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Lawmakers Urged To Scrap Medicare Lab Bidding Demo

CMS is moving ahead with the demo and plans to identify the initial launch site this summer, then get the project running by the spring of 2008. For more on the timeline and other project news, see the Focus, pp. 4-6.

At a House hearing on July 25, representatives of clinical laboratories, small and large alike, urged lawmakers to end Medicare's competitive bidding demonstration for lab services. The demo, required by the 2003 Medicare reform law, aims to see if bidding can be used to pay for Part B lab testing at rates below fee schedule amounts without sacrificing quality and access.

The demo would devastate small businesses, said a chorus of witnesses. Tod Schild, senior vice president of Shiel Medical Lab in Brooklyn, NY, said his lab, operating at only a 5% to 7% margin, would not survive if it had to bid and lost. Labs that bid and don't win get paid nothing by Medicare during the demo.

The nation's largest lab company, Quest Diagnostics, joined smaller labs in warning that the demo would imperil services to nursing home residents and homebound patients—local markets from which the national labs have largely withdrawn—and would disrupt long-established lab-to-lab referral arrangements.

The House Committee on Small Business held the hearing in response to lab industry concerns about the demo the Centers for Medicare & Medicaid Services is developing. Those concerns also flared up a week before at the CMS public forum on a draft bidder's package. For more on the controversy, see the *Focus*, pp. 4-6.

Crosswalks Proposed For New 2008 Lab Fees

National clinical laboratory and pathology groups are unanimous in recommending that the Centers for Medicare & Medicaid Services use the crosswalk method to establish payment for lab codes new to the Part B fee schedule in 2008.

Under this method, a new test code is matched to a similar code on the fee schedule and is paid at that rate. Payment is the lower of the local fee schedule amount or the national cap. Most lab codes are paid at the cap. The gap-fill alternative is used to set a fee when there is no comparable test and is based on local pricing patterns.

The lab and pathology groups' crosswalk recommendations were submitted to CMS's July 16 open-door forum held to obtain input on the fee-setting process, as required by statute and regulations.

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New 2008 Lab Fees, *from p. 1*

CPT lab codes new next year include an additional code for a basic metabolic panel (ionized calcium), three in chemistry, two in immunology, and two in microbiology. In addition, CMS proposes to create a new single HCPCS "G" code for hemoglobin A1c testing, replacing two CPT codes now in use.

Pathology and lab groups oppose the switch to the "G" code. The American Society for Clinical Pathology, the College of American Pathologists, and the Clinical Laboratory Management Association say it is unwarranted and an added reprogramming burden. Current codes work well for billing purposes, they say. But in the event CMS goes ahead, the groups say the "G" code should be priced the same as CPT 83036/$13.56, which is deleted in 2008.

The new codes also address disease conditions such as kidney dysfunction leading to higher cardiovascular risk, irritable bowel syndrome, pregnancy screening, hospital-acquired resistance to antibiotics, and acute respiratory syndrome in children.

Lab and pathology groups agree on payment levels for the crosswalked codes, either unanimously (as in the case of chemistry 82610 and 84704 and microbiology 87500 and 87809) or equal the same amount despite differing code assignments (chemistry 83993).

But the groups split over pricing of the new basic metabolic panel code, CPT 80047. The American Association for Clinical Chemistry, ASCP, and CAP favor a crosswalk to 80048/$11.83, but CLMA and the American Clinical Laboratory Association support a significantly higher amount—$30.51—which they say reflects the fact that separate instrumentation must be used to run the ionized calcium test in addition to the seven tests in the current basic metabolic panel (minus total calcium).

In other pathology/lab recommendations:

- ❑ Flow cytometry code 86356, payable under the physician fee schedule, should be reimbursed at $52.70, the rate for 86586, which it replaces in 2008.
- ❑ The skin test code 86486 belongs on the physician fee schedule matched to 86510, says AACC. ASCP and CAP say the new code belongs on the APC schedule.
- ❑ ACLA, ASCP, and CAP make crosswalk recommendations to cap fees for two reproductive medicine codes approved by CPT for 2008 but not on the CMS lab fee schedule:

• 8932X	Semen analysis; volume, count, motility and differential using strict morphologic criteria (eg, Kruger)	89320 + 85007 $21.65
• 8933X	Sperm evaluation; for retrograde ejaculation, urine (sperm concentration, motility and morphology, as indicated)	89320 + 87015 $26.17

Timetable For 2008 Lab Fee Schedule

CMS says it will make public its tentative fee decisions for the new lab codes by September 7 and will accept additional comments on these decisions through September 21.

Final fee decisions will be released when CMS publishes the final 2008 Part B lab fee schedule. The agency typically issues instructions on the fee schedule to local contractors by late October. The final fee schedule should be available online by mid-November, CMS says, at *www.cms.hhs.gov/ClinicalLabFeeSched*.

Fee Recommendations to Medicare for New 2008 Lab Codes: Laboratory & Pathology Organizations

Code	*Descriptor*	*Recommended Crosswalk, Related Medicare Fee Cap*
ORGAN/DISEASE-ORIENTED PANELS		
CPT 80047	Basic metabolic panel (Calcium, ionized): includes Calcium, ionized (82330), Carbon dioxide (82374), Chloride (82435), Creatinine (82565), Glucose (82947), Potassium (84132), Sodium (84295), Urea Nitrogen (BUN) (84520)	80048/$11.83: AACC, ASCP, CAP. ATP07/$11.42 + 82330/$19.09 = $30.51: ACLA, CLMA.
CHEMISTRY		
CPT 82610	Cystatin C	83883/$19.00: AACC, ACLA, ASCP, CAP, CLMA.
CPT 83993	Calprotectin, fecal	83520 + 87015 = $27.42: AACC. 83631/$27.42: ACLA, ASCP, CAP, CLMA.
CPT 84704	Gonadotropin, chorionic (hCG); free beta chain	82677/$33.79: AACC, ACLA, ASCP, CAP, CLMA.
IMMUNOLOGY		
CPT 86356	Mononuclear cell antigen, quantitative, (eg, flow cytometry) not otherwise specified, each antigen	86355/$52.70: ASCP, CAP, CLMA. 86586/$52.70: AACC, ACLA.
CPT 86486	Unlisted antigen, each	Codes on the physician fee schedule. 86510: AACC, ASCP. 86490 or 86510: CAP.
MICROBIOLOGY		
CPT 87500	Vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique	87471/$49.04: AACC, ACLA. 87498/$49.04: ASCP, CAP. 87641/$49.04: CLMA.
CPT 87809	Infectious agent antigen detection by immunoassay with direct optical observation; Adenovirus	87802/$16.76: AACC, ACLA. 87899/$16.76: ASCP, CAP. 87810/$16.76: CLMA.
NEW HCPCS LABORATORY CODE		
HCPCS Gxxxx	Hemoglobin; glycosylated (A1c). All sites of service including, but not limited to, home, office, or facility. Would replace 83036 and 83037	83036/$13.56: if CMS goes ahead, groups say the crosswalk should be to this code. ASCP, CAP, CLMA say the G code is not necessary and an added administrative burden.

CPT codes © American Medical Association.

House Bill Would Increase Medicare Physician Fees In '08

The bill also would eliminate cost sharing for Medicare preventive services and freeze payment updates in 2008 for nursing homes, home health agencies, and long-term care hospitals.

Under legislation working its way through the House at press time, pathologists and other physicians would escape a scheduled 10% cut in their Medicare fees in 2008 and instead get an increase of not less than 0.5% next year and in 2009. The cost would be an estimated $20 billion over five years. The 10% cut is required under the SGR update formula. Physician groups had been hoping for at least a 1.5% increase, and the Medicare Payment Advisory Commission had recommended a 1.7% hike (*NIR, 28, 18/Jul 16 '07, pp. 4-5*).

The physician fee provisions are packaged in a bill reauthorizing the State Children's Health Insurance Program (SCHIP), due to expire at the end of September. This popular program provides healthcare coverage to some six million children and adults in low-income families, and House and Senate bills *Continued on p. 7*

focus on: *Lab Competitive Bidding*

Sparks Fly In Latest Flare-up Over Medicare Lab Bidding Demo

Join us August 2 (2:00-3:30 p.m. Eastern) for the G-2 special audio conference, Competitive Bidding For Clinical Lab Services: Where's It Heading & What Can You Expect? *Get the latest on the Medicare demo and the implications for clinical labs. Details and registration at* www.g2reports.com.

After months of lying officially dormant, the Medicare competitive bidding demonstration for laboratory services sprang back to life in recent regulatory and legislative forums, triggering solid opposition across the clinical lab industry.

The Centers for Medicare & Medicaid Services got the project moving again with its July 16 open-door forum on a draft bidder's package. The aim of the demo, authorized in the 2003 Medicare Modernization Act, is to determine whether Part B can use competitive bidding to provide quality lab services at prices below current fee-for-service rates. It excludes Pap smears, colorectal cancer screening, and new tests added to the lab fee schedule during the demo.

The "new" news at the forum came from CMS project director Linda Lebovic, who announced a tentative timeline for the demo, with a start date of spring 2008 (*box below*).

Otherwise, the session generated a lot of flak from demo opponents who offered public statements and called in. Frustration on both sides was evident at times. It boiled down to the industry saying, "CMS has still left unanswered many of the major concerns we've raised over the past two years," and CMS saying, "No matter what we propose, you will find fault with it."

Immediately after the forum, the Clinical Lab Coalition (CLC) called on HHS Secretary Michael Leavitt to stop, and Congress to repeal, the Medicare bidding demo. In a statement, the CLC noted: "After nearly two decades and three major consulting projects, CMS still is unable to answer some of the most fundamental questions and concerns" about assuring quality, access, and market competition.

Stepping into the controversy, the House Committee on Small Business held a July 25 hearing to air industry concerns about the demo's impact on small business operations and local services to nursing home and homebound patients. Chairwoman Nydia Velazquez (D-NY) acknowledged that arguments against competitive bidding were compelling and pledged to monitor the situation, saying "CMS has ignored congressional intent and moved forward with a project that creates a cumbersome bureaucracy" threatening small labs.

Lab Bidding Demo: Tentative Timeline

Summer 2007	Finalize bidder's package
Summer 2007	Announce first Competitive Bid Area (CBA) where the demo will run
Late Summer 2007	Hold bidder's conference
Fall 2007	Bids due
Winter 2008	Labs notified of winning or non-winning status
Spring 2008	Demonstration begins

Source: CMS.

In pressing for the hearing, the CLC (*box, p. 5*) said CMS has given little regard to the issues its member groups have repeatedly raised with project officials, most recently at the open-door forum. One prime example cited: the provision in the draft bidder's package that defines a "small business"—thus exempt from the demo—as any lab with less than $100,000 in annual Medicare revenue from demo tests, whether done in-house or sent to reference labs. Though not required to bid, they would be paid at the competitively bid price. All labs above the $100,000 threshold would have to bid or risk

getting paid nothing at all for the duration of the demo.

Mark Birenbaum, administrator of the American Association of Bioanalysts, challenged the "small business" definition in his statement to the committee. "To meet [it], a lab cannot just be 'small,' it must be nano-size. There are likely to be few if any community-based labs in the demo site that can provide a full service menu of testing and meet the definition." The Small Business Administration, he noted, defines a small business lab as one with no more than $12.5 million in annual overall revenue, and these labs typically depend on Medicare for at least 40% of it.

The demo could result in less, not more, competition, Birenbaum told the *National Intelligence Report*. For the national labs, the percentage of business affected by the demo would be small, he said, but significant for small to medium-size labs whose business is concentrated in the demo site. They can't afford low-ball bids like their larger competitors who can absorb the competitively bid rate because the bulk of their business is outside the demo area. While the demo envisions multiple winners, that could mean "only a handful of labs are left," he said. "And in the long run, when you reduce competition, you raise, not lower, prices."

Birenbaum also took exception with assertions by CMS officials at the public forum that the demo development process has been wide open to industry views. "We sought to get representation of small to medium-size labs on the project's technical expert panel, but to no avail," he said.

He also questioned the many types of labs and the volume of testing that would be exempt from the demo, including POLs, hospitals, and ESRD facilities. "You end up with competitive bidding for a minority segment of the industry in the demo," he told *NIR*, "and how can you generalize at all to how this would apply in a national context?"

Tom Bejgrowicz, a client account manager for Aculabs, a lab that primarily serves nursing homes in New Jersey, faulted the draft bidder's package for not requiring assurances that a "winning lab" must provide testing to the long-term care setting. This is an especially vulnerable population typically served by local labs, he told the House panel. Several groups had asked CMS to include such a stipulation, but it has not, he added.

Addressing concerns over referral arrangements, Ronald Weiss, MD, president of ARUP Labs, board chairman of the American Clinical Laboratory Association, and a member of the technical expert panel on the CMS project, testified to the House committee that the demo would severely disrupt the web of arrangements between local labs that run many common tests and reference labs, such as ARUP, that perform the more complex tests for them.

"Some reference labs are thousands of miles from the demo area, yet will have to bid in the demo area if they provide more than $100,000 in services," Weiss said. "Other reference labs may choose not to bid or may not be selected as winners if they do." This would create a situation, he noted, where local labs cannot put together

Clinical Laboratory Coalition

Members oppose the idea of lab competitive bidding, saying it treats lab services as a commodity, rather than a complex medical service. In a CLC statement, members said: "No bidding model, whether limited regionally or nationwide, will meet the objective of providing lab services at fees below current Medicare payment rates, while simultaneously maintaining quality and access to care."

- ❑ American Association of Bioanalysts/National Independent Laboratory Association
- ❑ American Association for Clinical Chemistry
- ❑ American Clinical Laboratory Association
- ❑ American Medical Technologists
- ❑ American Society for Clinical Laboratory Science
- ❑ American Society for Clinical Pathology
- ❑ American Society for Microbiology
- ❑ Cleveland Clinic
- ❑ Clinical Laboratory Management Association
- ❑ College of American Pathologists
- ❑ Mayo Clinic

a winning bid on all demo tests, shutting them out of business and threatening beneficiary access.

"Is there a compelling need for the bidding demo?" Weiss asked. "Lab services account for only 1.7% of Medicare spending and payments have already been reduced by roughly 40% in inflation-adjusted terms between 1984 and 2004. If the goal is to seek savings, they have already been realized and this model will mean only disadvantages to providers and patients."

For an outside take on the issues, *NIR* contacted Stephen T. Mennemeyer, a PhD in economics, who worked on a Medicare lab bidding design in the late 1980s at Abt Associates. That effort was halted when Congress pulled it off the table. He is currently a professor at the University of Alabama/Birmingham in the Department of Healthcare Organization and Policy in the School of Public Health.

While he said he had not tracked the demo recently, he did offer some thoughts in favor of testing the bidding method for Medicare lab services. The method, he noted, was one viable alternative in the Institute of Medicine's report on lab payment policy, though it did not advocate a nationwide rollout.

It would be foolish for the industry to oppose competitive bidding, he told *NIR*, because it is a method immune to political manipulation, unlike current fee schedules. Prices now are set by a formulaic approach based on old and unreliable data, with occasional statistical fixes and congressional interventions. And they have historically been a tempting target when lawmakers need to cut Medicare spending. The fact that the lab industry is willing to accept deep discounts underscores the fact that Medicare fees bear no relation to reality and are susceptible to potential cuts. Competitive bidding would enable Medicare to determine an economically feasible price for a test, he said.

Mennemeyer also cited confusion over reporting results and paying for them on the one hand, and on the other, giving doctors expert advice on interpreting the results. Competitive bidding is concerned with results reporting and payment. Usually, however, the interpretation is bundled with it. A breakout of the consulting aspect would help, he said, and CMS could easily make this a line item on which to bid—for example, x consults at the bid rate; if more consults are needed, adjust the rate.

Lab Bidding Project At A Glance

- ❑ Will run for three years in two Metropolitan Statistical Areas within a single state.
- ❑ Includes lab services that do not involve "a face-to-face encounter" with the beneficiary. Excludes tests by physician office labs (POLs) and by hospitals for their patients. Does include outreach and/or non-patient services provided by a hospital or a POL where the lab is functioning, in effect, as an independent lab.
- ❑ Includes 358 "demonstration tests." The list corresponds to 99% of the fee schedule by national volume and total overall payment.
- ❑ Bid prices should be provided for all demo tests, whether done in-house or referred. Once the demo fee schedule is set, labs can send reference work to any lab other than a non-winning lab.
- ❑ Winning bidders are those that offer the lowest bids up to the cutoff point, when they cumulatively have the capacity to equal or exceed projected demand for demo tests in the demo site. Those that offer higher bids after capacity has been reached are considered non-winning bids. The competitively bid fee for each test will equal the average of winning bids for that test times an adjustment factor.

Medicare Physician Fees, *from p. 3*
would expand it by millions more. The House bill would reauthorize SCHIP at $50 billion over five years, paying for it with higher tobacco taxes and reduced Medicare managed care payments. The Senate bill would authorize $35 billion over five years and raise the tobacco tax, but does not include a physician fee fix.

The President has said he would veto a major SCHIP expansion, proposing only $5 billion over five years. He would fix the eligibility threshold at 200% of the federal poverty level; many states have a higher one, as much as 300% to 400%, and have relied on SCHIP to expand coverage of uninsured residents. The federal share of SCHIP funding is 70%, with the rest supplied by the states.

NPI Update

Provider NPPES Data Due For August 1 Release

In the latest news on the National Provider Identifier (NPI), the Centers for Medicare & Medicaid Services has confirmed that healthcare provider data from the National Plan & Provider Enumeration System (NPPES) will be available August 1, as planned (*NIR, 28, 18/Jul 16 '07, p. 2*).

The move is aimed at helping healthcare providers and their trading partners exchange NPIs. Use of NPIs is required in standard electronic transactions under HIPAA (the Health Insurance Portability & Accountability Act).

The NPPES data will be available from the NPI Registry, a query-only, real-time database. Users can search by NPI or provider name and get a list of all NPPES records that meet the query specifications. The user can select the records he or she wants to see. The NPI Registry will then display the disclosable data for those records.

About a week later, CMS will make available a file for downloading that will contain the disclosable NPPES data of enumerated healthcare providers. CMS will not disclose Social Security numbers, taxpayer ID numbers, date of birth, or country of origin.

Technical expertise will be required, CMS cautions, to download the file and import the data into a relational database or otherwise manipulate the data. The agency will be furnishing more information on this, including a "Read Me" file, Header File, and Code Value document for the downloadable file, on the NPI Web page at *www.cms.hhs.gov/NationalProvIdentStand/*.

Medicare Requires NPIs For Group Practice Members

CMS reminds pathologists and other members of group practices that Medicare requires use of their NPIs on fee-for-service claims. Group practices that bill Medicare electronically are "covered providers" under HIPAA and are required by regulation to use NPIs to identify themselves as the Billing and Pay-to Providers on claims.

Medicare also requires that providers who are identified as Rendering Providers on claims be identified by NPIs, whether or not these individuals are "covered providers." Therefore, CMS advises group practices enrolled in Medicare to make sure their members (physicians or other practitioners) obtain NPIs and avoid rejection of claims for payment.

Roundtable Scheduled On Common Billing Errors

As part of its NPI implementation effort, CMS will host a National Roundtable call-in on August 2 to address "Fee-for-Service Medicare Q&As: Common Billing Errors" (2-3:30 p.m. Eastern). For details, go to *www.cms.hhs.gov/NationalProvIdentStand/*.

FDA Issues Revised Guidance On Lab-Developed Tests

The agency dismissed calls from the lab industry to address LDT regulation through the formal rulemaking process, rather than issuing less binding guidance documents. The FDA said it had taken added steps to get broad input on the controversial issue.

The Food & Drug Administration on July 26 released for public comment a revised version of its draft guidance on expanded regulation of lab-developed tests (LDTs). The FDA is requiring premarket review for new types of DNA tests that combine assays and algorithms to produce patient-specific results. These devices are known as in vitro diagnostic multivariate index assays (IVDMIAs).

The revised draft clarifies several points in response to comments on the initial document issued last September (*NIR, 27, 22/Sep 25 '06, p. 1*). These include:

- ❑ The IVDMIA definition was misconstrued to cover a wider range of tests than the FDA had intended, so the agency is providing examples of tests it does and does not consider to be IVDMIAs.
- ❑ Addressing worries that further regulation would discourage innovation, the FDA said it would exercise enforcement discretion for lab-developed IVDMIAs intended to diagnose rare diseases.
- ❑ CLIA quality system requirements will be recognized as partially fulfilling FDA's post-market QS requirements until final guidance is issued.

The revised guidance is posted at *www.fda.gov/cdrh/oivd/guidance/1610.pdf*. Comments are due August 27.

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