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Medicare Lab Bidding Demo Set For April '07 Launch

Multiple lab winners are expected in the demo site. For more on who would win and who would lose, see the CMS policy outline, p. 2.

Medicare's competitive bidding demonstration for independent clinical laboratory services payable under Part B is scheduled for launch in its first site on April 1, 2007, the Centers for Medicare & Medicaid Services has announced. A second demo is to begin in another site on April 1, 2008. At press time, CMS had yet to specify the sites. In both areas, the demo will run for three years.

The demo timetable and CMS policy on the demo were spelled out for local Medicare contractors in an August 1 notice (Change Request 5205). The project's purpose is to see if competitive bidding can produce Medicare savings by reducing lab payment rates below what labs get now under the Part B lab fee schedule.

CNS also issued a revised bidding application for the demo in the July 28 *Federal Register* for a 30-day comment period. All labs in a demo site would have to complete the form, without exception. The revised form contains some changes to the original, notes an analysis by the American Clinical Laboratory Association. ACLA said it makes clear that physician office labs doing outreach testing are ➥ *p. 2*

INSIDE *NIR*

MD Specialties Aim For More Pathology Revenue

The insourcing of anatomic pathology work is a growing trend among certain physician specialties—in particular, urologists, gastroenterologists, and dermatologists—to add more ancillary services to their revenue stream. By bringing all or part of this work in-house, specialty groups can reap millions more dollars from Medicare and other third-party payers. Critics say this undercuts local pathology practices and usually requires pathologists to accept discounted fees.

Various insourcing business models are being used by specialty groups and promoted by pathology companies and consultants. These models attempt to avoid the pitfalls of the controversial "pod lab" arrangements that the HHS Office of Inspector General warned could violate the federal anti-kickback statute.

The "new" models also aim to fit within the exception for in-office ancillary services under the Stark self-referral ban. This law generally prohibits physicians from referring Medicare/Medicaid beneficiaries to facilities with which the physicians have a financial relationship. For more on the legal and ethical implications of insourcing, see the *Focus*, pp. 4-5.

Congress called for the lab demo in the 2003 Medicare reform law and required a progress report from CMS by December 31, 2005. In its notice to contractors, the agency essentially adopted the draft demo design in the report it sent to Congress earlier this year (NIR, 27, 14/May 8 '06, pp. 4-5).

Medicare Lab Bidding Demo, *from p. 1*

subject to the demo and CMS has recognized the lab's added costs to have multiple personnel complete the application.

The clinical laboratory industry has unanimously opposed the lab competitive bidding concept, saying it treats lab services as a commodity, rather than a complex medical service that ACLA says underpins 70% of medical decision-making. Opponents also say that bidding emphasizes price at the expense of quality and service.

CMS Policy On Lab Bidding Demo

Q Which lab tests are included, excluded?

A "Demo tests" include all codes on the current Part B lab fee schedule for services that do not involve a face-to-face encounter with the beneficiary. Pap smears and colorectal cancer screening are excluded by law. CMS also is excluding new codes added to the lab fee schedule during the duration of the demo.

Q Where will the demo run?

A In two sites handled by the same local Medicare carrier. Sites are expected to be within a single state and will be based on Metropolitan Statistical Areas.

Q Which providers are covered?

A Clinical labs that provide demo tests to beneficiaries living in the demo site. This includes independent clinical labs as well as outreach testing by hospital and physician office labs.

Q Which labs must bid?

A "Required bidders" are those with $100,000 or more in annual Part B fee-for-service payments as of calendar 2005 for demo tests provided to beneficiaries in the demo site.

Q Which labs don't have to bid?

A Small labs with less than the $100,000 threshold, defined as "passive labs." But they may bid if they choose.

Q Which labs will be paid by Medicare?

A Both required and non-required bidders that bid and win will be paid the competitively bid price for demo tests in the demo site (regardless of where the lab is located). This price will be set based on a composite of bids received and other calculations. To win, labs must bid at or below the composite rate. Multiple winners are expected in each demo site. Demo-excluded tests will continue to be paid via the Part B lab fee schedule.

Q Which labs will not be paid by Medicare?

A Both required and non-required bidders that bid and lose. Medicare will pay them nothing for demo tests (regardless of where the lab is located) for the duration of the demo. Similarly, Medicare will not pay for demo tests performed by required bidders that do not bid.

Q How will passive labs be paid?

A They will get the competitively bid rate for demo tests up to an annual ceiling of $100,000. If they exceed this ceiling by $25,000 or more, they will get no Medicare payment for demo tests for the duration of the demo.

Q Who can bill for demo tests?

A Only the lab that performs the test, and only winning and passive labs are eligible for the demo payment rate. Non-winning labs cannot bill Medicare or the beneficiary, but may refer demo tests to a winning or passive lab.

Medicare To Require Uniform Quality, E-Health Standards

Providers must comply with the requirements to be reimbursed by federally funded healthcare programs.

Medicare and all other federally funded healthcare programs will soon require healthcare providers to adopt quality performance standards for a range of health conditions as well as uniform standards for interoperable health information technology, Health & Human Services Secretary Michael Leavitt told the National Governors Association on August 6.

The standards for federal healthcare programs are expected to be promulgated by executive order within weeks, he said, as part of the Bush administration's initiative to have e-health records for most Americans by 2014. Leavitt urged the governors to adopt the standards in their Medicaid programs and said he has approached large employers to do the same.

Virtually all hospitals now report performance measures on a subset of health conditions (coronary artery disease, stroke, and pneumonia). As an incentive, they are rewarded with the full market basket update for Medicare inpatient services. Now, this reporting mandate is spreading to physicians, industry analysts note.

Leavitt said HHS already has endorsed standards for patient registration, reporting of lab test results, prescription orders, and firewalls to secure the sharing of confidential information.

Labs Included In Final E-Health Safe Harbors

In recent final rules, the government has established new anti-kickback and Stark physician self-referral safe harbors that allow healthcare providers, including clinical laboratories, to provide electronic prescribing and electronic health record technology to physician referral sources.

The rules were published in the August 8 *Federal Register* by the Centers for Medicare & Medicaid Services and the HHS Office of Inspector General. They take effect October 10, 2006, and will expire December 31, 2013.

Under the Stark exception, says the CMS rule, providers may donate interoperable e-health records software, health information technology, and training services. The OIG rule creates a safe harbor to let providers furnish HIT hardware, software, and training necessary for e-prescribing. Physicians who get HIT must pay 15% of the cost of the e-health items and services.

The American Clinical Laboratory quickly applauded inclusion of labs as covered providers in the final CMS/OIG rules. President Alan Mertz said in an August 8 statement, "For over a decade, labs have had a limited safe harbor to donate technology for lab orders and reporting of results. The new rules allow a broad class of entities, including labs, to donate technology for the entire e-health record, including e-prescribing and imaging."

Rules Differ From House Legislation

The final rules differ from the HIT safe harbors proposed in the House-passed bill (H.R. 4157) designed to promote wider physician adoption of HIT and improve the quality of care, reduce medical errors, and achieve efficiencies by moving away from paper-based systems (*NIR, 27, 16/Jun 12 '06, p. 1*).

➥ *p. 6*

focus on: Pathology Revenue Trends

Physician Specialties Gobble Up More Of The Pathology Pie

You'll see it popping up lately around the country—it's called "insourcing" anatomic pathology services. Certain physician specialties—most notably, urologists, gastroenterologists, and dermatologists—are using this business arrangement to capture ancillary revenue from work done by pathologists.

Two business models are prominent in this trend. In one scenario, the specialty group runs an in-office histology lab to prepare tissues and hires or contracts with pathologists to diagnose the specimens. The group may bill Medicare Part B a global fee for the service (professional and technical components). In the second scenario, the group hires or contracts with pathologists to diagnose specimens and bill for the professional services, while an off-site local lab prepares the specimens and bills for the technical work.

The first maneuver by physician specialties to earn more Medicare revenue from anatomic pathology involved "outsourcing" these services to "pod labs." In this scenario, a third party establishes a centralized collection of cubicle ("condo") labs, each for the exclusive of a different group practice. The labs can be located anywhere, even across the country from the practice. A single pathologist rotates among the labs, working as an independent contractor for each group. The group typically pays a management fee to the third party and a per-slide fee, and retains any profit from global billing for the pathology services.

Pod labs, however, have fallen out of favor since the HHS Inspector General warned they could violate federal anti-kickback law. They are still around, but the numbers are declining, attorney Jane Pine Wood, with McDonald, Hopkins, LPA (Cleveland, OH), told *NIR*. Joe Plandowski, principal at Lakewood Consulting Group (Lake Forest, IL), told *NIR* these labs tend to be in the Washington, DC-Philadelphia-New York corridor, while insourcing is increasingly popular on the West Coast.

Under Medicare policy, insourcing must pass different tests under two separate statutes—federal anti-kickback law and the Stark ban on physician self-referrals.

Anti-Kickback Safe Harbors

Insourcing arrangements can take advantage of these safe harbors for *bona fide* employees and personal services contracts with independent contractors. Contracts must be in writing and specify terms for the provision of services, with compensation set in advance, at fair market value, and not based on the volume or value of referrals. Fair market value is of particular concern,

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In addition to Medicare requirements, a specialty practice that insources anatomic pathology work must consider how the arrangement complies with state laws requiring direct billing or disclosure of physician mark-ups.

Wood says. "These arrangements often involve the provision of services by the pathology provider to the specialty practice at a discount from prevailing third-party payer rates, and the billing by the practice to third-party payers at prevailing rates."

In an advisory opinion (No. 04-17, December 10, 2004), the OIG warned that even if a relationship between a practice and the pathology provider fits within a safe harbor, the protection does not extend to the profit recognized by the practice from the pathologist's professional services (*NIR, 26, 6/Jan 10 '05, p. 3*).

Stark Physician Self-Referral Law

Insourcing can also be safe-harbored under this law's exception for in-office ancillary services, but the exception is available only to organizations that meet the Stark definition of "group practice." The specialty group must then satisfy Stark requirements that the pathology provider must be a "member of the group," either as an employee or an independent contractor. The Stark exception also stipulates that revenue from the specialty practice's TC services cannot be allocated among the practice's physicians based on referral volume.

There also are location and supervision requirements that must be met to qualify for the exception. This is not a problem if the lab is on-site in the specialty group's practice. If the lab is off-site, the group must lease or own the office space on a continuous 24/7 and exclusive basis, Wood cautions. Also, the TC services must be provided by or under the supervision of one of the practice's physicians or an independent contractor of the practice.

Medicare Reassignment Rules

Another test that insourcing must pass is compliance with Medicare reassignment rules. Medicare prohibits physicians from assigning benefits to anyone but the physician who rendered the service. There are exceptions, Wood points out. "An employed physician may assign benefits to his/her employer and an independent contractor may assign benefits to a medical group for services provided on the group's premises as long as there is a contract allowing the group to bill and collect for the physician's service."

Ethics On The Line

Plandowski notes that urologists, gastroenterologists, and dermatologists generate a large volume of tissue slides, making in-office anatomic pathology labs very profitable. Insourcing is an opportunity for hospital-based pathologists to offset declining reimbursement, he says. Little investment is required, and the hospital lab typically already does outreach work for local specialty groups.

When the specialty group bills for the PC and an off-site lab bills for the TC, this is not illegal, but it is unethical, Plandowski thinks. He says it violates several policies in the AMA Code of Ethics, most clearly the ban on split-billing at Policy 6.10: "When services are provided by more than one physician, each physician should submit his or her bill to the patient and be compensated separately, if possible. A physician should not charge a mark-up, commission, or profit on the services rendered by others."

Aside from the added revenue stream, an in-office pathology lab offers a specialty group other important advantages, Plandowski says. The specimen never leaves the lab, speeding up turnaround time; and the pathologist is available on-site to discuss cases with specialists in the group and even to meet with the patient.

CMS To Contractors: Get Ready For 'Medically Unlikely' Edits

Because CMS expects the first round of MUEs to be non-controversial, the agency says contractors can implement them without an appeals process or a claims modifier to bypass the edits.

Starting January 1, 2007, local Medicare contractors are to implement the first round of "medically unlikely" edits (MUEs)—the new name for the old "medically unbelievable" edits. MUEs are limits on the units of service that a healthcare provider can bill a particular CPT/HCPCS code per Medicare beneficiary per day. Claims exceeding the limits will be automatically denied.

In instructions to contractors (Change Request 4209, August 4, 2006), the Centers for Medicare & Medicaid Services said the initial round of MUEs will be limited to anatomic considerations and will not be based on utilization data. As previously reported, no lab or pathology codes in the CPT 80000 series will be included, but HCPCS "G" codes for Pap smears and screening for colorectal and prostate cancer will be (*NIR, 27, 19/Jul 31 '06, p. 5*).

Meantime, a top CMS official disclosed more details on the agency's intent and plans for the MUE initiative in a recent letter to the American Clinical Laboratory Association. Lisa Zone, deputy director of the CMS Program Integrity Group, said "we will follow a multi-phase implementation schedule to allow national organizations additional time to review and comment on proposed MUEs."

The original MUE list, unveiled last January, covered virtually all CPT/HCPCS codes, but CMS has since scaled it back. Subsequent MUEs will be implemented via quarterly updates that coincide with the Correct Coding Initiative edits. The next round is scheduled for April 2007 and will target typographical errors, Zone said, and CMS will then decide on the sequence of other MUEs. To allow Medicare payment for medically necessary services that exceed MUE levels, CMS is planning an appeals process, she said, and "is exploring the need for a claims modifier."

E-Health Safe Harbors, *from p. 3*

In announcing the new safe harbors, HHS Secretary Michael Leavitt said they remove major legal barriers to widespread adoption of e-health records, a priority of the Bush administration.

The legislation contains no requirements for the 15% cost-sharing or a "sunset" deadline, and sets no limits on the scope and nature of HIT donations, Jason DuBois, ACLA vice president for government relations, told *NIR*.

It's important to note, he said, that while H.R. 4157 would limit the category of covered providers to hospitals, group practices, prescription drug sponsors, and Medicare Advantage plans, the bill would allow the HHS Secretary to specify other services. This the Secretary has done by covering a broad array of providers, including clinical labs, in the CMS/OIG rules, he noted.

H.R. 4157 also includes a compromise on the controversial all-payer transition to ICD-10 diagnosis and procedure codes. The switch to ICD-10 for billing and payment purposes, involving more than 120,000 codes, would be required as of October 1, 2010. The Ways & Means Committee had approved a 2009 deadline, while Energy & Commerce was silent on the issue. A broad coalition of healthcare providers, including ACLA, supports a deadline of no earlier than 2012, citing the complexity and costs involved (*NIR, 27, 16/Jun 12 '06, pp. 4-5*).

The Senate-passed counterpart (S. 1418, the Wired For Healthcare Quality Act) has no provisions on ICD-10 or expanded safe harbors. The two bills now go to a House-Senate conference to iron out the differences. ACLA will continue to lobby lawmakers to specifically include labs in legislative safe harbors and to extend the ICD-10 deadline to 2012, DuBois said.

1st Contract Awarded For Combined Part A/B Claims Processing

Noridian Administrative Services (Fargo, ND) has been awarded the first competitively bid contract to serve as a Medicare Administrative Contractor (MAC) under a new structure that consolidates Part A/B claims processing and payment, replacing the current system that splits the work between fiscal intermediaries and carriers.

CMS is making the shift to Part A/B MACs in stages (NIR, 27, 14/May 8 '06, pp. 1-2). *Next up in the MAC bidding cycle are jurisdictions 4 (Colorado, New Mexico, Oklahoma, and Texas), 5 (Iowa, Kansas, Missouri, and Nebraska), and 12 (Delaware, the District of Columbia, Maryland, New Jersey, and Pennsylvania). These areas account for roughly 45% of the Part A/B claims workload.*

This is the first of 15 MAC contracts to be awarded by 2011, when the transition to the new structure is to be completed, said the Centers for Medicare & Medicaid Services in a July 31 statement. The MAC system is mandated by contractor reform requirements of the Medicare Modernization Act of 2003 (Section 911). Under the Act, MAC contracts must be open for competitive bidding at least every five years.

Noridian has long served as a local Medicare carrier under the old structure. In its new role as a MAC, it will process and pay fee-for-service claims from healthcare providers in six states—Arizona, Montana, North and South Dakota, Utah, and Wyoming. The Noridian contract is valued at $28.9 million for the first year of performance. The company will immediately begin implementation and complete it by no later than March 2007, CMS said. Noridian can gain award fees for meeting or exceeding performance standards set by CMS.

Medicare Hikes Inpatient PPS Rates, Starts DRG Changes

The threshold for outliers (or the more expensive cases) will be $24,475 in FY 2007 vs. $23,600 this year. Consistent with the law, Medicare expects outlier payments will equal 5.1% of total inpatient PPS spending.

Medicare payments to acute-care hospitals for operating expenses will rise 3.4% on average, or $3.4 billion, in fiscal year 2007, which begin this October 1, the Centers for Medicare & Medicaid Services has announced, The final 2007 inpatient PPS rule is scheduled to appear in the August 18 *Federal Register*. More than 1,000 rural hospitals will see a 3.7% average increase; urban hospitals less, 3.4%, CMS estimates. Cardiac specialty hospitals will see only a 1.2% increase as part of reduced incentives to select and provide only profitable services.

Hospitals that voluntarily report specified performance quality data will continue to get higher Medicare inpatient payments in FY 2007 than hospitals that choose not to report. Reporting hospitals will get the full market basket update. Non-reporters will get 2.0 percentage points less. CMS has added influenza vaccination as a new quality data-reporting requirement for FY 2007. This is in addition to the 20 measures now reported for conditions such as coronary artery disease, stroke, and pneumonia.

In response to congressional concerns, CMS said it will implement major DRG payment policy changes in stages. It will assign weights to DRGs (diagnosis-related groups) based on costs, not charges, starting in FY 2007, and will consider case-severity adjustments for the care for beneficiaries with severe illness. Both adjustments will be phased-in simultaneously over a three-year period, to minimize disruption to hospital operations, CMS said.

♦MEDICARE CODING A·D·V·I·S·O·R·Y

Deductible To Be Waived For Colorectal Cancer Screening

Starting January 1, 2007, Medicare will waive the annual Part B deductible for certain colorectal cancer screening procedures covered under the program's preventive services package. The waiver implements a requirement in the Deficit Reduction Act of 2005, said the Centers for Medicare & Medicaid Services (CMS Change Request 5127, July 21, 2006). Co-pay requirements will continue to apply.

Affected services are payable under the physician fee schedule and include:

- ❑ Flexible sigmoidoscopy (G0104).
- ❑ Colonoscopy (G0105 and G0121).
- ❑ Barium enemas (G0106 and G0120).

The policy change does *not* affect the fecal occult blood test covered under the colorectal cancer screening benefit. The test is payable under the Part B lab fee schedule, with no deductible or co-pay.

washington WATCH

Proposed Outpatient PPS Rates For 2007

Medicare payment for hospital outpatient department services would increase by 3.4% in calendar year 2007, under a proposed rule published August 8 by the Centers for Medicare & Medicaid Services, though when all payment and policy changes are taken into account, it will be more like 3%.

Hospitals would get $32.5 billion next year for outpatient services and would have to report quality data in line with that used for inpatient services. Outpatient departments that report will get the full market basket update. Those that don't will get 2.0 percentage points less.

Outpatient service spending continues to grow rapidly, CMS notes. Between 2005 and 2006 it rose by 12%, mainly due to growth in the volume and intensity of services. For next year, a 9.2% increase is projected.

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

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