



# NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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## CMS Discloses More Details On NPI Compliance Policy

Join us on Monday, April 30, for our special audio conference featuring the latest NPI developments and how they impact your operations. To register or get program information, visit our Web site at [www.g2reports.com](http://www.g2reports.com)

Following announcement earlier this month of a contingency period for HIPAA-covered entities that cannot meet the May 23 deadline to comply with National Provider Identifier (NPI) requirements, CMS followed up on April 18 with a roundtable conference call to spell out specifics on what these entities should be doing to reach compliance.

Under the contingency period, non-compliant entities—health plans, health clearinghouses, and healthcare providers—have up to an additional 12 months, through May 23, 2008, to come into NPI compliance. The NPI 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.

During the roundtable session, CMS officials emphasized three main points. First, the agency has yet to announce its NPI contingency plan for Medicare fee-for-service claims—but stay tuned, *Cont., p. 2*

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## Industry Dodges The Bullet, For Now, On Lab-Developed Tests

To the relief of clinical laboratory and pathology groups, the FDA user fee reauthorization bill (S. 1082) that the Senate HELP Committee approved April 18 did not include controversial provisions requiring premarket review of lab-developed tests (LDTs).

These provisions—Senate Bill 736, introduced March 1, with HELP Committee chairman Edward Kennedy (D-MA) as lead sponsor—would designate most LDTs as class II or III devices subject to Food & Drug Administration oversight. Kennedy’s staff had indicated they aimed to get it passed quickly by attaching it to the FDA bill on the committee’s “must-pass” list since the user fee programs are set to expire September 30 (*NIR, 28, 11/Mar 26 ‘07, p. 1*).

The omission of S. 736 opens the way for more time for backers of the bipartisan bill to obtain outside input from a variety of stakeholders. It’s “good news,” said Alan Mertz, president of the American Clinical Laboratory Association. Kennedy’s bill could be offered as an amendment later in the FDA user fee reauthorization process, he cautioned, but this looks unlikely at this point. *Cont., p. 7*



*If you cannot meet the May 23 NPI deadline, you should immediately draw up a contingency plan with measurable steps to achieve compliance as soon as possible, advised CMS officials during the April 18 roundtable call. Also, check with your trading partners to learn where they are in the process of becoming NPI-compliant.*

### **NPI Compliance Policy, from p. 1**

they said. Clarifying instructions are coming soon, and another roundtable call will be held to discuss the guidance and answer questions from providers.

Second, the data dissemination notice to facilitate NPI sharing via a centralized database has yet to be finalized. Currently, it is under review at the Office of Management & Budget, CMS officials said, but could not comment further. The notice will specify what data are available from the National Plan & Provider Enumeration System and how to access the data, plus offer help in NPI crosswalks. Government delay in issuing this notice has been a big factor impeding NPI readiness through the healthcare industry, lab sources noted. Quick access to NPIs is critical in preventing payment disruptions since claims require the number of both the primary billing provider and the ordering or referring provider.

Third, despite the delay on the data dissemination notice, CMS officials urged providers to continue, and document, their good-faith efforts to get in synch with the contingency plans of their non-compliant trading partners. This can be frustrating, the officials acknowledged, since even though a provider is NPI-compliant, it must also adapt to the progress of non-compliant trading partners, including allowing sufficient time to exchange and test NPI software.

### **Flexible Enforcement**

CMS officials in the conference call emphasized that while the agency cannot extend the statutory May 23 deadline for NPIs, it can provide flexibility in enforcement. In previously released guidance, CMS says it is stressing voluntary compliance and will handle complaints on a case-by-case basis (*NIR, 28, 12/Apr 9 '07, p. 1*).

If a HIPAA-covered entity cannot, despite good-faith efforts, meet the May 23 deadline, no penalties will be imposed if the entity can demonstrate it is making a diligent good-faith effort to become compliant as soon as possible and, in the case of health plans, to facilitate NPI compliance with their trading partners.

It is up to each covered entity to determine its own contingency plan. This may include accepting legacy identifiers on HIPAA transactions in order to maintain operations and cash flows, CMS says. An entity may complete the switch to NPI-only transactions if it is ready before the end of the contingency period on May 23, 2008. But thereafter, only claims with an NPI will be accepted and paid.

In explaining the decision to grant a contingency period, CMS officials said the agency heeded clear signs that “the lack of NPI readiness was widespread.” More than two million NPIs have been issued, they said, but this is only about 85% of those who need them. CMS also found that more than half of health plans, health clearingshouses, and software vendors were not ready to meet next month’s deadline.

The CMS contingency period is not without precedent. CMS deployed this approach to enforcement of HIPAA compliance before, when implementing standards for electronic transactions/code sets and remittance notices, giving most providers up to two years to become compliant.

To apply for an NPI, go to the National Plan/Provider Enumeration System (NPPES) Web site at <https://nppes.cms.hhs.gov>. Updates on NPI policy, CMS says, will be posted at [www.cms.hhs.gov/NationalProvidentStand](http://www.cms.hhs.gov/NationalProvidentStand). 

## CMS Gears Up For New Medicare Quality Reporting Program

Laboratory testing measures applicable to monitoring blood glucose and cholesterol levels in patients diagnosed with diabetes are among the quality measures for which reporting is approved.

On July 1, the Centers for Medicare & Medicaid Services plans to launch the 2007 Physician Quality Reporting Initiative (PQRI), which will provide a bonus payment (1.5%, subject to a cap) to eligible physicians and other practitioners who voluntarily report a designated set of quality care measures on their Medicare fee-for-service claims. The bonus payment period, authorized by the Tax Relief & Health Care Act of 2006, runs from July 1 through December 31, 2007.

In an April 19 roundtable conference call, CMS officials presented an overview of the PQRI and the agency's guidance on how to report from the list of 74 quality measures approved thus far for 2007, including applicable CPT and G-codes to use. The codes must be submitted on the same claim as the patient diagnosis and services to which they apply. There is no need, CMS says, to enroll or register to begin claims-based reporting for the 2007 PQRI.

Below are the specifications for reporting laboratory testing for diabetes control:

### Measure: Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus

Description: Percentage of patients aged 18-75 years with diabetes, type 1 or type 2, who had most recent hemoglobin A1c greater than 9.0%. This measure is to be reported a minimum of once per reporting period (12 months) for patients seen during this period.

#### Numerator: Population & Coding

Patients with most recent hemoglobin A1c > 9.0%. A lower rate indicates better care.

Most recent hemoglobin A1c performed:

CPT II 3046F: Most recent hemoglobin A1c level > 9.0% — OR —

CPT II 3044F: Most recent hemoglobin A1c level < 7.0% — OR —

CPT II 3045F: Most recent hemoglobin A1c level 7.0% to 9.0% — OR —

Hemoglobin A1c not performed, reason not specified. Append a reporting modifier (8P) to CPT category II code 3046F to report.

#### Denominator: Population & Coding

Patients aged 18-75 years with the diagnosis of diabetes.

ICD-9 diagnosis codes: 250.00-250.93 (DM), 648.00-648.04 (DM in pregnancy, not gestational) — AND —

CPT E/M codes: 99201-99205, 99211-99215 (E/M); 99341-99345, 99347-99350 (home visit); 99304-99310 (nursing facility); 99324-99328, 99334-99337 (domiciliary), G0344.

### Measure: Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus

Description: Percentage of patients aged 18-75 years with diabetes (type 1 or 2) who had most recent LDL-C level in control (less than 100 mg/dl). This measure is to be reported a minimum of once per reporting period (12 months) for patients seen during this period.

#### Numerator: Population & Coding

Patients with most recent LDL-C < 100 mg/dL

Most recent LDL-C performed:

CPT II 3048F: most recent LDL-C < 100 mg/dL — OR —

CPT II 3049F: most recent LDL-C 100-129 mg/dL — OR —

LDL-C level not performed for medical reasons. Append modifier 1P to CPT Category II codes above. — OR —

LDL-C level not performed, reason not specified. Append modifier 8P to CPT Category II code 3048F

#### Denominator: Population & Coding

Patients aged 18-75 years with the diagnosis of diabetes.

ICD-9 diagnosis codes: 250.00-250.93 (DM), 648.00-648.04 (DM in pregnancy, not gestational) — AND —

CPT E/M codes: 99201-99205, 99211-99215 (E/M); 99341-99345, 99347-99350 (home visit); 99304-99310 (nursing facility); 99324-99328, 99334-99337 (domiciliary), G0344. 



# focuson: Lab & Pathology Legislation

## Congressional Scorecard On Major Pending Bills

**W**ith Congress back in business after its two-week April spring break, here's a quick guide to the status of major legislation affecting clinical laboratories and pathologists that awaits action in the House and the Senate.

### • CLIA CYTOLOGY PROFICIENCY TESTING

#### House

*Bill:* H.R. 1237, the Cytology Proficiency Improvement Act of 2007. Introduced: February 28, 2007, as bipartisan bill. Lead sponsor: Rep. Bart Gordon (D-TN). Co-sponsors: 14. Latest action: Referred to the Committee on Energy & Commerce.

*Purpose:* Revise PT standards under CLIA (the Clinical Laboratory Improvement Amendments) to include requirements that each clinical lab (1) ensure that all individuals who screen and interpret cytological preparations participate annually in an approved continuing medical education program that provides each participant with gynecologic cytologic preparations designed to improve locator, recognition, and interpretive skills; and (2) maintain a record of program results. The Health & Human Services Secretary would be required to terminate the CLIA individual PT program in effect before enactment of H.R. 1237.

#### Senate

No similar legislation.

### Related Regulatory Action

The Centers for Medicare & Medicaid Services says it will propose revisions to the current CLIA cytology PT rules "sometime this year," in line with recommendations from the Clinical Laboratory Improvement Advisory Committee. These include changes to scoring, the number of challenges per testing event, testing intervals, slide field validation, and allowing new technologies as an alternative to glass slides. CMS agreed to revisit the cytology PT rules in late 2005, not long after the House passed a bill to suspend the current program until certain changes were made.

### • GENETIC INFORMATION/NON-DISCRIMINATION

#### House

*Bill:* H.R. 493, the Genetic Information Non-Discrimination Act of 2007. Introduced: January 16, 2007, as bipartisan bill. Lead sponsor: Rep. Louise McIntosh Slaughter (D-NY). Co-sponsors: 224. Latest action: The bill as amended has cleared the committees of jurisdiction and is ready for House floor action.

*Purpose:* Prohibit health insurers and employers from discriminating against individuals based on genetic information and establish penalties for violations. Bar employers from using genetic information when making decisions on hiring, firing, job placement, or promotion. 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 prohibitions also apply to employment agencies, labor unions, and Medicare supplemental policy plans.

## Senate

*Bill:* S. 358, the Genetic Information Non-Discrimination Act of 2007. Introduced: January 22, 2007, as bipartisan bill. Lead sponsor: Sen. Olympia J. Snowe (R-ME). Co-sponsors: 28. Latest action: Reported out of the HELP Committee on April 10, ready for Senate floor action.

*Purpose:* Similar to H.R. 493, barring employers and health plans from discriminating based on an individual's genetic information and establishing penalties for violations.

### • GENETIC TESTING/FEDERAL OVERSIGHT

## Senate

*Bill:* S. 736, the Laboratory Test Improvement Act. Introduced: March 1, 2007, as bipartisan bill. Sponsors: Edward Kennedy (D-MA), chairman of the Health, Education, Labor & Pensions (HELP) Committee, and ranking Republican Gordon Smith (OR). Latest action: Referred to the HELP Committee.

*Purpose:* Expand the Food & Drug Administration's regulation of lab-developed tests (LDTs), aka home-brews. Most LDTs would be designated as class II or III medical devices requiring premarket review. The bill would require LDT labeling for intended use and regulatory status, registration of manufacturers and their LDT tests, and reporting of adverse events. It also would establish a genetic testing specialty under CLIA and direct the HHS Secretary to find ways to enhance payment for genetic tests and increase patient access to such testing.

*Bill:* S. 976, the Genomics & Personalized Medicine Act. Introduced: March 23, 2007, as bipartisan bill. Sponsors: Barack Obama (D-IL) and Richard Burr (R-NC), both of them members of the HELP Committee. Latest action: Referred to the HELP Committee.

*Purpose:* Calls for studies to advise Congress on further regulation of genetic testing and genomics and the impact on patient access, along with a decision matrix to help labs and test makers know which level of review is required and who is responsible. The bill also would expand research on genetic testing and genomics and the sharing of data; medical workforce training; and monitoring of direct-to-consumer marketing practices. In addition, it would establish a CLIA specialty for genetic testing and direct the HHS Secretary to increase payment for new genetic tests, where appropriate.

## House

No similar legislation.

### • LAB PERSONNEL TRAINING

## Senate

*Bill:* S. 605, the Allied Health Reinvestment Act. Introduced: February 15, 2007, as bipartisan bill. Lead sponsor: Sen. Maria Cantwell (D-WA). Co-sponsors: 8, including HELP Committee chairman Edward Kennedy (D-MA). Latest action: Referred to the HELP Committee.

*Purpose:* Authorize funding for Title VII programs to promote careers in allied health and to educate and train allied health personnel, especially in critical shortage areas. Support would include grants to facilitate and expand student enrollment and to develop internship and resident programs; loans for faculty development; and scholarships for students who agree to provide service in rural and other medically



underserved areas. S. 605 specifically includes clinical lab sciences, medical technology, and cytotechnology. To carry out the above provisions, the bill would authorize appropriations of such sums as are necessary for fiscal 2008 through 2013.

Leading lab and pathology organizations support the bill, noting that the lab workforce is already identified in numerous studies as a critical personnel shortage area. Legislation similar to S. 605 was introduced in the House in 2005, but after being referred to committee, no further action was taken.

Currently, the Title VII allied health account is funded at \$4 million through fiscal 2007. This follows the steep cut in 2006, when funding was slashed from the FY 2005 level of \$11.8 million, or 66%, according to the Association of American Medical Colleges. The Bush administration's FY 2008 budget request would eliminate allied health funding and make major cuts in most other Title VII health professions programs, except nursing education and aid for disadvantaged students.

### **House**

No similar legislation.

#### **• PATHOLOGY 'GRANDFATHER' PROTECTION/BILLINGS BY INDEPENDENT LABS**

### **House**

*Bill:* H.R. 1105, the Physician Pathology Services Continuity Act of 2007. Introduced: February 15, 2007, as bipartisan bill. Lead sponsor: Rep. John Tanner (D-TN). Co-sponsors: 4. Latest action: Referred to the Ways & Means Subcommittee on Health.

*Purpose:* Make permanent the statutory provision that allows certain independent clinical laboratories to bill Medicare directly for the technical component of pathology services to hospital inpatients and outpatients. This provision, known as the "grandfather" protection, is set to expire at the end of 2007.

### **Senate**

*Bill:* S. 458, the Physician Pathology Services Continuity Act of 2007. Introduced: January 31, 2007, as bipartisan bill. Lead sponsor: Sen. Blanche Lincoln (AR). Co-sponsors: 3. Latest action: Referred to the Finance Committee.

*Purpose:* Identical to H.R. 1105.

### **Who qualifies for the protection?**

The "grandfather" protection applies to hospital-lab arrangements for certain pathology TC billings in effect as of July 22, 1999, the date when the Centers for Medicare & Medicaid Services first proposed eliminating such billings. CMS argued that Medicare pays for the TC as part of the hospital's DRG payment; thus, labs should seek TC reimbursement from the hospital, not from Part B. Congress has intervened repeatedly, however, to block CMS from going forward.

Under CMS policy, the hospital is the "protected" entity, not the lab. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include anatomic services, cytopathology, and surgical pathology.

The above bills are backed by the College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association. Similar legislation was introduced in Congress last year but failed to move. Congress instead extended the "grandfather" protection for an additional year, through December 31, 2007. 



### Lab-Developed Tests, from p. 1

ACLA joined 24 other lab and pathology groups in sending a letter to Kennedy last month, requesting a “time-out” to allow for more deliberation, including formal hearings and further consultations with committee staffers. Kennedy says that while he does not intend to stifle innovations, FDA oversight is needed because of the novel technologies used and their impact on patient safety and access.

The letter dated March 16 emphasized that more stakeholder input is needed because of the complex issues surrounding LDTs and the significant change it would make in FDA’s enforcement approach. They warned that regulatory burdens could impede testing advances in genetic testing and genomics that could improve patient care.

Despite differences over additional LDT oversight, the lab and pathology groups emphasized in the letter: “We are fully united in our request for more time to provide feedback and discuss pathways that will not have unintended consequences on lab services. We are further united in the opinion that any new legislative initiative in this area should be carefully crafted to focus on areas of concern and not be so broad as to encompass lab tests that are clinically established or that are serving a valuable purpose for rare disease groups and public health needs.”

Requiring premarket review for most LDTs would overwhelm both labs and the FDA, ACLA has noted. LDTs are common among its members, including in-house developed tests and modifications of FDA-approved test kits, and encompass a range of tests, not just genetic ones—anything from common routine tests to more complex molecular procedures. Moreover, labs using LDTs already are subject to the highest CLIA test performance standards.

An approach more palatable to lab and pathology interests at this point is reflected in legislation introduced March 23 by Sen. Barack Obama (D-IL), which takes a “go slow” approach to federal oversight of genetic testing and genomics (see congressional scorecard in the *Focus*, pp. 4-6). 🏛️



## Quality Care from Quality Professionals

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# CMS Updates Lab Coalition On Medicare Bidding Demo

OMB has signed off on the demo—that's the latest official word, but no word yet on demo site(s) or timeline for demo implementation.

As we go to press, the broad-based Clinical Laboratory Coalition just received an answer from the Centers for Medicare & Medicaid Services to its request for information on the status of the Part B competitive bidding demonstration for independent laboratory services. The project has been stalled for many months awaiting clearance from the Office of Management & Budget, CMS officials have repeatedly noted.

Now, CMS project director for the lab demo, Linda Lebovic, has confirmed, in response to the coalition's inquiry, that: "OMB has approved the key design elements for the demonstration. Further operational details are under development within CMS. We will make announcements, including the timeline, via the CMS (clinical labs, ODF, demonstration project) listservs. Links for those listservs are available on the demonstration project Web page at [www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp](http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp)? Thank you for your interest in the project."

The project missed the April 1, 2007, start date that CMS previously announced. If it goes forward, there are still a lot of steps necessary prior to launch, including holding a bidders conference, obtaining bids, selecting winners, and initiating payment based on competitively bid rates. 🏠

## Follow-Up On The 'Lab Lobbying Blitz'

In our report last month on the March 19-20 lab lobbying blitz (*NIR*, 28, 11/Mar 26 '07, p. 1), we cited various organizations that participated, but failed to mention similar efforts by the American Association of Bioanalysts on March 15.

This was brought to our attention by Annette Iacono, vice president and general manager of Brookside Clinical Laboratory (Brookhaven, PA), who wrote: "Approximately 50 members of AAB lobbied on Capitol Hill on March 15. Similar to ASCLS, ASCP, and CLMA, AAB members met with senators, representatives, and staff from their home state and brought them up to date on lab payment and policy issues, with a main focus on competitive bidding."

She concluded by saying, "It is important for all organizations that participate on behalf of a centralized issue, such as competitive bidding, be recognized."

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