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CMS Affirms Conservative Stand On CBC Reflex Billing

The issue arose after CPT 85023, Automated CBC with manual differential, was discontinued at the start of 2003, leaving labs unsure how to bill correctly for the procedures and avoid the risk of potential Medicare fraud allegations

The Centers for Medicare & Medicaid Services has provided a definitive answer at last to a question that has bedeviled lab billing personnel for the last few years—how should Medicare Part B be billed for a complete blood count with automated differential when the results are abnormal or inconclusive, requiring that a manual differential be performed?

The answer, in a nutshell, is that the reflex manual differential is not separately billable. Responding to a query from Carl Faulstick of Affiliated Healthcare Systems (Bangor, ME) during the April 25 lab open-door forum hosted by CMS, agency official Anita Greenberg said CMS has changed its National Correct Coding Policy Manual for Medicare Carriers to address this issue. The manual now says "it would be inappropriate to report a confirmatory test separate from the ordered CBC test," she noted.

Laboratory consultants have differed on how—or whether—to bill for the manual differential after the American Medical Association discontinued CPT 85023 (*National Intelligence Report, 25, 4/Nov 25 '03, pp. 5-6*). Many labs had used this code to bill for an automated CBC with a manual differential. In 2002, the code ranked 45 among ➥ *p. 2*

Worries Over P4P Aired At Lab Quality Forum

The head of the Medicare program has tossed a few more logs on the bonfire of expectations over healthcare provider pay-for-performance (P4P) initiatives, but many experts, including those in lab medicine, have reservations about how they will translate into better patient care.

Median quality scores at 270 hospitals in a three-year demonstration by the Centers for Medicare & Medicaid Services and Premier Inc., a group purchasing organization, increased 12% for heart failure and 3%-10% for four other conditions in just the first year, said CMS head Mark McClellan, MD, PhD, on May 3.

But quality experts who gathered in Atlanta late last month at a conference held by the Institute for Quality in Laboratory Medicine raised a variety of concerns about P4P. It's much easier to set and meet specific performance objectives than to improve patient care, they said—and there can be a big difference. Also, the proliferation of multiple, conflicting performance quality efforts in recent years has provided "a lot of signals, little direction," warned Kenneth Kizer of the National Quality Forum. For more on the IQLM conference, see the *Focus*, pp. 4-6.

INSIDE *NIR*

CBC Reflex Billing, *from p. 1*

the top 100 lab and pathology procedures in terms of volume, according to Medicare data analyzed by Washington G-2 Reports.

One interpretation was that when the automated results cannot be reported, this is not a true "reflex" situation, so a manual differential must be run to issue a report; in this case, a lab could bill 85027 and 85007, codes which reflect the old 85023. A conservative interpretation was that 85027 and 85007 should not be billed when a physician orders a CBC with differential (85025) in order to obtain payment for a manual diff. The reason: CMS considers the manual diff to be part of the procedure required to fulfill the physician's order. This approach, proponents said, was buttressed by CMS instructions citing 85007 among the component codes for CBCs with differential WBC testing and 85025 as the bundled code for a CBC with differential.

Coding consultant William Dettwyler, president of Codus Medicus (Salem, OR) has analyzed recently released CMS billing data compiled by *NIR* to find out which approach labs followed in 2003, the latest year for which data are available. He found that labs generally took the conservative approach, as the data showed neither a large increase in volume for 85007 nor reduced volume for 85025.

The Reflex Manual Diff: Relevant Policy Guidance

"If, after a test is ordered and performed, additional related procedures are necessary to provide or confirm the result, these would be considered part of the ordered test. For example, if a patient with leukemia has a thrombocytopenia, and a manual platelet count (CPT 85032) is performed in addition to the performance of an automated hemogram with automated platelet count (85027), it would be inappropriate to report codes 85032 and 85027 because the former provides a confirmatory test for the automated hemogram and platelet count (85027). As another example, if a patient has an abnormal test result and repeat performance of the test is done to verify the result, the test is reported as one unit of service rather than two."—Chapter 10, Pathology/Laboratory Services, National Correct Coding Policy Manual for Part B Medicare Carriers. Online at *www.cms.hhs.gov/physicians/cciedits/nccmanual.asp*

Open-Door Forum Sheds More Light On Key Lab Policy Issues

Along with the CBC reflex manual differential issue discussed above, a host of other major policies crucial to clinical laboratories were addressed at the open-door forum held April 25 in Washington, DC, by the Centers for Medicare & Medicaid Services. Among the highlights:

Getting Medicare Claims Processed & Paid

The CMS Office of Information Services is considering how it could change the Medicare Part B claims processing system to enable carriers to handle as many as eight ICD-9 diagnosis codes per claim. Currently, they can handle as many as four, but labs may have to submit as many as eight to get some claims paid. Labs have been using a workaround, submitting a claim a second time to add the fifth through eighth codes.

But as of July 5, Medicare carriers will deny the second filing, forcing a lab to file a paper appeal (*NIR, 26, 13/Apr 25 '05, p. 1*). For any given lab, "there would be thousands of claims a month to be appealed," said JoAnne Glisson, senior vice president of the American Clinical Laboratory Association. ACLA wants CMS to postpone the change until carriers can process eight ICD-9 codes per claim. Nonetheless, CMS plans to proceed as scheduled.

Also beginning July 5, providers must file all Part B claims in a HIPAA-compliant electronic format (there are some exceptions, as when Medicare is a secondary payer). For most labs and other providers, this means they will have to report all

ICD-9 codes to the highest degree of specificity to prevent their claims from being rejected as "unprocessable."

Lawlor asked clinical lab interests to e-mail information about their concerns over any additional paper v. Internet manual discrepancies to him at richard.lawlor@cms.hhs.gov

Discrepancies Between Paper & Internet-Only Manuals

Forum participants found out that Medicare's new Internet-only manuals trump the old paper-based manuals—except when they don't.

When CMS converted to the Internet-only manuals, "it wasn't just cut and pasted," said Richard Lawlor, director of the Outreach & Speech Writing Group in the CMS Office of External Affairs. "People tried to reword the language to make it more clear." So, as a general rule, he said, "if the Internet-only manual is completely different from what the paper manual said, it's the more accurate one," adding "if there is a wording change that has a nuance or more background, the Internet-only manual is supposed to be more accurate." But another CMS official (who did not identify herself) noted that according to a disclaimer on the agency's Website, if there is a discrepancy, the paper manual is the official policy.

Lawlor said that "when there was a major distinction or change intentionally made between the two, we should have issued some sort of release, whether it's a transmittal or change request, or that kind of thing, to go along with true policy changes that were meant to be there."

On specific discrepancies that have troubled clinical lab interests, CMS officials offered more detailed views (*see also NIR, 26, 11/Mar 21 '05, p. 4*):

• **Definition Of Non-Patient:** Jeff Boothe, the Holland & Knight attorney who represents the Clinical Laboratory Management Association, said this definition in the Internet-only manual is different from the paper manual. In the Internet-only version, non-patients become outpatients if a hospital phlebotomist draws their blood off-site, because this involves a "face-to-face" encounter. This has major implications for privacy safeguards, the collection of Medicare secondary payer information, and opportunities to bid under Medicare's upcoming competitive bidding demonstration for independent laboratory services. However, said Joan Proctor-Young of CMS, "What you see in the Internet-only manual now is our current reading of who is a non-patient."

• **SNF Blood Draws:** The paper manual had said that Medicare would pay labs that sent personnel to draw blood from residents, even if the skilled nursing facility had someone qualified on-site. The Internet manual says Medicare will only pay labs for the draws if they prove the SNF had no one qualified to do so on-site. Anita Greenberg of CMS said the old paper manual is correct. "I think that sentence is obsolete in the Internet-only manual."

Cytology Proficiency Testing: Further Guidance To Come

That's the word from the top CLIA official at CMS, Judy Yost, who told forum participants that the agency will develop additional guidance for its gynecologic cytology PT survey and enforcement policy "in the very near future." Meanwhile, she added, "Please encourage individuals and laboratories that you're aware of to enroll in the program and be tested on a timely basis." All personnel subject to gynecologic cytology PT must enroll in an approved program by June 30 and complete the initial test by December 31 of this year (*NIR, 26, 11/Apr 25 '05, p. 2*).

CMS got the message "loud and clear" from professional groups that it should update the CLIA cytology PT requirements to reflect current technology and terminology, Yost said. But formal rulemaking will take time and "We need to go through the first year's experience to see what the problems are."

focus on: Quality In Lab Testing

CDC Jump-Starts 'Best Practices' Lab Initiative

The quality standards that may emerge from the work of the IQLM could become a template for healthcare policy reforms linking lab reimbursement to recognized quality measures

The Institute for Quality in Laboratory Medicine (IQLM), a public-private partnership spearheaded by the Centers for Disease Control & Prevention, got heightened visibility and new momentum at a recent conference designed to showcase best practices and innovations in lab medicine and to recognize the contributions of organizations and individuals to the field.

The IQLM conference, held April 28-30 in Atlanta, GA, brought together leaders in quality improvement efforts from within and outside the lab medicine community. Proponents of the IQLM envision that it will bridge best-practice gaps that professional societies, by their very profession-specific nature, and regulatory agencies, by their very oversight-specific nature, cannot.

The IQLM got underway in 2003, with CDC providing initial support. CDC has since been working with the National Quality Forum to develop it further (*NIR, 25, 14/May 10 '04, p. 8; 26, 2/Oct 25 '04, p. 4*). The Forum is a nonprofit consensus standards-setting organization, incorporated in 1999, whose members include governmental bodies, health plans, consumer groups, and researchers.

CDC lab systems official Toby Merlin compared the Institute's boundary-transcending nature to his agency's recent reorganization where multiple separate units and strict hierarchical relationships were replaced with cross-cutting functions. The clinical lab also is a cross-organization function, not a silo, said Dennis O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations and one of 10 award recipients honored at the conference. "People who lead labs need to reach out and engage," he said.

Dropping The Ball

It's in the handoff between labs and clinicians where fumbles so often occur. Clinician Nancy Elder, MD, said the American Academy of Family Physicians' National Research Network recently found that 21% of 661 errors studied were in the ordering-and-implementation phase, and 18% were in the tracking-and-return phase. "These errors at the transition between lab and office were especially frustrating for primary care physicians," she said.

They're frustrating for laboratorians too. Brian Jackson, MD, MS, medical director of informatics at ARUP Laboratories (Salt Lake City, UT), knows that, based on inherited thrombophilia prevalence, his lab should get more orders for the cheaper Factor V Leiden test than for antithrombin proteins C and S. Yet, analysis of data that ARUP has been warehousing since 1997 shows that the lab gets fewer orders to test for the more common cause of this genetic disorder, which endangers fetuses with blood clots, indicating clinicians don't realize which test they should order. "Traditionally, we took the position that it's the responsibility of the clinicians to know what test to order and to read them appropriately," he said. "But it's not."

"The IQLM and managed care share many goals," said Robert Kropp, MD, of Aetna Health Inc. Managed care needs more access to lab data to improve outcomes and quality, he noted, mainly through assessing the appropriateness and effectiveness of care in disease and case management programs. Using MedQuery software, Aetna analyzes lab and other data to develop recommendations to physicians on how to improve patient safety

Michael Laposata, MD, PhD, another award recipient honored for his work in systematically communicating the meaning of lab test results to treating physicians, said the failure to do so can be tragic. Laposata, who directs clinical labs at Massachusetts General Hospital in Boston, cited the case of a pregnant woman who followed her obstetrician's recommendation for an abortion because he saw that her Protein S was low, indicating hypercoagulability. She later learned from Laposata that her blood coagulated normally, Protein S is always low during pregnancy, and she could have kept her baby.

"There are 30 reasons why clinicians order lab tests, four or five of them valid," said another award recipient, George Lundberg, MD, editor of Medscape and former editor of the *Journal of the American Medical Association*. The key to pre- and post-analytic quality is to find out "why did somebody order this—will it be useful, wasteful, or harmful?"

Survey Identifies Key Quality Issues

Clinical laboratories have always been in the vanguard of healthcare quality—but mainly in the analytical process. They have been isolated, perhaps by preference, from the surrounding chaos of healthcare. But it is increasingly clear that labs must play a much more active role in the delivery-of-care process if they are to make significant improvements in cost containment and health outcomes.

Much of this was brought into focus by a Web-based survey that the Clinical Laboratory Management Association conducted among its members. The aim was to give IQLM's Networks Committee a snapshot of quality management in hospital labs. Of 2,301 labs surveyed in November 2004, a representative group of 572 (25%) responded.

The key finding—shared at the conference by committee member Julie Gayken, MT (ASCP), administrative director of lab services for Regions Hospital in St. Paul, MN—is that hospital labs have strong quality management programs in areas required by regulation or patient safety goals, which typically focus on the analytic process. But they are weak in pre- and post-analytic areas that involve communication with others, such as clinicians, patients, and anyone responsible for ensuring that tests are used appropriately. Also, many labs lack guidelines for intervening if quality declines. Some highlights of the survey:

THE THREE MOST/LEAST IMPLEMENTED OF 25 QUALITY MANAGEMENT COMPONENTS ARE:

Most implemented		*Least implemented*	
Proficiency testing program	99.7%	Guidelines for physicians for testing	14.2%
External assessments	97.7%	Institutional rules for routine tests	9.8%
Instrument and reagent QC program	96.5%	Rules that limit esoteric testing	4.9%

SEVEN LEAST-TRACKED OF 30 QUALITY INDICATORS ARE IN IQLM PRIORITY AREAS:

Adequacy of information to interpret lab results	33.6%
Ordered test is appropriate for patient care	31.0%
Test utilization for best patient care	28.5%
Cost/benefit assessments	25.5%
Patient consent/shared decision-making	25.3%
Clinical and preventive action	11.9%
Result interpretation by clinician/patient	8.0%

What forces have put quality and pay-for-performance efforts high on the national healthcare agenda? New knowledge of quality deficiencies, rising healthcare costs, purchaser activism, and healthcare consumerism, said Kenneth Kizer, who heads the National Quality Forum

Societal Benefits Of Lab Innovation Quantified

Frank Lichtenberg of Columbia University and the National Bureau of Economic Research said he determined that clinical laboratory innovation accounted for 12% of the 3.57-year increase in mean age at death from 1979 to 1998. He figured the cost per life-year gained thereby was less than $20,000—well below the cost-effectiveness thresholds proposed by most medical decision-makers.

Similarly, Lichtenberg found that clinical lab innovation improved the quality of life. From 1982 to 1996, it reduced the probability that medical conditions would render someone unable to work to 4.7% from 6.4%. And the per-capita cost of this innovation was so low there would be a net savings for anyone thereby able to earn at least $1,882 per year, well below the 1996 average annual employee compensation of $34,000.

Pay-For-Performance Greeted With Skepticism

Many speakers at the conference were alarmed by the growing enthusiasm over pay-for-performance (P4P). Too many organizations are coming out with too many different performance measures, said JCAHO's Dennis O'Leary. "This is a measure food fight. It is not going to create anything useful except more waste."

Without electronic health records, hospitals are limited in what performance measures they can report. Under JCAHO's ORYX system, that limit is three measures reported on a quarterly basis, O'Leary said. Worse, the government's idea of P4P would exacerbate quality shortfalls, he added, by removing resources from providers who cannot afford the IT solutions needed for improvement, eventually creating an access problem.

Another IQLM award recipient—David Eddy, MD, PhD, an Aspen, CO, consultant—cautioned that the healthcare sector has only a qualitative understanding of the costs and benefits of quality. Consequently, it is unclear how much to pay for what performance on what measures. "I don't think the methodology is up to the task."

Another award recipient—Kenneth Kizer, MD, MPH, president and CEO of the National Quality Forum—cautioned that P4P is coming nevertheless. But "across the board, labs are not part of the discussion. No one's even thinking about them in how the dollars are being divided up. Lab medicine needs to be at the table."

What's Ahead For The IQLM

The IQLM's leading proponent, CDC's Joe Boone, PhD, said that coming soon is:

- ❑ Incorporation of the Institute as a 501c(3) non-profit organization in Virginia.
- ❑ An initial board of directors meeting.
- ❑ A succinct "elevator speech" describing the organization and its mission.

The Institute also will continue to evaluate quality indicators, develop networks to collect information, craft and post national report items, foster research and mentoring programs, and formulate best practices.

Boone said that the IQLM intends to hold a series of conferences with the National Quality Forum over the next two years on what quality laboratory services mean to the Forum's member organizations, what would be the best quality indicators and performance measures, what is the utility of tests now used in lab services, and what would be appropriate quality incentives.

However, Boone cautioned, "We do have a question about resources." CDC will continue to provide seed funding and technical assistance over the next two years. But the long-term goal is to have the private sector step up to sponsor projects and activities or to provide financial or in-kind support.

Hospitals That Report Quality Data To Get Medicare Pay Hike

The performance quality data include measures related to heart attack, heart failure, and pneumonia (NIR, 26, 13/Apr 25 '05, p. 5). *More quality measures are being planned, including how hospitals are reducing the rates of hospital-acquired infections, said CMS head Mark McClellan, MD, PhD*

For the second year in a row, Medicare will reward acute-care hospitals that voluntarily report certain performance quality measures with the full market basket update to their inpatient prospective pay rates. Under a rule proposed in the May 4 *Federal Register*, these hospitals would get an increase of 3.2% beginning October 1 (the start of fiscal 2006). Hospitals that do not report would get 0.4% less.

The pay-for-performance hospital initiative, authorized by the Medicare Modernization Act of 2003, was launched in the current fiscal year. Of the nation's nearly 4,000 acute-care hospitals, 98% began reporting the quality data and got the full 3.3% update for FY 2005. The Centers for Medicare & Medicaid Services says 3,717 hospitals have already signed up to provide the data in FY 2006. The proposed rule would add requirements to improve the accuracy of the data reported. To win the full pay update, hospitals will have to correctly abstract and report clinical data. And they will need to have at least two consecutive quarters of publishable data.

The proposed rule also noted that CMS would address in its report to Congress the recommendations by the Medicare Payment Advisory Commission to (1) extend the current moratorium on physician-owned single specialty hospitals (set to expire this June 8) until January 1, 2007 and (2) have Congress give the Health & Human Services Department the authority to allow gainsharing arrangements between physicians and hospitals and to regulate these arrangements to protect quality of care and minimize financial incentives that could affect physician referrals.

♦CODING A·D·V·I·S·O·R·Y

Laboratory coding and billing personnel should get ready for changes, effective July 1, in the ICD-9-CM diagnosis codes for testing that is subject to Medicare's lab National Coverage Decisions.

Added

• Thyroid testing
—733.02, Idiopathic osteoporosis.
• Tumor antigen by immunoassay CA 19-9:
—156.0, Malignant neoplasm of the gall bladder
—156.2, Malignant neoplasm of the Ampulla of Vater
• Tumor antigen by immunoassay CA 125
—789.39, Abdominal or pelvic swelling, mass or lump of other specified site
• Blood counts:*
—V77.1, Special screening for diabetes mellitus
—V81.0, Special screening for ischemic heart disease
—V81.1, Special screening for hypertension
—V81.2, Special screening for other unspecified cardiovascular conditions

Deleted

• Hepatitis panel
—784.69, Other symbolic dysfunction

*Of the current lab NCDs, only the one for blood counts uses an "exclusionary" approach. Instead of listing the covered codes that support a test's medical necessity, it lists codes that do *not* support medical necessity; if a code is on the list, the code is considered covered.

Budget Deal Okays Medicaid Spending Cuts, New Commission

Though Medicare cuts are off the table thus far, clinical laboratory interests want to be sure they stay off. Lab groups are already lobbying against any reimbursement cuts as well as any return of the co-pay, and are arguing against the lab fee update freeze, now set to run through 2008

Now that Congress has approved federal Medicaid spending cuts of $10 billion over five years, it will be up to a new Medicaid commission to suggest policy changes needed to achieve the savings. The cuts and the commission are part of the compromise budget blueprint for fiscal 2006 that Congress passed on April 28.

In the final deal, Congress settled on Medicaid cuts of $10 billion over FY 2006-2010, though none are required in 2006 (that's also the year when all members of the House and many Senators are up for re-election). The President had proposed a $14 billion cut over five years, starting in 2006; the House had approved a $20 billion cut over five years; the Senate had rejected any cuts (*NIR, 26, 11/Mar 21 '05, p. 1*).

The final budget authorizes $2.56 trillion in FY 2006 spending (up $80 billion over FY 2005), allows $106 billion more in tax cuts over five years, and leaves a $362 billion deficit. It includes increases for defense and homeland security, but cuts total appropriations other than for these purposes by almost 1%. The plan also creates a reserve fund for health information technology and pay-for-performance initiatives (*NIR, 26, 11/Mar 21 '05, p. 2*).

The budget deal passed by close margins in the House, 214-211, and in the Senate, 52-47. Most Democrats voted against the GOP-crafted final version because it approved Medicaid cuts in tandem with tax cuts. The budget sets target guidelines for spending ceilings and tax revenues; it's up to the committee that has jurisdiction to set specific funding levels and approve policy changes.

Call for Nominations

Laboratory Public Service National Leadership Award For 2005

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A nomination form and selection criteria are included with this issue and are also available online at *www.g2reports.com*

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