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Battle Shaping Up Over Medicare Lab Competitive Bidding

With both Congress and the Bush Administration intent on opening Medicare to more market forces, many lab groups suspect that competitive bidding is a Trojan horse for reducing lab fees

Last year, the chief threat perceived by the clinical laboratory industry in the Medicare reform debate was restoration of a 20% co-pay for Part B lab services. This year, with that threat avoided, the industry confronts another—the lab competitive bidding demonstration mandated under Medicare reform. For lab interests, the idea has an inherent bias toward securing the best price at the expense of quality and higher healthcare costs down the road.

As Medicare officials digest the points raised by the industry during a special "listening session" held Mar. 3, it appears that the lab pilot could become just as mired in the complexities of the lab business that scuttled or sidelined previous efforts to get a demonstration underway. There's also concern that the success touted for durable medical equipment bidding pilots is a seductive siren song, luring congressional and Bush Administration proponents to focus on money saved vs. isolated findings of reduced access and quality.

In Florida meantime, Royco ESRD (Fort Lauderdale) on Mar. 12 lodged a protest that halted a fast-track competitive bidding procurement for Medicaid lab services announced by the state on Mar. 2 (*National Intelligence Report, 25, 10/Mar. 8, '04, p. 2*). The complaint challenges the requirement of accreditation by the College of American Pathologists or JCAHO. Royco says its CLIA certificate and the COLA accreditation it hopes to obtain should be sufficient. For more on the Medicare lab bidding demo, see the *Focus*, pp. 4-6.

Ban Eased On Reassigning Doctors Benefits

A change in Medicare rules governing reassignment of benefits will make it easier for medical groups and medical staffing companies to hire physicians as independent contractors and bill Medicare directly for their services. The change was enacted in last year's Medicare reform law (Public Law 108-173), and the Centers for Medicare & Medicaid Services told carriers to implement it as of Mar. 12, though the effective date remains last Dec. 8 (the date when the legislation was signed into law).

Previous rules restricted the ability of a healthcare provider to bill for the services of a physician unless the provider was a hospital, clinic or other healthcare facility or unless the provider employed the physician. Typically, this deterred medical groups and staffing companies from engaging doctors as independent contractors and ➥ *p. 2*

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For pathology services, the change could help fill staffing gaps for extended periods of time, especially in rural or medically underserved areas, and expand off-site interpretation arrangements

Reassigning Doctors Benefits, *from p. 1*

submitting Medicare claims for their services unless the claims were submitted in the name of the independent contractor physicians. Now, Medicare will permit payment of benefits to a person or entity where the service was furnished under a contractual arrangement, regardless of whether the service was furnished on or off the premises.

The impact on pathology, says attorney Jane Pine Wood, with McDonald Hopkins Co., LPA (Cleveland, OH), depends on a specific pathology practice's situation. The "pluses balance the minuses." For small groups in small towns, the change makes it easier to share a pathologist in residency, she notes. Other legal experts add that the elimination of on-site restrictions on where the service must be furnished could promote telepathology interpretation services. On the downside, there is the potential in highly competitive markets that the global billing arrangement could be used to squeeze physicians to discount rates for their professional services. The only restraint is that, under anti-kickback rules, the physician must be paid fair market value for his or her services.

Wood cautions providers that employ physicians not to rush to convert them to independent contractors. IRS guidelines require that many of these arrangements be structured as employment relationships. Also, managed care plans may put limits on the use of contract workers and may specify that the services of a group be provided by employees.

New Benefits Reassignment Policy

"A carrier may make payment to an entity (i.e., a person, group or facility) enrolled in the Medicare program that submits a claim for services provided by a physician or other person under a contractual arrangement with that entity, regardless of where the service is furnished. Thus, the service may be furnished on or off the premises of the entity submitting the bill."

The contract should include the following program integrity safeguards:

- ❑ Joint and several liability is shared between the entity submitting the claim and the person actually furnishing the service, for any related Medicare overpayment.
- ❑ The person furnishing the service has unrestricted access to claims submitted by the entity for the services provided by that person.

Source: CMS Pub. 100-04, Transmittal 111 (Feb. 27, 2004).

CPT Gives Favorable Nod To Genetic Test Coding Change

Under the new approach, the modifier would signify the genetic condition being tested without altering the CPT code descriptor. It would be reported in addition to the ICD-9 diagnosis code and the suite of genetic test procedures indicated by the CPT code(s)

The CPT editorial panel at the American Medical Association appears on track to adopt a change in the 2005 update that would make it easier to bill and get paid for genetic tests. The proposed approach—to append numeric-alpha modifiers to existing CPT codes, rather than create an array of new codes specific to genetic testing—got a "favorable review" at the AMA panel's quarterly meeting held Feb. 5-8 in San Juan, PR, according to sources familiar with the CPT process.

The change should improve coverage and payment for genetic tests because "it will make it easier for third-party payers to know which disease is involved," Andrea Ferreira-Gonzalez, PhD, tells *NIR*. She is director of the Molecular Diagnostics Laboratory and associate professor of pathology at Virginia Commonwealth University Medical Center in Richmond.

Most lab groups back the new genetic test coding initiative, though AdvaMed, the medical device trade group, is said to have questions about how it would be implemented. A spokesperson for AdvaMed declined to comment, citing non-disclosure requirements imposed by CPT. There remains the possibility that the initiative could be reconsidered outside the CPT meeting process, but this is considered unlikely at this point. By August, the panel will already have started the 2006 cycle for CPT.

Genetic test coding erupted into an issue for CPT in 2002 after the American Clinical Laboratory Association proposed a specific code for cystic fibrosis testing. This sparked a discussion on whether to add new codes for specific genetic tests or amplify existing codes to accommodate genetic diseases or conditions. ACLA withdrew its proposal, even though AMA had approved it, and joined a workgroup established by the College of American Pathologists to devise a new approach. When the workgroup unveiled its recommendations in August 2003, the CPT panel deferred approval to get input from Medicare and private health insurers. At the panel's meeting last November, participants in a session conducted by the workgroup agreed the modifier system would allow accurate reporting and identification of genetic tests as well as better tracking of genetic test utilization.

Tips On Preparing For JCAHO's New Lab Accreditation Survey

Later this year or next, JCAHO plans to add a periodic performance review for labs, which would take place between surveys

In an interview with *NIR*, Joanne Born, chief of lab accreditation at the Joint Commission on Accreditation of Healthcare Organizations, suggested steps that labs it accredits can take to prepare for the new survey process that JCAHO began this year (*see below*). The Chicago-based organization, which accredits many of the nation's hospital labs, is using a priority-focused process that includes a novel tracer methodology and other innovations to make the surveys more relevant and safety-focused, she said.

Called "Shared Visions—New Pathways," the process starts well before the survey via a software application called the Priority Focus Tool, which draws on data from previous accreditation surveys, proficiency testing, the lab's survey request, and additional sources to identify the most significant areas of inquiry.

Surveyors will use a new "tracer methodology" for their surveys, which means "they will spend a lot less time buried in a conference room with books," such as maintenance and training records, Born said. They will ask to see a patient's records and chose some of the specimens listed in the records to track through the healthcare system. Along the way, they will assess the lab's quality control procedures through direct interaction with front-line staff who perform these procedures. "The neat thing about the tracer methodology is that it really connects the dots between standards and processes," Born noted. For example, a surveyor could ascertain that emergency-room lab results failed to follow a patient into intensive care because of poor communications.

JCAHO Lab Survey Tips

Tools To Get Ready For Review

- ❑ Read the standards and keep up with them
- ❑ Visit the JCAHO Website, *www.jcaho.org*
- ❑ Read the JCAHO newsletter, "Perspectives"
- ❑ Read JCAHO's new "Lab Focus" newsletter
- ❑ Concentrate on continual improvement of quality and processes
- ❑ Think about connecting the dots within your organization

The new survey process includes additional follow-up. Surveyed labs get 90 days to submit evidence that they have a plan to correct problems cited in the surveyor's report. But that's not all. Over the next 4-6 months, the lab would check to make sure the plan is keeping it in compliance and report findings to JCAHO.

To reduce the pressure on lab management to ace the survey with what Born termed "a percentage score that doesn't mean much," JCAHO has dropped the public scoring of surveys. Instead, labs will get a check mark on JCAHO's Website if they obtain accreditation, as well as a plus sign if they are above average or a minus sign if they are below average, but above the threshold for accreditation.

focus on: *Lab Competitive Bidding*

Major Questions Confront Work On Medicare Pilot Program

Since the mid-1980s, not long after Medicare switched to fee schedule reimbursement for Part B laboratory services, Congress and various Administrations have been intrigued by the potential of lab competitive bidding to produce cost savings for the mammoth federal program. But each time, the clinical laboratory industry has lobbied successfully against the idea, blocking even a pilot project to examine how the idea would work.

But the political climate changed late last year when Congress resurrected the issue in the Medicare reform law (the Medicare Modernization Act of 2003, or MMA, Public Law 108-173). Lawmakers directed the Centers for Medicare & Medicaid Services to conduct a competitive bidding demonstration for independent lab services, that is, those furnished without a face-to-face encounter with the beneficiary. While no deadline was set for the actual project, Congress did instruct CMS to submit a progress report by the end of 2005. Earlier this month, the agency took preliminary steps by holding a special "listening session" to gather industry input (*NIR, 25, 10/Mar. 8, '04, p. 1*).

RTI's Proposed Lab Demo Design

Scope: The demonstration would cover 99 lab tests for beneficiaries living in as many as three Standard Metropolitan Statistical Areas. For hospitals, it would only apply to "non-patient" outreach testing. There would be two or three bidding cycles over a three-year period.

Bidding: Labs would have to bid to keep getting Medicare lab work in the area, unless the amount of relevant testing they performed fell below a $100,000 threshold. In their bids, labs would have to show they had sufficient capacity and geographic coverage to do the requisite lab work, and explain how they would handle any of the 99 tests they couldn't perform themselves.

Awards: Medicare would weight the bids by anticipated test volume to form composite bids, which it would array from lowest to highest. It would select the lowest bidders that together had enough capacity and geographic coverage.

Reimbursement: Medicare would establish a new fee schedule based on the average of the winning bids. Losing bidders would be excluded, though in the very first bidding round they might be allowed to provide services at reduced rates. Non-bidders who do not fall below the $100,000 threshold would be excluded.

Quality: Medicare would rely on the CLIA regulatory system to ensure quality and would monitor quarterly reports from winning and losing labs on five indicators of pre- and post-analytic quality.

Source: Research Triangle Institute study, 1997.

Previous Effort Sidelined

CMS already has in hand a plan for a lab competitive bidding demo that the North Carolina-based Research Triangle Park prepared for the agency in 1997 (*see box left*). That study was conducted under the watchful eye of lab industry groups that served on the project's technical advisory committee. Further work got shelved as CMS grappled with instituting major payment policy reforms mandated under the 1997 Balanced Budget Act, including new prospective payment methodologies for hospital outpatient services, nursing home and home health agency services.

The Act did authorize competitive acquisition demonstrations for Part B services, excluding physician services, over a three-year period ending Dec. 31, 2002. CMS opted to target staff resources on bidding pilot programs for durable medical equipment. The pilots were run

in Polk County, FL, and San Antonio, TX, with savings of an estimated 17% reported for the former and 22% for the latter, prompting Congress to require, as part of the Medicare reform law, a phase-in of nationwide competitive bidding for selected DME services, beginning in 2007.

Influential Voice Against Lab Bidding

In response to a provision in the 1997 Balanced Budget Act, the Institute of Medicine assessed current and alternative payment methodologies for Part B lab services, and in its final report to Congress in 2000, recommended against basing payment on competitive bidding, citing a number of likely difficulties:

- If only winning bidders were allowed to compete for Medicare work, this would depress the financial health of the non-winning labs, disrupting the industry and possibly reducing access to care, at least in the short term. Even if losing bidders were not excluded, competitive bidding still could hurt some sectors of the industry and the patients those sectors serve.
- Efficiency gains in the marketplace would be offset to an unknown extent by the cost of administering the bidding process.
- Multiple winners would have multiple fee schedules, causing post-award administrative headaches.

The IOM was not averse, however, to selective use of competitive bidding "as a possible means of collecting data that could inform [the] calculation of the level of payment."

During this same time period, the Institute of Medicine, at the request of Congress, scrutinized various alternatives to payment for Part B lab services via the current fee schedule. Competitive bidding was rejected as an across-the-board approach (*see box left*).

Issues CMS Intends To Address

Now that Congress has mandated a focus on extending competitive bidding to lab services, CMS must resolve a number of key issues. The first order of business will be to dust off RTI's report on program design and implementation, and re-examine it in light of current law, the subsequent evolution of the lab sector and the results of the DME projects. Part of the process will involve clarifying the meaning of various provisions in the MMA relating to the lab demo.

Lab Industry Input: At this month's "listening session," CMS heard loud and clear that lab groups want to be closely involved in an advisory capacity as the agency develops the demonstration project. "We do want to ensure full public input, including industry groups," a CMS official told *NIR*. "We're still looking at whether it would be an advisory committee or a technical committee or both." The MMA requires CMS to form a "Program Advisory and Oversight Committee" to monitor the expansion of DME competitive bidding.

Face-To-Face Encounter: The MMA limits the lab demo to tests "furnished by entities that do not have a face-to-face encounter with the individual." Lab groups are very anxious about how CMS will interpret this provision. Will it apply just to specimen pickups by labs serving physician offices, or will it include specimens drawn by phlebotomists who are employed or hired by hospital outreach programs and independent labs to collect specimens in the doctor's office and at other draw stations? "We have been talking with attorneys and policymakers in the agency to get a reading on the face-to-face provision," the CMS official told *NIR*. "It's an important issue."

Multiple Awards: Lab groups all called for multiple awards to prevent a single contractor from using a low-ball bid to dominate the market, then later hike prices. CMS intends to issue multiple awards in the demo, mainly to foster continuing competition on quality by giving physicians a choice of labs for test ordering, but also to foster small business participation. In any case, Section 302(b) (2)(iv) of the MMA requires multiple winners.

Feds Already Contract For Clinical Lab Services

Outside the Medicare program, the Federal Government has a long history of contracting for clinical laboratory services. In fiscal 2002, the government contracted for $58 million of laboratory testing services, mostly from the Defense Department and HHS, according to data from the General Services Administration. That's a drop in the bucket compared to the $5+ billion spent for lab services under Medicare Part B that year, but it does indicate another template for contracting. In addition, the Department of Veterans Affairs has a supply schedule that includes in-vitro diagnostics, reagents, test kits and test sets.

Some typical lab service contracts last year include:

- A $780,121 one-year fixed-price contract awarded by the Veterans Affairs Department to Pathology Associates Medical Laboratories (Spokane, WA) for reference testing services at a VA medical center in Boise, ID. Quest Diagnostics and Esoterix also bid.
- A $1.28 million one-year fixed-price contract awarded by the VA to Quest Diagnostics for reference testing services performed at its facility in Chantilly, Virginia. The award covers three southern states. There were two other bidders.
- A $5.88 million one-year contract awarded by the HHS Indian Health Service to Sonora Quest Laboratories (Tempe, AZ) for reference testing and pathology consultation services. The agency is still considering whether to release information about other bidders.

Single Payment Amount: CMS has not decided whether the lab bidding demo will use the same price-setting process as the two DME demos. For these demos, CMS calculated composite bids, selected the lowest bidders, established a fee schedule based on their bids, and offered them the opportunity to win business on the basis of that schedule. Losing bidders had to wait until the next bidding round for a chance to compete for Medicare business. The MMA directs CMS to take the same approach in expanding DME competitive bidding nationwide.

Federal Acquisition Rules: CMS could choose to borrow from the competitive bidding procedures of the Federal Acquisition Regulation, which governs most federal contracting. FAR provisions could be used to set procedures for ensuring quality and to shield the thousands of small independent labs (those with annual receipts of less than $11.5 million) from direct competition with large labs. However, a CMS official said such protection may be unnecessary, since small businesses accounted for three-fourths of the winners in the DME demos.

A CMS spokesman told *NIR* that the FAR does not apply to the lab bidding demo, because it is for services provided to Medicare beneficiaries, while the FAR only covers supplies and services provided "by and for the use of the federal government." Additionally, the Medicare legislation gives the HHS Secretary the authority to waive application of nearly any FAR provision to the lab bidding pilot and the expansion of DME competitive bidding. A separate MMA provision applies the FAR to contracts the agency puts out to bid for the new role of Medicare Administrative Contractors, which eventually will take over the functions now exercised by carriers and fiscal intermediaries.

Colorectal Cancer Screening: Some lab groups believe the MMA allows CMS to include colorectal cancer screening in the lab demonstration. The agency's interpretation is that the statute excludes such screening from the demo. All agree that the statute is clear about excluding Pap smears.

What's Next?

The timing of the lab demonstration is open-ended, with no statutory requirement other than a progress report to Congress by Dec. 31, 2005. CMS has mapped out a series of design steps and consultations with various industry and government groups. However, a CMS official said, "We really don't have an implementation schedule or date that has been reviewed or agreed to."

Senate Clears McClellan To Head Medicare, Medicaid Agency

But in a change triggered by the drug importation controversy, McClellan won't be heading up the 13-member HHS task force studying this issue. U.S. Surgeon General Richard Carmona will hold that post. McClellan will serve as a member of the panel

In a unanimous voice vote, the Senate on Mar. 12 confirmed the nomination of Mark B. McClellan, MD, PhD, as administrator of the Centers for Medicare & Medicaid Services after a brief but fiery dispute over the issue of importing prescription drugs from Canada, which McClellan staunchly opposed in his previous role as head of the Food & Drug Administration.

The Senate Finance Committee on Mar. 9 voted 18-2, with one abstention, to send McClellan's nomination to the full Senate, though Sens. John McCain (R-AZ) and Byron Dorgan (D-ND) had threatened to put a hold on it. Dorgan made good on his threat, but released the hold after Majority Leader Bill Frist (R-TN) agreed to form a drug importation working group and McClellan agreed that, prior to confirmation, he would testify on the issue before the Senate Commerce, Science & Transportation Committee, which McCain chairs and on which Dorgan serves.

McClellan testified on Mar. 11, saying he opposes importing prescription drugs because of the problem of counterfeit drugs sold over the Internet, often from other countries. In an import "blitz exam" last November, he said, FDA found that 69% of the 3,375 products (80% of them from Canada) were potentially dangerous. Further, he said that re-importing drugs to take advantage of price controls overseas undercuts the U.S. approach to holding down drug costs, which is to rely on quicker patent expiration and cheaper generics.

Heading Into A Hornet's Nest

As newly confirmed Mark McClellan prepares to run CMS, the Bush Administration is taking major flak from Democrats for its role in the run-up to enactment of the landmark Medicare reform law and its TV ads on how the law will impact seniors.

HHS Secretary Tommy Thompson has ordered his Office of Inspector General to probe charges that Administration officials withheld from Congress a Medicare actuary's estimate that the new drug benefit and other program changes could cost some $550 billion over 10 years and never contradicted the Congressional Budget Office estimate of $400 billion, the figure lawmakers used to craft the law.

Also, the General Accounting Office has agreed to a request from Hill Democrats to investigate whether TV "news releases" prepared by HHS violated the ban on using taxpayer money for "publicity or propaganda." The ads tout Medicare reform as "the same Medicare with more benefits." Viewers aren't told that HHS produced the ads and had a consultant pose as a journalist.

BRIEFLY N·O·T·E·D

Red Cross Fined Again: The Food & Drug Administration has followed through on its warning and fined the American National Red Cross an additional $450,000 for continued shortfalls in management of its biomedical services program. The latest fine, announced Mar. 8, came after FDA concluded that the Red Cross "still has failed to correct significant deficiencies" in standard operating procedures for its blood services operations (*NIR, 25, 9/Feb. 22, '04, p. 3*).

Electronic Test Ordering Initiative: CMS officials plan to meet with representatives of the clinical laboratory community in Washington, DC, on Mar. 26 about a new pay-for-performance initiative to reward physicians who convert to electronic health record systems and start ordering lab tests electronically.

Big Increase Seen In Quality Care Reporting By Hospitals

Use of a financial carrot to reward quality performance by various provider groups is expected to spread throughout Medicare. For hospitals, the next steps in the quality initiative include finalizing a standardized survey on patients' experience and the collection and reporting of more clinical measures

About one of three hospitals in the U.S. that are reimbursed by Medicare and Medicaid are voluntarily reporting at least one quality measure from a set of 10 quality measures adopted by the federal Department of Health & Human Services. To date, says HHS, 1,407 hospitals are sharing at least one of the clinical quality measures, more than three times the number that did so in October 2003, when the Department began publishing this information. A total of 492 hospitals are sharing quality data in each of three clinical categories—heart failure, heart attack and pneumonia.

The number of hospitals that report quality data voluntarily is expected to grow under new financial incentives approved in the Medicare reform law. Under that law, from fiscal 2005-2007, hospitals that submit inpatient care quality data to HHS will get a full update to their inpatient prospective payment, based on the market basket for each year. Those that don't will see their update reduced by 0.4%.

The hospital quality initiative was launched in December 2002 as a collaborative effort involving HHS, its Agency for Healthcare Research & Quality, and major organizations representing hospitals, physicians, labor unions and consumer groups, among others. The aim is to promote public reporting of quality measures that can help hospitals improve patient care and that can enable patients and their families to make more informed decisions about the care they need and receive.

washington WATCH

Latest Blame Game In Town

Amid the furor over alleged "disinformation" tactics by the Bush Administration over what Medicare reform will cost, HHS Secretary Tommy Thompson has been quick to dodge hostile fire.

Medicare's chief cost analyst says he was threatened with losing his job if he disclosed to Congress that the drug benefit could cost upwards of $550 billion. Lawmakers instead relied on the $400 billion estimate from their own budget office. Thompson ordered an internal probe but denied knowing about the conflicting numbers, telling reporters, "Tom Scully was running this…[he] was making those decisions." Former CMS head Scully is now in private law practice. And the Medicare analyst, Richard Foster, suggests, but has no proof, that the White House took part in the decision to withhold his calculations from Congress.

Meantime, seniors are questioning Medicare reform. In a recent poll, more than half didn't think they'd benefit, despite government ads promising "the same Medicare, more benefits."

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