WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 26th Year of Publication

Vol. 26, No. 18, July 11, 2005

Push Is On To Expand Medicare Pay-For-Performance

Wider use of P4P is likely to highlight the key role that labs and pathologist play in disease diagnosis, treatment, and prevention—major factors in how providers are judged and ultimately paid. Meanwhile, a government-funded workgroup has suggested lab quality indicators that eventually could feed into P4P *(see p. 2)*

Pay-for-performance (P4P) healthcare programs are spreading rapidly among private payers, with more than 100 such initiatives reported nationwide, and Congress is showing increasing interest in using the P4P approach to make Medicare a "value purchaser" who rewards quality.

The latest P4P push on Capitol Hill comes from Senate Finance Committee leaders, chairman Charles Grassley (R-IA) and ranking Democrat Max Baucus (MT), who recently introduced legislation to give higher reimbursement to Medicare providers who meet specific performance measures or improve patient care outcomes. Those affected include hospitals, physicians, home health agencies, and health plans. In the House meantime, the Ways & Means Committee is working on its own version of Medicare P4P.

The Grassley-Baucus bill is based, its sponsors said, on recommendations of the Medicare Payment Advisory Commission. ➥ *p. 2*

Change In Handling Denied Claims Scrapped

The Medicare program will postpone indefinitely a policy change that was to have taken effect July 5 and would have required carriers to conduct only one medical review of lab and other Part B claims while rejecting as duplicates those resubmitted after denial or awaiting further documentation (Change Request 3622).

The American Clinical Laboratory Association lobbied hard to get the policy reversed, arguing that it would unfairly burden labs, forcing them to appeal claims denied as medically unnecessary when more than four ICD-9 diagnosis codes were reported on a claim. The change, ACLA added, would end up costing Medicare more to adjudicate valid claims than it would save on invalid ones (*National Intelligence Report, 26, 13/Apr 25 '05, p. 1*).

The Centers for Medicare & Medicaid Services recently notified ACLA of its change of heart and said that should it opt to test this claim edit with a few contractors in the future, lab claims would be excluded. Labs may continue resubmitting denied claims electronically in a form in which the carrier can read the additional ICD-9 codes and pay the rest of the claim.

INSIDE *NIR*

Pay-For-Performance, *from p. 1*

At its annual meeting last month, the American Medical Association advised caution on P4P, with delegates voting for strict P4P guidelines: participation should be voluntary, plus P4P should cover added administrative costs for data compilation and be pilot-tested before widespread implementation

No new money would be allotted for P4P, so better performing providers would gain financially at the expense of poorly performing providers.

P4P bonuses would be derived from a pool of money set aside for each provider group, beginning at 1% of Medicare payments per group and rising to 2% in five years. The pool would be valued at about $2.5 billion initially, increasing to $7.5 billion annually by 2013.

The Centers for Medicare & Medicaid Services would be charged with developing P4P quality measures and refining them as needed. The agency would work with a new quality organization established under the bill and with healthcare providers and others such as the National Quality Forum.

Provider bonuses would be phased-in. At first, they would be tied to the reporting of quality data, in much the same way that hospitals are now rewarded for inpatient PPS care (*NIR, 25, 20/Aug 16 '04, p. 4*). For most other providers, this phase would start in 2007. In the second phase, the higher pay would be tied to performance on specific quality measures: for hospitals and ESRD facilities in 2007, for physicians and home health agencies in 2008, and for health plans in 2009. Skilled nursing facilities would begin reporting quality data in 2009, but when they would move to the second phase has yet to be determined, according to a Finance staff summary of the legislation.

Grassley said he wants the P4P bill to move through the Senate later this year in conjunction with legislation to prevent projected Medicare cuts in physician fees, including the 4.3% cut estimated for 2006. Meanwhile, bills to mandate a minimum 2.7% increase instead are pending in both the House and the Senate (*NIR, 26, 16/Jun 6 '05, p. 3*).

Quality Indicators For Labs

While pending P4P legislation doesn't single out labs to compete for quality bonuses, work is underway to define a core set of lab quality indicators that government and private payers could end up tapping to support P4P.

The work is being led by the Institute for Quality in Lab Medicine, with seed money from the Centers for Disease Control & Prevention (*NIR, 26, 14/May 9 '05, pp. 4-6*). At the IQLM meeting last April, a workgroup on quality indicators concluded that while all phases of the testing process are important, focusing on pre- and post-analytic phases would have the greatest impact. Highest priority areas cited were:

Item	*Category*
Diabetes monitoring	System*
Hyperlipidemia screening	System
Patient identification	Pre-analytic
Test order accuracy	Pre-analytic
Blood culture contamination	Pre-analytic
Adequacy of specimen information	Pre-analytic
Accuracy of point-of-care testing	Analytic
Cervical cytology/biopsy correlation	Analytic
Critical value reporting	Post-analytic
Turnaround time	Infrastructure
Clinician satisfaction	Infrastructure
Clinician follow-up	System/general

*Interaction between the lab and its customers

Health IT Incentives

Grassley and Baucus say their bill is intended to work in tandem with another bipartisan Senate measure recently introduced to spur quality in healthcare and cut costs by accelerating providers' adoption of health information technology (HIT). The measure, sponsored by HELP chairman Michael Enzi (R-WY) and ranking Democrat Edward Kennedy (MA), joins competing HIT legislation introduced last month by Senate Majority

Leader Bill Frist (R-TN) and Hillary Rodham Clinton (D-NY), plus earlier Senate and House initiatives (*NIR, 26, 17/Jun 20 '05, p. 5*).

The Enzi-Kennedy bill would establish a public-private partnership to create national technical standards—"a common language for how one doctor's computer system will talk with another's"—and would authorize grants and loans to help providers acquire HIT and to support regional HIT exchange networks. The bill also would set up a Best Practices Center where HIT users can learn about new technologies, establish an HHS hotline to help providers with technical questions, and create HIT training programs for health professionals. Further, it would create a safe harbor to the Stark self-referral and anti-kickback laws to help promote HIT investments.

House Axes Training Funds For Lab, Allied Health Personnel

Funding for most Title VII health professions programs, including those training medical technologists and medical laboratory technicians, was eliminated in the fiscal 2006 HHS appropriations bill (H.R. 3010), approved by the House on June 24. Title VII currently is funded at $300 million. Of that, $11.7 million goes to allied health, with a small portion meted out for lab personnel training.

The only Title VII programs spared by the House were scholarships for disadvantaged students ($35.1 million, down from $47.1 million in fiscal 2005) and the Centers of Excellence ($12 million, down from $33.6 million). Nursing programs under Title VIII got $150 million, the same as the current fiscal year.

Title VII health professions training has been a political football for years, with the Administration proposing no support, the House acceding for the most part, the Senate balking, and in the end, a House-Senate conference bill restores some funds. A Senate and conference rescue is the hope again this year, says Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science. Toward this end, ASCLS is lobbying through its own members and jointly with the Health Professions & Nursing Education Coalition and the Coalition for Health Funding.

Even with funds restored, getting more of it for lab personnel is problematic, she notes, because the agency that administers the money—the Health Resources & Services Administration—favors programs with a multidisciplinary approach, and only a few lab personnel programs fit this criterion. ASCLS is backing pending legislation offering new federal incentives to alleviate the growing shortages of lab and other allied health personnel, including H.R. 1175 which specifically targets the lab workforce (*NIR, 26, 12/Apr 11 '05, p. 2*).

However, the immediate lab personnel outlook is not good, Passiment says. The number of such training programs continues to decline. "The

House-Approved HHS Bill

FY '06 Health Highlights

- New Medicare drug benefit: nearly $1B
- National Institutes of Health: $28.5B, up $142M from FY 2005 and the same as the President's request.
- Centers for Disease Control & Prevention: $6B, down $295M but $181M above the President's request. Special priorities: global disease detection and infectious disease outbreaks (such as influenza, SARS, West Nile Virus, HIV/AIDS, TB), bioterrorism, and vaccine stockpiles.
- Community health centers: $1.8 billion, up $100M
- Ryan White AIDS programs: $2.1B, up $10M and the same as the President's request.
- Health information technology: $75M, up $58M and $3M below the President's request.

dollars just aren't there to keep them open." Today, there are about 260 scientist-level programs (about 40-50% in hospitals, the remainder in universities), but 10 years ago, there were double that number, she notes. Today, there also are about 226 technical-level programs (almost all in community colleges) and a small number of histotechnologist programs. This array of programs gets little support from Title VII. To keep going, they rely on tuition, Medicare education payments, and grants that faculty secure for research.

West Nile Virus: Blood Donor Deferral Days Increased

The FDA no longer requires questioning donors about WNV symptoms, but does urge blood establishments to encourage donors to report unexplained post-donation flu-like symptoms suggestive of WNV infection that occur within two weeks after blood donation. As of June 30, three human cases of WNV had been reported in the United States, two of them in California

The Food & Drug Administration has recommended that blood establishments defer donors suspected of or diagnosed with West Nile Virus (WNV) infection for 120 days after diagnosis or onset of illness, whichever is later. Blood collection facilities have the discretion to re-enter donors after this period without additional testing. The previously recommended deferral period was 28 days. Also, draft FDA guidance had advised added testing prior to re-entry.

Donors who test reactive for WNV infection using the investigational nucleic acid screening tests should be deferred for 120 days from the date of their reactive donations. Blood establishments have the discretion to re-enter such donors after 120 days from the date of the reactive donation.

Additional testing of deferred donors during the 120-day period isn't required, the FDA says. But it encourages WNV testing of individual donations using a nucleic acid test on a follow-up sample obtained during this period. This gathers further useful scientific information on the duration of WNV viremia in donors, the FDA says. If a follow-up sample is WNV-reactive, the donor should be deferred for an extra 120 days from the date the sample was collected.

In revising its deferral and re-entry guidance, the FDA notes: "Although there are limited data on the natural course of WNV infection, the deferral periods we are recommending are based on a 14-day asymptomatic incubation period and a 120-day potential viremic period, which includes all known observations of prolonged viremia plus an additional margin of safety."

To guard against possible WNV transmission risk by blood transfusion, the FDA has revised recommendations for component retrieval and quarantine in line with the 120-day deferral period and has added a new category for "suspect" donations (those received by a patient who develops WNV within 120 days after the transfusion). The FDA's guidance, dated June 23, was announced in the June 30 *Federal Register* and is posted online at *www.fda.gov/cber/gdlns/wnvguid.htm*. Blood establishments are to implement the changes as soon as feasible, but not later than 30 days from issuance of the guidance.

The guidance applies to whole blood and blood components intended for transfusion and blood components intended for use in further manufacturing into injectable or non-injectable products, including recovered plasma, source leukocytes, and source plasma. It does not apply to human cells, tissues, or cellular and tissue-based products.

Criteria Proposed For Medicare Anti-Fraud/Abuse Contracts

In a recent proposed rule, the Medicare program spells out the criteria it would use to select private contractors to perform specific anti-fraud and abuse functions under the Medicare Integrity Program (MIP). Among these functions are utilization and claims reviews, cost report audits, recovery of overpayments, Medicare secondary payer review, and provider education.

The rule defines the types of entities eligible to become MIP contractors, outlines the process for awarding contracts, clarifies that new Medicare Administrative Contractors (MACs) may perform MIP functions under certain circumstances, and relaxes certain conflict-of-interest requirements.

Currently, the Centers for Medicare & Medicaid Services contracts with fiscal intermediaries to process Part A claims and with carriers to process Part B claims. Historically, about one-quarter of Part A and Part B contractor budgets has gone toward program integrity efforts. Effective October 1, 2005, CMS has the authority, under the 2003 Medicare Modernization Act, to begin replacing current intermediary and carrier contracts with competitively awarded MAC contracts. The transition is to be completed in 2011. The MACs will handle many of the basic functions now assigned to intermediaries and carriers, and also may be assigned specific program integrity duties.

Current intermediaries and carriers will be exempt from MAC competitive bidding until September 30, 2011, if they were performing program integrity functions under their contract as of August 21, 1996 (when the MIP authority was expanded under HIPAA, the Health Insurance Portability & Accountability Act).

Changeover To MACs

CMS has yet to propose regulations for the new MAC program, which will reduce the number of Medicare contractors to 15. The agency says it is in the process of crafting a statement of work and performance requirements, and will provide further guidance as these details are developed. Earlier this year, CMS released a map showing how it will divide the country into 15 primary MAC jurisdictions for combined Part A and Part B claims processing (*NIR, 26, 11/Mar 21, '05, p. 1*).

The changeover to MACs will begin with durable medical equipment nationwide, then spread to states in the new primary A/B jurisdictions, beginning with Jurisdiction 3, which includes Arizona, Montana, North and South Dakota, Utah, and Wyoming. MACs will be required to consolidate local coverage policies of existing contractors. Most MACs will cover areas previously served by two or three carriers and two to six intermediaries.

Current MIP Contracts

Under its expanded Medicare Integrity Program contracting authority, CMS currently maintains the following MIP contracts:

- Program Safeguard Contractors (PSCs) who concentrate on medical review, cost report audits, data analysis for potentially fraudulent billing schemes, provider education, and fraud detection and prevention. Since 1999, CMS has awarded more than 40 task orders under PSC contracts, including 17 benefit integrity model PSCs, 12 of which have since transitioned on their own. Some task orders have targeted areas with particular impact on laboratories and pathologists, such as correct coding and error rate testing.
- Coordination of Benefits, one contract.
- Medicare managed care, eight contracts.

PSC Contractors

—AdvanceMed, a CSC Company
—Aspen Systems Corp.
—Cahaba Safeguard Administrators, LLC
—Integriguard, LLC
—Computer Sciences Corp. (CSC)
—Electronic Data Systems (EDS)
—Lifecare Management Partners
—Mutual of Omaha Insurance Co.
—Reliance Safeguard Solutions, Inc.
—Science Applications International, Inc. (SAIC)
—TriCenturion
—TrustSolutions, LLC

Source: CMS

Task Force Calls For HIV Screening For All Pregnancies

The Centers for Disease Control & Prevention and the American College of Obstetricians & Gynecologists have backed HIV screening as part of routine prenatal care for several years

The U.S. Preventive Services Task Force is now recommending that all pregnant women be screened for the AIDS virus, not just those at high risk. In 1996, the independent panel of medical experts concluded there was insufficient evidence that such routine screening had any benefit.

But scientific advances have changed that, the panel said in the July 5 issue of the *Annals of Internal Medicine*. "Rapid testing can facilitate timely interventions in persons testing positive," the panel said, noting that combination antiretroviral regimens, elective caesarean section in selected patients, and avoidance of breastfeeding are associated with mother-to-child transmission rates of 1%-2%.

Previously, the task force had advised routine HIV screening only for expectant mothers at high risk and those in communities with high rates of HIV infection. Now, it recommends such screening for all pregnant women in their first trimester and follow-up testing in the third trimester for women at high risk.

The panel reiterated its recommendation for testing adolescents and adults at increased risk for HIV. It expanded the definition of high risk to encompass individuals receiving care at homeless shelters and clinics for sexually transmitted diseases.

CAP Calls For Grassroots Action On Cytology PT

Meanwhile, federal cytology PT requirements are in force. The deadline for enrollment in MIME's approved program was June 30. Enrollees must complete their initial test by the end of this year

The College of American Pathologists is fielding a full court press to get members of Congress involved in the campaign to overhaul the federal CLIA program for proficiency testing in gynecologic cytology. Nationwide enforcement of the PT program, dormant since 1992, began this year, with only one approved national provider—the Midwest Institute for Medical Education.

In early June, a coalition, led by CAP and including 10 national pathology organizations and 48 state pathology societies, urged Health & Human Services Secretary Michael Leavitt to undertake a comprehensive re-evaluation of the program and refrain from imposing punitive sanctions on individuals at least through 2007 (*NIR, 26, 17/Jun 20 '05, p. 3*).

Now, the College has asked all its members to contact their House representatives to sign a letter asking Leavitt to suspend federal cytology PT and re-evaluate its design and standards. CAP also has asked its partners in the coalition to rally their members in support of the letter.

According to CAP, Reps. Sue Myrick (R-NC) and Bart Gordon (D-TN) have agreed to take the lead on the congressional letter on behalf of the coalition. Myrick and Gordon are members of the House Energy & Commerce health subcommittee, which has jurisdiction over the CLIA program.

In related action, the American Medical Association's House of Delegates, at its annual meeting in June, passed a CAP-backed resolution urging that the federal program should remain "an educational pilot program at least through 2007" or until the Clinical Laboratory Improvement Advisory Committee can review scientific data and provide its views on "the validity and clinical relevance of the grading criteria, the importance of using field-validated Pap test slides, and the need for annual testing."

♦CODING A·D·V·I·S·O·R·Y

Our previous issue (June 20) featured new CPT lab codes that the Centers for Medicare & Medicaid Services is considering for the 2006 Part B lab fee schedule. What's the significance of the major coding additions and revisions?

The most striking addition is the new microbiology code 8720X, Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics. This isn't a test, but rather a personalized data analysis. A patient's lab test results are matched to a human genome database to help ascertain which drug therapies will be safe and effective for the patient. Such pharmacogenomics would involve, for example, immune-based diseases such as HIV and lupus. Both Charles Root, head of CodeMap (Barrington, IL) and Diana Voorhees, head of DV & Associates (Salt Lake City, UT), see the elevation of this former tracking (or emerging technology) code to a Level I CPT code as a major shift.

The new microbiology code, 8720x, is an extension of codes allowing pathologists to bill for more complex special stains, says Root. This new code also is a reminder that you can bill separately for trichome if you haven't done so before, Voorhees notes.

In the chemistry series, the revised and new molecular diagnostic codes, 83898-8390x, are designed to accommodate technology changes. Root says this should help genetic testing labs bill for more of the steps involved. Also in the chemistry series, coding changes for fecal occult blood specimen sources, 82270 and 8227x, should prompt providers to make sure they are coding correctly, Voorhees says. 82270 is for a simultaneous determination based on 1-3 specimens; 8227x is for a single determination based on a specimen derived from a digital rectal exam.

New lipoprotein codes, 8369x-8370x, are "housekeeping" changes, Root says, reflecting a rearrangement of methods. The new TB code, 8648x, accommodates a more sophisticated technology for diagnosis than the old tine test, he adds.

People In The News

Daniel R. Levinson was sworn in as HHS Inspector General on June 29. Nominated for the post by President Bush in July 2004, he has been acting IG since September 2004. The Senate Finance Committee unanimously approved his nomination on March 17, 2005. But Sen. Frank Lautenberg (D-NJ) stalled further action in a bid to punish former CMS head Thomas Scully for pressuring the Medicare actuary to withhold cost estimates for the Medicare drug benefit from Congress in 2003. Lautenberg lifted his hold on the nomination, his office said, after Levinson "satisfactorily answered" questions about resolving the Scully issue. Levinson was confirmed by the full Senate on June 8…..**Sean R. Tunis**, the chief medical officer at HHS, recently agreed to a $20,000 fine and a one-year suspension of his medical license from the Maryland Board of Physicians for altering documents to show he complied with state CME requirements. Tunis has been on administrative leave from CMS since April…..**David Mongillo** has been named as vice president for policy and medical affairs at the American Clinical Laboratory Association. He previously headed CAP's professional and regulatory affairs division and before that managed health issues at the American Petroleum Institute and Washington Occupational Health Associates.

CDC To Fund Lab Quality Work Against HIV/AIDS

The Centers for Disease Control & Prevention has announced its intent to enter into sole-source, non-competitive agreements with leading laboratory and pathology groups to improve quality in the global fight against HIV/AIDS. The awards are expected to begin on or before August 31.

The American Society for Clinical Pathology will support laboratory training and quality improvement in the diagnosis and monitoring of HIV/AIDS patients in countries with limited resources that are part of the President's emergency plan for AIDS relief. The work will involve 25 countries and three regional programs. Some $2 million is available in fiscal 2005 to launch this four-year effort.

The Clinical Laboratory & Standards Institute will conduct a project to develop easy-to-use global HIV/AIDS guidelines and standards for lab testing and quality systems for treatment, surveillance, prevention of mother-to-child transmission, and blood safety. Training in quality systems using CLSI standards has already begun in Africa and in Southeast Asia. Approximately $6 million is available in FY 2005 for this contract. The project period is for three years.

CDC says its choice of ASCP and CLSI reflects their unique qualifications: ASCP as the world's largest organization representing the entire lab team (pathologists, clinical scientists, medical technologists, and medical lab technicians) and CLSI as a global leader in setting consensus standards for clinical and lab testing.

washington WATCH

Close to 30 people representing organizations participating in the Clinical Laboratory Coalition fanned out across Capitol Hill, visiting some 60 congressional offices on both the House and the Senate side during the grassroots "fly-in" sponsored June 14 by the coalition (*NIR, 26, 15/May 23 '05, p. 1*).

The lobbying blitz centered on four main issues, said a coalition source: getting Congress to thaw the five-year freeze (through 2008) on Medicare lab fee updates; educating new staff on why restoring a 20% lab co-pay is bad policy; urging support for H.R. 1175 to alleviate lab personnel shortages; and backing H.R. 2218 to increase the Part B specimen collection fee from the current $3 to $5.78 in 2006 and provide future Consumer Price Index updates to the fee.

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December which are one-issue months) by Washington G-2 Reports (a division of the Institute of Management and Administration), 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. Website: www.g2reports.com. **Order Line: (212) 629-3679.**

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