WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 25th Year of Publication

Vol. 25, No. 19, July 19, 2004

CMS Leans Toward Narrow View On Heart Disease Screening

The screening is part of expanded preventive care authorized under the Medicare reform law and effective this coming Jan. 1. Also to be covered: diabetes screening and a host of cancer screening tests performed when an individual enters the Medicare program and gets a baseline physical exam by a physician

In developing coverage and payment policy for cardiovascular screening, a new Medicare benefit set to debut in 2005, the Centers for Medicare & Medicaid Services is inclined to adopt a less expansive approach than clinical laboratory groups have advocated, the *National Intelligence Report* has learned.

In a joint letter to CMS staff working on the issue, the American Society for Clinical Laboratory Science and the American Association for Clinical Chemistry called for a wide range of cardiovascular blood tests to screen the Medicare population, including high-sensitivity C-reactive protein and tests for lipoprotein particle size, said ASCLS executive vice president Elissa Passiment.

C-reactive protein is an indication of inflammation associated with increased heart-attack risk among people with high cholesterol, ➥ *p. 2*

INSIDE *NIR*

HMO, Tort Reforms Back In Political Play As Kerry Picks Edwards For VP

A patient's right to sue for personal injury, with no caps on jury awards for damages, is sure to become a "political football" in the Democratic and GOP election campaigns, now that Sen. John Kerry (MA), the presumed Democratic presidential nominee, has selected Sen. John Edwards (NC) as his running mate.

Kerry's choice plays into HMO and medical malpractice reforms that sharply divide the two parties. The Bush Administration supported arguments underpinning the U.S. Supreme Court's recent HMO ruling that the federal ERISA law pre-empts state right-to-sue laws, closing the door to enrollee lawsuits in state court against private employer and labor union health plans *(NIR, 25, 18/July 5, '04, p. 3)*. Edwards co-sponsored the Senate-passed Patients' Bill of Rights that remains stalled in conference, in part because of GOP opposition to granting a broad right to sue.

Edwards' career as a trial lawyer winning multimillion-dollar medical liability awards against hospitals, doctors and blood banks is already under GOP fire. The Administration backs a House-passed bill to cap non-economic and punitive damages at $250,000, arguing that this is needed to curb "frivolous" lawsuits and the rising cost of malpractice insurance premiums.

Coverage policy is struggling to keep up with the science of cardiovascular risk identification, laboratory scientists say. Alan Wu, PhD, DABCC, FACB, director of the chemistry section of the Pathology and Laboratory Medicine Department of Hartford Hospital in Hartford, CT, says researchers are searching for—and finding—new types of cardiovascular risk markers, because, "You can have normal cholesterol, high HDL and low LDL—and still have cardiovascular risk"

Heart Disease Screening, *from p. 1*
Passiment told *NIR*. For people with high cholesterol and inflammation, she added, it is helpful to know the levels of the individual lipoproteins, including A, B and A1, that make up total cholesterol, as well as high-density and low-density lipoprotein cholesterol (HDL and LDL, respectively) and lipid particle sizes.

But a CMS official has indicated to Passiment that the final policy will likely not include all the testing urged by ASCLS and AACC. Rather, it is expected to hew closely to recommendations of the Public Health Service's U.S. Preventive Services Task Force (*www.ahrq.gov/clinic/uspstfix.htm*). The official also noted that work on the policy has taken a back seat, for now, to efforts to update the Medicare physician fee schedule for 2005.

Cardiovascular screening was added to the Part B preventive services package by the Medicare Modernization Act, passed late last year (*NIR, 25, 5/Dec. 15, '03, p. 3*). In Section 612, Congress stipulated that the screening is to test for:
(a) Cholesterol levels and other lipid or triglyceride levels, and
(b) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the HHS Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by non-invasive testing. The Secretary may not approve an indication unless a blood test for such is recommended by the U.S. Preventive Services Task Force.

Further, while the government is to consult with appropriate organizations on standards to be set for the frequency for each type of covered cardiovascular screening blood tests, Congress limited frequency to once every two years.

Task Force Recommendations

The U.S. Preventive Services Task Force recommends periodic screening for high blood cholesterol among men ages 35-65 and women ages 45-65. It found insufficient evidence to recommend for or against routine screening of asymptomatic individuals over age 65, but does advise screening those ages 65-75 who have major risk factors for coronary heart disease (smoking, hypertension or diabetes), even if they are otherwise healthy.

The task force found insufficient evidence for or against routine testing for HDL or triglycerides at initial screening, but did approve use of such tests for high-risk middle-aged people with high cholesterol or multiple non-lipid risk factors for coronary heart disease.

Physicians should rely on at least two measures of cholesterol and an assessment of the individual's risk of coronary heart disease before deciding on interventions, the task force advised. The assessment should include results of lipoprotein analysis or the ratio of total cholesterol to HDL.

What Lab Groups Propose

In their joint letter, AACC and ASCLS told CMS that the initial group of covered tests should include total cholesterol (CPT 82465), HDL (83718), the lipid panel (80061), direct LDL measurement (83721), high-resolution fractionation and quantitation of lipoproteins (83716) and lipoprotein (83520, immunoassay, quanti-

fied, not otherwise specified). They noted too that guidelines from the National Cholesterol Education Panel advise that all lipid tests should measure all four cholesterol components: total, HDL, LDL and triglycerides.

The two associations also identified several risk tests that likely would fall under provision (B) above and thus would require a stamp of approval from the federal task force, including homocysteine (83090), apolipoproteins (82172), C-reactive protein (86141) and fibrinogen (85384).

With regard to frequency, AACC and ASCLS said one way to abide by the "once every two years" limit would be to allow a physician to order one of the following tests initially: total cholesterol, HDL, the lipid panel or direct LDL measurement. Patients with abnormal results would qualify for follow-up diagnostic tests as medically necessary. Patients with normal results, but having other risk factors (such as family history, high blood pressure, etc.), would qualify for additional lipoprotein screening; those with an abnormal result would qualify for follow-up diagnostic work as medically necessary.

Anticipating that CMS will establish HCPCS codes for the cardiovascular screening tests to be covered, the two associations recommended cross-walking these codes to corresponding CPT codes to determine reimbursement. For example, the current national Medicare fee cap for total cholesterol is $6.08; for HDL, $11.44; and for direct LDL measurement, $13.33. For the lipid panel, most carriers pay $18.72.

Feds Escalate Battle To Lower Blood Cholesterol Levels

Even as Medicare officials grapple with designing a new cardiovascular screening benefit (*related story, p. 1*), the government is urging more aggressive drug therapy to protect people at high or moderate risk for heart attack or stroke.

The National Cholesterol Education Program this month called for lower thresholds at which patients should begin treatment with cholesterol-lowering drugs, known as statins. The thresholds are well below those previously recommended. The NCEP guidelines focus on low-density lipoprotein (LDL) levels in the blood. For high-risk patients, the goal is an LDL of less than 100 mg/dL (vs. the previous 130 mg/dL) ; for a subset of these patients at very high risk, the aim is to reduce LDL to less than 70 mg/dL. For moderately high-risk patients, the NCEP leaves the goal at LDL of less than 130 mg/dL, but adds a therapeutic option to use drug therapy to reduce it below 100 mg/dL.

A new type of recommendation is added regarding the intensity of LDL-lowering drug therapy for both high-risk and moderately high-risk patients. The guidelines say this therapy should be intense enough to reduce LDL by at least 30% to 40%.

Risk Categories In Cholesterol Guidelines

- High-risk patients have coronary heart disease or disease of the blood vessels to the brain or extremities, or diabetes, or multiple (two or more) risk factors (*e.g.*, smoking, hypertension) that give them a greater than 20% chance of having a heart attack within 10 years.
- Very high-risk patients have cardiovascular disease together with either multiple risk factors (especially diabetes), or severe and poorly controlled risk factors (*e.g.*, continued smoking), or metabolic syndrome (a constellation of risk factors associated with obesity, including high triglycerides and low HDL). Patients hospitalized for acute coronary syndromes such as heart attack are also at very high risk.
- Moderately high-risk patients have multiple (two or more) risk factors for coronary heart disease, together with a 10% to 20% risk of heart attack within 10 years.
- Lower-risk persons have either moderate risk factors (two or more, plus less than a 10% risk of a heart attack in 10 years) or have zero to one risk factor.

The change will impact millions more Americans and likely increase the volume of testing needed to diagnose their condition and monitor their treatment

The NCEP still calls for therapeutic lifestyle changes for any patients whose LDL does not meet the goals, but also advocates these changes among patients who have lifestyle-related risk factors, even if their LDL is within the target range.

The new recommendations update NCEP's clinical practice guidelines on cholesterol management, based on a review of five major clinical trials of statin therapy conducted since the program released its 2001 guidelines, known as the Adult Treatment Panel (ATP) III Report. The National Heart, Lung & Blood Institute, part of the National Institutes of Health, coordinates the NCEP and has endorsed the updated guidelines, as have the American College of Cardiology and the American Heart Association.

Healthcare Bills Losing Momentum As National Elections Near

Time is rapidly running out on the 2004 congressional calendar. Both Houses are set to recess from July 26-Sept. 6, and both want to wrap up work by Oct. 1 to concentrate on the Nov. 2 elections

With Republicans and Democrats alike anxious to recess to get ready for their national nominating conventions and the fall election campaigns, the chances look slim that Congress will enact many pending healthcare initiatives.

Capitol Hill staff on both sides of the political aisle foresee little legislative movement on health policy issues for the rest of this second and final session of the 108th Congress. But watch out next year, they add. Whatever votes are taken this year, Hill observers say, are likely to be symbolic as the GOP majority aims to put Democrats on the spot on politically sensitive issues.

Dean Rosen, who directs health policy for Senate Majority Leader Bill Frist (R-TN), said the Senate will focus mainly on appropriations bills and judicial nominations for the rest of the year. Chances for passage of a drug import bill are fading, he said, and prospects for medical liability reform are even grimmer. Here's a legislative rundown:

Medical Malpractice Liability

The House-passed bill (H.R. 5), which the White House supports, would cap noneconomic and punitive damages at $250,000 and impose other restrictions. Senate Republicans have been unable to muster the 60-vote filibuster-proof majority needed to pass similar legislation. They twice tried but failed to get a majority behind specialty-specific tort reforms, S. 2061 for obstetricians and gynecologists and S. 2207 for ob-gyns and emergency and trauma centers (*NIR, 25, 10/ Mar. 8, '04, p. 8*). No significant bipartisan effort toward compromise appears to be underway.

Drug Imports

Earlier this year, there seemed to be enough momentum behind this issue to convince many in Washington that it stood a real chance, especially in view of this year's elections. Senior advocacy groups have blasted the federal refusal to allow drugs to be imported from Canada and other nations where they are cheaper. U.S. pharmaceutical interests, joined by the Food & Drug Administration, say they can't guarantee the safety of imported drugs. The Medicare Modernization Act of 2003 allows the HHS Secretary to lift the import ban if FDA finds it would pose no harm to patients and result in major cost savings. But the Bush Administration says safety and costs are sufficient concerns to keep the drug import prohibition.

The House last year approved a drug import bill, H.R. 2427. The main question this year was whether the Senate would follow suit. It has yet to do so. Charles Grassley (R-IA), chairman of the Finance Committee, on Apr. 8 introduced S. 2307, which would ease the ban. It lost momentum, however, when Edward Kennedy (MA) broke off negotiations with Grassley and backed a bipartisan bill allowing drug imports, S. 2328, introduced on May 21 by Byron Dorgan (D-ND) and Olympia Snowe (R-ME). Meanwhile, the head of the Senate HELP Committee, Judd Gregg (R-NH), has offered another bill, S. 2493, which has Frist's backing. If Gregg can get his bill through committee, Dorgan hopes to offer his bill as a substitute.

Patient Safety/Medical Errors Reduction

Partisan deadlock prevails in the Senate on S. 720, which, like its House-passed counterpart (H.R. 663), would establish a new voluntary system for reporting medical errors and certify a number of public and private organizations to act as patient safety organizations. These entities would analyze data and promote education on lessons learned and best practices. S. 720 passed the HELP Committee this month, but has since languished. Attempts to move it to the Senate floor have been unsuccessful. The Bush Administration has endorsed the House-passed bill.

BioShield

Prospects look good, though by no means certain, for BioShield legislation (S. 15), which the Senate approved 99-0 on May 19. The measure, a White House initiative in the President's budget request, would speed approval and production of bioterrorism countermeasures. These could include drugs, biologics or medical devices such as diagnostic tests that the HHS secretary determines to be a priority to "treat, identify or prevent harm from any biological, chemical, radiological or nuclear agent that may cause a public health emergency affecting national security" (*NIR, 25, 16/June 7, '04, p. 3*).

A spokesman for House Majority Leader Tom DeLay (R-Texas) said July 7 that no decision has been made on bringing S. 15 to the House floor. Last July, the House approved its own BioShield bill (H.R. 2122) in a 421-2 vote.

What's Likely Next Year?

Lobbyists for healthcare providers are girding for battle in the first session of the 109th Congress that will open in January 2005. They expect lawmakers to renew efforts to close the widening gap between revenue and spending by cutting provider reimbursement. The American Clinical Laboratory Association in February hired Jason DuBois as vice president for government relations. DuBois, who previously was manager of congressional and regulatory affairs for the American Society for Clinical Pathology, has been focusing on educating members of Congress and staff on key clinical lab issues.

Lab-Related Bills Dormant…

…And most will stay that way, predicts Don Lavanty, legislative consultant for the American Society for Clinical Laboratory Science. The Allied Health Reinvestment Act and the more narrowly tailored H.R. 623, the Medical Laboratory Personnel Shortage Act, are "lying out there," he notes, as is a bill to raise the Medicare fee for specimen collection, sponsored by Rep. Phil English (R-PA).

But these and other health policy bills are unlikely to go anywhere, Lavanty thinks. "The Ways & Means and Energy & Commerce Committees are closed for the year." Even so, it's possible, he acknowledges, that the drug import bill might advance. So too could the anti-bioterrorism bill, but he cautions that, as in the past, Congress is not likely to approve the money to carry out provisions of interest to clinical labs, such as training.

Information technology and its applications to healthcare are getting more serious attention in Congress, and this could translate to the funding required to establish the prerequisite standards, he says. But the bottom-line, he thinks, is "we're pretty quiet this year."

CDC Seeks Partner For Lab Quality Institute

The Centers for Disease Control & Prevention recently announced an opportunity for a cooperative agreement to carry out various activities associated with development of an Institute of Quality in Laboratory Medicine. The agency envisions the Institute as a public/private partnership, says Toby Merlin, MD, associate director for laboratory medicine in CDC's Division of Laboratory Systems. "We want an organization where the people affected by it feel like they are participating in it," he tells *NIR*.

Merlin hopes the Institute will help expedite quality-related decision-making. "Public/private partnerships can operate much more quickly than the government. The turnaround time is five to 10 years for most of the regulations affecting clinical labs." The aim is to enhance the quality and effectiveness of laboratory testing in areas of public health significance, such as detection and prevention of cancer, identification of genetic conditions and assessment of human health.

CDC contemplates awarding as much as $200,000 toward the project this year, with optional second- and third-year awards possible, based on funding availability and satisfactory progress. In the first year, the winning bidder would:

- Develop plans to establish and evaluate a core set of quality measures.
- Develop plans for sentinel networks to evaluate changes in lab practices, including efforts to overcome regulatory barriers.
- Provide a plan for a national quality report that would include strategies for improving quality assurance, recognition of where most testing errors occur, and issues surrounding near-patient testing.
- Manage the process of incorporating and establishing the Institute, including structure, logistics and legal requirements.
- Lead efforts to improve lab quality systems via consensus standards, guidelines and reports, as well as training, education and mentoring.

In 2005, the contractor would develop a plan for evaluating the cost-effectiveness of interventions and practices to improve quality; help with integration of information systems, and help labs share best practices. In 2006, the contractor would help plan health services research.

Under a cooperative agreement negotiated with the winning bidder, CDC staff would be "substantially involved," Merlin says. They would provide consulting, technical assistance and advisory services to help write a business plan, develop data collection instruments and address CLIA-related issues. The Institute's inaugural conference is planned for April 2005 in Atlanta, GA.

CDC will accept only proposals from nonprofit groups or state or local governments, or those governments' bona fide agents. The deadline for letters of intent is July 22 (contact: Tracy Carter, MPH, tel: 770-488-2523; fax: 770-488-8282). The program contact is Joe Boone, PhD, associate director for science in CDC's Laboratory Systems Division, 770-488-8080.

HHS Sets Forth Plan To Transfer Medicare Appeals

In accord with the Medicare Modernization Act of 2003, the U.S. Department of Health & Human Services has published a plan to transfer responsibility for Medicare appeals from the Social Security Administration to HHS. Section 931 of the Act also requires that administrative law judges (ALJs) who handle appeals be organizationally and functionally separate from the Centers for Medicare & Medicaid Services and report to, and be under the general supervision of, the HHS Secretary.

The transfer from SSA to HHS is to occur no earlier than July 1, 2005, and no later than Oct. 1, 2005. The transition plan addresses the workload of ALJs, cost projections and financing, a timetable, the feasibility of giving precedential weight to certain decisions of the Departmental Appeals Board and a number of other issues.

HHS Secretary Tommy Thompson and Social Security Commissioner Jo Anne Barnhart submitted a report on the plan to Congress on March 25. It was published for public comment on June 28. The deadline to submit commits is July 28. They can be emailed to *fdadockets@oc.fda.gov* as long as the subject line includes the docket number, 2004S-0270. Comments also can be mailed to FDA's Division of Dockets Management, 5630 Fishers Lane, Room 1061, Rockville, MD 20852-20201. The HHS contact is Catherine Tyrell, 202-690-7431. The report is online at *hhs.gov/medicare/appealsrpt.pdf.*

♦ QUESTION *of the* M·O·N·T·H

A physician office laboratory that often refers tests to our independent reference lab tells us it will now bill Medicare directly for them. This POL says it can do so because of a provision in CMS Change Request 3090, which took effect July 1. We don't think Medicare policy allows this. Who is right?

You are. While the Change Request you cite is targeted to independent labs, it does not change Medicare policy on the lab-to-lab referral exception to the direct billing requirement—this continues to apply only to independent and hospital laboratories. For the lab-to-lab referral exception to apply, one of the following three conditions must be met:

1) The referring lab is in, or part of, a hospital designated as a "rural" hospital. (Note too that the hospital must bill for inpatient and outpatient testing that it refers to an outside lab.)
2) The referring lab and the performing lab are each commonly owned: that is, the referring lab owns the performing lab or vice versa, or both are owned by a third entity.
3) The referring lab may bill for testing it does not perform if not more than 30% of all tests (Medicare and non-Medicare) for which it receives requests in a year are performed by another lab (testing done at a commonly owned facility is not included in this calculation). Put another way, the referring lab must perform at least 70% of its testing on-site (unless the tests referred are performed at another facility that shares ownership with the referring lab). This 70/30 rule is designed to discourage creation of "shell" labs that refer tests to an outside facility, pay for them at a discount, then bill Medicare at full price.

OIG Clears Scully Of Medicare Cost Estimate Charges

The OIG's findings contradict those of the Congressional Research Service, which asserted in an Apr. 26 memo that Scully's gag order went against federal law

Thomas Scully broke no criminal laws when, as chief of the Medicare agency, he withheld from Congress last year his own agency's cost estimate for Medicare reform, the HHS Office of Inspector General announced July 6. The Medicare chief actuary, Richard Foster, has alleged that Scully, then his boss, threatened to fire him if he disclosed to Congress that Medicare reform could cost an estimated $534 billion while lawmakers agreed to approve the legislation only if it came in under $400 billion as projected by the Congressional Budget Office (*NIR, 25, 16/June 7, '04, p. 7; 25, 12/Apr. 5, '04, p. 3*). The final CBO estimate was $395 billion. Disclosure of Foster's much higher figure could have scuttled the GOP's bid to enact a prescription drug benefit, with an eye on elderly voters in 2004.

The OIG found that Scully did gag Foster and threatened him with job retaliation, but there is no evidence that Scully violated any criminal statutes, said acting principal deputy IG Dara Corrigan in a statement. Foster "had no legal authority to disclose information independently to Congress," the OIG concluded. "The Administrator of CMS has the final authority to determine the flow of information to Congress." The matter would have been referred to an HHS ethics office for possible administrative action, the OIG added, had Scully not resigned to join the law firm of Alston & Bird (Washington, DC). Still under OIG investigation: the waiver given by HHS Secretary Tommy Thompson that allowed Scully to interview for jobs with potential private employers, including Alston & Bird, even as such firms lobbied his agency and Congress on the Medicare reform bill.

washington WATCH

OIG Turmoil Continues

Dara Corrigan, named acting principal deputy Inspector General at HHS in June 2003, is recusing herself from all hospital-related cases because she is negotiating for employment with a hospital system. Corrigan, a former U.S. attorney and head of program integrity at CMS, replaced IG Janet Rehnquist, who resigned following congressional reports sharply critical of her performance and behavior.

Corrigan was once thought to be a contender for the permanent IG post, having boosted staff morale, winning favorable nods from provider interests and conducting high-profile probes, including allegations against former CMS chief Tom Scully (*see story above*). Now rumored as the White House choice: Dan Levinson, IG at the General Services Administration. President Bush has delayed filling the post, vacant for some 16 months, until the Scully probe was completed, according to informed sources.

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December which are one-issue months) by Washington G-2 Reports, 1111 14th Street NW, Suite 500, Washington DC 20005-5663. Tel: (202) 789-1034. Fax: (202) 289-4062. Website: www.g2reports.com

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