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Providers Can Apply Now For New National ID Number

Most HIPAA-covered entities must use the new provider identifier by May 2007. Health plans may require it before then. Medicare isn't accepting the provider ID yet. Instructions on the ID's use when billing Medicare are to be issued in 2006

Starting May 23, clinical laboratories, pathology practices, and other healthcare providers can apply for a new National Provider Identifier that eventually will be used in all Medicare and non-Medicare standard electronic transactions, including submission of claims, inquiries about eligibility and claims status, referral authorizations, and remittance advices. The NPI will replace the plethora of provider identifiers in use today for standard transactions.

In a letter to providers, the Centers for Medicare & Medicaid Services has listed three options to apply for an NPI (*see box, p. 2*). The NPI consists of nine numeric digits followed by one numeric check digit. Providers will be assigned only one NPI, and it will not change over time.

All providers are eligible for an NPI; those that are "covered entities" under HIPAA (the Health Insurance Portability & Accountability Act of 1996) must obtain and use NPIs, even if they use business associates, such as billing agencies, to prepare the standard transactions. Providers are "covered entities," CMS says, if they transmit any data in electronic form in connection with a transaction for which ➥ *p. 2*

INSIDE *NIR*

Lab Coalition Plans 'Fly-In' Lobbying Blitz

The Clinical Laboratory Coalition decided May 10 to organize a June 14 grassroots "fly-in" to lobby Congress on key concerns, coalition members told the *National Intelligence Report*. The main focus will be to express their opposition to any further cuts in Part B lab fees that Congress might consider to reduce spending, as well as their opposition to continuing the current freeze on lab fee updates. The freeze keeps lab fees at 2003 levels through 2008.

The lobbying blitz also will urge Congress to resist any temptation to restore a 20% Part B lab co-pay. Lab groups defeated such a proposal in 2003, but Congress, at the last minute, imposed a five-year fee freeze instead. The blitz will further lobby for passage of legislation targeting the shortage of medical lab personnel (*NIR, 26, 12/Apr 11 '05, p. 2*).

The fly-in "is part of [our] strategy this year," said Kathy Ayres, who directs legislative/regulatory affairs for the Clinical Laboratory Management Association. "Instead of waiting until something happens and react to it, we're laying some groundwork." CLMA is a member of the coalition, whose roster includes some 21 leading national lab/pathology groups and national lab and diagnostics companies.

New National ID Number, *from p. 1*

the HHS Secretary has adopted a standard. Applying for an NPI does not replace any enrollment or credentialing processes with any health plan, including Medicare.

The transition from existing provider ID numbers to the NPIs will occur over the next couple of years. Use of NPIs in standard transactions will be required of covered entities, including Medicare and Medicaid, as of May 23, 2007 (for small health plans, May 23, 2008).

Each health plan with which a provider does business will notify the provider when it is ready to accept NPIs in standard transactions such as claims submission. CMS urges providers to apply for an NPI well before the above compliance dates because health plans could require providers to use the NPI before then.

The NPI was established in a final rule in early 2004 (*NIR, 25, 7/Jan 26 '04, p. 2*). CMS has picked Fox Systems, Inc. (Scottsdale, AZ) to support NPI operations. As the project's Enumerator, Fox will process applications and run a help desk (*NIR, 26, 12/Apr 11 '05, p. 8*).

To date, the following HIPAA standards have been adopted and implemented: electronic healthcare transactions and code sets, privacy, security, and the national employer identifier.

Three Ways To Apply For An NPI

You must apply for a National Provider Identifier in one of three ways:

1. Via the Web, beginning May 23, at *https://nppes.cms.hhs.gov*

2. On paper, beginning July 1. The application will be available on *https://nppes.cms.hhs.gov*, or you can call the NPI contractor (called the Enumerator) at 1-800-465-3202 (TTY 1-800-692-2326) for a copy.

3. With your permission, an organization may submit your NPI application in an electronic file. This option will be available in the fall of this year. By choosing this avenue, CMS notes, a professional association or a healthcare provider that is your employer could submit the file containing your information and that of other providers.

Starting May 23, Enumerator staff will be available to answer telephone and e-mail inquiries about the NPI application process. The call center hours of operation will be 9 a.m. to 5 p.m. (Eastern), Monday through Friday (see phone numbers in #2 above). Send e-mail inquiries to *customerservice@NPIenumerator.com*

Labs Can Collect 'Past Due' Amounts On Medicare Trip Fee

The new, higher fees are to be implemented July 5, but they're retroactive to January 1

If your laboratory bills Medicare for the Part B travel allowance, you're entitled to more this year than you've been getting—but to get the extra money, you must bring your trip fee claims that have already been paid to the attention of your local carrier or fiscal intermediary. Neither contractor is required to search past claims and make the adjustment.

Medicare this month announced a correction that raises the 2005 trip fee to $0.855 per mile (HCPCS code P9603) and $8.55 per flat-rate trip basis (P9604). The previously announced rates were $0.835 and $8.35, respectively. Labs can bill for the trip fee when travel is necessary to collect specimens from Medicare beneficiaries who are homebound or in nursing homes.

The new rates stem from a change Medicare made to one of the two components of the travel allowance—namely, the federal standard mileage rate (Change Request 3785, May 6, 2005). The Internal Revenue Service sets this rate annually; for 2005, it is $0.405 per mile. But Medicare used a different figure, $0.385. (The personnel component of the trip fee remains unchanged at $0.45 per mile.)

Why The Correction?

It turns out that the Centers for Medicare & Medicaid Services relied on what was merely preliminary information from the IRS. Section 1833(h) of the Social Security Act says Medicare "may" estimate a travel allowance, but doesn't specify how. Since July 1998, CMS, responding to complaints that local contractors were setting the fee too low, has based the travel portion on the IRS-established standard mileage rate (Program Memo AB 9833).

On November 4, 2004, when CMS published the 2005 lab fee schedule, the memo sent with it used $0.385 per mile for the travel portion of the 2005 trip fee. Then, on November 17, the IRS established the mileage rate at $0.405 (IR-2004-139). This three-cent increase from the 2004 level "was the largest one-year rise ever," the IRS said, attributing it primarily to higher prices for vehicles and fuel during the year ending in September.

CMS soon drafted a Change Request to correct Medicare's travel rates, but it got stuck in the queue behind numerous other, higher priority issues, such as establishing other 2005 fee schedules, said agency official Anita Greenberg on May 16. She said she has received calls from some labs saying it wouldn't be worth their while to request any retroactive adjustments. The new, higher rates would be of greatest interest to labs whose testing involves collecting a high volume of specimens from homebound or nursing home patients. Though contractors don't have to implement the new rates until July 5, many have already done so, Greenberg noted.

Bill Introduced To Raise Specimen Collection Fee

U.S. Rep. Phil English (R-PA) on May 10 introduced legislation that would increase the Medicare Part B specimen collection fee, which has been fixed at $3.00 for more than 20 years. He sponsored a similar measure last year.

His bill (H.R. 2218) would raise the fee to $5.78 in 2006, based on what the amount would be if it had been indexed to the yearly Consumer Price Index update. The bill also would provide for future CPI updates to the fee.

Labs Win Some, Lose Some In Florida Medicaid Initiative

Clinical laboratory groups have foiled a last-ditch attempt in the Florida legislature to shield, from regulatory challenge or judicial review, the state health agency's efforts to put Medicaid independent lab services up for bidding. But the groups were unable to lift a 10% cut in Medicaid lab fees that the legislature mandated while the state tries to obtain a competitively bid contract.

On the morning of May 5, lab groups learned that a provision they had gotten removed from the House appropriations bill on March 31 had popped up again, this time in the final budget legislation. By 11 p.m. on May 6, the final day of the legislative session, the groups got it removed again.

The provision would have authorized Florida's Agency for Health Care Administration to reissue its invitation to negotiate (ITN) a winner-take-all contract to provide independent lab services to Medicaid recipients statewide, but without having to go through a formal rulemaking or being subject to judicial review (*NIR, 26, 12/Apr 11, '05, p. 3*).

The rulemaking requirement was critical for lab interests—the Florida AHCA on February 18 had withdrawn an ITN after the American Clinical Laboratory Association challenged it, contenting that the state failed to authorize the contract through formal rulemaking (*NIR, 26, 10/Mar 7, '05, p. 3*).

ACLA worked with members of the Clinical Laboratory Coalition in a grassroots effort to pressure state lawmakers, said ACLA president Alan Mertz. The association also got state hospital and physician associations involved, because the provision would have impacted all Medicaid fee schedules, not just the one for clinical lab services.

Unfortunately, Mertz said, the state agency "did get authority extended another year to issue an ITN or RFP." The legislative language gives the state the option of awarding either a statewide winner-take-all contract or multiple regional winner-take-all contracts. This language also calls for the state to continue imposing a 10% reduction in lab fees while it tries to obtain lab contracts.

Lab Coalition Opposes Results Reporting Requirement

The coalition does support integrating lab clinical values into electronic medical records, but favors an incremental approach

The Clinical Laboratory Coalition has registered the unanimous objections of its member organizations to a recommendation from the Medicare Payment Advisory Commission urging Medicare to require labs to attach test results with claims for their services (*NIR, 26, 10/Mar 7 '05, p. 1*).

The coalition detailed its members' concerns in a May 18 letter to the chairs of the Senate Finance Committee and the House Ways & Means and Energy & Commerce Committees, as well as to Herb Kuhn, director of the CMS Center for Medicare Management, and MedPAC executive director Mark Miller, PhD. The coalition is comprised of some 21 national lab and pathology associations, national lab companies, and test manufacturers.

Coalition members are worried that Congress might adopt the MedPAC recommendation in conjunction with any healthcare information technology legislation that might advance on Capitol Hill.

Among the concerns raised, many involving the Centers for Medicare & Medicaid Services:

- There are no commonly accepted standards for transmission of lab data.
- Lab values should not be viewed independently of a medical record (for example, CMS ought to know if a diabetes patient also has congestive heart failure).
- Most labs would not be able to comply due to the disconnect between their systems for test results and for billing.
- Many lab results contain free-form narratives rather than reference values, which would be difficult to shoehorn into a standardized data set such as LOINC.
- CLIA regulations require labs to release test results only to the individual who will use them in diagnosis, treatment, prevention, or health assessment, or to people who are authorized under state law to order lab tests or receive the results.
- The HIPAA privacy rule permits labs to disclose protected health information to CMS such as test results, but they would first have to make reasonable efforts to determine the "minimum necessary" disclosure needed (such as disclosures supporting physician pay-for-performance determinations that CMS might make).

- ❑ "The sheer volume of lab test results contemplated … is astronomical," leading to "enormous" security risks, the coalition noted.
- ❑ CMS is still in the early stages of developing a HIPAA transaction standard for electronic claims attachments, with specifications still in the industry consensus-building process and no rule proposed yet.
- ❑ Many labs contract out the submission of claims.

Jury Award Faults Physician, National Lab For Misread Pap Smears

The jury award included $4 million for Vicki Malouf's pain and suffering; $1 million for the loss experienced by her husband and two children; $1.8 million for care of the younger child, who has cerebral palsy; and $2.4 million for loss of earnings by Malouf, who was a fashion industry sales executive

An $11.8 million jury award last month against a Manhattan gynecologist and Quest Diagnostics Inc. (Teterboro, NJ), brought home a powerful message to clinical laboratories: liability for misread Pap smears is still great cause for concern. The jury split liability: 55% to the physician, 45% to Quest.

In the 1980s, a *Wall Street Journal* expose of Pap testing errors, sometimes with lethal consequences, triggered a flurry of litigation, briefly elevating gynecologic cytology to the leading specialty in terms of medical liability. Though passage of CLIA (the Clinical Laboratory Improvement Amendments of 1988) has since helped improve quality, the jury award underscores the still-present legal risks.

The Case At Issue

In the Manhattan case, Vicki Malouf died at age 45 in August 2001 of advanced metastatic cervical cancer, even though a 1994 Pap smear had indicated an abnormality and an October 1994 colposcopy had indicated moderate cervical dysplasia, the plaintiff's attorney, Judith Livingston, told *NIR*.

An October 1995 Pap test by SeaPath (since closed) was read as normal. Later that year, Malouf's gynecologist, Heidi Rosenberg, MD, established a new practice, Murray Hill Ob Gyn, and contracted with Quest for lab work. Quest read Pap tests of Malouf in August 1996 and January 1997 as normal, then found a high-grade intraepithelial lesion in an April 1998 Pap test and squamous cell carcinoma in a May 1998 biopsy. At Rosenberg's request, Quest on May 29, 1998, reviewed the first two slides. Livingston told *NIR* that Quest concluded they actually had a few abnormal and atypical cells. Quest spokesman Gary Samuels said the results of the re-check were within normal limits, which is possible even if there are a few abnormal cells.

"It's a tragic story," Samuels said. "Our sympathies go out to the family . . . This was a very complicated case and we vigorously defended our interpretations in court. " Quest is considering an appeal on grounds that its portion of the damages is excessive.

With an estimated 5% to 20% of false positives, Pap testing is fraught with error, Livingston said. "The rationale out there is that cervical is a slow growing cancer and we'll catch it next year. But for this woman, it was missed and missed and missed." Livingston, a senior partner with Kramer, Dillof, Livingston & Moore (New York City) and a specialist in medical malpractice, concluded ominously: "There are far more cases of misread Pap smears out there than women realize."

New Tests Should Steer Drug Development, Hill Staff Told

Industry advocates for personalized medicine told congressional staffers at an April 25 lunch briefing on Capitol Hill that the pharmacogenomic development process should be reversed, so that new molecular diagnostics would guide the practice of medicine, instead of coming as an afterthought. The briefing was sponsored by the Personalized Medicine Coalition, which is backed by pharmaceutical, biotech, clinical lab, healthcare information technology, and genetic advocacy groups (see *www.personalizedmedicinecoalition.org*).

In the view of Ronenn Roubenoff, MD, MHS, senior director, molecular medicine, Millennium Pharmaceuticals Inc. (Cambridge, MA), researchers should develop new biomarkers as a way to identify and characterize the greatest treatment needs in general patient populations. "We must establish clinical registries of patients being treated today," he said at the Hill briefing. "But neither pharmaceutical companies nor academia do this."

For an in-depth look at what personalized medicine will mean for labs and pathologists, join us for a special presentation on this promising new frontier at Lab Institute 2005, to be held October 19-22 in Arlington, VA. Featured speaker: Dr. Jorge Leon, president of Leomics, a molecular diagnostics consulting firm and a former head of DNA testing at Quest Diagnostics

By showing which patients don't respond to conventional treatment, or respond adversely to it, researchers can use the biomarkers to steer development of drugs that will help patients. By identifying distinguishing genomic traits, biomarkers also can provide clues for potential treatments. Roubenoff said this approach pays dividends to drug makers in the clinical trials process—the most expensive, time-consuming, and risky part of drug development.

Roubenoff said Millennium and its research partners have been taking this path, establishing registries of patients with rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease, and atherosclerosis. Of 243 patients with rheumatoid arthritis, 82 were found to have severe joint damage erosions. Of 50 biomarkers studied, two were closely associated with the severe symptoms. Now Millennium has a drug in development for people who are more susceptible to severe joint erosion—and a biomarker already in place to identify them.

New Push To Give Doctors Real-Time Lab Test Results

The California HealthCare Foundation, an Oakland-based philanthrophy, is supporting development of a national standard to encourage adoption of electronic health records and the electronic delivery of laboratory test results in ambulatory healthcare. The effort is called the EHR-Lab Interoperability and Connectivity Standards project (ELINCS).

The ELINCS project is accepting comments through May 26 on Draft 0.2 of the new standard. The project's steering committee aims to develop the standard within 6-9 months and get it adopted by EHR vendors and labs within another nine months. The committee includes Jason DuBois of the American Clinical Laboratory Association as well as senior executives from the American College of Physicians and various leading healthcare information and EHR groups.

The ELINCS specification is based on the HL7 version 2.4 messaging standard and the LOINC coding standard. Though ELINCS initially focuses on electronic test results reporting, it may later be expanded to include electronic test ordering. Also, the initial focus is on the results reporting application itself, not related data-interchange processes such as choice-of-transport technologies, encryption and authentication methods, and message addressing and routing infrastructure. For more on ELINCS, including a link to the draft specifications, go to *www.chcf.org/topics/chronicdisease/index.cfm?itemID-108868*.

Meanwhile, President George W. Bush has called for personal EHRs for most Americans within 10 years and public-private collaboration to achieve nationwide adoption of health information technology. On May 11, the health IT leadership panel, convened by the Department of Health & Human Services, released its final report calling health IT an urgent priority and offering guidance to government and the private sector to spur its adoption. The panel included CEOs from major companies such as FedEx, General Motors, International Paper, Target Corp., Pepsico, Procter & Gamble, and others.

♦ QUESTION *of the* M·O·N·T·H

I've heard that the HHS Office of Inspector General has reversed its position that a hospital might violate the anti-kickback statute by requiring pathologists and other hospital-based physicians to furnish services to the hospital without being compensated. Is that true?

Yes and no. In supplemental guidance on hospital compliance programs issued in January 2005, the OIG states: "[A]rrangements that require physicians to provide Medicare Part A supervision and management services for token or no payment in exchange for the ability to provide physician-billable Part B services at the hospital *potentially* violate the anti-kickback statute and should be closely scrutinized." This was not the clear-cut prohibition against "token or no" Part A payment that the College of American Pathologists had sought.

But the OIG did introduce a framework for anti-kickback evaluation of exclusive contracts, noted attorney Robert Mazer, a shareholder with Ober/Kaler (Baltimore, MD), who spoke at the May 12 audio conference sponsored by Washington G-2 Reports to examine the OIG's guidance. According to Mazer, under the OIG's analysis, benefits to hospital-based physicians from exclusive contracts might serve as a basis to require them to provide otherwise compensated services. The OIG concluded: "Whether the scope and volume of the required services … reasonably reflect the value of the exclusivity will depend on the facts and circumstances of the arrangement." At the same time, the OIG cautioned, hospital-based physicians would not be required to furnish such services, stating that "nothing . . . should be construed as requiring [them] to perform administrative or clinical services at no or a reduced charge."

Mazer thinks the OIG has sent mixed signals about its intent to scrutinize such arrangements, but added, "Difficulty in applying the principles [in the guidance] may continue to dissuade the OIG from pursuing arrangements between hospitals and hospital-based physicians as unlawful kickbacks."

For more on the compensation issue and other risk areas in the OIG hospital compliance guidance, a recording of the full session of the May 12 G-2 'hot topic' audio conference is available for purchase. Log on to www.g2reports.com *and click on "Products." Or you can order by calling 800-401-5937, ext. 2.*

Pathologists Score Wins With Direct Billing Campaign

Under direct billing, payment is made only to the person or entity that performs or supervises a service, with few exceptions. Medicare Part B has had this policy since 1984

Pathology groups have added another to a string of state victories on the direct billing issue, with Montana joining eight other states in requiring all-payer direct billing for anatomic and clinical pathology services when Gov. Brian Schweitzer (D) on April 15 signed Senate Bill 479, which had passed the Senate unanimously and the House by a vote of 99-1.

The College of American Pathologists, American Society for Clinical Pathology, and state pathology societies are lobbying states to require direct billing to prevent treating physicians from demanding discounts from pathologists, then overusing their services to boost profits.

Iowa joined the direct-bill camp in February, with the signing of legislation by Gov. Thomas Vilsak (D). South Carolina came around to it in dramatic fashion on January 13, when the legislature, responding to intensive lobbying by state and national pathology groups, overturned Republican Gov. Mark Sanford's December 14, 2004 veto of a direct-bill measure. Meanwhile, pathology groups are battling to protect a direct billing law passed last year in Louisiana. The legislature is considering two House bills that would repeal all or part of the law.

Direct-Bill States

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- Iowa
- Louisiana
- Montana
- Nevada
- New Jersey
- New York
- South Carolina
- Rhode Island

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