



NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 26th Year of Publication

Vol. 26, No. 3, November 8, 2004

Medicare To Raise Pathology, Other Physician Fees

The final rule establishing the 2005 physician fee schedule is to be published in the Nov. 15 Federal Register and will be effective Jan. 1

The Centers for Medicare & Medicaid Services on Nov. 3 announced that under the final Medicare physician fee schedule for 2005, aggregate spending for physician services will increase 4%, to \$55.3 billion, from \$53.1 billion this year. The rise is due in part to the 1.5% update mandated by last year's Medicare Modernization Act (MMA), which prevented a scheduled 3.3% cut. The impact of the physician fee increase on a particular specialty will depend on its Medicare payment locality and its patient mix/volume.

For pathologists and independent laboratories, the fee hikes are as proposed earlier this year—roughly 4% and 8%, respectively. The pathology boost includes the 1.5% update, as well as adjustments to relative values, including practice expense gains based on a survey from the College of American Pathologists. The increase in physician fees for independent labs (about 20% of their Medicare revenue) includes 6% from the CAP survey and the 1.5% update.

Regarding the "pod" lab controversy, CMS agreed there is a potential for fraud and abuse and is amending the reassignment rules to clarify other obligations under Medicare anti-kickback and Stark → p. 2

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GOP Wins Herald More Market-Based Medicare

With President Bush reelected and an expanded, more conservative, GOP majority in the House and the Senate, political analysts expect a renewed push to convert more of Medicare to managed care and to establish other market-based approaches such as competitive bidding.

Observers also anticipate reinvigorated efforts to protect physicians from medical liability and to increase the number of Americans who rely on tax-free health savings accounts to cover their medical costs.

Analysts expect the Senate's Democratic minority, reduced to 44 members, to nevertheless continue blocking major legislation and forcing compromises by threatening to use stalling tactics that require 60 votes to overcome.

As the federal budget deficit continues to widen, Congress is likely to look for potential savings in expensive programs such as Medicare. That's why the spectre of a 20% lab co-pay could reappear, says attorney Colin Roskey with Alston & Bird in Washington, DC. 🏛️

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Medicare To Raise, from p. 1

self-referral statutes, as well as Medicare rules for purchased diagnostic services and “incident to” services.

In a separate announcement, CMS said that Medicare outpatient PPS payments will get a 3.3% update in 2005, to \$24.6 billion compared to \$23.1 billion in 2004. Also, when the “Welcome to Medicare” initial physical checkup is furnished in a hospital outpatient department, Medicare will pay the facility about \$78; the physician’s professional service is separately payable under the Medicare physician fee schedule. The outpatient PPS rule will be published in the Nov. 15 Federal Register

Beginning Jan. 1, 2005, Medicare will cover several new lab Part B screening benefits, as required by the MMA:

- ❑ Cardiovascular blood screening tests: While the MMA allowed coverage every two years for approved tests (total and HDL cholesterol, plus triglycerides), CMS retained the once-every-five-year limit it previously proposed. The agency declined to cover high-sensitivity C-reactive protein, but left the door open to requests to add it via a national coverage decision (NCD).
- ❑ Diabetes screening: CMS opted to keep its proposed two-tier approach to testing frequency—for those with pre-diabetes, once a year; for all others, once every two years. The agency declined to add C-peptide testing, reserving it for diagnostic evaluation, but did agree with the American Society for Clinical Pathology to cover CPT 82950—glucose; post glucose dose (includes glucose). CMS said the proposed exclusion was an oversight. But CMS nixed a request from the American Clinical Laboratory Association that Medicare should cover all the ICD-9 diagnosis codes on the NCD routine screening list that currently result in a diabetes denial.

Medicare also will begin to cover an initial physical examination for beneficiaries who obtain Part B coverage on or after Jan. 1, 2005, but only during the first six months of their coverage. In key changes from the proposed benefit, physicians can get paid separately for the screening electrocardiogram, in addition to payment for the physical; and doctors can bill for a more extensive office visit at the time of the physical, if medically necessary. There’s a catch though, CMS acknowledges. Physicians probably will have to “welcome” beneficiaries with an Advance Beneficiary Notice to alert them that they may be liable for the full cost of the physical. That’s because doctors aren’t able to determine independently when people join Medicare and whether they have since received other initial physical exams. 🏠

HHS Genetic Testing Panel Punts On Coverage, Payment

Elsewhere within HHS, a rule that would propose to establish a genetic testing specialty under CLIA continues to languish in the final approval process (see NIR, 25, 14/ May 10, ‘04, p. 3)

The top-level committee that advises Health & Human Services Secretary Tommy Thompson on genetic issues has deferred acting on its top priority: finding ways to improve coverage and reimbursement for genetic testing. At its Oct. 18-19 meeting in Bethesda, MD, the Secretary’s Advisory Committee on Genetics, Health & Society reviewed a 77-page draft report by its Coverage and Reimbursement Task Force that was chock full of ideas, such as:

- ❑ Expanding the Medicare benefit for preventive services.
- ❑ Urging CMS to issue a rule clarifying that genetic tests are diagnostic, not screening, in the presence of a strong family history of a disease.
- ❑ Recommending that the “inherent reasonableness” authority be used to increase Medicare reimbursement for genetic tests.

However, the more the committee deliberated, the more questions it raised. The task force will work on the draft report some more, and the committee will have another go at it when it meets again in February. The plan is to publish the draft report for public comment after that meeting, then after reviewing the comments, approve a final report in October 2005. 🏠



CMS To Fix Purchased Diagnostic Test Problems

The solution affects laboratories, physicians, and independent diagnostic test facilities. Until further notice, they must bill their local carrier for all purchased diagnostic tests and interpretations, regardless of where the service was furnished

The Centers for Medicare & Medicaid Services is taking steps to resolve a billing problem that has arisen over the past year for pathologists and other physicians/suppliers who purchase diagnostic tests/interpretations payable under Medicare's Part B physician fee schedule. The problem flows from a CMS policy against billing Medicare globally for these services where a provider in one carrier area performed the technical component, while a provider in another carrier area handled the professional component, says attorney Peter Kazon, senior counsel at Alston & Bird (Washington, DC).

Effective last Apr. 1, these providers were barred from billing the out-of-jurisdiction portions to their own carriers; they also could not bill the carrier for the entity that performed the service, unless they got a provider number from that carrier. But enrollment restrictions have meant many weren't getting paid, CMS notes.

The agency has a 2-step fix. The first is temporary. Effective this Nov. 22, providers who purchase out-of-jurisdiction diagnostic tests/interpretations must bill their local carrier for these services, regardless of where the service was furnished; they may no longer use provider ID numbers issued by out-of-jurisdiction carriers (CMS Change Request 3464, Oct. 24, 2004). To determine who has jurisdiction over the claim and the correct amount to pay, carriers are to use the zip code of the billing facility.

Carriers also are to inform affected providers that they won't be penalized by the HHS Office of Inspector General. If the carrier determines (during claim review, for example) that the service was performed at a location other than the one indicated on the claim, the carrier must hold the provider harmless for this discrepancy and may not deny the claim on this basis. For audit purposes, the provider must maintain supporting documentation that the service was purchased and where it was performed.

The second, long-term fix takes effect Apr. 1, 2005. CMS will establish a "national abstract file" of the CPT/HCPCS codes on the physician fee schedule that are billable as a purchased diagnostic test/interpretation, for every U.S. payment locality. Carriers must use the file for the listed tests billed by providers under its jurisdiction for work performed elsewhere. CMS will hold the billing provider responsible for ensuring that the out-of-jurisdiction provider is enrolled in Medicare and is in good standing (Change Request 3481, Oct. 29, 2004).

Also as of Apr. 1, 2005, carriers are to establish a duplicate claim edit for diagnostic test claims referred to facilities in other jurisdictions, whether paid via the Part B laboratory or the physician fee schedule. This edit will look for instances where both facilities filed claims with their own carrier for the same tests, and will deny the second one found (Change Request 3551, Oct. 29, 2004). C.R. 3551 includes a draft list of applicable purchased diagnostic services paid under the physician fee schedule, including 72 CPT codes from 84182 to 89060. CMS plans to issue a test abstract file in December for planning purposes. The pre-implementation contact at CMS is Susan Webster, 410-786-3384. 



focuson: Healthcare Technology

In Pursuit of a National Electronic Health Record System

Legislation to provide more seed money has bipartisan support in the House and the Senate, but allocating the funds may prove difficult, as the growing federal budget deficit squeezes spending for discretionary and entitlement programs

Imagine a medium other than paper that would be “consumer-centric”—following patients wherever they go—as well as “information-rich”—giving clinicians and other caregivers the latest data on a patient’s health status, laboratory tests, pathologist interpretations, prescription medications and potential allergic reactions.

That’s the promise of electronic health records (EHRs), with its enticing potential for healthcare quality and savings. And it’s no longer a pipe dream. Ever-increasing computer power and connectivity have brought the dream within reach, and efforts are underway to make it a workable reality.

Impetus from the Feds

In the currently fragmented U.S. healthcare system, it has proven impossible for any single player—hospitals, health insurers, information technology (IT) vendors, and the like—to set standards like those that enable credit card transactions worldwide. But many think the Federal Government has the necessary clout to get the job done. It serves a larger market share than any other player—providing coverage to some 53 million via Medicare, the Departments of Defense and of Veterans Affairs, and the Federal Employees Health Benefits Program. And Congress can mandate standards for electronic data exchange throughout the healthcare sector, as it did in 1996 when enacting HIPAA (the Health Insurance Portability & Accountability Act).

Federal involvement has already increased dramatically. In his 2004 State of the Union address and in an Apr. 27 executive order (No. 13335), President George W. Bush called for adoption of an EHR system within a decade, and in May appointed a healthcare IT czar, David Brailer, MD, PhD, to kick-start the process. In July, Health & Human Services Secretary Tommy Thompson unveiled a strategic report from Brailer’s office that said IT could reduce national healthcare spending by 10%, while improving care and giving providers added support. To date, however, only 13% of hospitals and 14-28% of physician practices have adopted EHRs. The report comes after many EHR initiatives dating back to the Institute of Medicine’s 1991 Computerized Patient Record Study, updated in 1997.

Legislative Outlook

On Capitol Hill, key congressional staff expect a renewed bipartisan legislative push next year to expand and improve healthcare IT efforts. Several related bills are pending in the current 108th Congress. Most aren’t given much chance of passage in the lame-duck session ahead, but could be re-introduced in the 109th Congress that opens in January.

The House on Mar. 12, 2003, passed a patient safety bill (H.R. 663) that promoted investment in healthcare IT. A Senate version (S. 270), passed on July 22, 2004, lacked

any similar provisions. Meantime, members of the Senate Health, Education, Labor & Pensions (HELP) Committee have unveiled two freestanding healthcare IT bills. One, S. 2710, was introduced July 21 by HELP chairman Judd Gregg (R-NH). The Democratic alternative was introduced Oct. 6 by Christopher Dodd (CT) and co-sponsored by HELP's ranking Democrat, Edward Kennedy (MA). The bills are very similar—for example, they back voluntary healthcare IT standards as well as grant and loan programs for EHR systems. The main difference? Dodd's bill would

elevate Brailer's office to the White House and authorize about \$250 million per year over fiscal years 2005-2010 (\$1.5 billion total); Gregg's bill proposes \$50 million per year over that time period (\$300 million total).

Advantages Touted for EHRs

The perceived advantages of establishing electronic health records throughout the healthcare system and making them interoperable are many. For example, it could:

- Eliminate duplicate lab testing, estimated to account for 20% of all tests.
- Reduce medication errors by an estimated 55%.
- Avoid one in seven hospitalizations.
- Provide real-time clinical decision support.
- Give payers the data needed to offer physicians quality incentives.
- Enable public health authorities to detect infectious disease outbreaks and bioterror attacks in real time.

Sources tell *NIR* that HELP committee staff are working to resolve the differences, with a view toward re-introducing the legislation next year. Its best chance of passage is likely to be as an attachment to a widely anticipated bill making "technical corrections" to the Medicare Modernization Act of 2003

(MMA) and also providing additional funding for some programs along with provider payment cuts. The MMA authorizes \$50 million in 50% matching grants in fiscal 2007 for physicians who adopt electronic prescribing tools and also calls for care management demonstrations that reward doctors for adopting EHRs and other ITs. Rep. Nancy Johnson (R-CT), who chairs the House Ways & Means health subcommittee, has signaled her desire to add healthcare IT incentives to Medicare reform legislation next year.

Bringing Physicians on Board

Physicians have proven reluctant to invest in EHRs because of the upfront costs and because they expect little economic benefit in return. Mindful of this barrier, the Bush Administration has directed HHS and the Office of Personnel Management to develop incentives to get physicians to adopt EHRs, and for the Departments of Defense and of Veterans Affairs to offer use of their health information systems in rural and underserved communities. And the San Francisco-based Health Technology Center has called for creation of a federal revolving loan fund to help physician practices acquire EHRs.

Paying for Performance

Much of today's thinking at the Centers for Medicare & Medicaid Services revolves around incentives similar to those of the Leapfrog Group's ambulatory care initiative and the later Bridges to Excellence initiative, which reward physician groups with publicity and reimbursement bonuses for investing in EHRs. CMS is talking about expanding its pay-for-performance initiative, which debuted this year to reward hospitals for quality care. Physicians acquiring EHRs would qualify for additional performance incentives. CMS could tap into the expanded clinical data flow from EHRs to reward best practices, such as timely screening tests. Reimbursement for other physicians could be reduced to keep the scheme budget-neutral.



Healthcare IT could reduce lab test ordering by 9-15% and trim ancillary test charges by up to 8%, according to studies cited by HHS. At the Departments of Defense and of Veteran Affairs, use of computerized physician order entry systems has "largely eliminated lost laboratory reports ... and the duplication of tests"

Stronger incentives are possible, if needed. CMS could increase payment for physicians who use EHRs, perhaps via evaluation/management service modifiers or new HCPCS codes. Or the government could underwrite insurance to protect physicians from the financial and liability risks of implementation failure.

Medicare could condition a provider's participation on use of EHRs, while Defense and the VA could make it a contract requirement. Such tighter requirements may be necessary for "late adopters," but could disrupt access to care at this early stage in EHR development. There is some belief that physicians resist going electronic partly to avoid leaving a clinical decision-making trail that medical liability lawyers could one day use against them. Accordingly, EHR advocates would like federal liability relief to protect only physicians who use EHRs.

Building the Information Infrastructure

The Center for Information Technology Leadership (Wellesley, MA) last February estimated that a standardized health information exchange enabling data-sharing among EHR systems would save the U.S. healthcare sector \$86.8 billion a year. Such an exchange would require seed money and is the focus of current federal efforts, said William Yasnoff, MD, PhD, FACMI, at the Health Information Technology Summit held Oct. 20-23 in Washington, DC. He is senior advisor to HHS' National Health Information Infrastructure Initiative.

As envisioned in a groundbreaking 2001 report by HHS' National Committee on Vital & Health Statistics, this exchange would rely on local health information infrastructures (LHIIs). Here's how it would work: local physicians would request patient records from their LHII system. The system would use its index of patient records to retrieve hospital records, laboratory test results, and specialist records into a "temporary aggregate patient history," which it would deliver to the physician. The system also could forward the request to other LHIIs, which would reply with whatever data might be stored in their areas.

Lab Groups Determined To Play a Role Upfront

Establishing an electronic healthcare infrastructure is a slow-moving process, involving a huge cast of players from government and the private sector, including insurers, hospitals, medical specialties, other providers, and consumer groups. And clinical laboratory interests are keenly aware of the importance of taking part in how the infrastructure is developed to assure that what's built works for them.

This point was driven home by what happened with the HIPAA standards for electronic transactions and code sets. One provision would have barred payment for any tests billed unless the claims were fully and correctly filed, with data such as the patient's address and the relevant ICD-9-CM diagnosis codes. The American Clinical Laboratory Association and others persuaded Medicare to temporarily allow continued processing of imperfect claims. Many private insurers followed suit.

ACLA drew a lesson from that experience—clinical labs had been absent from the industry standard-setting discussions that resulted in the troubling provision. The association has since taken steps to get a seat at the table where the national health information infrastructure is being crafted.

Congress approved \$50 million for HHS' Agency for Healthcare Research & Quality to spend on projects demonstrating LHIIs in fiscal 2004, which ended last Sept. 30, and the Bush Administration has requested an additional \$50 million for such pilots in FY 2005. Also, HHS' Health Resources & Services Administration has launched a Connecting Communities for Better Health grant program. Meanwhile, Health Level 7, a healthcare standards development organization based in Ann Arbor, MI, has devised a draft standard functional model for EHR systems for trial use over a two-year period.

HHS is expected soon to issue a request for information, inviting private-sector consortia to respond with plans for local or regional health information networks. 🏠



◆ CODING A · D · V · I · S · O · R · Y

CPT Pathology/Lab Codes, 2005: Additions, Revisions & Deletions

Dial in on Nov. 18 for our "hot topic" audioconference, *No Room for Error: Preparing for 2005 Lab & Pathology Coding Changes*, featuring coding expert Diana Voorhees, who heads DV & Associates (Salt Lake City, UT). Seize this opportunity to get up to speed on changes necessary by Jan. 1.

The 90-minute session runs from 2:00-3:30 p.m. (Eastern). To register, call 800-401-5937, ext. 2 or visit our Website, www.g2reports.com

The CPT coding update, effective Jan. 1, 2005, adds 19 new codes to the Pathology & Laboratory Medicine Section (80000 series), including 11 payable under the Medicare Part B lab fee schedule (marked below with an asterisk *) and eight payable under the physician fee schedule (**). Revisions to existing codes affect six codes in chemistry, hematology/coagulation, immunology, and microbiology, and two in surgical pathology. Within revised codes, the deleted language appears with a strikethrough, while the new text is underlined. Reminder: The coding changes must be implemented Jan. 1. Medicare will no longer grant a 90-day grace period to make the changes (*NIR*, 26, 2/Oct 25, '04, p. 7). 🏠

CHEMISTRY

Codes added

- 82045* Albumin; ischemia modified
- 82656* Elastase, pancreatic (EL-1), fecal, qual. or semi-quant.
- 83009* H. pylori, blood test analysis for urease activity, non-radioactive isotope (eg, C-13)
- 83630* Lactoferrin, fecal, qual.
- 84163* Pregnancy-associated plasma protein-A (PAPP-A)
- 84166* Protein; electrophoretic fractionation and quantitation, other fluids with concentration (eg, urine, CSF)

Codes revised

- 83013 H. pylori; breath test analysis for urease activity, non-radioactive isotope (eg, C-13)
- 83014 H. pylori; drug administration ~~and sample collection~~
- 84165 Protein; electrophoretic fractionation and quantitation, serum

HEMATOLOGY & COAGULATION

Code revised

- 85046 Blood count; reticulocytes, hemoglobin concentration automated, including one or more cellular parameters (eg, reticulocyte hemoglobin content (CHR), immature reticulocyte fraction (IRF), reticulocyte volume (MRV), RNA content), direct measurement

IMMUNOLOGY

Codes added

- 86064* B cells, total count
- 86335* Immunofixation electrophoresis; other fluids with concentration (eg, urine, CSF)
- 86379* Natural killer (NK) cells, total count
- 86587* Stem cells (ie, CD34), total count

Code revised

- 86334 Immunofixation electrophoresis; serum

MICROBIOLOGY

Code added

- 87807* Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus

MICROBIOLOGY (continued)

Code revised

- 87046 Cultural, bacterial; stool, aerobic, additional pathogens, isolation and presumptive ID of isolates, each plate

CYTOPATHOLOGY

Codes added

- 88184** Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
- 88185** each additional marker (list separately in addition to code for first marker)
- 88187** Flow cytometry, interpretation; 2 to 8 markers
- 88188** 9-15 markers
- 88189** 16 or more markers

SURGICAL PATHOLOGY

Codes added

- 88360** Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semi-quant., each antibody; manual
- 88367** Morphometric analysis, in situ hybridization (quant. or semi-quant.), each probe; using computer-assisted technology
- 88368** manual

Codes revised

- 88361 ~~tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semi-quant.; using computer-assisted technology~~
- 88365 Tissue In situ hybridization (eg, FISH), interpretation and report each probe

Code deleted

- 88180 Flow cytometry; each cell surface, cytoplasmic or nuclear marker (To report, see 88182, 88189)

Source: CPT 2005 © American Medical Assn.



Medicare to Provide More Info on Claims Denials

The change is aimed at directing beneficiaries to the specific coverage policies that prohibit reimbursement

Beneficiaries who get notices from Medicare that their Part B lab claims are denied because of local or national coverage limits are slated to get more information next year on why the claims were rejected.

On Oct. 22 the Centers for Medicare & Medicaid Services instructed its local carriers to get ready for the change. The instructions in Change Request 3363 apply to Medicare Summary Notices (MSNs) regarding claims that were denied in part or in full because of local medical review policies (LMRPs), local coverage determinations (LCDs), or national coverage determinations (NCDs).

Part B carriers must be prepared by Apr. 4, 2005, to auto-fill such MSNs with the relevant LMRP/LCD identification numbers or NCD numbers. CMS said there will be an additional phase for testing and documentation before carriers begin exercising this new capability.



Surprise Lab Survey Legislation Proposed

Prior notice for lab accreditation surveys would be forbidden under legislation Rep. Elijah Cummings (D-MD) introduced last month. Though no action is likely in the coming lame duck session, an aide said Cummings will reintroduce it in the 109th Congress, which convenes in January. The Clinical Laboratory Compliance Improvement Act of 2004 (H.R. 5311) is the latest fallout in the controversy over whistleblower allegations of quality failures at Baltimore's Maryland General Hospital, located in Cummings' district (National Intelligence Report, 25, 16/June 7, '04, pp. 4-6). The bill also would make labs encourage whistleblowing and require lab regulators to share information better.

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Currently, MSNs state whether one or more LMRPs were involved in particular claims denials, but don't identify which LMRPs were used (as per the original Change Request 2916, Oct. 28, 2003). CMS addressed only LMRPs in order to resolve litigation focused on them. The new notice covers LCDs, which were established Nov. 7, 2003, about a week after the original change request, as well as NCDs, because the agency believed that adding this information made sense, the agency said in a "frequently asked questions" notice. 🏠

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