



NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 28th Year of Publication

Vol. 28, No. 14, May 7, 2007

Medicare Contingency Plan Aims For NPI ‘Early Adoption’

CMS will conduct a national roundtable for healthcare providers on May 10 to discuss details of its recently announced National Provider Identifier contingency plan for Medicare fee-for-service. For details, see p. 4.

You may not have as much time as you think to start using National Provider Identifiers (NPIs) on Medicare fee-for-service (FFS) claims to avoid having them rejected. That’s the rub in the contingency plan that the Centers for Medicare & Medicaid Services has adopted for FFS providers that cannot meet the May 23, 2007 deadline for NPI compliance.

In earlier enforcement guidance, CMS alerted HIPAA-covered entities—health plans, healthcare providers, and health information clearinghouses—that if they cannot reach compliance by that date, they could have up to an additional 12 months to become compliant, as long as they made a good-faith effort to do so.

But in announcing its NPI compliance contingency plan for Medicare FFS, CMS noted that the time frame could be considerably shorter. As early as July 1, 2007, the agency said it could start requiring NPI use by primary providers if it judged a sufficient number of claims contained these NPIs. If not then, CMS said it could start rejecting claims without NPIs in August, depending on a review in June of claims submitted with NPIs. Providers will get advance notice of any such decision, the agency noted. For more on Medicare’s contingency plan for NPI implementation, see the *Focus*, pp. 4-5. 🏛️

INSIDE NIR

Ball is in the Senate’s court on genetic information safeguards 3

Medicare ‘fast-tracks’ NPI use in fee-for-service, see *Focus*..... 4-5

Funding warning thrusts Medicare spending into 2008 campaign spotlight 6

CAP, ACLA urge delay on proposed single ABN 6

New HHS Web site discloses more on HIPAA privacy rules, enforcement..... 7

Breast, cervical cancer screening bill signed into law 8

Boost your molecular momentum, get sure you’re paid correctly: G-2 conference details 8

AMA To Congress: ‘Avoid Physician Fee Meltdown’

Facing a scheduled 10% cut in Medicare fees next year, pathologists and other medical specialties are giving top priority this year to a legislative overhaul of the current fee update system.

In the latest in this campaign, the American Medical Association is urging Congress to scrap the system and “avoid the looming meltdown” in Part B physician fees. In an April 27 letter to members of the House and the Senate, AMA warned that projected fee cuts—10% in 2008 and 5% annually for the following nine years—threaten beneficiary access to quality care and further erosion of physicians’ participation in Medicare.

Canceling the cuts would cause Part B spending to rise 8% to 9% annually over the above time period, Bush administration officials have estimated. Implementing the cuts would increase this spending by 6.6% over the same period. *Continued on p. 2*



'Avoid Physician Fee Meltdown', from p. 1

Paying for any fix, however, requires cuts elsewhere in the Medicare budget under congressional pay-as-you-go rules, and lab spending could again become a tempting target, as it has repeatedly in recent years. To prevent this from happening again, the Clinical Laboratory Coalition is lobbying lawmakers about the crucial value that lab testing offers in prevention, diagnosis, treatment, and monitoring and urges them to thaw the current lab fee update freeze (which runs through 2008), approve no future extension of the freeze, restore annual Consumer Price Index (CPI) lab fee updates, and eschew any introduction of a 20% lab co-pay.

Lab cuts to pay for a physician fee fix aren't on the table at this point, Rep. Frank Pallone (D-NJ), chairman of the House Energy & Commerce health subcommittee, said in response to a question posed during the April 19-20 annual meeting of the American Clinical Laboratory Association.

But providing a permanent fix to the current SGR (Sustainable Growth Rate) formula is on the Democratic majority's high-priority list, Rep. Pete Stark (D-CA), who chairs the House Ways & Means health subcommittee, told the ACLA audience.

The SGR formula sets a target rate for growth in Medicare spending for physician services, linking fees to a number of factors, including growth in the volume of services relative to growth in the national economy. The SGR compares actual spending to the target and adjusts the update. If expenditures exceed the target, as has happened since 2001, the fee update is reduced.

Congress has repeatedly stepped in to prevent a negative update. Most recently, it blocked the 5% cut scheduled for 2007 and opted to freeze the update at zero and to create a new 1.5% bonus payment for physicians who report certain quality measures, though pathologists sustained a 6% reduction in total allowed charges due to changes in work and practice expenses under the Medicare physician fee schedule (*NIR*, 28, 5/Dec 15 '06, p. 1).

Unless Congress blocks the cut projected for 2008, the conversion factor that translates relative value units on the physician fee schedule into dollar amounts will be \$34.1350 in 2008, down from \$37.8975 in 2006 and 2007.

The House-passed budget blueprint for FY 2008 makes provision for preventing a 10% cut in 2008 by establishing a reserve fund of an undisclosed amount. While the blueprint is advisory and not binding on the committees of jurisdiction, it does identify spending priorities. Reserve funds are available only if the committees pass the requested changes with cost offsets.

Meantime, the AMA continues to push for a long-term fix. In the April 27 letter, the medical group said, "Unfortunately, the economics of the current system make it difficult for physicians to maintain their current level of practice, let alone allow them to make future investments needed to modernize medicine. Without adequate and predictable payments, physicians cannot invest in important new tools such as e-health record systems."

While stopping short of offering a specific legislative proposal, AMA said, "It's time to replace a fatally flawed policy with a framework that is equitable in comparison to other providers and that recognizes the economic realities of medical practice." 🏛️



Protecting Genetic Information: Ball Is In The Senate's Court

Now that the House has passed its bill prohibiting health insurers and employers from discriminating against individuals based on their genetic information or test results, it's up to the Senate leadership to schedule floor action on a similar bill (S. 358) that the HELP Committee reported out on April 10.

No timeline for floor action has yet been set, but it remains under discussion, *NIR* learned when checking, at press time, with staff of the office of Majority Leader Harry Reid (D-NV) and the office of Olympia Snowe (R-ME). Snowe is the lead sponsor of S. 358 (*NIR*, 28, 13/Apr 23 '07, p. 4). One staffer observed that the Senate calendar is crowded now by other high-priority issues such as immigration reform and Iraq war funding.

The House approved H.R. 493—the Genetic Information Non-Discrimination Act of 2007 (GINA)—by a 420 to 3 majority on April 15. The bill would make it unlawful for employers to use genetic information in making decisions on hiring, firing, job placement, or promotion. It would prohibit group health plans and other health insurers in the group and individual market from using genetic information to deny coverage or set premium rates and from requiring that individuals undergo genetic testing. The anti-discrimination ban applies as well to employment agencies, labor unions, and Medicare supplemental policy plans. The bill also establishes penalties, including fines, for violations.

The bill's lead sponsor, Rep. Louise McIntosh Slaughter (D-NY), said H.R. 493 is intended to allay public fears about misuse of genetic information. "For years we've held up genetic research because people were afraid that their genetic information would be used against them." Slaughter first introduced such legislation 12 years ago.

The White House supported H.R. 493 in a policy statement issued the same day that the House acted, adding that the administration "appreciates that the bill clarifies that its protections cover unborn children," referring to an amendment for embryos and fetuses.

Genetic Information: Key Definitions In H.R. 493

As defined in the House-passed bill:

- ❑ *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. It does not mean:
 - an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or
 - an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a healthcare professional with appropriate training and expertise in the field of medicine involved.
- ❑ *Genetic services* means a genetic test; genetic counseling (including obtaining, interpreting, or assessing genetic information); or genetic education.

Laboratory and pathology groups hailed the House protections. As the College of American Pathologists noted, "There have been many documented cases of discrimination after disclosing genetic predisposition to various conditions, even when individuals carried only a recessive gene for a disease and were not the carrier themselves."

The American Clinical Laboratory Association noted, in a statement by its president Alan Mertz: "Spectacular innovation in genetic testing is playing an increasingly critical role in transforming our healthcare system in the direction of 'personalized medicine.' This legislation is needed to remove a key obstacle to this much-heralded transformation." 



focuson: NPI Compliance Policy

Medicare Fee-For-Service Takes Fast Track On NPI Transition

The National Provider Identifier is a 10-digit numeric identifier that neither expires nor changes and is required in standard electronic transactions, in accord with HIPAA (the Health Insurance Portability & Accountability Act). The NPI replaces multiple legacy provider numbers such as UPINs now in use.

The 23rd of this month remains the final deadline for HIPAA-covered entities (other than small health plans) to comply with National Provider Identifier (NPI) requirements, the Centers for Medicare & Medicaid Services emphasizes.

But while CMS gave entities that cannot meet the deadline up to 12 more months to become compliant, it plans to accelerate the move to required NPI use on Medicare fee-for-service (FFS) claims from certain providers, perhaps as early as July 1, 2007.

General Policy On NPI Contingency Plans

Citing a lack of industry-wide readiness to conduct NPI-only HIPAA standard electronic transactions, CMS says it will enforce NPI compliance flexibly to assure a smooth transition and minimize cash flow disruptions. Covered entities—health plans, healthcare providers, and health information clearinghouses—have until May 23, 2008, to become compliant. They may establish contingency plans to facilitate NPI implementation with their trading partners. No penalties for non-compliance will be imposed and claims will continue to be paid, as long as they are making a good-faith effort to become compliant, “meaning working toward being able to accept and send NPIs,” CMS said (*NIR*, 28, 12/Apr 9 ‘07, p. 1).

It is up to each covered entity to determine its own contingency plan. Medicaid programs in California and four other states have already announced delays in their NPI transition. Anthem Blue Cross and Blue Shield says it aims to complete the switch in early 2008, and Aetna says it will accept legacy identifiers until May 23, 2008.

Medicare FFS Contingency Plan

When it comes to Medicare, labs and other providers shouldn’t be complacent. In recently released contingency guidance, CMS lays out its NPI policy for FFS providers (CMS Change Request 5955, April 24, 2007):

- ❑ For some period after May 23, 2007, Medicare FFS will:
 - Allow continued use of legacy numbers on transactions;
 - Accept transactions with only NPIs; and
 - Accept transactions with both legacy numbers and NPIs.
- ❑ After May 23, 2008, legacy numbers will not be permitted on any inbound or outbound transactions.

As soon as the number of claims submitted with an NPI for primary providers is sufficient, Medicare will begin rejecting claims without an NPI for these providers following advance notice. If the number of claims is sufficient in May, the start date for rejections will be July 1, 2007. If the number is insufficient, CMS will look again in June and decide whether to start rejecting claims in August 2007.

Primary providers are defined as billing, pay-to, and rendering providers. All other providers are defined as secondary—they include “referring, ordering, supervising, facility, care plan oversight, purchase service, attending, operating, and ‘other’

CMS To Hold NPI Roundtable On Medicare Fee-For-Service

Mark May 10 on your calendar. That's when the Centers for Medicare & Medicaid Services will hold a National Roundtable to discuss its National Provider Identifier contingency plan for Medicare fee-for-service claims. The toll-free call will take place from 2:00-3:30 p.m. (Eastern). To register, go to www.cms.hhs.gov/NationalProvIdentStand/.

providers," says CMS. Legacy numbers are acceptable for secondary providers until May 23, 2008. 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.

Industry Challenges

For labs and other providers, the core challenge is how you interact with your trading partners, emphasized the two speakers featured in the April 30 NPI compliance audio conference sponsored by Washington G-2 Reports/IOMA. Your compliance will depend on theirs, and they are likely to be at different stages of preparedness and to have differing contingency timetables.

When getting in synch with their trading partners, labs should recognize that time will be needed to get full NPI enumeration and test software, but labs should also be sure there is a mutually agreed-upon date for achieving compliance, said LabCorp associate vice president Kimberly Williams during the audio conference.

Getting in synch is a big job, Williams said. For example, you could have 200,000 relationships, and right now that would mean 200,000 requests. What the industry needs sooner rather than later is a single-source repository for accessing NPIs and crosswalks to legacy identifiers, she said. This is vital in preventing payment disruptions since claims will require the number of both the primary billing provider and the ordering or referring provider. CMS is scheduled to issue guidance in this area this month, according to the HHS semiannual regulatory agenda, Williams said. At press time, the notice was not yet published, though CMS officials have said it is expected out shortly (*NIR, 28, 13/Apr 23 '07, p. 1*).

The transition to sole NPI use can be a complex chore, but it also is a new paradigm for doing business and simplifying administrative procedures, Williams observed. Providers will own their identifiers; payers will no longer assign them. Providers will identify themselves in all standard transactions with one set of identifiers. Providers will request and receive payment on all claims to existing and future payers with one set of identifiers.

Lâle White, executive chairman & CEO, Xifin, Inc. (San Diego, CA), advised the audio conference audience to act immediately to get an NPI and begin collecting and testing NPIs from trading partners. To demonstrate good-faith and avoid penalties, you need to show that you have already obtained and started using NPIs in HIPAA

standard transactions, she said. CMS is likely to be strict on this point, since it began issuing NPIs in May 2005, giving providers two years to get and start using them.

Provider NPI Compliance: Flow Chart For The Basics

Activity	Responsible Party
Get it.....	Providers
Share it.....	Providers Ordering Physicians Reference Labs
Test it.....	Provider/Payer Provider/Clearinghouse/Payer
Use it.....	Provider/Payer/Clearinghouse

Source: Kimberly Williams, LabCorp.

Resources

- To apply for an NPI, go to the National Plan/Provider Enumeration System (NPPES) Web site at <https://nppes.cms.hhs.gov>.
- For updates on NPI policy, go to www.cms.hhs.gov/National-ProvidentStand.
- Recordings of the April 30 G-2 audio conference *NPI Countdown To Compliance: Are You Ready?* may be purchased for \$219 (\$199 for G-2 subscribers). To order, go to www.g2reports.com and click on "Recordings." 



Warning Thrusts Medicare Into Campaign 2008 Spotlight

The warning requires the President to propose in February 2008, and the Congress to quickly consider, ways to rein in Medicare spending, reducing outlays below the 45% threshold.

The latest report by the Medicare trustees on the program's failing financial health has triggered a controversial process that is sure to provoke sharp partisan debate in Congress next year over benefit cuts, tax increases, or a combination of both—propelling Medicare spending and provider issues into the 2008 election spotlight.

For the second year in a row, the trustees noted in their April 23 report, general revenue funding is projected to exceed 45% of Medicare financing within the next seven years, thus prompting the "funding warning" mandated by the 2003 Medicare Modernization Act. The trustees issued their first warning in 2006, estimating that the 45% threshold would be reached in 2012. In the 2007 report, they projected it would be reached in 2013.

Now that the second consecutive warning has been sounded, the law requires the President to propose legislation within 15 days of the release of his next federal budget request, due in February 2008, to bring Medicare funding below the 45% threshold. Congress then must "fast-track" consideration of the plan, but is not required to enact any specific proposal.

House Democratic health leaders Charles Rangel (D-NY), who chairs the Ways & Means Committee, and Pete Stark (D-NY), who chairs its health subcommittee, have been openly skeptical of the 45% trigger, calling it "arbitrary" and noting that no other federal program is subject to such a warning. Stark has dismissed it as a device that the GOP-controlled Congress rammed through in 2003 to "dismantle Medicare as an entitlement." Both the House and the Senate have already rejected Medicare and other entitlement cuts that the President proposed in his fiscal 2008 budget request (*NIR*, 28, 8/Feb 12 '07, pp. 4-6).

The Medicare trustees' report warned that the Part A fund would be exhausted by 2019. While spending for the Part D drug benefit has not been as high as first feared, spending for Part B medical services has continued to rise, setting off the funding alarm. Part B outlays are set to increase by 6.6% annually over the next 10 years, even if Medicare physician fees are cut, as scheduled under current law (*related story*, p. 1). 🏛️

CAP, ACLA Urge Delay On Proposed ABN Change

The College of American Pathologists and the American Clinical Laboratory Association are calling on Medicare to hold off on combining the two currently approved Advance Beneficiary Notices (ABNs) into a single all-purpose format and to take more time to consider issues they have raised in formal comments.

The Centers for Medicare & Medicaid Services earlier this year proposed to replace forms CMS-R-131-G (for general use) and CMS-R-131-L (specific to physician-ordered lab tests) with a single version that clinical labs and physicians would have to use, though the agency specified no planned effective date (*NIR*, 28, 10/Mar 12 '07, p. 4). CMS has mandated use of the two current standardized ABNs since 2003. The agency said the new single form is written in more beneficiary-friendly language and meets both general and lab-specific needs.

ACLA wants CMS to reconsider, saying there is no compelling rationale for eliminating the lab-specific ABN. Much time and expense were poured into developing



The ABN is used when there's genuine doubt that Medicare will pay for a covered service for medical necessity or other reasons. By signing an ABN before getting the service, the beneficiary agrees to be financially liable if Medicare later denies it.

it with the capacity to be customized for physicians and beneficiaries, and it has worked well in practice, ACLA said: "Changing the form would require labs to re-educate physicians and beneficiaries and incur considerable new costs in reprogramming software and systems."

The College of American Pathologists urged CMS to keep the lab-specific form until the agency responds to concerns that CAP has over customizing the proposed combined form, requiring an estimated cost for the lab testing, and provider liability when a different entity executes the ABN for lab services.

The current ABNs are set to expire at the end of May under terms of the Paperwork Reduction Act. But until any ABN change is finalized, Medicare providers and suppliers must continue to use the two approved ABNs, either of which suffice for lab services. To view the proposed combined ABN (draft CMS-R-131), go to www.cms.hhs.gov/PaperworkReductionActof1995. At the menu on the left, click on "PRA listing," then scroll down or search for "CMS-R-131." 🏛️

HHS Unveils Revamped Web Site On Privacy Rules, Enforcement

When periodically updating compliance programs and how complaints are handled, clinical laboratories and other healthcare providers have a new resource to check to see if they are in synch with federal requirements protecting the privacy of personal health information. The privacy rules, required by HIPAA (the Health Insurance Portability & Accountability Act of 1996), took effect in April 2003.

The U.S. Department of Health & Human Services has launched what it hails as an enhanced Web site to make it easier for providers, consumers, and others to get information about how the department enforces the privacy rights and standards through its Office of Civil Rights. Noted OCR director Winston Wilkinson: "The new information describes HHS enforcement activities and [presents] statistics showing which types of complaints are received most frequently and which entities are most often required to take corrective action as a result of consumer complaints." The site also features information on the rights of patients to access their health records and control how their personal health information is used and disclosed.

HHS announced the enhanced Web site—www.hhs.gov/ocr/privacy/enforcement—on April 20, coinciding with the fourth anniversary of the compliance date for the privacy rules for most HIPAA-covered entities—providers, payers, and clearinghouses.

How many complaints have been received, investigated, and closed?

Since the compliance date in April 2003, HHS has received over 26,408 HIPAA privacy complaints. Three-quarters (over 20,477) have been resolved: through investigation and enforcement (over 4,447), through investigation and finding no violation (2,155), and through closure of cases that were not eligible for enforcement (13,875).

What compliance issues are investigated most frequently, in order of frequency?

- Impermissible uses and disclosures of protected health information (PHI).
- Lack of safeguards for PHI.
- Lack of patient access to their PHI.
- Uses or disclosures of more than the minimum necessary PHI.
- Lack of or invalid authorizations for uses and disclosures of PHI.

What are the most common types of HIPAA-covered entities that have been required to take corrective action, in order of frequency?

Private practices, general hospitals, outpatient facilities, health plans (group health plans and health insurance issuers), and pharmacies. 🏛️



Breast, Cervical Cancer Screening Bill Becomes Law

President George W. Bush has signed into law legislation that reauthorizes the early detection program to provide breast and cervical cancer screening to low-income, uninsured, and underserved women. In an April 20 signing ceremony at the White House, Mr. Bush noted that the program, which is run by the Centers for Disease Control & Prevention, is expected to provide more than 700,000 screenings for eligible women in 2007.

Since its inception in 1991, CDC says, the program, known by its acronym NBC-CEDP, has served more than 2.9 million women, provided more than 6.9 million screening exams, and diagnosed more than 29,000 breast cancers, 94,000 precursor cervical lesions, and 1,800 cervical cancers.

An estimated 8% to 11% of U.S. women of screening age are eligible for the program's services. Federal guidelines set an eligibility baseline to direct services to uninsured and underinsured women at or below 250% of the federal poverty level; ages 18 to 64 for cervical screening; and ages 40 to 64 for breast screening. The program is a vital effort in the fight against cancer-related deaths for American women, the President noted. Together, breast and cervical cancer will claim the lives of more than an estimated 44,000 Americans this year. 🏠

Boost Your Molecular Momentum & Get The Right Payment!

For the latest news and expert advice on those all-important coding and reimbursement issues for molecular diagnostics, join us at our upcoming conference:

**From Bench to Bedside:
Onco-Molecular Diagnostics
June 6-8, 2007
Sofitel San Francisco Bay Hotel
San Francisco, CA**

Molecular diagnostics has experienced phenomenal growth in technology and related applications, and to support the desired outcome—improved quality care for patients—appropriate remuneration levels must be in place. Get a key update at our “cutting-edge” workshop featuring Diana W. Voorhees, principal & CEO, DV & Associates, Inc., in Salt Lake City.

For more on the program and to register, go to www.g2reports.com/onco-molecular, or call 800-401-5937, ext. 2.

NIR Subscription Order or Renewal Form

- YES**, enter my one-year subscription to the *National Intelligence Report (NIR)* at the rate of \$409/Yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues at www.ioma.com/g2reports/issues/NIR. Subscribers outside the U.S. add \$50 postal.*
- AAB & NILA members qualify for special discount of 25% off — or \$344.25 (Offer code NIR11)
- I would like to save \$182 with a 2-year subscription to *NIR* for \$736.*
- YES**, I would also like to order the *Lab Industry Strategic Outlook 2007: Market Trends & Analysis* for \$1195 (\$1095 for Washington G-2 Reports subscribers. (Report #1866C)

Please Choose One:

- Check enclosed (payable to Washington G-2 Reports)
- American Express VISA MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

MAIL TO: Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Or call 212-629-3679 and order via credit card or fax order to 212-564-0465 NIR 5/07A

© 2007 Washington G-2 Reports, a division of the Institute of Management and Administration, New York City. All rights reserved. Copyright and licensing information: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact IOMA's corporate licensing department at 212-576-8741, or e-mail jjping@ioma.com. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. 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 212-244-0360, ext. 2.