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Industry Warns CMS On Pitfalls In Lab Competitive Bidding

The demo required by the Medicare reform law targets lab tests (excluding Pap smears and colorectal cancer screening) that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the tests

Officials at the Centers for Medicare & Medicaid Services got an earful at a special "listening session" convened Mar. 3 at agency headquarters in Baltimore, MD, to obtain input on a competitive bidding demonstration for independent clinical laboratory services mandated under the Medicare reform law (Public Law 108-173).

Lab groups are decidedly wary, if not hostile, to bidding as a payment alternative to the current Part B fee schedule and in the past have blocked the government from launching any pilot program to examine this approach. Faced now with a congressional go-ahead, the groups emphasized to CMS officials at the forum the problems and pitfalls that lie ahead.

Seeking to calm the waters, Linda Magno, director of CMS's Medicare demonstration programs group, told participants, "Rest assured, we have not made significant decisions. I'm not sure that much is written on paper, let alone set in stone or poured into concrete … CMS will choose multiple winners in each competitive acquisition area. We expect this will provide continuing incentives for labs to compete for business on the basis of high quality services," adding that while Congress requires a progress report by Dec. 31, 2005, "the statute does not specify an implementation date." ➠ *p. 2*

Bar Coding Required For Blood, Other Products

In a move to reduce medical errors that result in patient harm or death, the Food & Drug Administration is requiring machine-readable information on labels for blood and blood components intended for transfusion. The agency also is requiring linear bar codes (similar to those on food and other consumer products) on the labels of most prescription drugs and certain over-the-counter drugs commonly used in hospitals.

Most blood establishments already use FDA-approved symbols that identify the collecting facility, the lot number relating to the donor, the product code, and the donor's blood group and type. FDA also now specifies that the machine-readable information must be unique to the blood or blood component, be surrounded by enough blank space to permit proper scanning, and remain intact under normal conditions of use. ➠ *p. 7*

INSIDE NIR

ACLA opposes lab competitive bidding under Medicare, citing "significant concerns that the emphasis on obtaining the best price, which is inherent in the process, will result in lower quality … and ultimately in higher, not lower, healthcare costs." AAB also worries that it could decimate smaller labs serving areas that aren't profitable for low-ball bidders

Pitfalls In Lab Competitive Bidding, *from p. 1*

Lab groups raised a number of points that CMS should consider in crafting any lab bidding pilot:

- The demonstration should reflect the reality that labs compete not just on price, but also on quality and access to care in settings like nursing homes which are expensive to serve. Given the national priority on reducing medical errors, "we should be focused on improving quality, not reducing price," said Jeff Jacobs of the American Society for Clinical Pathology.
- All lab tests should be included in the pilot, not just high-volume procedures. Revenue from the latter help underwrite low-volume tests which are typically run at a loss.
- The pilot should allow multiple winners to prevent any one entity from monopolizing the market with low bids and then hiking prices to fee schedule levels. Contracts should run long enough to discourage low-ball bids, but not so long as to drive losing bidders out of business.

Alan Mertz, president of the American Clinical Laboratory Association, urged CMS to recognize that lab competitive bidding would be more complex than pilots conducted for durable medical equipment. These involved relatively simple commodities, he noted, but lab services require significant training, expertise and supervision. Moreover, there are more than 1,100 different codes for lab tests, ranging from simple chemistries to highly complex molecular analyses. No one lab furnishes all these tests, he pointed out, and some tests are unique to a single lab.

"Previous attempts [at lab competitive bidding] collapsed," he concluded, "because of the difficulty of developing a workable, relatively simple bidding model, which was not encumbered by overly complex rules and procedures."

Attorney Bob Waters, who represents the American Association of Bioanalysts, warned CMS officials that "competitive bidding sounds like a panacea, but can be a Pandora's box—so you should open it very carefully." Waters, who is with Arent Fox (Washington, DC), stressed that one mistake could put a lot of smaller labs, such as AAB members, out of business, even though these labs serve communities that no low bidder would touch. And even if the market is later corrected, there are "significant barriers to re-entry," he said.

Florida Medicaid Opens Lab Bidding Competition

The Medicaid program for the state of Florida on Mar. 2 issued a request-for-proposals inviting independent clinical laboratories to bid to provide Medicaid recipients with a full suite of testing services. The state is looking to contract with a single lab for three years, and the deal could be renewed for an additional two years. Currently, Florida's Medicaid program obtains these services through agreements with more than 160 labs statewide.

More than 1.1 million Medicaid recipients in the state will be required to use the contracting lab. A roughly equal amount of recipients covered by HMOs or eligible for Medicare will have an option to use the lab.

Florida Lab Bidding RFP
Contacts, Schedule

The issuing officer at Florida's Agency for Health Care Administration is Susan Rinaldi, program analyst in the Bureau of Medicaid Services, 860-922-7308. The contracting officer is Bob Sharpe, the agency's deputy secretary for Medicaid, 850-488-3560.

A pre-proposal conference has been scheduled for Mar. 9, 1 p.m., at the Agency for Health Care Administration in Tallahassee. Notices of intent to propose are due Mar. 16, proposals by Mar. 30. The state intends to award a contract by Apr. 23.

The RFP is posted at *http://fcn.state.fl.us/owa_vbspdf/owa/39455_AHCARFP0412_1_0.pdf*

In their cost proposals, labs must bid a percentage reduction from the Florida Medicaid lab fee schedule. In their technical proposals, they must show the ability to interface electronically with the state's real-time prescription tracking and dispensing system, and their ability to transmit test results electronically to the Medicaid fiscal agent. The state also is looking for signs of quality, reliability and statewide accessibility. To compete, labs must be accredited by the College of American Pathologists or the Joint Commission on Accreditation of Healthcare Organizations. Hospital and physician office labs are excluded.

An earlier draft of the RFP called for 11 contracts, one for each of the state's area offices (*National Intelligence Report, 24, 12/Apr. 7, '03, p. 4*). A similar initiative last year for durable medical equipment got tangled up in a series of bid protests and eventually was cancelled. According to an industry source, the problem with the DME solicitation was a technical matter that has since been resolved, and that should not affect the lab contracting solicitation.

Certain Reference Testing Exempted From 2ndary Payer Rules

CMS's decision to sweep away any MSP requirements on independent or hospital labs surprised many in the legal community. Attorney Robert Mazer with Ober/Kaler (Baltimore, MD) reiterates that a provider that knows, or has reason to know, that Medicare is not the primary payer should not bill the program

Hospital outreach testing that does not involve a face-to-face encounter with a Medicare beneficiary is free from Medicare secondary payer (MSP) requirements, the Centers for Medicare & Medicaid Services has instructed local fiscal intermediaries. Previously, hospital labs performing reference work could not bill Medicare unless they had obtained information on whether another payer was primary and had verified this information every 90 days.

The change implements Section 943 of the Medicare reform law (Public Law 108-173), which barred CMS from requiring hospitals to do more under MSP rules than it requires of independent clinical labs. The agency says its policy will be to not require independent labs to collect MSP information for reference testing services defined in Section 943 and, thus, won't require hospitals to do so either. The law defines the affected services as "clinical lab diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under Part A or enrolled under Part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation."

The policy change—announced in Pub. 100-05, Transmittal 11 (Feb. 27, 2004)—is effective as of last Dec. 8 (when the Medicare reform bill was signed into law). Medicare intermediaries are to implement it by this coming Mar. 29. Claims for reference lab testing with dates of service on and after Dec. 8, 2003 are to be excluded from MSP hospital audits. The policy change does not alter MSP requirements for hospital inpatient admission, outpatient registration, or recurring outpatient services.

HHS Panel To Focus On Genetic Test Coverage, Payment

Medicare officials identified some steps the advisory committee could consider to expand genetic test coverage and increase payments, including recognizing family history or predisposition to disease as a diagnostic tool and setting fees based on inherent reasonableness

A federal advisory committee on Mar. 2 decided to focus on improving Medicare coverage and reimbursement for genetic tests after learning that, absent a coordinated coding and regulatory initiative, these bread-and-butter issues are impeding access to care. But first it opted to dash off a letter to Health & Human Services Secretary Tommy Thompson, urging the Bush Administration to lean on House GOP leaders to secure passage of S. 1053, a bill the Senate passed 95-0 to protect individuals from employer and insurer discrimination based on genetic tests (*related stories: NIR, 25, 2/Oct. 24, '03, p. 1; 24, 17/June 23, '03, p. 2*).

On genetic testing payment issues, the panel—the HHS Secretary's Advisory Committee on Genetics, Health & Society—heard from Andrea Ferreira-Gonzales, PhD, director of the Molecular Diagnostics Laboratory and associate professor of pathology at Virginia Commonwealth University in Richmond. There has been an "explosion" in the amount of genetic testing since 1999, she noted, but reimbursement remains generally below cost. In her experience, the lab has been able to perform this testing by using revenue from other tests, but the ability to continue this will be reduced in the future. This is a common situation at many of the university-affiliated labs that do the bulk of genetic testing today, she said. For example, it costs $266.34 to test for the Fragile X Syndrome, the most common cause of mental retardation, while the Medicare lab fee schedule applicable to Virginia pays only $62.30.

Addressing coding issues, Ferreira-Gonzales noted that the American Medical Association's CPT Editorial Panel on Feb. 7 "favorably received" a proposal from its genetic testing workgroup to create a series of alpha-numeric modifiers to code molecular genetic tests. The scheme, which AMA might add to the CPT 2005 update, could accommodate the anticipated flood of new genetic tests without a concomitant increase in the number of individual codes.

In noting a major obstacle to coverage, CMS medical director, Sean Tunis, MD, MSc, told the advisory panel that genetic testing typically screens for predisposition to a disease and does not diagnose disease. Coverage of screening tests under the Part B preventive services benefit has required congressional approval. Tunis suggested that the committee might want to approach HHS about broadening "diagnosis" to include a family history of a disease.

Regarding genetic test payment, CMS' Don Thompson noted that Part B lab fees are frozen through 2008, but fees for specific tests could be raised under Medicare's inherent reasonableness rule. The agency is, in fact, considering doing so for HIV and HCV viral load. CMS aims to issue final instructions on inherent reasonableness this year, he said, then begin using it to adjust payment rates. Fees for new lab tests are now set via gap-filling, which has its flaws, or cross-walking them to out-of-date, low prices of old tests, Thompson noted. But this could be modified under a provision in the Medicare reform law requiring HHS to establish procedures for setting fees for lab tests with new or substantially revised codes. CMS will likely seek comment, he said, on whether the modifiers that CPT is considering would result in "substantially revised" codes.

McClellan Nomination Hits Snag In The Senate

Nominated to lead CMS, Mark McClellan, MD, PhD, if ultimately confirmed, faces the challenge of making Medicare reform work, including creation of a prescription drug benefit and boosting the role of private health plans in serving beneficiaries

It was expected to be a cakewalk, but the President's nomination of FDA chief Mark McClellan to head the Centers for Medicare & Medicaid Services has run into a bipartisan buzzsaw. Sens. John McCain (R-AZ) and Byron Dorgan (D-ND) say they will stall the confirmation to protest McClellan's opposition to importing prescription drugs from Canada, where they sell for considerably less than in the U.S. A growing number of individuals, local elected officials and states are already seeking lower drug costs from Canada.

Under the Medicare reform law, Congress authorized U.S. pharmacists and wholesalers to reimport drugs from Canada as long as the U.S. Department of Health & Human Services certifies that this would generate significant cost savings and not pose any additional risk of harm. But McClellan, who was Mr. Bush's chief health policy adviser before becoming FDA commissioner, has been outspoken against it. "Under current law, we have neither the authority nor the resources to ensure the safety of drugs outside the federal-state system for regulating drugs," he told a recent Medicare conference in Washington, DC.

McClellan has also come under fire for heading a federal task force studying reimportation. Critics say his views could cloud the panel's work, but he has vowed to provide an "open, transparent, fact-based analysis." The task force will hold meetings over the next few months with consumer groups, elected officials and international organizations. Its report is due in December.

Despite the confirmation snag, the President's choice of McClellan to head CMS has been applauded by leaders of both parties on Capitol Hill and by a broad range of healthcare interests, including clinical laboratories. With his background as a physician and an economist and his support for private-sector innovation, McClellan "understands that new tests on the horizon will really improve healthcare—and he will be fair in evaluating new technologies and deciding how to reimburse them," said Alan Mertz, who heads the American Clinical Laboratory Association.

♦ QUESTION *of the* M·O·N·T·H

We are an independent lab, and our local carrier is very good about sending us copies of new transmittals from the Centers for Medicare & Medicaid Services to help us keep up with Medicare coding and billing policies. The problem is, these documents are written in technical language, and much of what they say would only be of interest to the carrier. I don't always have time to study them or explain them to everyone here that's affected, not to mention the hospitals and physicians with whom we must coordinate. Is there an easier way?

Yes. Help is on the way. CMS has developed provider outreach materials for use by carriers and fiscal intermediaries. In fact, CMS is requiring the contractors to send you these provider-focused, nationally consistent materials for all Medicare change requests that take effect on or after July 1. See *www.cms.hhs.gov/medlearn/matters*. To be notified whenever a new Medlearn Matters article is posted, sign up with the listserv at *list.nih.gov/archives/medlearn-matters-1.html*.

Hospitals May Discount, Waive Charges For Uninsured, HHS Says

Nothing in Medicare law or policy prevents hospitals from discounting or waiving charges to the uninsured or underinsured, Health & Human Services Secretary Tommy Thompson affirmed Feb. 19, brushing aside concerns raised by the American Hospital Association. And to ram the point home, he directed the Centers for Medicare & Medicaid Services and the Office of Inspector General to prepare summaries of current policy to guide hospitals.

Thompson was responding to a Dec. 16 letter from AHA president Dick Davidson who contended that Medicare rules hamper a hospital's ability to reduce rates for patients in need and require a hospital to undertake aggressive collection efforts against patients who can't afford to pay. According to an AHA legal analysis, the problem lies with Medicare's uniform charge requirement, limits on indigent and "gross-up" exceptions, and bad debt policy, as well as OIG enforcement.

AHA asked HHS to create a safe harbor for hospital discounts or waivers for patients of limited means, to offer timely advisory opinions that are binding on both CMS and the OIG, and to establish a panel of hospitals and others to resolve regulatory conflicts. But Thompson said summaries of existing policy should offer sufficient help.

Key Documents

- HHS Frequently Asked Questions, Feb. 20, 2004: *www.cms.hhs.gov/FAQ_Uninsured.pdf*
- OIG Guidance, Feb. 19, 2004: *oig.hhs.gov/fraud/docs/alertsandbulletins/2004/hospitaldiscounts.pdf*
- AHA legal analysis, Dec. 17, 2003: *www.hospitalconnect.com/aha/key_issues/bcp/content/analysisfinalweb.pdf*

Key Points Made By HHS

- Discounts for uninsured patients who can't afford to pay are not prohibited or restricted under the federal anti-kickback statute as long as they are not tied directly or indirectly to the generation of business payable by a federal healthcare program. Moreover, the OIG's enforcement policy against discriminatory billing will continue to exclude from "usual charges" free or substantially reduced charges to uninsured or underinsured patients.
- A waiver of all or part of a Medicare cost-sharing amount is permitted on a case-by-case basis for financially needy beneficiaries. "Financial need" is not limited to "indigence," but can include any reasonable measures of financial hardship. HHS notes that hospitals can define "indigents" as those who would become indigent if forced to pay their hospital bills.
- Routinely waiving Medicare cost-sharing or offering a waiver as an inducement to select a particular provider or supplier is prohibited. But there are two main exceptions to the general ban that hospitals can utilize. One exception is for financial hardship. But to qualify, the waiver may not be offered as part of any advertisement or solicitation, the hospital may not routinely waive cost-sharing, and the hospital waives cost-sharing after determining in good faith that the beneficiary is in financial need or reasonable collection efforts have failed. The other exception is the safe harbor for inpatient hospital services reimbursed under prospective payment. A waiver is allowed if the hospital does not claim it as bad debt (or otherwise shift the burden to other payers or individuals); the waiver is made without regard to the reason for admission, length of stay, or diagnosis-related group; and the waiver is not part of a price reduction agreement with a third-party payer (other than a Medicare SELECT plan).

Uncharitable Hospitals Face Bad PR—& Taxes

Hospitals have come under harsh scrutiny recently from patient advocacy groups and Congress for charging the uninsured full price for treatment or services, while patients covered under a private or government plan get lower negotiated prices. Hospitals also have been sharply criticized for debt collection practices. Venerable not-for-profit institutions like Yale New Haven Hospital have been excoriated in the news media for garnishing wages and trying to repossess homes of low-income workers. And last month, the Illinois Department of Revenue ruled that Provena Covenant Medical Center in Urbana no longer deserves the tax status of a charitable institution, partly because of aggressive collection practices that included sending uninsured debtors to jail. The hospital is appealing the decision, which would force it to pay $1.1 million a year in property taxes.

- ❑ Hospitals do not need permission from the government before offering discounts. HHS says discounts would not affect a hospital's cost-to-charge ratio or Medicare cost apportionment as long as full charges are noted on the Medicare cost report. Hospitals that want assurance that their discounting practices don't run afoul of fraud and abuse laws should request an OIG advisory opinion. This is legally binding, HHS says, on it, the OIG, and the requester.
- ❑ Nothing in Medicare instructions requires hospitals to take low-income patients to court, seize their homes or send claims to a collection agency. Under federal law, hospitals do not have to engage in any specific level of collection.

Bar Coding, *from p. 1*

Under a final rule announced Feb. 25, all blood and blood products and most previously approved medicines must be in compliance with the new requirements within two years (by Apr. 26, 2006). New medications covered by the rule must include bar codes within 60 days of approval.

In a study at a Veterans Affairs Medical Center that used bar code scanning from a patient's admission to bedside drug dosing, 5.7 million doses were administered with no medication errors, the government in finalizing the new bar code labeling requirement

In its initial proposal on Mar. 14, 2003, FDA requested comments on whether to specify a standard, such as the ABC Codabar (which many U.S. blood establishments use) or the international standard ISBT 128 (which is touted as more secure, more flexible and able to handle more information). After receiving comments backing both standards as well as a third, the EAN.UCC standard, FDA decided to let stand its original language, allowing blood establishments to adopt whatever standard they prefer and switch to newer and better standards if they choose, as long as the standards are approved for use by the agency's Center for Biologics Evaluation & Research.

The burden of complying with requirements in the final rule falls on manufacturers, repackers, relabelers and private label distributors. Hospitals don't have to use the bar coding system, but the government hopes the new rule will prod them to invest in advanced information systems. Most hospital pharmacies manage their inventory with bar code scanners, but only about 1% of the 5,000 hospitals in the U.S. use bar coding at the patient's bedside. When fully implemented, FDA estimates, the final rule will help prevent nearly 500,00 adverse events and transfusion errors over 20 years.

According to FDA, studies show there are ABO-incompatible transfusion errors once every 38,000 transfusions. With 15.7 million units transfused in the U.S. annually, that comes out to 414 errors per year; two-thirds, or 276, were preventable. Of those, an estimated 55% were in patient care. FDA figured that 75% of those errors, such as phlebotomy errors and incorrect patient identification, could be detected by bedside barcoding systems, for a total of 114 prevented annually.

Targeted Medical Liability Bill Stumbles In The Senate

The bill had broad support from organized medicine, including the AMA, the College of American Pathologists, and the Alliance for Specialty Medicine, which says its members fully back the strategy targeting high-risk providers

Senate Republicans on Feb. 24 failed to win passage of a bill offering medical liability relief to obstetricians and gynecologists and backed by the White House, but the GOP leadership aims to keep pushing for malpractice damage limits for these physicians and other specialties hardest hit by soaring insurance premiums. The latter include physicians providing emergency room services and trauma care as well as physicians practicing in underserved rural and inner city areas.

The bill, S. 2061, fell 12 votes short of the 60 votes needed to force floor debate. The measure sets no limits on economic damages, but would cap pain and suffering damages at $250,000 and limit punitive damages to twice the award for economic damages or $250,000, whichever is greater. It also would let courts restrict attorney's contingency fees. Last year, a bill with similar curbs but affecting all medical specialties passed the House, where the GOP has a solid majority, while its Senate counterpart fell 11 votes shy of the total needed for floor action (*NIR, 24, 19/July 24, '03, p. 3*).

Thwarted from making across-the-board medical tort reforms, Senate GOP strategists are hoping an incremental specialty-specific approach will prove more successful and help in this year's election campaigns. They accuse trial lawyers and exorbitant jury awards for causing malpractice premiums to soar, forcing doctors to close their practices and leaving patients with no alternative access. Senate Democrats, while sensitive to the issue, argue that a better solution lies in tax relief for high-risk specialties, rather than limiting the individual's recourse for damages. They blame insurers for the rising cost of premiums and favor ending insurers' antitrust exemption.

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