



# NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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## Draft Guidance On CLIA Waivers Due Soon, Says FDA

*Waived testing is the least regulated CLIA category, so expansion of these types of tests on the market would be a big boon for physician office labs and other point-of-care sites as well as test manufacturers*

The Food & Drug Administration is close to completing work on draft guidance for medical device makers on criteria that must be met to obtain CLIA-waived testing status for their products, an official in the agency's Office of In Vitro Diagnostics tells the *National Intelligence Report*.

According to deputy director Don St. Pierre, FDA is on track to produce the draft late this spring or early summer. After a 90-day comment period, work will begin on a final version, expected by early 2005. He anticipates this will trigger a flurry of waiver applications from test manufacturers who won't wait for FDA to complete the formal rulemaking process that would follow issuance of the final guidance, because that could take years.

As a framework for developing the draft guidance, FDA is tapping recommendations that the Clinical Laboratory Improvement Advisory Committee endorsed at its meeting last February (*NIR*, 25, 9/Feb. 23, '04, p. 4). The advice included:

- No plasma or serum specimens for now because they require centrifugation (though future technologies could change that).
- Quality control materials should be "provided with, → p. 2

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## Will Hospitals Escape Excessive Billing Rule?

Word around Washington is they will. The HHS Office of Inspector General is expected to exempt inpatient and outpatient services reimbursed under prospective payment if and when it finalizes a proposed rule threatening Medicare/Medicaid exclusion of providers that charge the programs "substantially in excess" (or 120% above) their "usual charges" (*NIR*, 24, 22/Sept. 29, '04, p. 1). Physician services, including anatomic pathology, are already exempt.

Hospitals and hospital interests filed nearly two-thirds of the 300+ comments the OIG has received, notes attorney Ron Wisor with Arent Fox (Washington, DC). Their primary concern was the apparent inclusion of services paid under prospective payment. Kevin McAnaney, previously with the OIG and now in private practice in Washington, DC, thinks this was an oversight. "The problem is, it was so clear to [OIG officials] that it wouldn't apply to PPS, they didn't even address it." Other sources think hospital outreach testing won't be spared. Lab providers fear the rule will force them to limit discounts and accept less than fee schedule rates. 🏠

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Draft Guidance On CLIA, from p. 1

- preferably in, test kits to facilitate the performance of QC testing.”
- ❑ Studies of waived tests should demonstrate their likely performance in actual clinical use by including intended users at intended clinical testing sites.
- ❑ Tests that could be affected by color blindness are okay as long as the label warns users (a departure from CLIAC’s initial inclination not to waive such tests).
- ❑ Labels should warn users that failure to follow instructions, including those for quality control, constitutes off-label use, which changes the test’s CLIA category to high complexity and subjects the user to the most stringent of CLIA requirements.

*CLIAC shared its waiver criteria advice with the leading medical device trade group, AdvaMed, and in a cover letter highlighted those recommendations that test manufacturers could address: fail-safe mechanisms, alternative failure-alert mechanisms including external quality control testing, and improved waived test labeling. “In designing future test systems, the committee encourages manufacturers, wherever possible, to find ways to incorporate internal fail-safe or failure-alert mechanisms to prevent erroneous results,” CLIAC said in the letter.*

Criteria for CLIA waivers have become increasingly controversial as the number of waived devices on the market proliferates. Lab professionals have raised quality concerns, citing various government studies that faulted waived labs for test performance. Adding to the controversy was the tug-of-war among federal agencies over the authority to grant waivers. That was settled recently when HHS Secretary Tommy Thompson affirmed that the Food & Drug Administration had sole authority over CLIA test complexity categorizations.

The FDA previously had its own set of CLIA waiver criteria, but withdrew them under fire and pledged to base waivers on a 1995 proposal by the Centers for Disease Control & Prevention. St. Pierre said the FDA has been receiving only one or two waiver applications a month for tests covered under these rules. In most cases, however, test manufacturers have been waiting for more definitive waiver criteria before completing and submitting applications. 🏠

## Florida Medicaid To Require Capitated Lab Contract

*The state’s procurement initiative aims to give a single lab all the business now handled by some 160 labs in Florida. Labs large and small oppose that approach, and the original RFP was stalled twice by lab protests, including one from LabCorp (NIR, 25, 13/Apr. 19, ‘04, p. 3)*

**M**any independent clinical laboratories, including the two biggest, Quest Diagnostics and LabCorp, cheered when they learned that the Florida Agency for Health Care Administration had withdrawn a controversial call for competitive bids to serve Medicaid recipients throughout the state. But the relief was shortlived. The state intends to reissue it as an RFP for a capitated contract.

The state is following new directions from its legislature to request bids for the Medicaid contract on a per-eligible per-month basis. Recognizing that labs might try to stall the measure, the legislature added language to the appropriations bill for the fiscal year beginning July 1 (HB 1835) to require the agency to impose a 10% reduction in Medicaid reimbursement for independent labs if litigation or other factors stall the procurement, preventing any contract signings by Apr. 1, 2005.

“We’re obviously pleased they withdrew it,” says Alan Mertz, president of the American Clinical Laboratory Association. But rather than re-issue the RFP, “we think they should just rescind it.”

The state appears to be holding fast to the winner-take-all approach, despite an Apr. 13 meeting in which labs and lab groups warned Gov. Jeb Bush’s deputy chief of staff and key healthcare policy advisor, Alan Levine, that it could seriously disrupt access to quality care in Florida. 🏠



## Work On CLIA Genetic Testing Specialty Close To Wrap-Up

*The scope of the proposal is one key issue under discussion, along with whether special requirements are needed for quality assurance, informed consent and genetic counseling*

A proposed rule to establish a genetic testing specialty under CLIA is in the final stages of development, the top CLIA official at the Centers for Medicare & Medicaid Services tells *NIR*. The rule is being crafted by CMS and the Centers for Disease Control & Prevention, but it is not yet clear how soon the proposal will be published for comment.

According to Judy Yost, who heads the CLIA program at CMS, both CMS and CDC are still working to resolve some major issues, including the scope of the regulatory proposal. They also are going back to some organizations that filed comments on a previous notice of intent to carve out a CLIA specialty for genetic testing (*Federal Register*, May 4, 2000). The two agencies are asking some commenters who had fallen “on both sides of the fence” on some issues to elaborate on their concerns.

Once decisions on the issues are reached, CMS will “expeditiously” write the preamble to the proposed rule and get it on the agency’s regulatory calendar. “Our plan is to have it there in the near future,” Yost told a recent meeting of the HHS Secretary’s Advisory Committee on Genetics, Health & Society. But the rule faces a long queue at CMS, which is concentrating on priority rules stemming from last year’s Medicare Modernization Act.

Some issues to be raised in the proposed rule are reflected in the notice of intent:

- Would it be too broad or restrictive for a genetics specialty to include molecular genetic and cytogenetic tests, as well as biochemical genetic tests, as proposed by the Clinical Laboratory Improvement Advisory Committee?
- Should laboratory directors play a role in documenting the clinical validity of genetic tests? If so, what role?
- Should CLIA rules specify who is authorized to order genetic tests, even though the rules defer to states on authorization to order other tests?
- Should CLIA require labs to document the informed consent of test subjects prior to performing genetic tests?
- Should there be enhanced confidentiality surrounding genetic tests?
- Should labs be required to offer genetic counseling if they provide genetic testing?

In the notice of intent, CDC also asked whether, if a genetics specialty were added under CLIA, there should be additional requirements governing reuse of tested specimens for quality assurance and quality control, lab personnel qualifications, patient test management, specimen integrity, analytic and clinical test validation, proficiency testing, post-analytic reporting and retention of specimens and test result records. 🏠

## CDC Overhaul Expected To Sharpen Focus On Lab Issues

Clinical and public health laboratory interests expect a plan to reorganize the Centers for Disease Control & Prevention in Atlanta, GA, will consolidate the agency’s scattered laboratory-related programs and give them a higher profile.

The reorganization stems from the Futures Initiative, an effort by CDC’s director, Julie Gerberding, MD, MPH, to concentrate the agency’s attention more on preventing health risks such as obesity, while continuing with priority efforts to control the spread of infectious diseases such as HIV and SARS.



*The aim is to pull together lab functions now scattered throughout the agency. But the public health lab association is particularly anxious about how the lab systems division, whose responsibilities include lab training, will fare*

The Futures Initiative and the associated reorganization are “very laudable, constructive and progressive,” says David Sundwall, who, as chairman of the CDC-staffed Clinical Laboratory Improvement Advisory Committee, was among those whom Gerberding recently briefed in a mid-April conference call.

The reorganization will include a clustering of laboratory functions now scattered among three distinct organizations, Sundwall says. They are the Public Health Practice Program Office (PHPPPO), which among other things handles CLIA-related responsibilities; the infectious disease group, whose efforts are based on lab work; and the emergency preparedness unit, which reports on emerging threats through clinical laboratory systems. The agency is considering various options on how to combine lab-related functions, but has not yet made a final decision on that aspect of the reorganization, Sundwall notes.

After considering three main options for the overall reorganization, CDC settled on a hybrid of two approaches, something the Association of Public Health Laboratories had recommended. However, “we remain concerned about where the Division of Laboratory Systems will land,” Scott Becker, APHL executive director, tells *NIR*. That’s the division in PHPPPO that manages CLIAC and laboratory training, among other things. “I don’t want it to get lost,” Becker says. That could easily happen to the division, the only laboratory unit at CDC that does not have a lab of its own. Integration of lab functions makes sense, Becker thinks, noting these are scattered not only in PHPPPO, but also among programs for infectious disease, environmental health, HIV/AIDS and emergency preparedness (for the select agent rule).

CDC chose to base its reorganization primarily on its current structure, relying on its various centers to integrate science and programs, enhanced by “robust” health marketing and goal management functions. In a notice posted online Apr. 22, CDC said it will keep its centers, institutes and agencies, though regrouped to improve efficiency, but it may change the structure of cross-cutting offices such as PHPPPO. A new agency-wide health marketing unit will promote health protection to the general public. 🏛️

## CMS To Set Payments For Care Of Undocumented Aliens

*Three states stand to reap the most. California hosts 31.6% of all undocumented aliens, Texas 14.9% and New York 7%, according to government tallies*

**D**uring a recent “listening session,” officials at the Centers for Medicare & Medicaid Services disclosed the key issues they intend to tackle in deciding how to disburse \$1 billion over four years, starting in 2005, for medical services to undocumented aliens. The money, authorized in the Medicare reform law, will go to hospitals, physicians and ambulance providers that furnish emergency care, much of it currently unreimbursed, to this population.

Liz Richter of CMS said the agency intends to provide quarterly advance payments with retrospective adjustments based on a complex formula in the Medicare Modernization Act (MMA) of 2003. She cited several aspects of the formula that need to be fleshed out, including:

- ❑ How to obtain reliable information on the volume of services provided to undocumented aliens.
- ❑ How to reliably approximate the unreimbursed costs of this care without imposing burdensome reporting and recordkeeping requirements.
- ❑ How to implement the new provisions in a way that is not inconsistent with requirements of EMTALA, the patient anti-dumping statute.



Under Section 1011 of the MMA, CMS is to allocate \$167 million per year from 2005 to 2008 among the states in proportion to the total number of their alien residents. For each state, CMS must divide the money based on how much it costs each provider to serve this population. If the estimate exceeds available funding, the agency must pro-rate payments. An additional \$83 million per year over four years is to be allotted among the six states with the highest number of undocumented alien apprehensions for that fiscal year, as reported by the U.S. Department of Homeland Security. ▲

## Congress Feels The Heat On Drug Imports

*The Bush Administration and many congressional Republicans are strongly opposed, contending the U.S. can't guarantee purity and safety once the drugs are shipped overseas. The pharmaceutical industry agrees and adds that lower prices mean less R&D for new drugs*

**A**s public demand pumps up the political momentum this election year to make it legal to import prescription drugs from Canada, a bipartisan group of Senators has come together behind legislation that would do just that.

Former Senate Majority Leader Trent Lott (R-MS) has joined a group of liberal Democrats and moderate Republicans backing S. 2328, and the bill's lead sponsor, Byron Dorgan (D-ND), says he has secured a commitment from the current Majority Leader, Bill Frist (R-TN), to let the Senate vote on the issue this year. Last July, the House easily passed, 243-186, a drug importation bill (H.R. 2427) sponsored by Rep. Gil Gutknecht (R-MN).

Lott, a staunch opponent of importing prescription drugs, explained his change of mind in a recent weekly column to supporters. "I can no longer explain to my 90-year-old mother why her medications cost more than the same drugs from other countries ... I'm telling pharmaceutical companies to address the overall rising cost of their products or the Federal Government will, and it won't be pretty."

Other co-sponsors include GOP Sens. John McCain (AZ) and Olympia Snowe (ME), and Democratic Sens. Tom Daschle (SD and the Minority Leader), Edward Kennedy (MA) and Debbie Stabenow (MI).

Dorgan's bill differs from S. 2307 offered Apr. 8 by Sen. Charles Grassley (R-IA), chairman of the Senate Finance Committee, mainly by adding provisions guarding against companies circumventing drug importation. Dorgan's bill also lacks Grassley's tax provisions, which increase the R&D tax credit for pharmaceutical companies that comply with importation and remove the drug advertising tax credit from companies that try to block importation.

In enacting Medicare reform last year, Congress included a provision requiring the U.S. Department of Health & Human Services to study the matter and report back. HHS Secretary Tommy Thompson established a 13-member task force to tackle the job and gave it a Dec. 1 deadline. However, he says he hopes to send its recommendations to Capitol Hill this summer.

Meanwhile, the Administration is intent on focusing U.S. opinion on the drug discount card program, despite the flap over Thompson's view that drug imports are "inevitable" (see box, p. 6). The program, which began enrolling seniors this month, will continue until a full Medicare drug benefit debuts in 2006. Those enrolling can start using their card next month. In an \$18 million TV advertising campaign na-



### Is Congressional Okay “Inevitable”?

Yes, opined HHS Secretary Tommy Thompson in a May 4 news conference with reporters from regional newspapers, it’s “inevitable” that Congress will pass legislation permitting importation of prescription medications exported to nations, such as Canada, that have price controls. Thompson added that he would advise Mr. Bush against vetoing such a measure.

But Thompson did not endorse drug imports and said the savings would not be as much as people think, in part because the cost of increased oversight by the Food & Drug Administration would eat into those savings. The Congressional Budget Office doesn’t see big savings either by allowing imports from Canada alone. It pegged the savings at \$40 billion over 10 years or about 10% of the \$400 billion Congress approved for a Medicare prescription drug benefit.

Administration officials were quick to qualify Thompson’s remarks. HHS spokesman Bill Pierce said Thompson was “not talking about whether we would support it. This does not represent a change in policy.” White House spokesman Trent Duffy noted that the FDA has said that drug imports cannot be safely done, and that remains a concern. “It’s one thing if you get a Kool-Aid recipe wrong. It’s another if you get someone’s prescription drugs wrong.”

Still, according to a report in the *Los Angeles Times*, as many as two million Americans bought U.S.-made prescription drugs from Canada last year, at savings of up to 70%. And both local and state governments are either encouraging such buys by individuals or looking into doing it themselves.

tionwide, the Centers for Medicare & Medicaid Services is directing seniors to the Website, [www.medicare.gov](http://www.medicare.gov), and to its 24-hour call center at 1-800-633-4227, where the agency has more than tripled the number of service representatives to nearly 1,400. The Administration said that on May 3 the toll-free line logged 407,000 calls.

CMS has posted online the discounts that the various approved cards offer, as well as a guide to choosing cards from among the 40 national and 33 regional plans that offer them. The guide notes that the plans decide which drugs to discount and by how much. One catch is that while the plans can change their lists and prices virtually at will, seniors can’t switch cards correspondingly; they must wait till the next enrollment period. CMS intends to monitor card sponsors for “bait and switch” tactics and ensure that price fluctuations reflect changes in a sponsor’s costs, including price concessions from drug makers or pharmacies. Further, the agency has pledged to use “mystery shoppers” to keep card-sponsor call centers honest. 🏠

## CLIA Surveyor Guidelines To Remain Unchanged For Now

*The guidelines were issued last Jan. 12 and incorporate revised CLIA quality system requirements that took effect Apr. 24, 2003. See NIR, 25, 7/ Jan. 26, '04, p. 1*

Despite concerns raised in various quarters, the Centers for Medicare & Medicaid Services won’t change the interpretive guidelines that CLIA inspectors use when checking labs for quality control compliance until the end of 2004 or later, the agency’s top CLIA official, Judy Yost, told lab interests last month.

Yost and her staff met Apr. 20 with the American Clinical Laboratory Association regarding numerous clarifications and generally minor changes that the ACLA membership had recommended. But Yost said any changes would have to wait until later, so the surveyors could get them all at once. As she later told *NIR*, “We can’t have surveyors doing their job based on a process that keeps changing.”

Last February, she noted that the next revision of the guidelines would include a clarification of a provision that some labs had read to mean they would be in trouble with the Food & Drug Administration if they were involved in any “off-label” use of tests. In the meantime, she said, she would clarify it verbally at a bimonthly meeting of the regional CMS officials who oversee state surveyors (*NIR*, 25, 8/Feb. 9, '04, p. 4).

The “equivalent QC” provisions in the guidelines have also drawn fire. Lab consultant James Westgard, PhD, NACB, says they let labs get by with too little quality checking, possibly compromising their test results. He advises labs to follow a more

stringent regimen. Greg Cooper, manager of clinical standards and practices at Bio-Rad Laboratories (Irvine, CA), presented similar concerns to the Clinical Laboratory Improvement Advisory Committee. 🏠

## ◆ QUESTION of the M·O·N·T·H

*Our hospital laboratory performs testing on inpatient specimens as well as specimens referred through our outreach program. We also do outpatient testing, but refer some of it to outside labs. We are helping train new billing staff on how to submit claims to Medicare. Can you summarize the basic rules that apply?*

- ❑ Inpatient testing: When a hospital performs testing for its inpatients, it bills and is paid under Part A DRG prospective payment (PPS). If the work is referred to an outside lab (whether independent or hospital-based), that lab may not bill or seek payment directly from Medicare; it must bill “under arrangements,” meaning it bills and is paid by the hospital.
- ❑ Outpatient testing: This must be provided by the hospital or “under arrangements.” In either case, the hospital bills Medicare and is paid under the Part B lab fee schedule (for certain rural hospitals, payment is 100% of reasonable costs starting this July 1; see *NIR*, 25, 9/Feb. 23, '04, p. 2). If a patient leaves the hospital and goes elsewhere for testing, the hospital is not responsible for the billing because the patient would no longer be considered an outpatient.
- ❑ Outreach testing: This “non-patient” testing usually involves beneficiaries who are seen in a physician’s office and for whom the doctor orders lab tests. Your hospital lab may bill Medicare for this work and be reimbursed under the Part B lab fee schedule.
- ❑ Preadmission diagnostic services: If a hospital is paid under PPS, all diagnostic services, including lab tests, that are furnished by the admitting hospital—or an entity it wholly owns or operates or another entity under arrangements with the hospital—within three days prior to inpatient admission are considered inpatient services. They are paid under DRGs and may not be separately billed by the hospital. If a hospital refers a patient to an independent lab for preadmission work and the services are not provided “under arrangements,” the testing is not subject to the 3-day DRG payment window. For hospitals not paid under PPS, the payment window is one day before admission.

Hospital labs that bill for either outpatient or non-patient work submit claims to their fiscal intermediary. Neither deductible nor co-insurance applies to lab tests paid via the fee schedule. Also, virtually all clinical laboratory testing, except that performed by a rural health clinic, is billed on “assignment,” meaning that Medicare payment must be accepted as payment in full; no further payment may be sought from the beneficiary.

Medicare also gives certain hospital and independent labs flexibility in billing under the lab-to-lab referral exception. This occurs when one lab sends work to another lab and the referring lab bills for the testing that the other lab performs. The exception applies only when the referring lab is part of a hospital designated as a “rural” hospital, or the referring and performing lab are commonly owned, or the referring lab does not send out more than 30% of all testing for which it receives requests during a year. 🏠



# CDC Gears Up For New Lab Quality Institute

The Institute would establish quality indicators for labs comparable to the Health Plan Employer and Data Set (HEDIS), which the National Committee for Quality Assurance uses to measure managed care quality

The Centers for Disease Control & Prevention is preparing to request applications for a cooperative agreement to handle various laboratory quality-related initiatives that a new Institute for Quality in Laboratory Medicine would eventually take over. The Institute will be an independent entity, a yet-to-be-incorporated public-private partnership.

Three project teams, formed after CDC kicked off the initiative by hosting a Quality Institute Conference in April 2003, are carrying out the key activities:

- The awards team, led by Ana Stankovic, MD, PhD, Becton Dickinson & Co., is working to create an awards and grants program to promote innovation, build partnerships, save money and improve patient and public health outcomes.
- The quality indicators team, led by Lee Hilborne, MD, of the University of California at Los Angeles, is looking to develop a core set of quality indicators.
- The network team, led by Michael Noble, MD, of the University of British Columbia Vancouver Hospital, is looking to develop a sentinel network to track lab quality measures and share best practices.



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CDC staff have devised a business plan for the Institute, which stakeholders will review over the next few months. An Oct. 14-15 meeting in Atlanta is planned to review workgroup products. Formal announcement of the Institute is scheduled for March 2005, followed by a CDC-funded national conference in April. CDC contacts are Toby Merlin, MD, 770-488-8256, and Joe Boone, PhD, 770-488-8080. 🏠

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