WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 27th Year of Publication

Vol. 27, No. 22, September 25, 2006

FDA Expands Oversight Of 'Home-Brew' Lab Tests

The FDA says tighter controls are needed for new types of DNA tests that calculate patient-specific results because of the novel technologies involved and the potentially lethal risks.

Clinical laboratories and diagnostics manufacturers have been put on notice that the Food & Drug Administration is tightening the rules for in-house developed lab tests and will require premarket review for new types of DNA tests that combine assays and algorithms to produce results tailored to a specific patient.

In recently released draft guidance, the FDA says it will regulate tests known as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), and most of them will likely be subject to class II and III special controls. Examples include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease, among others.

The FDA's announcement marks a dramatic turn in its approach to regulating "home-brew" tests, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR*, and ACLA is looking carefully at this development. Gene- and protein-based testing is a fast-growing lab sector, and ACLA is concerned that it not be stifled by added regulatory burdens. The Association also questions why the FDA chose to address the issue in a draft guidance. Given the expanded regulatory reach the agency is asserting, ACLA thinks the formal rulemaking route is a more appropriate avenue. For details, see the *Focus*, pp. 4-5.

INSIDE *NIR*

Proposed Medicare crosswalks, fees for new 2007 lab tests 2

Big challenges ahead in ICD-10 switch, labs advised to name transition team to prepare 3

FDA clamps new controls on certain new types of DNA 'home-brew' tests, warns about ASR marketing practices—see *Focus* 4-5

Red Cross slapped with $4.2M fine for blood safety problems 6

Medicare Coverage Advisory: 7
— New waived tests
— ICD-9 changes to National Lab Policies
— Reminder: 9-day payment hold

Medicare to start increasing Part B premiums based on income January 1 ... 8

Washington Watch: Problem seen in how Medicare would pay pathologists, other 'indirect' providers based on quality measures 8

CMS Proposes Crosswalks To Set New Lab Fees

The Medicare program is proposing to use the crosswalk method to set payment levels for all eleven new CPT lab test codes to be added to the Part B lab fee schedule, starting January 1, 2007. The new tests are for conditions such as liver cancer, heart disease, West Nile virus, and staphylococcus (*table, p. 2*).

The Centers for Medicare & Medicaid Services has published the crosswalks for an additional round of public comment before the fees are finalized at the end of October. Under the crosswalk method, a new lab test code is matched to an existing code on the lab fee schedule and is payable at that code's fee schedule amount or national fee cap.

The proposed crosswalks are consistent with the majority pricing opinions that organizations representing clinical lab industry and professional groups submitted at the public forum CMS hosted July 17 to receive fee-setting input. All the organizations supported the crosswalk method, though for some tests there were differences over the codes to which they should be matched (*NIR, 27, 19/Jul 31 '06, p. 2*). ➥ *p. 2*

New Lab Fees, *from p. 1*

The final crosswalks and related fees will be sent to Medicare carriers and fiscal intermediaries on or after the last week of October, CMS said, and the public will have access to this program instruction at *www.cms.hhs.gov/manuals*.

Proposed Medicare Crosswalks, Fees For New 2007 CPT Lab Codes

Code	Descriptor	Crosswalk, Related Fee Cap	Supported by
Chemistry			
1) 8210x:*	Alpha-fetoprotein; AFP-L3 fraction isoform and total AFP (including ratio)	**83950/$89.99**	AACC, ACLA, ASCLS, ASCP, CAP, CLMA. No recommendation: ASM
2) 8369x	Lipoprotein-associated phospholipase A2, (Lp-PLA2)	**83880/$47.43**	AACC, ACLA, ASCLS, ASCP, CAP, CLMA. No recommendation: ASM.
3) 8391x	Molecular diagnostics; RNA stabilization	**83907/$18.66**	AACC, ACLA, ASCLS, ASCP, ASM, CAP, CLMA
Immunology			
4) 8678x	Antibody; West Nile virus, IgM	**86645/$23.54**	AACC, ACLA, ASM, ASCP, CAP, CLMA
5) 8678x	Antibody; West Nile virus	**86644/$20.11**	AACC, ACLA, ASM, CLMA
Microbiology			
6) 8730x	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; Aspergillus	**87327/$16.76** + **87015/$9.33**	ASCP, CAP supported 87327. AACC supported 87015 + 87449
7) 8749x	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique	**87496/$49.04**	ASCP, CAP, CLMA
8) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique	**87651/$49.04**	ACLA, ASM, ASCP, CAP, CLMA
9) 8764x	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique	**87651/$49.04**	ACLA, ASM, ASCP, CAP, CLMA
10) 8765x	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique	**87651/$49.04**	AACC, ACLA, ASM, ASCP, CAP, CLMA
11) 8780x	Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis	**87802/$16.76**	ACLA, ASM

Acronyms in table: AACC-American Association for Clinical Chemistry; ACLA-American Clinical Laboratory Association; ASCLS-American Society for Clinical Laboratory Science; ASCP-American Society for Clinical Pathology; ASM-American Society for Microbiology; CAP-College of American Pathologists; and CLMA-Clinical Laboratory Management Association. (Note: the American Association of Bioanalysts did not submit comments.)
*Fifth digit to be finalized later. CPT codes © American Medical Assn.

Labs Urged To Get Ready For ICD-10 Transition

The proposed nationwide switch to ICD-10 diagnosis and procedure coding for billing and payment purposes poses major operational issues for the clinical laboratory industry. Medicare requires labs to provide a diagnosis code on all claims for reimbursement under the Part B lab fee schedule.

A changeover to version 10 is expected one way or another—by either congressional or regulatory fiat. Legislation pending at press time would mandate a switch by 2010. The Bush administration also has asserted it already has the authority to institute ICD-10 by administrative means.

At press time, differences over the ICD-10 transition contained in health information technology bills passed by the House (H.R. 4157) and the Senate (S. 1418) have yet to be reconciled.

The House bill mandates a transition from ICD-9 to ICD-10, beginning October 1, 2010. The Senate bill is silent on the issue.

Providers have been lobbying for a longer timetable. ACLA favors no sooner than 2012.

Implementation issues and timelines were highlighted during the recent inaugural session of the American Clinical Laboratory Association's LabLine audio conference series on September 14.

Pressure for the change is coming from experts' views that the ICD-9 version is outdated, relying on what was known about diseases over 20 years ago, and is not in global use, said Donna Pickett, medical systems administrator at the National Center for Health Statistics. ICD-10 also codes for diseases and disabilities at a greater level of specificity, she said, but "unspecified" codes are still available for use in certain instances.

Whatever the transition time to ICD-10, physician training will be an ongoing crucial factor, noted LabCorp executive Donald E. Horton, Jr., because labs depend on doctors to provide the diagnosis codes. "Many labs experience significant front-end claim suspensions due to missing ICD-9 coding, requiring follow-up. Without adequate physician training on ICD-10, lab claim suspension could increase significantly, requiring more follow-up and impacting cash flow."

Comparing ICD-9 To ICD-10

Scope Of The Change

	ICD-9	ICD-10-CM	ICD-10-PCS
Diagnosis Usage	Inpatient, outpatient	Inpatient, outpatient	
No. of characters	3-5 alphanumeric	3-7 alphanumeric	
No. of codes	13,000	120,000	
Procedure Usage	Inpatient only		Inpatient only
No. of characters	3-4 numeric		7 alphanumeric
No. of codes	4,000	90,000	
Total	ICD-9, 17,000	ICD-10, 210,000	% change, 1, 235

Structural Differences

ICD-10 is:
— 3-7 digits
— digit 1 is alpha
— digits 2 and 3 are numeric
— digits 4-7 are alpha or numeric
- 66 Yaws
- A69.21 Meningitis due to Lyme disease
- S52.131a Displaced fracture of neck of right radius, initial encounter for closed fracture

There are, however, practical steps that labs can begin to take to prepare for the massive change. Start by forming an ICD-10 transition team, Horton said, to study the impact on company systems and trading partners such as hospitals, physicians, and payers. Be sure you have the right people, he emphasized. ICD-10 is not limited to information systems, but extends to all company business systems. Make sure the transition team is truly multidisciplinary, he advised. ➥ *p. 6*

focus on: *In-House Developed Lab Tests*

FDA To Regulate New Types Of 'Home Brew' DNA Tests

Such tests are now used for care and management of patients with breast cancer, prostate cancer, cardiovascular heart disease, and Alzheimer's, among others—and they can be pricey, running into thousands of dollars. Some well known test offerings are made by Genomic Health (Redwood City, CA) and Correlogic.

The Food & Drug Administration requires approval of diagnostic test kits sold to clinical laboratories, hospitals, and doctors, regarding these kits as medical devices subject to the agency's regulation. But the FDA has generally exercised discretion in its oversight of in-house developed (home-brew) lab tests.

The agency regulates analyte-specific reagents (ASRs)—the "active ingredients" of in-house developed lab tests—but has not extended the rules to labs that develop tests in-house using commercially available ASRs or lab-developed ASRs. ASRs typically are ranked at the lowest risk level (class I, exempt from premarket review and subject to general controls), and the FDA has set minimal rules on their sale, marketing, and labeling.

Raising The Bar

Now, the FDA is setting the bar higher for certain new types of home-brew tests that use DNA data and an algorithm to provide physicians with results tailored to a specific patient's disease condition and therapy management.

In draft guidance issued September 8, the FDA says it will regulate such tests—which it calls In Vitro Diagnostic Multivariate Index Assays (IVDMIAs)—defined as: "test systems that employ data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software to generate a result that diagnoses a disease or condition or is used in the cure, treatment, or prevention of disease."

Why The FDA Acted

"More and more of these kinds of medical tests are being made available each year," said Daniel Schultz, MD, director of FDA's Center for Devices & Radiological Health in a statement. The agency regards IVDMIAs not as ASRs, but as test systems subject to its regulation, noting that use of the complete IVDMIA—the assay and the algorithm—is required to get a meaningful result.

What makes these tests different, Schultz said, is that the algorithms are usually proprietary, marking it hard for physicians to interpret the results and ensure they are valid. "It's important for the FDA to look at the data on which these tests are developed," he noted. The agency also says closer scrutiny is warranted because these types of tests are used to diagnosis and treat cancer and contagious diseases where a wrongful result could be fatal.

Market Impact

The FDA's new direction is very significant for the clinical lab industry, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR*. Gene- and protein-based testing is a major industry growth sector with enormous potential for benefits to patients, especially in determining therapy, so ACLA is concerned that added requirements do not stifle innovation and speed in this cutting-edge sector of personalized medicine.

Some diagnostics companies have already warned that the added time and costs for premarket review could hamper their progress in tapping new technologies.

Nor are the added costs likely to be recouped, unlike for drug development. FDA officials have said that IVDMIAs on the market will be evaluated case-by-case. While some may require more data submissions, others might pass muster with little trouble.

Warning On ASR Marketing Practices

In separate draft guidance, also issued September 8, the FDA warned against certain marketing practices that are "inconsistent with the ASR rules":

- Combining, or promoting for use, a single ASR with another product such as other ASRs, general purpose reagents, controls, lab equipment, software, etc.
- Promoting an ASR with specific analytical or clinical performance claims, instructions for use in a particular test, or instructions for validation of a specific test using the ASR.

The agency also reiterated in the draft guidance its position that clinical labs that developed ASRs are acting as manufacturers of medical devices and are subject to FDA jurisdiction. While most ASRs are class I and do not need premarket review, certain ASRs when used as a component in a blood banking test are class II devices requiring 501(k) clearance, while ASRs in tests to diagnose contagious diseases, such as HIV or TB, or other tests used to screen blood donors, are class III devices requiring premarket approval (PMA).

Under the ASR rules, labs and diagnostics manufacturers must meet minimal requirements:

- ***Labeling:*** Must include a statement disclosing that the lab developed the test and it has not been cleared or approved by the FDA.
- ***Sale:*** ASRs may only be sold to manufacturers of in vitro diagnostics, labs certified under CLIA for high-complexity testing, and organizations that use the tests for research or other non-diagnostic purposes.
- ***Controls:*** Must comply with CLIA quality control requirements for such tests.

At-Home DNA Tests: Let The Buyer Beware…

Meantime, some in Congress are putting the heat on federal agencies to be more proactive in oversight of genetic tests being marketed directly to consumers over the Internet. The Senate Select Committee on Aging held a hearing late last July to highlight the issue: "Marketing Scam or Medical Breakthrough?"

In a report presented at the hearing, the Government Accountability Office looked at particular tests that purport to offer health and diet advice based on analysis of a person's DNA and concluded that they lack "scientific validity" and produce misleading results.

GAO investigators tested the accuracy of kits by Suracell (New Jersey), Genelex (Seattle), Sciona (Colorado), and Market America (North Carolina). All four companies advertised that the kits, which cost $100 to $400, analyze four to 19 genes to determine a consumer's personalized diet and lifestyle needs. Using DNA samples from two test subjects—a nine-month old girl and a 48-year-old man—researchers created 14 fictitious consumer samples and returned them to the companies for analysis. GAO found:

- The personalized information returned from the companies, which predicted that the fictitious consumers were at risk for developing cancer, diabetes, high blood pressure, and heart disease "cannot be medically proven at this time."
- Advice and health predictions from the companies varied widely, even among samples from the same individual.
- Suracell and Market America used their results to market expensive dietary supplements.

ICD-10 Transition, *from p. 3*

You can also expect added difficulty by having to maintain dual versions, ICD-9 and 10, for a time to accommodate the different implementation schedules of your trading partners, Horton said.

For payers, the challenges to business processes and relationships are just as sweeping, said Tom Vossler, manager, IS planning, with Blue Cross and Blue Shield of North Carolina. Payers will have to realign benefit packages with ICD-10, rewrite medical policies, and in some instances seek premium rate changes.

Moving too quickly to replace ICD-9 would be especially burdensome, Horton noted, because labs already must implement a host of HIPAA standards, including electronic transaction updates, claims attachments, and national identifiers for providers and health plans.

Background On ICD-10

The International Classification of Diseases (ICD), version 10, was endorsed by the 43rd World Health Assembly in May 1990 and came into use in WHO member states beginning in 1994.

The ICD is the international standard diagnostic classification for all general epidemiological and many health management purposes. It is used to classify diseases and other health problems recorded on many types of health and vital records, including death certificates and hospital records.

In addition to enabling the storage and retrieval of diagnostic information for clinical and epidemiological purposes, these records provide the basis for compilation of national mortality and morbidity statistics by WHO member states.

FDA Fines American Red Cross $4.2M For Blood Safety Lapses

The ARC handles approximately 45% of the nation's blood supply, other independent community-based blood centers together provide another 45%, and hospitals collect most of the remaining 10%.

The Food & Drug Administration has fined the American Red Cross $4.2 million for failure to meet established blood safety requirements for collection of blood products. The ARC acknowledged that it had received an adverse determination letter from the FDA and said in a September 8 statement it will respond to agency concerns within 20 days.

The $4.2 million in fines were assessed under an amended 2003 consent decree that calls for financial penalties when the ARC fails to comply with FDA regulations and consent decree provisions regarding blood safety.

The fines stem from a recently completed FDA review of recalls conducted by ARC between 2003 and 2005 that found these events were preventable by the ARC. The violations include breaches of good manufacturing practice, the FDA said, such as failure to ask appropriate donor screening questions and to follow manufacturer test protocols. But there is no evidence that the safety of the blood supply was compromised, the agency concluded.

The amended consent decree is a measure of last resort that the FDA wielded to get the ARC to address its blood safety concerns. FDA has required the Red Cross to establish clear lines of managerial control over comprehensive quality assurance system in all regions, beef up training programs, and improve computer systems, records management, and policies for investigating and reporting problems, including adverse reactions.

Since the 2003 consent decree was signed and prior to today's action, FDA said it has issued the ARC seven similar adverse determination letters and assessed a total of $5.7 million in penalties.

Medicare Coverage & Claims Advisory

New Waived Tests

In the latest update of the list of clinical laboratory tests that the Food & Drug Administration has approved as waived under CLIA, local Medicare contractors have been notified by the Centers for Medicare & Medicaid Services to recognize the following waived test billing codes, effective October 1, 2006:

CPT Code/Modifier	*Test Kit*
82274QW, G0328QW	immoCare Fecal Occult Blood Test
87804QW	BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126
80101QW	First Check Diagnostics LLC, First Check Home Drug Test Marijuana
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}

Source: Change Request 5231.

The CPT codes above must be billed with the QW modifier to be recognized as a waived test, CMS emphasizes.

ICD-9 Changes To National Policies For Lab Tests

Effective October 1, 2006, Medicare will add and delete a number of ICD-9 diagnosis codes covered under its National Coverage Determinations (NCDs) for 23 of the most frequently ordered clinical laboratory tests. For lab tests covered under the NCDs to be payable, active valid ICD-9 codes must be used on Part B lab claims to document that the testing is medically necessary. There is no grace period to shift to new codes and delete old ones.

Additions and deletions are made to all lab NCDs, as well as the following specific national policies (Change Request 5293): Alpha-Fetoprotein, Blood Counts, Blood Glucose Testing, Carcinoembryonic Antigen, Digoxin/Therapeutic Drug Assay, Fecal Occult Blood Test, Gamma Glutamyl Transferase, Hepatitis Panel/Acute Hepatitis Panel, HIV Diagnosis, Human Chorionic Gonadotropin, Lipids Testing, Partial Thromboplastin Time, Prostate Specific Antigen (PSA), Prothrombin Time, Serum Iron Studies, Thyroid Testing, Tumor Antigen by Immunoassay CA 15-3/CA27.29, CA 19, CA 125, and Urine Culture, Bacterial. To get the official instructions on the above changes go to *cms.hhs.gov/transmittals/downloads,R1050CP.pdf*.

Reminder: Medicare To Impose Brief 'Payment Hold'

As required by the Deficit Reduction Act of 2005, a brief hold will be placed on Medicare payments for all claims during the last nine days of the federal fiscal year 2006 (September 22 through September 30). All claims held during this period will be paid on October 2, CMS has announced, but getting payments to providers may take a few days. No interest or late penalty will be paid to an entity or individual for any delay in a payment caused by the one-time hold.

Medicare To Increase Part B Premium, Begin 'Means-Testing'

Financial advisors urge seniors to beware of one-time events, such as sale of stock or property or retirement account distributions, which could swell their income and require them to pay more in premiums.

The Medicare Part B premium will increase to $93.50 in 2007 and, for the first time, will be scaled to income—or "means-tested"—as beneficiaries with higher incomes pay more, the Centers for Medicare & Medicaid Services announced.

Individuals with income over $80,000 (couples, $160,000) as reported on their most recent tax return, will pay an additional "income-related monthly adjustment," the agency said that could run from $12.50 to $70 more a month. About 4% of Part B enrollees will be affected, CMS estimates. "Means-testing" of the premium is required by the 2003 Medicare reform law, which adopted the provision, to be phased-in over three years, to offset Part D drug benefit costs.

The premium rise to $93.50 is a 5.6% increase, the smallest in six years and well below the 13% jump between 2005 and 2006. The lower-than-expected increase reflects slower growth in the volume and intensity of physician services, including clinical laboratory tests, but higher spending for outpatient services. "Although outpatient hospital spending accounts for only about 12% of total Part B spending, it accounts for one-third of the increase in the 2007 premium," CMS said.

washington WATCH

Amid pressure to fix Medicare's physician fee update and prevent big cuts in coming years, sentiment is growing to link doctors' payments to quality reporting, as Medicare now does with hospitals. Those that report get paid more.

But it's unclear how to handle payments to "indirect providers," such as pathologists, radiologists, and other who don't have direct contact with the patient. Currently, there aren't agreed-upon measures for reporting the quality of their work beyond such basics as turnaround time.

Meantime, a key proponent of physician pay-for-performance, Mark McClellan, MD, will leave his post as head of the Centers for Medicare & Medicaid Services in early October. He announced his resignation earlier this month. He expects to move to a think tank in the Washington, DC area. The buzz is an insider is likely to be named acting CMS head until February when a Senate confirmation hearing can be held on the President's nominee.

 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 Group 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.