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Medicare Coverage Terms Proposed For Heart, Diabetes Screening

As of Jan. 1, 2005, Medicare will begin paying for cholesterol, lipids and triglycerides screening, plus plasma fasting glucose and glucose tolerance screening

The Centers for Medicare & Medicaid Services recently detailed how it intends to reimburse laboratory and physician procedures added to the Medicare Part B screening package by last year's Medicare Modernization Act (MMA). The Act approved coverage of cardiovascular disease and diabetes screening for beneficiaries already in the program, plus a comprehensive baseline physical exam for those new to the program, starting in 2005.

On heart disease screening, CMS, as expected, takes a less expansive approach than that advocated by several clinical laboratory groups (*National Intelligence Report, 25, 19/July 19, '04, p. 1*). The agency hews closely to the statutory language and recommendations of the U.S. Preventive Services Task Force, but says it would consider adding more tests via its process for making Medicare national coverage decisions.

CMS proposes to cover tests for total cholesterol, HDL cholesterol and triglycerides—and the lipid panel (which includes these tests)—but declines to cover LDL cholesterol, contending that these results can be calculated from the above testing and *Continued on p. 2*

Candidates Offer Divergent Healthcare Visions

As recent polls show many seniors unhappy with the new Medicare drug benefit and other program reforms, as unions battle to prevent erosion of healthcare benefits, and as the ranks of the uninsured continue to grow, the Bush and Kerry campaigns are prescribing different remedies for what ails U.S. healthcare.

President Bush clearly favors market-oriented solutions. On Aug. 9, he said that one of his economic initiatives under the "Era of Ownership" banner would be to promote tax-free, flexible health savings accounts for individuals. The deputy policy director of his re-election campaign, Megan Hauck, echoed this theme: "When you give people control of their own healthcare decisions, they make smarter decisions for themselves, and that lowers costs."

The Kerry campaign calls for repealing tax cuts for the richest 2% of Americans to help pay for expanded coverage of the uninsured. And with an eye on senior discontent, the Democratic nominee has vowed to let Medicare negotiate prices directly with drug companies and to permit importation of cheaper drugs from Canada. For details on the healthcare stakes in Campaign '04, see the *Focus on the Politics of Healthcare*, p. 5.

INSIDE *NIR*

Medicare will reimburse the covered heart disease and diabetes screening at the same rate it pays when these tests are performed for diagnostic purposes

Medicare Coverage Terms, *from p. 1*
should not be reimbursed separately. The cardiovascular screening, CMS adds, should be done as a panel after a 12-hour fast.

The proposed frequency is more restrictive than what the MMA allows, but is in line with Task Force recommendations. CMS would cover heart disease screening tests once every five years. The MMA limit is not more often than once every two years.

In terms of diabetes screening, CMS would cover at-risk beneficiaries for a fasting plasma glucose and post-glucose challenge tests. Those at risk include people with hypertension, dyslipidemia, obesity, impaired fasting glucose or glucose tolerance, and a risk factor consisting of at least two of the following: overweight, family history of diabetes, a history of gestational diabetes mellitus and age 65 or older.

Heart Disease, Diabetes Screening: *Proposed Medicare Coverage*

Cardiovascular disease
ICD-9 codes: V81.0, V81.1, V81.2
Frequency: once every 5 yrs

Test	*CPT code*	*Fee**
Cholesterol	82465	$6.08
HDL	83718	11.44
Triglycerides	84478	8.04
Lipid panel	80061	18.72**

Diabetes
ICD-9 code: V77.1
Frequency: "pre-diabetes" beneficiaries, no more than twice per 12-month period following most recent diabetes screening; others, once per yr

Test	*CPT code*	*Fee**
Glucose, quant. (except reagent strip)	82947	$5.48
Glucose tolerance, 3 specimens, includes glucose	82951	17.99

*Current Medicare fee cap, frozen through 2008.
**Not capped, but most carriers pay at this price.
CPT codes © American Medical Assn.

For those with "pre-diabetes" conditions (previous fasting glucose level of 100-125 mg/dL or a two-hour post-glucose challenge of 140-199 mg/dL), the testing frequency would be no more often than twice per 12-month period following their most recent diabetes screening (for others, once per 12-month period). CMS invites comments on its definition of "pre-diabetes" and how it should define "family history" as a risk category.

"Welcome to Medicare" Physical

Also next year, Medicare will begin covering an initial comprehensive physical exam of new enrollees. The exam must be performed within the first six months after the effective date of the beneficiary's first Part B coverage period, but only if that period begins on or after Jan. 1, 2005. The service would be billed under a new HCPCS code, G0XX2, Initial preventive physical examination, and doctors performing the service would be paid under the Medicare physician fee schedule at $124.30 (non-facility rate) or $82.24 (facility rate).

In addition to measurement of vital signs and an electrocardiogram, the exam is to include education, counseling and referral to other Part B preventive services, such as Pap smears, pelvic exams, screening for colon and prostate cancer, diabetes and cardiovascular disease, among others. These services would be separately payable under their existing codes on their respective Medicare fee schedules.

The coverage conditions for the new screening benefits are contained in the proposed 2005 Medicare physician fee schedule rule, published in the Aug. 5 *Federal Register* (online at *www.gpoaccess.gov*). Comments are due by Sept. 24. CMS plans to publish the final rule by Nov. 1, with an effective date of Jan. 1, 2005.

Expanded Screening Benefits: Medicare Cost Estimates ($MM)

	FY 2005	*FY 2006*	*FY 2007*	*FY 2008*	*FY 2009*
Cholesterol, blood lipids	$50	$80	$90	$90	$100
Diabetes	20	40	50	60	80
Preventive physical exam	65	75	75	75	75

Source: Medicare physician fee schedule, 2005 (proposed)

Medicare Pathology Spending Next Year To Rise Nearly 4%

The actual impact on a physician practice's revenue depends on its volume and mix of tests and patients (Medicare and non-Medicare). For the most frequently billed pathology service, CPT 88305 (tissue exam), the interpretation fee is set to increase from $41.44 this year to $42.07 (unadjusted for geographic overhead differences)

Because of changes to relative value units (RVUs) for practice expense and malpractice costs, combined with a congressionally mandated fee update, Medicare projects that in 2005 its payments for pathology services under the Part B physician fee schedule will increase by 3.7%, while outlays for pathology services billed by independent laboratories (specialty 69) will rise 7.7%. The figures are contained in the proposed 2005 physician fee schedule, published in the Aug. 5 *Federal Register*.

The increased spending stems from three main factors. First, for physician services overall, Congress mandated no less than a 1.5% increase in the annual update to the fee schedule. Otherwise, under the existing statutory formula, fees would have been hit with a –3.7% reduction. Second, there is a net increase of 2% for pathologists and 6% for independent labs now that the Centers for Medicare & Medicaid Services has adopted practice expense survey data from the College of American Pathologists. Third, there is a slight boost of 0.2% in RVUs for malpractice expense because recent data show that these insurance premiums are higher than CMS had previously estimated.

Back in 2002, CMS had proposed calculating practice expense RVUs by setting the technical component (TC) of a physician service as the difference between RVUs for the global service and the professional component (PC or physician's intepretation). But the agency opted not to apply this to pathology services, so CAP could submit supplemental survey data. Those data have now been incorporated into the practice expense methodology, and CMS will begin calculating RVUs for the TC of a pathology service as the difference between global and PC RVUs. In its survey, CAP found, for example, that Medicare had undervalued independent lab practice expenses by using a default "all physician average" of $69/hour. CAP showed the figure should be $163.80, or 137% higher.

Impact of RVU Changes, Fee Update on Total Medicare-Allowed Charges
How Pathology Fares vs. Other Physician Specialties

Specialty	*Allowed Charges ($MM)*	*RVU Changes*	*Fee Update*	*Total*
Pathology	$869	2%	1.5%	4%
Anesthesiology	1,416	0	1.5	2
Cardiology	6,583	0	1.5	2
Dermatology	1,870	1	1.5	2
Emergency Medicine	1,672	0	1.5	2
Family Practice	4,448	0	1.5	1
Gastroenterology	1,636	0	1.5	2
General Practice	998	0	1.5	1
Internal Medicine	8,846	0	1.5	1
Interventional Radiology	190	2	1.5	4
Nuclear Medicine	85	0	1.5	1
Radiation Oncology	1,164	0	1.5	1
Radiology	4,690	0	1.5	1
All Physician Fee Schedule Spending	$66,395	0%	1.5%	2%

Source: 2005 Medicare physician fee schedule (proposed)

In other pathology-related provisions, CMS:

- ❑ Would create a new HCPCS "G" code for bone marrow aspiration and biopsy through the same incision on the same date of service.
- ❑ Clarifies the relaxed rules that now apply to reassignment of benefits (*NIR, 25, 11/Mar. 22, '04, p. 1*). CMS reiterates that "parties should be mindful that contractual arrangements may not be used to camouflage inappropriate fee-splitting arrangements or payments for referrals."

Medicare To Reward Hospitals For Quality Performance

As of mid-July, the vast majority of hospitals have registered to report quality data, says CMS, and thus are eligible for higher payments

For the first time ever, starting this Oct. 1 (the beginning of the federal fiscal year 2005), hospitals that voluntarily report quality performance data will get higher Medicare payments than those that don't. Hospitals that report the data will get the full market basket update of 3.3%; those that don't will get a lesser update, 2.9%. The pay-for-performance policy, required by the Medicare Modernization Act (MMA), is being implemented under the final inpatient prospective payment rule for FY 2005, published in the Aug. 11 *Federal Register* (*related coverage: NIR, 25, 15/May 24, '04, p. 1*).

Overall, the inflation update and other changes translate into an average 5.7% increase in payments to urban hospitals in FY 2005 and an average 6.2% increase for rural hospitals, says the Centers for Medicare & Medicaid Services. In FY 2005, Medicare expects inpatient PPS outlays to some 3,900 acute-care hospitals to reach $105 billion, up from a projected $100 billion in FY 2004.

The final rule offers further financial help to rural hospitals by reducing the impact of the wage index, accounting for the higher costs of hospitals with fewer total discharges, and re-classifying many hospitals into higher-paying areas under the switch to new Metropolitan Statistical Areas based on the 2000 Census.

CMS also is implementing provisions in the MMA that would help critical access hospitals serve rural beneficiaries, redistribute unused residency slots among teaching hospitals, and increase payments for certain new medical technologies. The outlier threshold is set at $25,800, down from $31,000 in FY 2004 and the $35,085 previously proposed for FY 2005.

Preventive Services Get Boost Under Medicare Outpatient Rule

In a proposed rule governing Medicare prospective payment to hospital outpatient departments next year, the Centers for Medicare & Medicaid Services would increase spending for preventive procedures already covered under Part B and would reduce beneficiary co-payments for outpatient care. These and other policy changes, together with a 3.3% inflation update, will raise total projected Medicare outpatient payments by 6.6%, starting Jan. 1, 2005—from $22.7 billion this year to $24.2 billion.

When the "Welcome to Medicare" physical exam for new beneficiaries is performed in a hospital's outpatient department, Medicare will pay the hospital $75 for use of its facilities; the doctor's professional service will remain separately payable under the physician fee schedule (*related story in this issue, pp. 1-2*). As an added bonus, analysts note, any lab work generated as a result of this baseline exam will likely go to the hospital's own lab for processing and be separately payable under the Part B lab fee schedule.

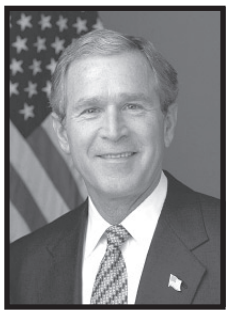
Payment hikes are proposed for the following screening exams, already covered by Medicare, when performed on an outpatient basis:

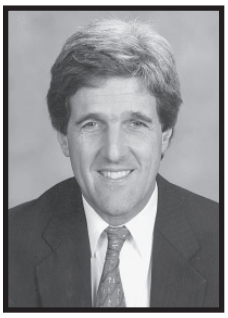
- ❑ 3.24% for pelvic and breast exams to detect cervical and breast cancer
- ❑ 4.25% for barium enema to detect colorectal cancer

Continued on p. 9

focus on: *The Politics of Healthcare*

Bush, Kerry "Duke It Out" On Key Coverage, Liability Issues





Polls show President George W. Bush and Sen. John Kerry (D-MA) in a dead heat in the race for the White House, with the campaign clamor thus far dominated by the war in Iraq, the war on terrorism and the economy. But polls also reveal anxiety over healthcare issues, some of which could influence voters' presidential pick in November. The Bush re-election campaign has been quick to react on two politically sensitive issues where it could be vulnerable—the Medicare prescription drug benefit and stem cell research.

Dismay On The Drug Front

According to a just-released national poll of Medicare beneficiaries, nearly half had an unfavorable view of Medicare reform, including the drug benefit, about one-quarter had a favorable view and the rest had no opinion. More ominously for the GOP, four out of five seniors and disabled persons favored changing the law to allow Medicare to negotiate directly with drug companies to get lower prices and to permit importation of cheaper drugs from Canada. Three in 10 said this issue could influence their choice for President. The Medicare Modernization Act (MMA, enacted Dec. 8, 2003) forbids both direct negotiations and drug imports. The Bush Administration agrees. Kerry supports rewriting the Act to allow both.

The national poll was conducted from June 16 to July 21 by the Kaiser Family Foundation and the Harvard School of Public Health, just ahead of the Democrats' national nominating convention. Most beneficiaries who responded were dissatisfied, if not in the dark, about the new drug benefit. The major complaints were that the benefit is too stingy, that it will cost too much out-of-pocket, and that it favors drugmakers too much. The drug benefit debuts in 2006; for now, seniors can get a drug discount card to save on prescription medications.

Beneficiary dismay is not yet a backlash, caution the pollsters. Further education and outreach could turn this sentiment around. But the President and the GOP majority in Congress have yet to reap the political capital they hoped for when they engineered introduction of the drug benefit, the biggest shakeup in Medicare since the program's inception nearly 40 years ago. In response to the poll, Administration officials were upbeat, confident that the more beneficiaries learn, the more they'll like the GOP-crafted benefit. Kevin Keane, HHS assistant secretary for public affairs, said: "Despite the political demagoguery that has taken place, the survey shows that seniors believe the new benefit will be helpful … and that they want to know more about it. They won't want it taken away. That's a powerful statement."

The GOP also hoped to woo voters by beefing-up Medicare managed care with a new Medicare Advantage program that gives a host of tax advantages to HMOs, PPOs and other private health plans to enter and serve the Medicare market. One provision designed to shift more beneficiaries away from traditional fee-for-service has sparked sharp controversy. In 2010, the government is to conduct a competition demonstration program that critics say would lead to the "privatization" of Medicare.

Stem Cell Research

This issue took on new resonance after the death of former president Ronald Reagan, who suffered for years from Alzheimer's, and after his son Ron addressed the Democratic nominating convention, urging people to vote for the candidate who favors stem cell research.

In an Aug. 7 national radio address, Kerry pledged to lift the restrictions that Bush has placed on federal funding for embryonic stem cell research, declaring that "here in America, we don't sacrifice science for ideology." Kerry spoke on the third anniversary of the ban limiting federal funding to a small number of existing cell lines. Bush's position is that this limit "allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos," as he stated when announcing the ban. It's a compromise that protects human fetuses from science, but lets research continue, backers say. Anti-abortion groups oppose stem cell research because, to use the cells, human embryos must be destroyed.

But outside pressure is building to relax existing curbs. Bipartisan groups in the House and the Senate and former First Lady Nancy Reagan have said that further research could trigger scientific breakthroughs against such illnesses as Alzheimer's, Parkinson's, juvenile diabetes and paralysis. First Lady Laura Bush has broken her customary silence to support her husband and to warn against raising "false" hopes. Forty-eight Nobel laureates have endorsed Kerry, saying the Administration had ignored "scientific consensus on critical issues."

Some 64% of conservatives recently polled said they were likely to support stem cell research in the wake of Reagan's death. The poll, conducted by Opinion Research Center for the liberal nonprofit group, Results for America, also found that 73% of respondents supported research from stem cells removed from unused or unwanted frozen embryos stored in fertility clinics. A Zogby poll for American Demographics Institute, conducted in late July, found that one in five Bush voters would switch to Kerry if he proposed a bold stem cell research program.

The Medically Uninsured

Of all healthcare issues throughout campaign 2004, this has received the most ink in the newspapers. It's also one that could generate the most new red ink in the federal budget.

The Bush plan would cover 6-10 million of an estimated 41 million uninsured Americans and cost $70 billion over 10 years. Kerry's approach would cover an estimated 27 million uninsured at a cost of $895 billion over 10 years. The financing would come from repeal of Bush's tax cuts benefiting the wealthiest 2% of Americans (those earning more than $200,000 annually).

The Bush approach emphasizes tax credits for the low-income uninsured who buy individual insurance policies. Single adults would get credits worth as much as $1,000 a year, which phase out at annual incomes of $15,000 to $30,000. For families with two or more children, the credits would be worth as much as $3,000 per year, with eligibility phasing out at incomes between $25,000 and $60,000.

The Bush plan also calls for:

- ❑ Subsidizing non-group, individual market insurance that meets certain standards in the hopes of attracting young, healthy people into the individual health insurance market, thereby broadening the risk pool and reducing premiums.

- ❑ Promote tax-free, flexible Health Savings Accounts by letting participants deduct their premiums. These accounts allow individuals to set aside money to cover their healthcare and pocket any savings.
- ❑ Allow small businesses to band together across state lines to form associations to secure private coverage for their workers, free from state regulation.

Kerry's approach would expand children's health programs so that all children are covered and would offer tax credits to make health insurance more affordable. The government would cover 75% of catastrophic costs (when a patient's expenses exceed $53,000) through a "re-insurance" program. Specifically, Kerry would:

- ❑ Create a Congressional Health Plan, a new group insurance pool within the Federal Employees Health Benefits Program, for individuals and employers who need affordable coverage.
- ❑ Extend tax credits to individuals and employers who can least afford Congressional Health Plan premiums.
- ❑ Expand Medicaid, with the Federal Government covering the costs of all children enrolled in Medicaid in states that agree to expand their children's health insurance programs beyond certain specified levels.

Major Healthcare Issues: Where Bush, Kerry Stand

Issue	Bush	Kerry
The Uninsured	Tax credits to individuals to buy private health coverage, association plans to help small businesses get coverage. Would cover 6-10 million uninsured at $70 billion over 10 years.	Expand Medicaid and congressional health plans, take other steps to cover 27 million uninsured at $895 billion over 10 years.
Medicare Modernization	Touts achievement in engineering passage of new drug benefit, new tax advantages to strengthen Medicare managed care as alternative to fee-for-service.	Would change the law to let Medicare bargain directly with drug companies for lower prices and to allow cheaper drug imports from Canada, plus take other steps to curb drug prices.
Provider Liability	Calls for national standards that would make medical liability system more fair, predictable, timely. Supports House-passed bill capping non-economic and punitive damages at $250,000.	Would protect providers from frivolous lawsuits, oppose punitive damages in many cases and promote mediation.
HMO Liability	Backs Supreme court ruling on ERISA pre-emption of state right-to-sue laws. Favors limits on denial-of-care lawsuits against HMOs.	Supports enrollees' right to sue in state courts for damages.
Stem Cell Research	Current restrictions protect human embryos, but allow research to continue on existing stem cell lines.	Would lift restrictions on federal funding to spur research on life-saving potential.

Healthcare Provider Liability

Reform of the medical liability system is one of Bush's top healthcare priorities. His Administration supports House-passed legislation that would cap non-economic (pain and suffering) damages at $250,000 and punitive damages at the greater of twice the amount of economic damages or $250,000. The bill would allow unlimited damages for lost wages and medical care (*NIR, 25, 19/Jul 19 '04, p. 4*).

The American Medical Association backs medical liability reform, and while it says it does not take a position on elections, it did run an article in its Aug. 2 newsletter, noting that the past of Sen. John Edwards (NC), a former trial lawyer whom Kerry picked as his running mate, "raises red flags" for physicians on the liability issue.

Kerry favors targeted medical liability reforms. He would prevent and punish frivolous

lawsuits against healthcare providers, oppose punitive damages in many cases and promote mediation as an alternative.

HMO Liability

A Patients' Bill of Rights for private managed care enrollees remains stalled in the Senate over enrollees' right to sue, but it flared into a campaign issue in late June after a unanimous U.S. Supreme Court ruling that ERISA, the federal law governing pensions and benefits, pre-empts state right-to-sue laws. Enrollees can still sue in federal court, but damages are minimal. The decision affects some 130 million Americans in private employer and labor union health plans. It also voids right-to-sue laws in at least 10 states, including California and Texas *(NIR, 25, 18/ Jul 5, '04, p. 3)*.

The Administration filed a brief with the high court, supporting the ERISA preemption arguments. Democrats have pounced on the Administration for "flip-flopping," noting that Bush took credit in the 2000 campaign for the Texas right-to-sue bill that he had fought as governor, but allowed to become law. Kerry pointedly criticized Bush for not supporting "the same legislation he used to brag about in Texas."

Budgetary, Political Constraints To Persist

Whoever sits in the White House come January will face severe budgetary and political constraints on his ability to advance his healthcare agenda. The occupant will also have to appeal to the business sector which likes help to make private health insurance more affordable and to cover catastrophic costs, though business interests tend to be wary of Kerry because of strings attached to the help with these costs.

The Kerry campaign also must be sensitive to the healthcare provider community. Kerry's shop has been warning that as long as Bush wants to extend tax cuts permanently, provider reimbursement under federal programs may have to be reduced to help restrain growth in the federal budget deficit, now pegged at close to $500 billion.

Looking ahead, veteran political analysts say that domestic initiatives of either major party are bound to be constrained in the upcoming 109th Congress by the deficit growth. Partisan divisions will further complicate the healthcare agenda. The GOP is expected to retain control of the House after the November elections, but analysts are less sure about the Senate where the GOP's current margin of control is tight. Also in the Senate, neither party is expected to secure a 60-vote, filibuster-proof majority to enact majot5vegislation, including healthcare reforms. So, the prospect is for cosmetic, rather than radical, surgery on the U.S. healthcare system.

Ted Halstead, founding president and CEO of the New America Foundation, is a featured speaker at Lab Institute 2004, sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 in Arlington, VA. Details on our Website, www.g2reports.com

An Independent View

In an interview with *NIR*, Ted Halstead of the New America Foundation offered his critique of the dueling Bush, Kerry healthcare plans. "Neither provides universal coverage. Clearly, the Kerry plan would cover more people, but neither it nor Bush's plan gets us to universal coverage." Halstead is chief executive of the Foundation, an independent, nonprofit public policy think tank in Washington, DC.

"The Kerry approach is particularly expensive, though it does cover 27 million Americans. Still, neither [candidate] get us away from the employer-based healthcare paradigm. One of the core themes I will [address at Lab Institute] is the need to move to citizen-based health insurance, where individuals can choose from among competing private providers and take their insurance with them from job to job, instead of being constrained by whether they have a job or the healthcare choices of their employers.

"On all three fronts—employer-based benefits, affordability and universal coverage—neither the Bush nor the Kerry plan moves us in a very good direction."

To help beneficiaries get state-of-the-art treatments, Medicare would let hospitals get paid for new drugs and biologicals as soon as approved by the FDA, rather than wait months for a code to be assigned

Preventive Services Get Boost, *from p. 4*

- ❑ 4.25% for bone density studies
- ❑ 7.42% for flexible sigmoidoscopy to detect colorectal cancer
- ❑ 9.9% for screening colonoscopy, also for colorectal cancer
- ❑ 10.4% for glaucoma screening

Diagnostic mammograms, currently subject to outpatient PPS, would be paid, like screening mammograms, under the Part B physician fee schedule. This change is expected to increase payments for traditional diagnostic mammograms by nearly 40% and for digital diagnostic mammograms by nearly 60%.

To improve the accuracy of payments for blood and blood products used in the outpatient setting, CMS advances a number of strategies. It proposes a new method for calculating payment rates and creation of individual ambulatory payment classifications, or APCs, for all blood products.

As more and more medical care is delivered in the outpatient setting, Medicare is lowering related beneficiary co-payments. The current maximum rate for any such service is 50%. CMS would lower it next year to 45%. The result, says the agency, is that the average co-pay rate would drop from 34% in 2004 to 32% in 2005. Under Medicare law, the co-pay rate is to be reduced gradually to 20% of the total payment.

Comment Sought On Drug Benefit, Medicare Advantage

Deadline for comments is Oct. 4. Comments may be submitted electronically to cms.hhs.gov/regulations/ecomments. *The proposed rules are posted online at* www.gpoaccess.gov. *Related fact sheets are available at* cms.hhs.gov

The Centers for Medicare & Medicaid Services has taken the first in a series of steps to implement the Part D prescription drug benefit and the Medicare Advantage program that were approved in last year's Medicare Modernization Act and take effect at the start of 2006. In separate rules proposed in the Aug. 3 *Federal Register*, the agency spelled out some details, but left some big questions open. The intent, says one agency observer, is to let the major players—private managed care plans, insurers, drug-benefit companies and large employers—help craft the final rules and better understand what they must do to participate.

For the drug benefit, a major concern is to persuade employers and unions to keep, if not expand, their drug coverage of retirees. Under options proposed by CMS, employer and union plans could offer a standard Medicare drug benefit (whose formulary is yet to be defined) or could offer enhanced drug coverage. Either way, the costs would be subsidized. But CMS is anxious to avoid windfalls, warning that it may be legally difficult to prevent plans from getting more in subsidies than they pay out in benefits.

The Medicare Advantage program replaces the Medicare+Choice program, and aims to offer a range of HMO, PPO, and private fee-for-service choices as an alternative to traditional Part B fee-for-service. Much attention thus far has been focused on regional PPOs which must serve a CMS-designated region (local plans may cover single or multi-county areas). CMS presents a set of options on how to determine potential regions. CMS expects MA enrollment to reach 13.6 million in 2009, up from 4.7 million enrolled in Medicare+Choice plans in 2004. Over that five-year period, the agency expects to transfer an additional $23.4 billion to health insurers that offer MA plans and $1.4 billion in additional benefits or cost-sharing reductions to beneficiaries in these plans.

♦CODING A·D·V·I·S·O·R·Y

Leading laboratory and pathology groups have submitted their recommendations to the Centers for Medicare & Medicaid Services on how Medicare fees should be set for CPT codes new in 2005. There's unanimity that the cross-walk method should be used, whereby a new code is priced the same as an equivalent existing code. The table below summarizes recommendations from the College of American Pathologists, the American Association for Clinical Chemistry, the Clinical Laboratory Management Association, the American Clinical Laboratory Association, the American Society for Microbiology and the American Society for Clinical Pathology.

CMS also asked whether new CPT flow cytometry and surgical pathology codes should be assigned to the clinical lab fee schedule *(NIR, 25, 18/Jul 5, '04, p. 2)*. CAP, AACC, ACLA and ASCP opposed this.

New CPT Lab Codes For 2005 Medicare Lab Fee Schedule
Recommended Crosswalks, Related Fees

Code	*Descriptor*	*Crosswalk to*	*Agree*	*Disagree*
CHEMISTRY				
8204x	Albumin; ischemia modified	83880 ($47.43*)	CAP, AACC, CLMA, ASCP	ACLA, 84484 ($13.75)
8265x	Elastase, pancreatic (EL-1), fecal, qual. or semiquant.	83516 ($16.12)	CAP, AACC, CLMA, ACLA, ASCP	
8300x	Helicobacter pylori; blood test analysis for urease activity, non-radioactive isotope (eg, CC-13)	83013 ($94.11)	CAP, AACC, CLMA, ACLA, ASCP	ASM, 83013 ($94.11) + 83014 ($10.98)
8363x	Lactoferrin, fecal, qual.	83516 ($16.12)	All groups	
8416x	Pregnancy-associated plasma protein-A (PAPP-A)	84702 ($21.03)	CAP, AACC, CLMA, ACLA, ASCP	
8416x	Protein, electrophoretic fractionation and quantitation; other fluids with concentration (eg, urine, CSF)	84165 ($15.01) + 87015 ($9.33)	CAP, AACC, ACLA, ASM, ASCP	CLMA, 84156 or 84157 ($5.12)
IMMUNOLOGY				
8606x	B cells, total count	86359 ($52.70)	CAP, AACC, ACLA, ASM, ASCP	CLMA, 88180**
8633x	Immunofixation electrophoresis; other fluids with concentration (eg, urine, CSF)	86334 ($31.21) + 87015 ($9.33)	CAP, AACC, ACLA, ASM, ASCP	CLMA, 86334 + 10%
8637x	Natural Killer (NK) cells, total count	86359 ($52.70)	AACC, ACLA, ASM	CAP, ASCP, 86361 ($37.41); CLMA, 88180
8658x	Stem cells (i.e., CD34), total count	86359 ($52.70)	AACC, CLMA, ACLA	CAP, ASCP, 86361 ($37.41); ASM, 86359 + 86361 (x2)
MICROBIOLOGY				
8780x	Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus	87802 ($16.76)	All groups	

*Current Medicare national fee cap, frozen through 2008. **Code on the physician fee schedule. CPT codes © American Medical Assn.

TrailBlazer To Establish LMRP For Certain Infectious Disease Tests

Mitchell Burken, MD, TrailBlazer's Mid-Atlantic Medicare medical director, is a featured speaker on lab coding and reimbursement issues at Lab Institute 2004, sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 in Arlington, VA

One of the largest Medicare contractors, Dallas-based TrailBlazer Health Enterprises LLC, intends to go final soon with a potentially precedent-setting local medical review policy (LMRP) for coverage of infectious disease molecular testing. It will provide "laboratories and clinicians with a more firm understanding of what will and won't be paid," says Mitchell Burken, MD, TrailBlazer's Mid-Atlantic Medicare medical director. He acknowledged that "the previous system was overly restrictive, because we non-covered some tests but didn't have the [clear] policy to support that."

The LMRP, when finalized, would take effect 45 days after publication for Part B services in Maryland, Texas, Virginia, Delaware and the District of Columbia. It also would affect Part A services in Colorado, New Mexico and Texas.

Laboratories had complained after TrailBlazer began strictly enforcing a legal requirement not to reimburse tests not cleared by the Food & Drug Administration, such as home-brew tests, says Alice Weissfeld, PhD, president and director of Microbiology Specialists Inc. (Houston) and chair of professional affairs at the American Society for Microbiology. For example, the carrier was no longer covering the only test available for diagnosing herpes and encephalitis. Discussions with TrailBlazer led to the current draft LMRP, she says, calling the effort a process that should be a template for addressing such matters. ASM intends to ask the Centers for Medicare & Medicaid Services to develop a national coverage decision "based on all the work that went into this."

Privately, medical directors for other carriers say they tend to follow TrailBlazer's lead on pathology- and lab-related coverage issues due to Burken's background as a board-certified clinical pathologist. Burken tells *NIR* that even though he initially drafted the policy, it represents the consensus of all four TrailBlazer medical directors. If enough other carriers follow suit, this could lay the groundwork for a CMS national coverage decision, one medical director says.

"The policy is written in such a way as to accommodate adjudication of organisms with CPT codes with those that don't yet have a code," Burken tells *NIR*. It provides auto-adjudication for tests of coded organisms, while allowing manual adjudication for other organisms listed under certain non-specific codes. The LMRP includes a table that groups organisms by clusters of clinical features. For each cluster, organisms with CPT codes (and those without codes) are listed separately. For each organism with a CPT code, the policy cites the ICD-9 diagnosis codes that will be covered. See *www.trailblazerhealth.com/draftindex.asp?ID=29*.

Testing Targeted By The LMRP

The Trailblazer LMRP focuses on molecular diagnostic testing, including DNA or RNA-based analysis, with or without amplification/quantification, which provides sensitive and specific identification of diverse microorganisms in a more timely fashion than traditional culture-based methods. Such testing mainly uses three basic nucleic acid assay platforms:

- A standardized nucleic acid probe, or Nucleic Acid Test (NAT), which reacts directly with nucleic acids in the test sample to create a detectable endpoint;
- A Nucleic Acid Amplification Test (NAAT), which detects sample nucleic acid after amplification (such as by PCR), which increases diagnostic sensitivity by decreasing the lower limit of detection; and
- A NAAT test used to quantify the microorganisms present. This helps determine if therapy for HIV, hepatitis C and cytomegalovirus is reducing the circulating levels of the virus as intended.

Other techniques such as nucleic acid sequencing are used to assay anti-viral resistance signatures for HIV-1 and hepatitis C. Either genotypic or phenotypic analysis can allow therapy to be directed in response to such observed resistance markers.

Preventing Another Lab Quality Lapse At Maryland General

At a follow-up hearing late last month, members of a House Government Reform subcommittee mulled over how to forestall a recurrence of quality failures in the clinical laboratory at Maryland General Hospital in Baltimore, including better coordination of state, federal and private accrediting oversight. The lab reported invalid HIV and hepatitis C test results over a 14-month period ending in August 2003, despite passing state and private inspections; the incident came to light because of internal whistleblowers (*NIR, 25, 16/Jun 7, '04, pp. 4-6*).

The subcommittee's ranking Democrat, Rep. Elijah Cummings (MD), whose district includes the hospital, said it was "disturbing that the process for detecting deficiencies was so easily circumvented." The College of American Pathologists, which provides CLIA accreditation for the hospital lab, has come under fire for not detecting the problems earlier. But CAP president Mary Kass, MD, FCAP, told the hearing that "based on the state's report, we have concluded that neither our inspection process nor any other would have detected these problems without the benefit of the whistleblower complaint information." For this reason, CAP will soon require all its accredited labs to notify employees how to report problems to a toll-free number. It is also considering adding some "red flag" questions on its checklists and conducting more on-site follow-up surveys, instead of paper follow-up.

washington WATCH

Lab reps for two major clinical lab groups switch DC law firms and take their association clients with them ….. **Peter Kazon**, who practiced with Hope Foster at Mintz Levin and prior to that at O'Connor & Hannan, is now a senior counsel at Alston & Bird, the firm that hired former Medicare chief **Tom Scully** after he shepherded the Medicare reform law through Congress last year. Kazon, who will remain general counsel for the American Clinical Laboratory Association, is the third lab-savvy lawyer to join Alston & Bird after a stint with Mintz Levin. The others are **Erin Darling** and **Colin Roskey**. Between law-firm jobs Roskey had a key role in the Medicare debate as health policy adviser and counsel to the Senate Finance Committee ….. **Robert Waters**, previously a partner with Arent Fox, has now become a partner with the health law dept. of Gardner Carton & Douglas. He will continue to represent the American Association of Bioanalysts and play a lead role with the Laboratory Coalition.

Reminder: August is a one-issue month for *NIR*.

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