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CMS Discloses Provider Data To Aid NPI Implementation

The data disclosure is intended, CMS says, to help providers develop linkages between legacy identifiers and NPIs and to obtain the NPIs of other providers in order to submit HIPAA-compliant healthcare claims. For details, see the Focus, *pp. 4-6.*

In a move long awaited by clinical laboratories and other providers to make it easier to obtain and exchange National Provider Identifiers (NPIs), the Centers for Medicare & Medicaid Services has disclosed the data it will make available from the National Plan & Provider Enumeration System (NPPES) and who can access these data.

The data will be available from the Internet and in a query-only database on June 28, CMS said in the May 30 *Federal Register*. The data will not include Social Security and taxpayer ID numbers or date of birth.

CMS will hold a national roundtable June 14 to discuss and field questions about the NPIs and other data to be disclosed from the NPPES. Registration details are posted at *www.cms.hhs.gov/NationalProvIdentStand/downloads/RegistrationInfoNPI614.pdf*.

Also since the NPI replaces all legacy numbers, CMS is closing its registry of physician identifiers known as UPINs this year. It will stop assigning UPINs on June 29 and maintain the registry through September 30.

INSIDE *NIR*

Medicare Opens Lab Fee-Setting Process For '08

The process for establishing Medicare reimbursement rates for new CPT lab codes in 2008 will kick off with a July 16 public meeting, the Centers for Medicare & Medicaid Services has announced.

The meeting will be held at CMS headquarters in Baltimore, MD, and will run from 10 a.m. to 2 p.m. (Eastern), with telephone dial-in. Its aim is to invite recommendations from clinical laboratory, pathology, and other interested parties on how to price the new codes, using one of two approved methods—crosswalk or gap-fill.

The crosswalk method is used to match a new test code to a similar existing code and pay at that code's rate. Payment for the new test is made at the lower of the crosswalk to the local fee schedule amount for the test or the national cap. Most lab fee schedule codes are paid at the national cap.

The gap-fill method is used when there is no comparable existing test. In this case, local carriers set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years. *Continued on p. 2*

Lab Fee-Setting Process, *from p. 1*

CMS specified the 2008 lab fee-setting timetable in a May 25 *Federal Register* notice:

- ❑ The new 2008 lab codes will be posted on or after June 18 at *www.cms.hhs.gov/ClinicalLabFeeSched*.
- ❑ A summary of the payment recommendations and CMS's tentative fee determinations will be posted at the same site by September 7.
- ❑ The agency will accept additional comments on the posting through September 21.
- ❑ Final fee decisions will be released when CMS publishes the final 2008 Part B lab fee schedule (expected in November).

Public Meeting On Lab Fees

- ❑ ***Registration:*** Begins June 18 online at *www.cms.hhs.gov/ClinicalLabFeeSched*. Deadline: July 11. Individuals who wish to make a presentation on-site must specify the new lab codes they will be discussing.
- ❑ ***Dial-in for the July 16 meeting:*** 1-888-889-1954. Conference passcode: Ambulatorys. After the on-site presentations, a question-and-answer period will be opened to both the participants in the room and the audio listeners.

The lab fee-setting procedures were codified in federal regulations last year, as required by the 2003 Medicare Modernization Act, and were published as part of the final 2007 Medicare physician fee schedule rule (*NIR, 28, 4/Nov 20 '06, p. 1*). CMS basically adopted the procedures it has followed since 2002 to solicit public input, in accord with the Benefits Improvement & Protection Act of 2000.

CMS Seeks More Comment On Switch To Single ABN

The revised draft ABN and supporting documents are posted at www.cms.hhs.gov/PaperworkReductionActof1995. *To the left of the page, click on "PRA Listing," then scroll down or search for "CMS-R-131." Comments are due by June 24 at: CMS, Office of Strategic Operations & Regulatory Affairs, Division of Regulations Development C, Attn: Bonnie L. Harkless, Rm. C4-26-05, 7500 Security Blvd., Baltimore, MD 21233-1850.*

A second round of public comment is underway until June 24 on a revised draft of a new single-page Advance Beneficiary Notice (CMS-R-131). In a *Federal Register* notice on May 25, the Centers for Medicare & Medicaid Services invited additional input on changes made to the original proposed version after the first round of public comment earlier this year.

Currently, CMS maintains two versions of the ABN, one general and the other specific to laboratory testing. They are due to expire soon and CMS is proposing to combine the two into a single notice (with an identical OMB form number) that the agency says will meet both needs (*NIR, 28, 10/Mar 12 '07, pp. 4-5*).

The ABN is used to inform beneficiaries of potential financial liability, except for certain institutional benefits such as home health services and inpatient hospital services. Physicians, practitioners, providers, and suppliers that are required to use ABNs should continue using the currently approved forms until further notice, CMS says.

The revised ABN draft makes several changes of note to clinical laboratories:

- ❑ The term "items/services" was removed from the header and replaced with a blank that users can customize to their business. Labs, for example, can use "laboratory tests" in the space.
- ❑ In addition to the above generic version, there are two other versions of the single-page ABN available. One specifies "laboratory tests" in the header (*see draft version, p. 3*). Preprinting of lab-specific information and denial reasons used on the current ABN-L is still permitted, CMS notes.
- ❑ More space is allowed for customization. The ABN may be on either letter or legal size paper.
- ❑ The Option Box for beneficiaries was rewritten to make the language less formal and bureaucratic. The first option makes beneficiaries aware of their right to receive services and appeal to Medicare should the services be denied.

Notifier(s):
Patient Name: Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for laboratory tests 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 laboratory tests below.

Laboratory Tests:	Reason Medicare May Not Pay:	Estimated Cost:
	Medicare does not pay for these tests for your condition.	
	Medicare does not pay for these tests as often as ordered for you.	
	Medicare does not pay for experimental or research use tests.	

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 laboratory tests 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.

OPTIONS: Check only one box. We cannot choose a box for you.

❑ **OPTION 1**. I want the laboratory tests listed above. You may collect money from me now, but I also 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 laboratory tests 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 laboratory tests listed above. I understand with this choice I am not responsible for payment, and **I cannot appeal to see if Medicare would pay**.

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.

Signature:	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

focus on: NPI Compliance Policy

CMS Releases Provider Data To Aid NPI Exchange

To the relief of clinical laboratories and other healthcare providers, the government has set forth the data details it will make available from the National Plan & Provider Enumeration System (NPPES) and who can access the data. Labs and other provider groups have long complained that lack of guidance on the data availability has been a big factor impeding NPI readiness among various trading partners.

The NPPES assigns a National Provider Identifier (NPI) to a provider and houses the NPI and information from the NPI application/updates. The NPPES creates a record for each provider to whom it assigns an NPI. Providers are categorized as two types: individuals, such as physicians; and organizations, such as hospitals.

Below are major policy points in the NPPES data dissemination notice in the May 30 *Federal Register*:

What healthcare provider data will not be available from the NPPES?
Social Security numbers, IRS individual taxpayer ID numbers, and date of birth. HHS has determined that under terms of the Freedom of Information Act (FOIA), these data do not have to be disclosed. Accordingly, HHS says that to prevent or minimize fraud in Medicare/Medicaid, it will not release these data.

What provider data will be available from the NPPES?
Data that HHS has determined to be "disclosable" under the FOIA (*see table, p. 5*). HHS says these data should be sufficient to enable HIPAA-covered entities to match provider records in the NPPES with the providers for whom they have data.

Who can request NPIs and other provider data?
Anyone may request NPIs and other NPPES provider data from HHS under the FOIA.

How will the data be available?
HHS will make the FOIA-disclosable NPPES healthcare provider data available in downloadable files and in a query-only database whereby users can search by NPI or provider name. Monthly update files will also be posted for downloading from the Internet, though CMS may later opt for less frequent updates.

When will the initial data file and query-only database be publicly available?
On June 28, 2007.

Will there be any charge to use the query-only database?
There will be no charge.

If providers have been assigned NPIs, what should they do before June 28?
Review their NPPES data and make any necessary updates or corrections. This will ensure that their information is accurate when disclosed by CMS. (Reminder: Providers that are HIPAA-covered entities are required by regulation to update their NPPES data *within 30 days of any change*.)

Healthcare Provider Data Available From NPPES

For health care providers/individuals	*For health care providers/organizations*
NPI (This is the provider's NPI. If the provider has had an NPI replaced, this will be the same NPI as the Replacement NPI.)	NPI (This is the provider's NPI. If the provider has had an NPI replaced, this will be the same NPI as the Replacement NPI.)
Entity Type Code: 1=Individual	Entity Type Code: 2=Organization
Replacement NPI (This is the provider's NPI if the provider has been assigned a Replacement NPI. If the provider has never been assigned a Replacement NPI, this data element will be blank.)	Replacement NPI (This is the provider's NPI if the provider has been assigned a Replacement NPI. If the provider has never been assigned a Replacement NPI, this data element will be blank.)
—	Employer Identification Number (EIN)
Provider Last Name (Legal Name)	Provider Organization Name (Legal Business Name)
Provider First Name	—
Provider Middle Name	—
Provider Other Last Name	Provider Other Organization Name
Provider Other Last Name Type Code 1=Former Name 2=Professional Name 5=Other	Provider Other Organization Name Type Code 3=Doing Business As Name 4=Former Legal Business Name 5=Other
Provider Other First Name	—
Provider Other Middle Name	—
Provider Name Prefix Text	—
Provider Name Suffix Text	—
Provider Credential Text	—
Provider First Line Business Mailing Address	Provider First Line Business Mailing Address
Provider Second Line Business Mailing Address	Provider Second Line Business Mailing Address
Provider Business Mailing Address City Name	Provider Business Mailing Address City Name
Provider Business Mailing Address State Name	Provider Business Mailing Address State Name
Provider Business Mailing Address Postal Code	Provider Business Mailing Address Postal Code
Provider Business Mailing Address Country Code (If outside U.S.)	Provider Business Mailing Address Country Code (If outside U.S.)
Provider Business Mailing Address Telephone Number	Provider Business Mailing Address Telephone Number
Provider Business Mailing Address Fax Number	Provider Business Mailing Address Fax Number
Provider First Line Business Location Address	Provider First Line Business Location Address
Provider Second Line Business Location Address	Provider Second Line Business Location Address
Provider Business Location Address City Name	Provider Business Location Address City Name
Provider Business Location Address State Name	Provider Business Location Address State Name
Provider Business Location Address Postal Code	Provider Business Location Address Postal Code
Provider Business Location Address Country Code (If outside U.S.)	Provider Business Location Address Country Code (If outside U.S.)
Provider Business Location Address Telephone Number	Provider Business Location Address Telephone Number
Provider Business Location Address Fax Number	Provider Business Location Address Fax Number
Healthcare Provider Taxonomy Code (Primary Taxonomy required; up to 15 may be reported)	Healthcare Provider Taxonomy Code (Primary Taxonomy required; up to 15 may be reported)
Other Provider Identifier	Other Provider Identifier
Other Provider Identifier Type Code	Other Provider Identifier Type Code
Provider Enumeration Date	Provider Enumeration Date
Last Update Date	Last Update Date
NPI Deactivation Reason Code	NPI Deactivation Reason Code
NPI Deactivation Date	NPI Deactivation Date
NPI Reactivation Date	NPI Reactivation Date
Provider Gender Code	—
Provider License Number	—
Provider License Number State Code	—
—	Authorized Official Last Name
—	Authorized Official First Name
—	Authorized Official Middle Name
—	Authorized Official Title or Position
—	Authorized Official Telephone Number

Source: *Federal Register*, May 30, 2007.

Also, providers that want to delete any NPPES data that was not required to be furnished in order to obtain an NPI may do so prior to June 28 if they prefer that such data not be disclosed by CMS.

Will a group practice be able to submit NPI applications and obtain NPIs for physician members of the group?
Yes, if the member gives permission for the NPI application/update data to be submitted by the group. The data are submitted to the NPPES for enumeration electronically in a format defined by HHS. The NPPES processes the NPI application data and makes available to the practice the NPIs assigned to the physician members. If NPIs were not assigned to all the members, HHS indicates why the NPIs were not assigned. This process is known as electronic file interchange (EFI) for bulk enumeration.

EFI information can be found at *www.cms.hhs.gov/NationalProvIdentStand/*. Providers assigned NPIs via this process may update their own NPPES data electronically on the Web with user identifiers and passwords they select. Information on the format of EFI files is at *https://NPPES.cms.hhs.gov*. The EFI process became available on May 1, 2006.

Will CMS accept custom requests for NPIs?
Yes, but such requests for FOIA-disclosable data will be considered in accord with FOIA procedures and charges *(www.cms.hhs.gov/AboutWebsite/04_FOIA.asp)*. For example, there could be requests for data for specific healthcare providers, or for healthcare providers in certain states or with certain Healthcare Provider Taxonomy Codes, or requests for the data on CD, diskette, or paper. These requests must be submitted in detail to: CMS, Office of Strategic Operations & Regulatory Affairs, Freedom of Information Group, Rm. N2-20-16, 7500 Security Blvd., Baltimore, MD 21244-1850. Requests may be faxed to 410-786-0474.

When will Medicare fee-for-service begin rejecting claims without an NPI in the primary provider field, and what is meant by a primary provider?
Primary providers are billing, pay-to, and rendering providers. When CMS judges that a sufficient number of claims contain the NPIs of these providers, it may start rejecting claims that do not contain these NPIs. At press time, the agency said this could be July 1 or soon after.

All other providers are defined as secondary. These include referring, ordering, supervising, facility, care plan oversight, purchase service, attending, operating, and "other" providers. Legacy numbers are acceptable for these providers until May 23, 2008. Under NPI contingency plans, UPINs and surrogate UPINs may still be used to identify ordering and referring providers until further notice, CMS said.

If a secondary provider's NPI is on a claim, it will only be edited to assure that it has 10 digits, that it begins with "1", "2", "3", or "4", and that the 10th position of the number is a correct check digit.

When will paper claims start being rejected?
Medicare will begin rejecting the old Part A paper form, the UB-92, after May 22, 2007, and will only accept the UB-04.

Medicare will continue accepting the old CMS-1500 (12-90) form to July 1, 2007. Its use had been set for April 1 but was delayed when CMS discovered printing errors on the new form. Medicare will accept only the new CMS-1500 (08-05) as of July 1.

Lab Spending: How Ripe A Target For Medicare Cuts?

When pressed to cut Medicare spending, Congress has historically eyed Part B lab spending as a "tempting target." Since establishing the lab fee schedule in 1984, lawmakers have canceled the annual update 12 times in 23 years, including the latest freeze that runs through 2008, and have reduced the national fee caps from 115% to 74% of the national median.

What are the financial stakes in any policy discussion of Part B clinical laboratory services? The latest data are presented in the recently released Medicare trustees report for 2007:

- Part B spending for lab services increased by 9.6%, to reach $7.12 billion in calendar year 2006. After declining in the 1990s, it has rebounded strongly, rising at an average rate of 9.5% per year since 2000.
- Intermediary labs (hospital outpatient/outreach) accounted for $3.394 billion (48%) of Part B lab services in 2006, up 14.9%, compared to $2.954 billion in 2005.
- Carrier labs (independents and physician office labs) accounted for $3.734 billion (52%), up 5.2% from $3.551 billion in 2005.
- Part B lab services represented 1.7% of overall Medicare program expenditures in 2006.
- Lab spending per enrollee was $165 in 2006, up from $153 in 2005 and $103 in 2000.
- The total Part B budget rose by 11.2%, to $165.6 billion in 2006. The fastest growing components were managed care, up 43% to $31.5 billion, and hospital (excluding lab), up 18% to $23.8 billion.
- Total Medicare expenditures reached $408.3 billion in 2006 vs. $336.4 billion in 2005, with most of the increase attributed to the start of the drug program.

CLIA Advisory

CMS Announces New Waived Tests & Billing Codes

The Centers for Medicare & Medicaid Services has recently updated its list of clinical laboratory tests approved by the Food & Drug Administration as waived under CLIA (the Clinical Laboratory Improvement Amendments). Effective July 1, the following tests are added and must be billed with the QW modifier in order to be recognized by local Medicare contractors as a waived test.

CPT Code/Modifier	*Description*
80101QW	Wolfe Drug Testing RealityCheck Integrated Specimen Cup
80101QW	Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup
82274QW, G0328QW	InSure Quik Fecal Immunochemical Test (F.I.T.)
82947QW, 82950QW, 82951QW, 82952QW, 83718QW and 84478QW	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips)
86318QW	Inverness Medical Clearview H. pylori Test {whole blood}
80101QW	Innovacon Integrated E-Z Split Key Cup II {Professional Use}
80101QW	Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}
85610QW	Roche Diagnostics CoaguChek XS

The list of CLIA waived tests and billing codes is typically updated quarterly. The complete list, including codes effective July 1, is contained in CMS Change Request 5600, posted at *www.cms.hhs.gov/transmittals*.

Genetic Testing Study Approved In Senate FDA Bill

Neither of two genetic testing oversight bills got on the fast track as the Senate took up legislation reauthorizing Food & Drug Administration user fees for drug and device makers. But the final measure the Senate passed by a vote of 93 to 1 (S. 1082) included an amendment calling for an Institute of Medicine study to assess the safety and quality of genetic testing and to make recommendations to improve federal oversight and regulation of such tests.

The amendment mirrors a provision in the bill that Sen. Barack Obama (D-IL) introduced (*NIR, 28, 12/Apr 9 '07, pp. 4-5*). But as Jason DuBois, vice president for government relations at the American Clinical Laboratory Association explained to *NIR*, it was modified at the request of the office of Sen. Orrin Hatch (R-UT) to focus the study on the "overall safety and quality of genetic tests." It also requires that the study "take into consideration relevant reports by the [HHS] Secretary's Advisory Committee on Genetic Testing and other groups."

The office of Sen. Edward Kennedy (D-MA) pulled back from an attempt to fast-track his bill that would require FDA premarket review of most lab-developed tests, including genetic tests. The lab industry lobbied against attaching the bill to the FDA measure, urging consideration of the issues via hearings and other formal channels.

washington WATCH

Holsinger Nominated As Surgeon General

The President has nominated James W. Holsinger, a cardiologist who served in the Veterans Affairs Department and as secretary of health and family services in Kentucky, as the 18th Surgeon General of the United States. The post requires Senate confirmation.

Mr. Bush praised Holsinger as "an accomplished physician who had led one of the nation's largest healthcare systems, the state of Kentucky's healthcare system."

HHS Secretary Michael Leavitt noted that Holsinger's 26-year career with the VA culminated in his appointment as undersecretary for health in 1992. He also has served more than 30 years in the U.S. Army Reserve, retiring with the rank of major general in 1992.

The Surgeon General post has been vacant since Vice Admiral Richard Carmona, MD, MPH, resigned in 2006. Its acting head is Kenneth Moritsugu, MD, MPH.

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