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Medicare Expands Lab Screening Benefits This Month

The added lab screening tests are payable under the Part B lab fee schedule at the same rates as when the testing is performed for diagnostic purposes, CMS notes

For clinical laboratories, the New Year dawned with some good news. As of January 1, Medicare began Part B coverage and payment of screening tests for cardiovascular disease and diabetes, along with a "Welcome to Medicare" physical examination for new Part B enrollees. The benefits were added to the Part B preventive service package by the Medicare Modernization Act of 2003, and the Centers for Medicare & Medicare Services recently sent instructions to its local contractors on how to implement the new coverage.

If enough seniors take advantage of the new benefits, it could have a significant impact on clinical laboratory revenue. Over fiscal years 2005-2009, CMS has projected additional spending of $660 million for the new lab screenings, plus $365 million for the physical exam. By comparison, previously approved screening benefits paid under the Part B lab fee schedule accounted for only $64.6 million in 2002, the latest year for which Medicare carrier data are available. ➥ *p. 2*

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Providers Under The Gun In New Congress

As the first session of the 109th Congress opened last week, the Washington scuttlebutt was not whether the White House and lawmakers will trim healthcare spending, but by how much and at whose expense, given the growing federal budget deficit, the costs of the war in Iraq, and tsunami aid pledges.

In this climate, lab interests will likely have to play defense on Capitol Hill, focusing their lobbying on why lab services should be spared the ax. Already, 26 hospital and specialty physician groups have sent a letter urging President George W. Bush not to back caps on Medicare and Medicaid spending in fiscal 2006.

Mark Hayes, a GOP Senate Finance Committee aide, has suggested that lawmakers may face budget reconciliation instructions to cut Medicare by $55 billion and Medicaid by $27 billion over the next five years. Plus, fixing the Medicare fee formula for pathologists and other physicians could require further cuts of $25 billion over five years and $90 billion over 10 years, he told a recent forum held by the Alliance for Health Reform and the Kaiser Family Foundation. On the Medicaid front, congressional aides anticipate a major battle as well, with the White House and the GOP Hill leadership expected to press for switching to block grant funding.

New Part B Screening Benefits, *from p. 1*

Coverage of the "Welcome to Medicare" exam also is expected to trigger more lab screening outlays as beneficiaries get referred for other lab testing that is separately payable under the Part B preventive services package.

Cardiovascular Disease Screening

CMS has instructed its local contractors to cover three blood screening tests for cardiovascular disease—total cholesterol, HDL cholesterol, and triglycerides. Beneficiaries are covered for the tests once every five years. The tests should be performed as part of a panel (CPT 80061, lipid panel), CMS advises, though physicians may still order the tests individually.

The CMS Common Working File will reject—and contractors won't pay—claims for any of the approved tests for beneficiaries who had been screened with the same test in the previous five years. Also, CMS will reject the lipid panel code 80061 for beneficiaries screened with any of its three component tests in the previous five years. Likewise, it will reject payment for the component tests for beneficiaries screened with the lipid panel over the same period.

The instructions on cardiovascular disease screening are found in CMS Change Request 3411 (December 17, 2004), *cms.hhs.gov/manuals/pm_trans/R408CP.pdf*. Contacts are Joyce Eng, 410-786-4619, and Joan Proctor-Young, 410-786-0949.

Diabetes Screening

CMS has instructed contractors to begin coverage and payment for a series of diabetes screening tests, including blood glucose, post glucose dose, and glucose tolerance. Coverage is limited to once a year for beneficiaries who are at risk for diabetes and who either have never been tested for it or were tested and found not to have either diabetes or pre-diabetes. Coverage is more frequent—twice a year—for beneficiaries diagnosed with pre-diabetes, defined as a fasting glucose level of 100 to 125 mg/dL or a two-hour post-glucose challenge of 140 to 199 mg/dL.

Under conditions of coverage, CMS defines beneficiaries at risk for diabetes if they have: hypertension, dyslipidemia, obesity, or previously identified elevated impaired fasting glucose or glucose intolerance. They also are at risk if they have at least two of the following characteristics: overweight, a family history of diabetes, age 65 or older, or a history of gestational diabetes mellitus or delivering a baby weighing more than nine pounds.

The agency said that it will later instruct contractors on a modifier "xx" to indicate which diabetes screening recipients have been diagnosed with pre-diabetes and therefore qualify for twice-a-year screening. As it stands, the Common Working File will deny claims for only two of the diabetes screening codes, 82947 and 82951, if the frequency exceeds six months—in effect, treating all the claims as if they were for pre-diabetics.

New Screening Benefits: *Covered CPT, ICD-9 Codes*

CARDIOVASCULAR DISEASE
ICD-9 codes: V81.0, V81.1, V81.2
CPT codes:
82465 ..... Cholesterol, total
83718 ..... HDL cholesterol
84478 ..... Triglycerides
80061 ..... Lipid panel (includes above tests)

DIABETES
ICD-9 code: V.77.1
CPT codes:
82974 ..... Glucose; quant., blood (except reagent strip)
82950 ..... Post glucose dose (includes glucose)
82951 ..... Glucose; tolerance test (GTT), three specimens includes glucose

"WELCOME TO MEDICARE" PHYSICAL EXAM
G0344 ..... Initial preventive exam
G0366 ..... EKG for initial prev exam
G0367 ..... EKG tracing for initial prev exam
G0368 ..... EKG interpret & report prev

The diabetes screening instructions are found in Change Request 3637 (December 21, 2004), *cms.hhs.gov/manuals/pm_trans/R409CP.pdf*. The contact for labs is Danford Layne, 410-786-3320; for coverage issues, Betty Shaw, 410-786-4165.

"Welcome to Medicare" Physical

This baseline physical examination for new Part B enrollees is covered and payable on or after January 1 for beneficiaries who receive it within the first six months after their Part B coverage began. By law, the exam must include a screening electrocardiogram, measurement of vital signs, a review of the beneficiary's medical and social history, plus potential risk for depression and decreased functional ability and safety. The exam is payable under the Medicare physician fee schedule and is subject to the deductible and co-insurance.

Though the benefit specifies no lab testing, the physician is to provide education, counseling, and referral to other screening and preventive services covered under Part B, including a brief written plan (such as a checklist) for obtaining these services. These services include not only the new cardiovascular disease and diabetes coverage, but also screenings for breast, vaginal, and cervical cancer as well as colorectal and prostate cancer, and glaucoma; diabetes outpatient self-management training; bone mass measurements; and medical nutrition therapy for beneficiaries with diabetes or renal disease.

Instructions on the baseline physical are found in Change Request 3638 (December 22, 2004), *cms.hhs.gov/manuals/pm_trans/R417CP.pdf*. Contact: Bill Larson, 410-786-4639.

'Pod' Labs Run Risk Of Kickback Sanctions, OIG Warns

"There is a significant risk that the proposed arrangement would be an improper contractual joint venture that would be used to reward the physician groups for their referrals," the HHS Office of Inspector General concluded

In a recent advisory opinion, the HHS Office of Inspector General sent a clear warning that parties involved in "pod" or "condo" laboratory joint ventures could face steep fines and/or Medicare exclusion for violating the federal anti-kickback statute. The opinion was hailed by lawyers and pathology advocacy groups concerned over the spread of such arrangements under which certain specialty physicians seek to increase revenue from pathology referrals.

The OIG said, in Advisory Opinion No. 04-17 (December 17, 2004; see *oig.hhs.gov*), that a proposed condo lab arrangement "could potentially generate prohibited remuneration under the anti-kickback statute." If the requestor proceeded with its plans, the OIG "could potentially impose administrative sanctions" such as civil monetary penalties or exclusion from Medicare.

In its analysis, the OIG said that physician groups could contract out substantially the entire pathology operation, enabling them to profit from their own pathology referrals without facing any business risks. The proposed condo lab could easily bill Medicare directly for the pathology services, so it only needs the specialty physicians for referrals and thus could be taking a pay cut to induce referrals.

While conceding that only the Centers for Medicare & Medicaid Services is authorized to say whether the proposed arrangement complies with the Stark restrictions on physician referrals, the OIG observed in a footnote that the arrangement could easily run afoul of its warning on contractual joint ventures. The careful steps

proposed to segregate space and equipment and account for the time that rotating pathologists and technicians spend in each lab would be for naught if the actual operation differs, resulting in inappropriate utilization and improper claims.

"To a large extent, the advisory opinion confirms what most healthcare lawyers had thought," attorney Jane Pine Wood, with McDonald Hopkins Co., LPA (Cleveland, OH), told the *National Intelligence Report*. The OIG, echoing Wood and other pathology advocates, including officials of the College of American Pathologists with whom it had met on this issue just days earlier, said it believes the proposed arrangement mirrors a type of suspect contractual joint venture described in a special advisory bulletin issued April 30, 2003.

Proposed Arrangement At A Glance

1. A company arranges for provision of pathology laboratory services with as many as five specialty physician group practices to operate pathology labs for them at an off-site location.
2. The company would charge a flat monthly management fee and a per-specimen fee, and would offer billing and collection services for 5% of revenue.
3. It would separately lease lab space to each urology, dermatology or gastroenterology practice.
4. Part-time pathologists from a licensed, Medicare-certified anatomic pathology lab and technical lab personnel from a lab staffing firm, both affiliated with the company, would rotate through the labs to ensure compliance with the Stark exception for in-office ancillary services.

"My reaction to it is extremely positive," said Thomas Sodeman, MD, CAP's president-elect and chair of laboratory medicine at North Shore-LIJ Health System (Lake Success, NY). He believes it's just a first step. "There will be a lot more from the OIG on this," he told *NIR*. For example, the OIG could dispatch field auditors to study "condo" labs.

Gray Area Remains Gray

Wood cautioned that the advisory opinion does not address a wide range of potentially problematic, more commonly used arrangements that are not as extreme as the off-site condo lab approach. In many cases, pathologists willingly accept lower pay to avoid the risk and hassle of collecting from public and private payers as well as beneficiaries. These situations can involve part-time employment or even piece-work contracting and still be legitimate under both the Stark and the anti-kickback safe harbors. "It will turn on the intent, and whether the compensation is at fair market value," she told *NIR*.

Wood advises that pathologists contemplating joining a "pod"-type arrangement make sure it complies with the Stark law and the anti-kickback statute and that their compensation is reasonable. She suggests documenting internally that the compensation was established at arm's length, accounting fairly for the transfer of collections-related risk to the referring physicians.

"Pod" Lab Audioconference Scheduled

For more on this "hot" topic, join in a special audioconference sponsored by Washington G-2 Reports: *Putting 'Pod' Labs Under the Microscope: Which Way Are the Feds Heading?*, February 10, 2:00 – 3:30 p.m. (Eastern). Featured speakers are Jane Pine Wood and W. Bradley Tully, Esq., who is with Hooper, Lundy & Bookman (Los Angeles, CA). They'll discuss not only the OIG's analysis, but also CMS's stance, plus how the "pod" lab model is evolving in response to government concerns and what issues remain to be resolved. To register, call 1-800-401-5937, ext. 2 or go online to *https: secure2.iproduction.com/products-ioma/g2_reg.php?confid=351*. Regular price is $277; for G-2 subscribers, $227.

Florida Lab Bidding Plan Mired In New Dispute

"The ITN [issued by Florida Medicaid] treats the acquisition of complex clinical laboratory services as though they were comparable to unsophisticated medical equipment, such as a bedpan," the American Clinical Laboratory Association said

The Florida Medicaid program has halted, for the third time, a controversial procurement for independent laboratory services for all recipients statewide, this time in response to a petition for an administration hearing by the American Clinical Laboratory Association.

The stoppage comes just two weeks after the state's Agency for Health Care Administration reissued the solicitation, following a seven-month hiatus triggered by a previous protest (*NIR, 25, 14/May 10, 2004, p. 2; 25, 13/Apr. 19, 2004, p. 3*). Last December 13, the agency had reissued an Invitation To Negotiate (AHCA ITN 0508) a winner-take-all contract to provide independent lab services to Florida Medicaid for three to four years. The ITN had an ambitious schedule, with a contract to be awarded by April 4 of this year. As required by the state legislature, AHCA invited bids based on monthly capitated payments. But the agency also wanted to negotiate a percentage reduction of at least 9% from the Medicaid fee schedule to adjudicate fee-for-service claims for beneficiaries not included in monthly capitation rates.

If there is no contract by April 1, the state must cut lab reimbursement by 10% below the Medicaid fee schedule, as per the state legislature (HB 1835). Bid protests don't alter this statutory deadline.

ACLA's Protest

ACLA challenged Florida Medicaid's ITN on behalf of its 24 members, saying they provide more than 45,000 tests per week to the state's Medicaid recipients. The association said its two largest members, Quest Diagnostics and LabCorp, provided nearly $25 million of the $37 million of lab services Florida Medicaid paid for in fiscal 2003.

In its petition, ACLA claimed the ITN would deprive Medicaid recipients of their right under federal law to obtain tests from any lab qualified to perform the service. The association said the state had obtained from the federal Health & Human Services Department neither an exception nor a waiver from this freedom-of-choice requirement.

Further, ACLA said, the solicitation would violate state Medicaid requirements for "delivery of quality healthcare." Also, lab test prices would skyrocket as soon as the winning bidder's contract ends, because there would no longer be any competitors in Florida, the trade group asserted.

In another petition, ACLA challenged the solicitation as an "unpromulgated rule," saying there is no regulatory basis for the performance standards, monitoring and reporting requirements, and capitated payment system set forth in the solicitation.

In Other Competitive Bidding News . . .

On the Medicare front, RTI International Inc. (Research Triangle Park, NC), the contractor for the Part B lab bidding demo required under the Medicare Modernization Act of 2003, is developing a set of design options, which its Technical Expert Panel is expected to review in the spring (*NIR, 26, 5/Dec. 16, 2004, p. 2*).

In California, the state's Medicaid program—Medi-Cal—is reviewing applications from independent laboratories for two-year contracts allowing them to continue providing moderate or high complexity testing services. Other types of labs will be asked to apply later. California intends to contract only with labs that provide quality services and agree to reduced Medi-Cal reimbursement. The state plans to announce contract awards next month.

Watch Out For Surprises In Medicare's Web-Based Manuals

The new Internet-only manuals, along with explanations of their use and a cross-walk from the old paper versions, are found at cms.hhs.gov/manuals

Beginning in October 2003, Medicare initiated a conversion from its old paper-based system of Contractor and Provider Manuals to new Internet-Only Manuals, organized by functional area (for example, eligibility, entitlement, benefits, claims processing, program integrity). But in recent months, laboratory compliance officials have been discovering changes that occurred in the switch, none of them announced and some causing problems.

"This has come up a lot since we switched," Dr. Rich Lawler of the Centers for Medicare & Medicaid Services told a recent ESRD/Clinical Labs open-door forum. Changes were made, he acknowledged, but they were meant only to clarify the meaning, not to alter it. "Unless there was a Change Request issued at the same time, the changes in language should mean basically the same thing." But if for some reason there is a difference, labs must abide by the Internet-only version, he said.

Two such changes recently came to the attention of Christopher Young, president of Phoenix-based Laboratory Management Support Services. One case involves payment for specimen collection from nursing home patients. In the old paper manual, it was clear that labs sending personnel for blood draws from these patients were entitled to the $3 collection fee, even if the nursing facility had on-duty personnel qualified to do the draw—Carriers Manual, Part 3, Chapter 5: Reasonable Charges, Section 5114.1(D), *cms.hhs.gov/manuals/14 car/3b5111.asp*. However, the Internet-only Claims Processing Manual (Chapter 16) states: "Medicare does not allow a specimen collection fee to the visiting technician if … the facility has personnel on duty qualified to perform the specimen collection." Further, all independent lab claims for such draws should be annotated, "patient in nursing home, no qualified person on duty to draw specimen."

In another case, Young said, he could not find in any of the new Internet-only manuals any mention of a provision from the old paper Carriers Manual that allowed pathologists to order additional tests they deem necessary when reading a tissue sample. It appears pathologists now must ask the ordering physician to request these additional tests.

CMS Sets Deadlines For Cytology Proficiency Testing

The new requirement took effect January 1 of this year, a decade after CLIA rules required enrollment in a CMS-approved cytology proficiency program, if available

The Centers for Medicare & Medicaid Services will require clinical laboratories that perform gynecologic cytology testing to meet a series of deadlines for proficiency testing now that it has approved a national proficiency testing provider, the agency told state survey agency directors in a memo last month (*NIR, 26, 5/Dec. 16, 2004, p. 1*).

The deadlines are:

- By June 30, 2005, enroll all individuals who examine gynecologic cytology slides in a CMS-approved cytology PT program.
- By April 2, 2006, ensure that all affected individuals have been tested for cytology proficiency at least once (they get four chances to pass the test).
- By December 31, 2006, and annually thereafter, ensure that all such individuals pass the test.

New hires who have worked less than six months in any lab get a break, as long as they're enrolled in a CMS-approved cytology PT program. CMS said it hopes to see labs achieve the goals "well in advance" of the deadlines, saying its aim is "the achievement of full and demonstrated proficiency, rather than enforcement" (see *cms.hhs.gov/medicaid/survey-cert/sc0511.pdf*).

CMS has scheduled a January 21 open-door forum to discuss enforcement of cytology PT requirements under CLIA (the Clinical Laboratory Improvement Amendments of 1988), as well as to get input on determining payment for new lab tests, as required by the Medicare Modernization Act of 2003.

CMS regional offices will work with state agencies to enforce the deadlines, if necessary, by imposing intermediate sanctions, limiting a lab's CLIA certificate for cytology and, if applicable, suspending Medicare/Medicaid payments for gynecologic cytology testing.

The newly approved nationwide gynecologic cytology PT provider is Midwest Institute for Medical Education (MIME), based in Indianapolis and provider of the CytoQuest educational glass-slide program. The Maryland Department of Health & Mental Hygiene also provides it, but only for labs that test Maryland residents' specimens.

The College of American Pathologists and the American Society for Clinical Pathology had asked CMS last November 10 to delay by one year the requirement for labs to enroll with MIME. Meanwhile, they both requested expedited approval of their own glass-slide continuing education programs, CAP PAP and ASCP Star, for cytology PT.

♦CODING A·D·V·I·S·O·R·Y

How do I code for immunofixation electrophoresis of urine under the CPT 2005 update if we're not concentrating the urine first?

In years past, you probably used CPT 86334, immunofixation electrophoresis. But under the CPT 2005 update it's not at all obvious. That code was changed to read immunofixation electrophoresis; serum—and CPT 86335, other fluids with concentration (eg, urine, CSF) was added. Now, there's no longer a code for what you are doing.

We put your question to Charles Root of CodeMap (Barrington, IL). He said the American Medical Association added 86335 to make sure labs get paid for the extra concentration step that is typically required when performing immunofixation electrophoresis on urine or cerebrospinal fluid. The term "serum" was added to the old code to indicate that it applies to fluids like serum that don't require a concentration step.

Root's advice: "Use the closest code to what you are doing, so use the serum code, 86334, even though it's urine, because you're not concentrating it."

CMS To Continue Scrutiny Of CLIA-Waived Labs

The Centers for Medicare & Medicaid Services last month decided to continue, for two more years, the funding of an initiative to survey laboratories operating with a certificate of waiver under CLIA (Clinical Laboratory Improvement Amendments of 1988), according to the agency's top CLIA official, Judy Yost.

CMS is conducting the visits—which are primarily educational and information-gathering in nature—under its regulatory authority to confirm that waived labs are only performing waived testing, Yost told *NIR*, and the agency does "follow-up on any serious quality problems we find."

Waived testing, the least regulated of all CLIA test categories, mainly requires the lab to follow the test manufacturer's instructions. Inspections typically are random or in response to a complaint

In surveys of 897 CLIA-waived labs in 2002 and 1,756 in 2003, CMS found indications that 2% to 3% had serious quality control problems that may have put patients in "immediate jeopardy." Many others had high personnel turnover and very little quality control training or oversight (*NIR, 26, 1/Oct. 11, 2004, p. 4; 25, 9/Feb. 23, 2004, pp. 4-6*).

Meanwhile, a workgroup of the Clinical Laboratory Improvement Advisory Committee (CLIAC, which advises the government on scientific and technical issues under CLIA) will report on its findings regarding good laboratory practices for waived testing when the committee meets February 16-17 in Atlanta.

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