



CMS Adopts Contingency Plan For NPI Compliance

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To the relief of the lab industry and other healthcare providers, the Centers for Medicare & Medicaid Services is adopting a contingency plan for covered entities (other than small health plans) that will not meet the May 23 deadline to comply with National Provider Identifier (NPI) requirements under HIPAA (the Health Insurance Portability & Accountability Act).

If you cannot, despite good-faith efforts, meet the deadline, you have up to 12 more months—through May 23, 2008—to achieve compliance, CMS says.

Your claims can still get paid and you won't be penalized, as long as you can show that "you have made, and continue to make, reasonable and diligent efforts to achieve compliance and, in the case of health plans, to facilitate NPI compliance with their trading partners," the agency states in enforcement guidance issued April 3. *Cont., p. 2*

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Obama Jumps Into Senate Debate On Genetic Testing

Sen. Barack Obama (D-IL) has introduced a bill to increase federal involvement in genetic testing and genomics, with the aim of promoting scientific advances and their use in personalized medicine.

The bill—S. 976, the Genomics & Personalized Medicine Act of 2007, co-sponsored by Sen. Richard Burr (R-NC)—includes provisions for expanded research, collection, and sharing of data; medical workforce training; and clear delineation of the level of regulatory oversight required and the responsible federal agency.

The measure drew quick support from the American Clinical Laboratory Association, which prefers it to the tougher genetic testing bill authored by Sen. Edward Kennedy (D-MA). ACLA opposes fast-tracking his bill—S. 736, the Lab Test Improvement Act—which would expand the Food & Drug Administration's regulatory reach by requiring premarket review of lab-developed tests (*NIR*, 28, 11/Mar 26 '07, p. 1).

The Kennedy and Obama bills have been referred to the HELP Committee, which Kennedy chairs and on which Obama and Burr serve as members. For more on how the bills differ and what they would require of clinical laboratories, see the *Focus*, pp. 4-5. 🏠



NPI Compliance, from p. 1

It is up to each covered entity to determine its specific contingency plan. This can include “accepting legacy provider numbers on HIPAA transactions in order to maintain operations and cash flows,” notes acting CMS administrator Leslie V. Norwalk, Esq.

In enforcing NPI guidance, CMS says it is emphasizing voluntary compliance and will handle complaints on a case-by-case basis.

The NPI is a unique standard identifier for use in HIPAA standard transactions, replacing multiple legacy provider numbers such as UPINs, Medicaid provider IDs, and individual plan provider IDs. Every healthcare provider is required to obtain an NPI and use it; claims without it will be rejected.

More Time Needed, CMS Acknowledges

CMS said it decided on the contingency plan option after considering warnings from health plans and provider groups that they need more time to carry out NPI testing among trading partners. Full compliance also is not feasible, CMS was warned, because many providers still do not have an NPI, including many who don’t yet realize they must get one. The American Clinical Laboratory Association had urged CMS to grant a year’s grace period to allow testing with trading partners before completing the switch to NPI-only transactions, thus avoiding serious disruptions to claims processing and the potential loss of millions in reimbursement (*NIR*, 28, 10/Mar 12 ‘06, p. 1).

Granting a contingency period for HIPAA compliance is not unprecedented. CMS did so when implementing standards for electronic transactions/code sets and remittance notices, giving most providers up to two years to become compliant. But the agency has set a clear ending date for NPI contingency plans—May 23, 2008. Covered entities may elect, however, to complete the switch to NPI-only transactions before that. After May 23, 2008, however, only the NPI will be recognized.

Crosswalk Help Coming, CMS Says

Lack of NPI readiness is also due to CMS’s delay in issuing guidance on NPI sharing, the agency concedes. “A critical aspect of implementing the NPI is the ability of covered entities to match a provider’s NPI with the many legacy provider identifiers that have been used to process administrative transactions. CMS plans to make data available from the NPPES system that will assist covered entities in developing these crosswalks.”

“Getting an NPI is free—not having one can be costly”

That’s the tag line of CMS’s outreach campaign to get healthcare providers to obtain and use their National Provider Identifier, a 10-digit numeric identifier that neither expires nor changes. CMS published a final rule in 2004 mandating use of the NPI in HIPAA standard transactions, effective May 23, 2007, for covered entities (for small health plans, a year later).

If you haven’t yet got an NPI, apply for it immediately, CMS urges, and use it in HIPAA transactions as soon as possible. Applying is fast, easy, and free, CMS says. Go to the National Plan/Provider Enumeration System Web site at <https://nppes.cms.hhs.gov>. More information on the NPI is found at www.cms.hhs.gov/NationalProvidentStand.

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The agency will publish an NPI dissemination notice in the *Federal Register*. NPI data from the NPPES (National Plan/Provider Enumeration System) cannot be released otherwise. The data are critical not just to match NPIs with legacy identifiers, but also to help providers obtain the NPIs of other providers since claims require the NPIs of both the primary billing provider and the ordering or referring provider.

Evaluating Good-Faith Efforts

If a complaint is filed against a covered entity, CMS says it will evaluate the entity’s good-faith effort to comply with NPI standards and will not impose penalties on an

entity that has deployed a contingency plan to ensure that the payment flow continues smoothly. Indications of a good-faith effort might include, the agency says:

- ❑ Increased external testing with trading partners.
- ❑ Lack of availability of, or refusal by, the trading partners prior to the May 23 deadline for health plans (other than small ones) to test the transaction(s) with the covered entity whose compliance is at issue.
- ❑ In the case of such a health plan, concerted efforts in advance of the May 23 deadline and continued efforts afterwards to conduct outreach and make testing opportunities available to its provider community.
- ❑ For a healthcare provider, having obtained an NPI and having the ability to use it on HIPAA transactions.

You are advised to document your contingency plan's good-faith steps to correct problems and make the changes required to comply with HIPAA, just in case a complaint is filed against you. 🏛️

Senate, House Pass FY 2008 Budget Blueprints

Before recessing for a two-week spring break through mid-April, the House and the Senate passed budget resolutions to guide congressional committees in setting Medicare and other spending priorities for fiscal year 2008 (which begins October 1, 2007). The resolutions are advisory, not binding, but do identify priorities for Medicare policy changes, including a physician fee fix, and for reauthorization of the State Children's Health Insurance Program (SCHIP).

SCHIP reauthorization is especially important to the many states that are banking on it (along with Medicaid) to help reduce their ranks of uninsured residents by expanding health insurance coverage to more children in low-income families (*NIR*, 28, 7/Jan 29 '07, pp. 4-6). Both the House resolution (H. Con. Res. 99) and its Senate counterpart (S. Con. Res. 21) would authorize \$50 billion for SCHIP over the next five years vs. the \$5 billion over five years proposed in the President's budget request. The Senate measure includes an amendment that would allow raising the federal tobacco tax to help fund SCHIP, a move that could bring in as much as \$35 billion, supporters said.

Change In Number Of Uninsured

While many states and Congress are grappling with ways to cover more uninsured Americans, the Census Bureau has issued new estimates showing that in 2005, 44.8 million people, or 15.3% of the population, lacked health insurance, about 1.8 million fewer than the Bureau reported in August 2006.

The need to revise the estimate emerged during a conversion to a more accurate operating system for the Current Population Survey, the Bureau said. In a small percentage of cases, some residents of a household were tabulated as not covered by insurance when they had in fact reported coverage.

Nonetheless, says Families USA, the number of uninsured Americans continues to rise from year to year and health insurance premiums are soaring faster than family earnings.

The House approved its budget blueprint March 29 by a vote of 216-210. The Senate passed its version March 23 by a 52-47 margin. The bills now await reconciliation by a conference committee in advance of final congressional action.

The House blueprint establishes reserve funds of undisclosed amounts to address the projected 10% cut in Medicare physician fees next year and to modify the Part D drug benefit. These funds are budget "placeholders" to advise the committees of jurisdiction, but are available only if the committees pass the requested changes with cost offsets. For example, a physician fee fix would have to be financed by savings elsewhere in the Medicare budget or by hiking revenues. The President's budget is silent on a fee fix for doctors and assumes the 10% cut would be made. *Cont.*, p. 6



focuson: Genetic Testing Policy

Senate Bills Take Differing Tack On Genetic Test Oversight

Clinical lab and pathology groups caution that added federal regulation could stifle innovations in molecular diagnostics that tailor treatment, drug therapies, and monitoring to patients with cancer, heart disease, diabetes, and other chronic conditions.

Bipartisan bills recently introduced in the Senate have sharpened the legislative focus on federal regulation of genetic testing. Both agree that some level of oversight is needed in this fast-growing—and promising—diagnostics and therapeutics market, but the bills diverge on what that level should be and who should enforce it.

The bills are:

- S. 736, the Laboratory Test Improvement Act, sponsored by Edward Kennedy (D-MA), chairman of the Health, Education, Labor & Pensions (HELP) Committee, with ranking Republican Gordon Smith (OR) as co-sponsor, and
- S. 976, the Genomics & Personalized Medicine Act, sponsored by Barack Obama (D-IL), with co-sponsor Richard Burr (R-NC), both members of the HELP Committee.

Clinical laboratory and pathology organizations warn that more federal oversight could impede progress in personalized medicine based on genomics. Lab-developed tests (LDTs) make up a large portion of this work, the groups note, including in-house developed tests and in-house modifications of approved kits. And LDTs already are regulated for analytic validity under the highest CLIA category for lab test performance (high complexity), they note.

Different Courses To The Same Goal

While acknowledging that it is important not to stifle innovations or impede patient access, both Kennedy and Obama say federal oversight is needed to assure the analytical and clinical validity of genetic testing and to monitor direct-to-consumer marketing that makes questionable medical claims for unapproved test kits.

The Kennedy bill, S. 736, would target LDTs (also known as home-brews) as medical devices requiring premarket review by the Food & Drug Administration. This represents a “significant departure” from the current enforcement approach and “would subject thousands of LDTs to a level of regulation they have never undergone before,” noted Peter Kazon, Esq., a partner in Alston & Bird, LLP, during his presentation at the LABLine audio conference sponsored April 3 by the American Clinical Laboratory Association. The paperwork alone could overwhelm both labs and the FDA, ACLA has observed.

Until last year, the FDA limited itself to regulating analyte-specific reagents (ASRs) used in LDTs. But last fall, the agency issued draft guidance on its plan to require premarket review for a specific category of widely used lab-developed tests, called in vitro diagnostic multivariate index assays (IVDMIAAs), which use an assay and an algorithm to generate patient-specific results. The FDA argued that because of their novel and often proprietary nature, special oversight is needed to make sure physicians can properly interpret the results (*NIR*, 27, 22/Sep 25 '06, p. 1).

Under S. 736, LDTs generally would be class II devices subject to special controls. LDTs intended to screen donated blood or to diagnose a contagious disease or condition that is highly likely to be fatal would be subject to the most stringent

controls, class III. The Health & Human Services Secretary would have discretion to assign an LDT to class I (general controls only) if certain safety and effectiveness requirements are met.

The bill directs the Secretary to issue guidance on the special controls to which all LDTs or subcategories will be subject. Also, labs that make class II LDTs would generally be exempt from biennial FDA inspection. Further, the bill would require LDT labeling for intended use and regulatory status, registration of manufacturers and their LDT tests, and reporting of adverse events.

Under the Obama bill, S. 976, Congress would solicit outside expert advice before further regulation of genetic testing and genomics. The HHS Secretary is to contract with the Institute of Medicine to study and make recommendations on the key issues. Once the report is submitted, the Secretary is to develop and propose a decision matrix to help labs and other test makers know which types of tests require which level of review and who is responsible for the review—CMS or the FDA, or both. The bill also requests a study by the National Academies of Sciences on incentives to stimulate advances in designing and developing new genetic testing technologies.

As Obama’s health policy advisor, Dora Hughes, MD, MPH, explained in the ACLA audio conference, the Senator’s approach is to “fashion an overall strategic plan” addressing not only federal oversight, but also the need for increased federal support for research, data collection and sharing, genomics training of the medical workforce, and monitoring of direct-to-consumer marketing practices. ACLA supports the Obama bill, noting in particular that it recognizes these “interlocking needs.”

As part of this strategic plan, Hughes said, the bill would create an interagency working group to expand and accelerate genomics research in public and private sectors through enhanced communication, collaboration, and integration of relevant activities. It also would require HHS to establish a national database for genetic test information sharing.

Key Common Ground

Both the Kennedy and Obama bills would:

- ❑ Establish a CLIA specialty for genetic testing. CMS last year pulled the plug on years’ worth of work to draft a proposal for such a specialty, saying it was not practical to write hard-and-fast rules that science and clinical practice could

Legislative Outlook

The Kennedy and Obama bills have been referred to the HELP Committee, but there is a big concern among lab and pathology groups that the Kennedy bill could be “fast-tracked” by being attached to pending “must-pass” legislation reauthorizing FDA user fee programs for drugs and medical devices.

In a recent joint letter, 25 of these groups urged Kennedy to allow more time for hearings and other input on issues raised by his bill (*NIR*, 28, 11/Mar 26 ‘07, p. 1). And SACGHS has agreed to join the call for more time, said David Mongillo, ACLA vice president for policy and medical affairs, who spoke on the matter at the panel’s meeting held March 26-27. Also, during the ACLA audio conference, Hughes surmised that, at this point, it was not likely that the committee would rush to markup either bill during the FDA reauthorization process.

quickly render outmoded. Nor is it clear, CMS said, how such rules could address sensitive issues typically outside CLIA purview, such as counseling, informed consent, confidentiality, and liability (*NIR*, 28, 1/Oct 9 ‘06, p. 1). Instead, the agency said it would beef up scrutiny of genetic testing labs under existing CLIA rules.

- ❑ Direct the HHS Secretary to determine if reimbursement is adequate for new genetic tests and, where appropriate, grant higher rates. Neither bill is specific, however, as to how the Secretary should proceed. Pay rates have fallen far below testing costs, creating a major barrier to patient access, the HHS Secretary’s Advisory Committee on Genetics, Health & Safety (SACGHS) has noted. 



FY 2008 Budget Blueprints, from p. 3

Medicare providers, including managed care plans, will be expected to contribute to the savings needed to underwrite various healthcare initiatives, said House Ways & Means health subcommittee chairman Pete Stark (D-CA). He and some other congressional Democrats have sharply criticized Medicare for overpayments to managed care plans. Stark's panel and the Senate Finance Committee plan hearings to examine payments to these and other providers (*NIR*, 28, 10/Mar 12 '07, p. 8).

Both Democratic-controlled Houses rejected GOP calls for Medicare/Medicaid spending cuts, including the President's request for net Medicare savings of nearly \$76 billion over the next five years (mostly by freezing or cutting provider payments) and net Medicaid savings of nearly \$26 billion over five years (mostly by lowering the administrative match rate to 50% across the board)[*NIR*, 28, 8/Feb 12 '07, pp. 4-6]. 🏛️

CMS To Reconsider 'Pod Labs' In Proposed Rule

The Centers for Medicare & Medicaid Services plans to take a second look at "pod lab" issues this year, potentially as part of the 2008 Medicare physician fee schedule proposal due out this summer. Agency officials confirmed this with representatives of the College of American Pathologists, reported Gretchen Schaefer, CAP's director of communications advocacy.

CMS said it plans to address the pod lab controversy in a proposed rule because the policy will include "significant changes" from what the agency proposed, then shelved last year.

"Pod" labs is a term that describes a variety of business arrangements by which physician specialty groups seek to increase their revenue from pathology referrals by taking advantage of relaxed Medicare benefits reassignment rules and the Stark exception for in-office ancillary services. Specialty groups most prominent in the pod lab arena include urologists, gastroenterologists, and dermatologists.

CAP and the American Society for Clinical Pathology continue to call for a crack-down on pod labs and have lobbied to get CMS to reconsider its hands-off policy. CMS last year proposed tighter controls over pod labs in the 2007 Medicare physician fee schedule proposal, including more stringent requirements for benefits reassignment and the Stark exception. These were needed, the agency said, to curb the spread of pod labs, citing their potential to overutilize services and raise costs (*NIR*, 27, 21/Sep 11 '06, p. 5). In the end, however, the agency delayed any final action to allow further consideration of the issues (*NIR*, 28, 3/Nov 6 '06, p. 2). CMS said it "did not want to interfere with legitimate group practice arrangements that enable beneficiaries to get medical services at one location." This is the argument that the American Medical Association made to CMS against the proposed controls (*NIR*, 28, 9/Feb 27 '07, p. 7).

Meantime, the American Clinical Laboratory Association has asked the HHS Office of Inspector General to issue a Special Fraud Alert on pod lab arrangements, warning of potential violations of the federal anti-kickback statute. The OIG began warning about pod labs in 2004 (*NIR*, 25, 17/Jun 21 '04, p. 1).

CAP says that pushing for legislative curbs on pod labs would be premature, since CMS officials have said they plan a proposed rule on the issues this year, Schaefer told *NIR*: "We'll wait and see what comes out from CMS, then decide." Since 2004,

CAP has opposed pod lab proliferation on both regulatory and legislative fronts.

Given the controversy surrounding pod labs, and particularly the OIG's warnings, more physician specialties have been turning to "insourcing" anatomic pathology—bringing all or part of the work in-house—as a less legally risky way to capture more pathology revenue (*NIR*, 27, 20/Aug. 14 '06, pp. 4-5). For example, the specialty group runs an in-office histology lab to prepare tissues and hires or contracts with pathologists to diagnose the specimens. The group may bill Medicare Part B a global fee for the service (professional and technical components). Or the specialty group hires or contracts with pathologists to diagnose specimens and bill for the professional services, while its off-site local lab prepares the specimens and bills for the technical work. 🏠

◆ **CLIA Advisory**

New Waived Tests & Billing Codes

The Centers for Medicare & Medicaid Services has updated its list of clinical laboratory tests approved by the Food & Drug Administration as waived tests under CLIA (the Clinical Laboratory Improvement Amendments). The CPT codes for the following tests must have the modifier QW to be recognized as a waived test, effective April 1, 2007:

<i>Code/Modifier</i>	<i>Test Kit</i>
84450QW, 84460QW	Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc)(whole blood)
86308QW	PerMaxim RediScreen Mononucleosis (Whole Blood)
82274QW, G0328QW	Enterix Insure II Fecal Immunochemical Test Teco Rapid Fecal Occult Blood (FOB) Care Test OcculTech Fecal Occult Blood Rapid Test
82042QW, 82150QW, 82247QW, 82977QW, 84075QW, 84157QW	Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc)(whole blood)
84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer (whole blood) for urea (BUN)
84450QW	Arkay SPOTCHEM EZ Chemistry Analyzer (whole blood) for aspartate aminotransferase (AST)(SGOT)
85018QW	HemoCue Hb 301 System
87999QW	Gryphus Diagnostics BVBlue
87880QW	Inverness Medical Biostar Aceava Strep A Test
80101QW	Branan Medical Corporation, QuickTox Drug Screen Dipcard Branan Medical Corporation, FastTox Multiple Drug Dipcard
86308QW	LifeSign Status Mono (for whole blood)

CMS also corrected a test code in the list the agency previously issued with an effective date of January 1, 2007 (*NIR*, 28, 5/Dec 15 '06, p. 7). CPT 87899 QW was incorrectly assigned to the Gryphus Diagnostics BVBlue test. The correct code, noted above, is 87999QW. The CLIA waived tests and billing codes can be downloaded at www.cms.hhs.gov/transmittals. Search for Change Requests 5484 and 5482 (March 9, 2007). 🏠



ACLA Campaign To Highlight Value Of Lab Testing

The official rollout will be held April 18 at a special event on Capitol Hill. Details at www.clinical-labs.org

The American Clinical Laboratory Association is gearing up to launch a new outreach campaign to raise awareness—among legislators, policymakers, and the public—of the unique value of lab testing in assuring quality patient care. The campaign—*Results for Life: Lab Testing, Better Health, Improved Outcomes*—will kick off April 18 at a Capitol Hill gathering. Featured speakers include Rep. Charles Rangel (D-NY), chairman of the House Ways & Means Committee, which has key jurisdiction over lab payment and policy issues.

The effort is especially important, ACLA president Alan Mertz told *NIR*, as healthcare is being transformed by scientific advances in gene- and protein-based testing. With these new tools, labs increasingly are partnering with physicians and other providers in the treatment and monitoring of disease or predisposition to disease, he noted.

Results for Life is structured as a 501(c)(3) educational entity, noted David Mongillo, ACLA vice president for policy and medical affairs, facilitating partnering with other organizations. Already on board are Bayer, Roche, Sysmex, the College of American Pathologists, the American Society for Microbiology, and the American Association for Clinical Chemistry, he said. 🏠

washington WATCH

April 1 has come and gone, and there's still no official word that the Medicare competitive bidding demo for independent lab services has been plucked from regulatory limbo.

The demo was slated for launch April 1 in at least one of two sites, the Centers for Medicare & Medicaid Services previously announced. But CMS has yet to disclose the demo sites, let alone obtain bids and determine winners.

At press time, the demo remains in clearance at the Office of Management & Budget, but CMS informally has signaled there's still time for the lab industry to register its concerns. Nonetheless, lab and pathology groups are lobbying for repeal of the demo, saying competitive bidding treats lab services as a commodity, rather than a complex medical service. But some observers question whether large lab discounts to health plans might leave lawmakers wondering why Medicare shouldn't get bids for similar bargains.

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