opposing the motion to dismiss is a strategic move, he said, to get CMS to respond to requests to resolve the bid information issues. A hearing on the motion to dismiss is scheduled for Sept. 22.

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