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CMS Issues Lab Bidding Project Report, Draft Application

The purpose of the demo, says CMS, is to test whether competitive bidding can be used to obtain lab services at prices below current Part B pay rates without jeopardizing the quality of services and beneficiary access to services.

Nearly four months late, the Centers for Medicare & Medicaid Services has sent an initial report to Congress on progress made in the Part B laboratory competitive bidding demonstration. Congress required the report as part of the 2003 Medicare reform law, with a deadline of December 31, 2005.

The report generally reflects the recommended demo design developed for CMS by Research Triangle Institute International (RTI). It calls for running a three-year pilot project in two test sites within a single state. The demo would be limited to independent lab services, but this would include hospital outreach work as well as physician office labs serving as referral facilities.

CMS also has taken the first step to get regulatory clearance for a single application form that all clinical labs providing Part B lab services to Medicare beneficiaries in the demo sites would have to complete, whether bidding or not (labs under common ownership or control would have to submit only one application). The agency published a call for public comment on the proposed application in the April 21 *Federal Register*, with a deadline of June 20. For more on the recommended design for the lab bidding demo and the draft application, see the *Focus*, pp. 4-5.

INSIDE *NIR*

Medicare To Award 1st MAC Part A/B Contract

By the end of June, Medicare intends to take a big step in the transition from the current claims processing system of carriers and fiscal intermediaries to a competitively bid system of new entities known as Medicare Administrative Contractors (MACs) to handle both Part A and Part B claims processing in specified geographic jurisdictions (*see table, p. 2*).

The Centers for Medicare & Medicaid Services said it plans to announce, by the end of next month, the award of the first A/B MAC contract—for Jurisdiction 3, which includes Arizona, Montana, North and South Dakota, Utah, and Wyoming. The complete handover of the work to the new MAC is planned for July 2007, CMS noted in an April 27 statement.

At present, Part A claims from hospitals and other institutional providers, as well as hospital outpatient lab claims payable under Part B, generally go to intermediaries, while Part B claims ➥ *p. 2*

In all, CMS is planning for 23 MACs, with no national MAC. They will include 15 to serve most Part A/Part B providers, four for home health and hospice providers, and four to serve durable medical equipment suppliers.

1st MAC Part A/B Contract, *from p. 1*

from independent and physician office labs, pathologists, and other providers generally go to carriers. The MAC system, established as part of a series of contractor reforms in the Medicare Modernization Act of 2003, will eliminate this split.

Moreover, under the MAC program, companies other than health insurance firms can, for the first time, bid for contracts to handle Medicare A/B claims processing. Previously, this was limited to health insurers, and many of these that now have contracts to handle Part A and/or Part B work are expected to bid to become a MAC.

CMS said its staff are working on the scope-of-work statement and other information that will be part of a Request-for-Proposal for the next group of MAC contractors, referred to by CMS as Cycle One. This will involve separate competitions for seven MAC jurisdictions that account for approximately 45% of Medicare's A/B claims workload. The competitions will run in two rounds. The first will cover three jurisdictions, CMS said: J4, J5, and J12. A notice of the draft scope-of-work statement for Cycle One, Round One, was published May 3 on the Federal Business Opportunities Web site, *www.FedBizOpps.gov*.

The transition to the MAC administrative structure is to be implemented, CMS said, through a series of acquisition cycles (nine to 12 months from solicitation to award). The subsequent workload shift is projected to take six to 13 months after award of the contract.

Fifteen MACs will be chosen for the following Primary A/B jurisdictions under the procurement schedule below:

Jurisdiction	States	RFP Issuance	Award Date
1	American Samoa, California, Guam, Hawaii, Nevada, Northern Mariana Islands	Sep 06	Sep 07
2	Alaska, Idaho, Oregon, Washington	Sep 06	Sep 07
3	Arizona, Montana, North and South Dakota, Utah, Wyoming	Sep 05	Jun 06
4	Colorado, New Mexico, Oklahoma, Texas	Sep 06	Sep 07
5	Iowa, Kansas, Missouri, Nebraska	Sep 06	Sep 07
6	Illinois, Minnesota, Wisconsin	Sep 07	Sep 08
7	Arkansas, Louisiana, Mississippi	Sep 06	Sep 07
8	Indiana, Michigan	Sep 07	Sep 08
9	Florida, Puerto Rico, U.S. Virgin Islands	Sep 07	Sep 08
10	Alabama, Georgia, Tennessee	Sep 07	Sep 08
11	North and South Carolina, Virginia, West Virginia	Sep 07	Sep 08
12	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania	Sep 06	Sep 07
13	Connecticut, New York	Sep 06	Sep 07
14	Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	Sep 07	Sep 08
15	Kentucky, Ohio	Sep 07	Sep 08

CMS To Standardize Medicare Enrollment Requirements

Effective June 20, clinical laboratories, pathologists, and all other Medicare providers will have to comply with a revamped enrollment process to maintain billing privileges with the program, the Centers for Medicare & Medicaid Services announced in a final rule.

In an effort to streamline the entire process, CMS has standardized requirements for enrollment and periodic updates of enrollment information. And in one key bit of regulatory relief, the agency has extended provider re-certification of the accuracy of enrollment information to five years from the three years proposed in the April 25, 2003 rule. CMS also said it will phase-in the enrollment of physicians and other providers/suppliers who are currently billing Medicare but have not completed and submitted an enrollment form.

But CMS declined to make other changes in response to comments. For example, the agency said it will continue unannounced site inspections, calling them a "useful tool to ensure that enrollment requirements are met." CMS also turned down a request to "grandfather" providers/suppliers that already have billing numbers.

While all providers and suppliers—both new and those already in the Medicare program—must complete the CMS-855 Medicare enrollment application, those now in the program need not take any action at this time, CMS said; the agency will notify them when it is time to re-certify their Medicare enrollment information. Changes in enrollment data, however, must be reported within 90 days of the change (within 30 days for durable medical equipment prosthetics and orthotics suppliers). On May 1, CMS issued a revised CMS-855 application form (*www.cms.hhs.gov/MLNMattersArticles/downloads/SE0612.pdf* at the CMS Web site).

OIG Touts Provider Self-Disclosure To Resolve Fraud Risks

Hospitals and physicians who worry whether their financial ties might be improper under prohibitions in the physician self-referral law and/or the federal anti-kickback statute would benefit by coming forward voluntarily using a self-disclosure protocol to help resolve these issues, said HHS Inspector General Daniel R. Levinson in an April 24 Open Letter to healthcare providers.

Levinson is promoting the self-disclosure protocol (SDP) to resolve liability for civil monetary penalties (CMPs) under the Stark physician self-referral and anti-kickback statutes (*see box, p. 7*). It has worked well since the last Open Letter in 2001, he pointed out: "We have required a corporate integrity agreement in only 27 of the 136 self-disclosures resolved with a monetary payment."

But he noted that his Office has heard from hospitals that, through their compliance programs, have discovered potentially improper financial arrangements with physicians under these statutes and want to clear up violations promptly. "The SDP is one vehicle to resolve this type of administrative liability," Levinson stated.

The SDP promotion is targeted in particular to situations involving a financial benefit knowingly conferred by a hospital upon one or more physicians. The financial benefit can take many forms, Levinson noted, "for example, the physician pays the hospital below fair market value for lease of office space." ➥ *p. 7*

focus on: Laboratory Competitive Bidding

Quick Guide To The Recommended Medicare Demo Design

What could your clinical laboratory expect if you're in a geographic area selected to take part in a Medicare competitive bidding demonstration for independent lab services now paid under the Part B lab fee schedule?

Here's a quick guide, based on the report to Congress recently released by the Centers for Medicare & Medicaid Services, as required under the Medicare Modernization Act of 2003. The Act directed CMS to develop a bidding demo for lab services that do not involve a face-to-face encounter with the beneficiary. The CMS report summarizes the demo design recommended by Research Triangle Institute International (RTI).

Demo Duration

The bidding pilot would run for three years in two demo sites, with a staggered start date. Early data from the project would be used to see if it is feasible to expand the competitive bidding areas and also to estimate the range of Medicare savings.

Demo Sites

RTI recommends using Metropolitan Statistical Areas (MSAs) to define two demo sites. The sites should be within a single state. Each site should have a moderately large Medicare population (roughly 100,000 to 400,000 fee-for-service beneficiaries and a total population of one to four million) and should have neither very high nor very low Medicare managed care penetration (defined as greater than 5% but less than 50%). Twenty-two MSAs are potential candidates, but actual sites have yet to be proposed.

RTI recommends MSAs in a single state with a single carrier to reduce administrative costs. Running the demo in sites with a high Medicare population would increase potential Part B savings, but would also result in greater administrative complexity and potential service disruption, RTI notes.

Tests Covered

The demo would encompass all tests payable under the lab fee schedule that are provided to Part B beneficiaries in the demo sites, with certain exceptions. By law, Pap smears and colorectal cancer screening tests are excluded. CMS also would exclude new tests added to the fee schedule during the demonstration.

Bidding Process

A $100,000 threshold determines whether or not a lab must bid (*see box*). Bidding labs won't

To Bid Or Not To Bid

- ***Who In The Demo Sites Must Bid***
  - ❑ Labs with at least $100,000 or more in annual Part B fee-for-service payment for non-patient services, based on the most recent 12-month period for which data are available.
  - ❑ Required bidders that bid and lose or decline to bid are paid nothing by Medicare for the duration of the demo.
- ***Who May Bid***
  - ❑ Non-required bidders are labs that fall below the $100,000 threshold. They may submit a bid, in which case their Medicare revenues for tests included in the demo would not be capped.
  - ❑ Non-required bidders that do not bid will be paid the competitively bid fee schedule up to a pre-determined cap on total Medicare demo-covered test revenue per year.
- ***Who Is Exempt From The Demo***
  - ❑ Hospital labs performing inpatient testing (this is payable under Part A).
  - ❑ Hospital outpatient labs and physician office labs, except when they function as independent facilities doing work on referral for non-patients.

Having multiple winners would help assure both quality and access, CMS says, since the labs would have to compete with each other on these factors.

have to bid to provide coverage to the entire demo site, but would have to provide information on their capacity and geographic service area. They also are subject to prohibitions against collusion or antitrust behavior that are enforced by the Federal Trade Commission and the Justice Department.

CMS will conduct a "bidders conference" after release of the bid solicitation package to inform potential bidders about the demo rules. There will be a single bidding competition, and the agency expects multiple winning labs in each demo site.

Bidding labs would have to submit a bid price for each HCPCS/CPT code covered by the demo. They also would have to identify covered tests they do not perform in-house and how they would handle tests that are referred or subcontracted out. Further, a lab's bid would have to furnish information on ownership, location of affiliated labs and drawing stations, CLIA certification, laboratory finances, and quality.

Lab Bidding Demo Downloads

- ***CMS report to Congress***

Go to *www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_NewCongress.pdf*

- ***Application form and call for comments:***

— Solicitation of public comment: *Federal Register*, April 21, 2006, at *www.access.gpo.gov/su_docs/fedreg/a060421c.html*. Select CMS Notice 20697 (E6-5833).

— Application form: Google "CMS 10193" and it will pull up the site where you can access the draft eight-page form.

A lab's bid for individual tests would be weighted (based on each test's share of total expected demo volume) and summed to form a single composite bid. Composite bids would be arrayed from lowest to highest, and the array would be used, along with other criteria, to set the "pivotal" composite bid that will determine the winning labs. Bidders with composite bids less than or equal to the pivotal bid would be winners; those with composite bids greater than the pivotal bid would be losers. The government would establish a maximum acceptable composite bid, or "reservation bid," that would be slightly less than the composite bid obtained using the Part B lab fee schedule. Labs whose composite bids exceed the reservation bid would automatically be losers.

Reimbursement

The demo would create a competitively bid fee schedule for covered tests after the pivotal bid is selected and winning labs are determined. All winning labs would be paid the same for each test. Labs below the $100,000 threshold would be paid under the bid-set fee schedule. Payment for excluded tests would be via the Part B fee schedule, whether the lab wins or loses.

Service Quality, Access

To assure quality, the project would rely on compliance with CLIA rules and add standardized measures for turnaround time—total testing, specimen transport and processing, stat work, reporting of critical values, and public health disease notification. Log-in error rates, physician satisfaction, and the number of unusable or lost specimens would also be monitored. Labs in the demo would have to designate a quality assurance staff member as a contact point for CMS, physicians, and beneficiaries. The labs would have to submit information on service and quality standards that CMS would send to physicians in their communities. CMS also would run a toll-free complaint hotline.

To ensure access, the project would pick sites where there are enough labs to provide needed services and would monitor testing rates per beneficiary for diabetes, congestive heart failure, and coronary artery disease.

More From JCAHO On Switch To Surprise Inspections

The switch should be an impetus "for each organization to be in compliance with 100% of the standards 100% of the time," said JCAHO president Dennis O'Leary. "Making on-site evaluations is intended to satisfy both public demand for greater accountability and organizational demand for greater value when undergoing outside evaluations."

The Joint Commission on Accreditation of Healthcare Organizations has spelled out more details on the impact of its changeover this year to unannounced inspections for the more than 15,000 healthcare entities it accredits or certifies.

For fall 2006 through 2008, the unannounced survey will occur in the year in which the organization is due for its next survey. Lab surveys will be conducted six months prior to the lab's accreditation due date. In 2009 and beyond, unannounced surveys will occur between 18 months and 39 months after the previous full survey. Lab surveys will occur within 24 months of the lab's previous survey.

Labs and other facilities can "black-out" up to 10 dates each year for no inspection. These dates should not include federal holidays, JCAHO says, but may include regional events that would make it difficult to conduct an unannounced survey. For-cause unannounced surveys will continue to be conducted where warranted.

JCAHO also will continue, through the end of 2007, one-day random unannounced surveys of an annual 5% sample of organizations that have not yet undergone a full unannounced inspection. Over time, these will be replaced by random unannounced on-site evaluations of steps that accredited organizations have taken to remediate previous citations.

During 2004 and 2005, the Joint Commission pilot-tested the unannounced survey process in various types of volunteer organizations and identified the need to provide short notice of surveys to certain types of organizations. Accordingly, JCAHO has exempted prison facilities, Defense Department installations, foster care programs, immigration facilities, a first-time JCAHO survey, disease-specific care reviews, and small entities such as some physician offices where an on-site visit might totally disrupt daily operations.

The changeover to surprise surveys is part of the Shared Vision–New Pathways accreditation reform that JCAHO launched in January 2004, which also provides for in-depth periodic self-assessments. As of 2006, these are required annually. Organizations also periodically review performance data, including core measure data, that JCAHO gathers and displays on the Joint Commission's Quality Check® Web site.

JCAHO and the College of American Pathologists made the switch to unannounced CLIA inspections as of January 1 of this year. COLA did likewise for the subset of labs it accredits under a cooperative agreement with JCAHO (*NIR, 27, 5/Dec. 19 '05, pp. 3-4*).

STATE SPOTLIGHT

ARIZONA: Gov. Janet Napolitano signed into law legislation requiring all-payer direct billing for anatomic pathology services. The measure prevents clinicians and other providers from overcharging or marking up the cost of laboratory services.

With the Governor's signature, Arizona became the 10th state to pass such legislation, the American Society for Clinical Pathology noted, joining Louisiana, New York, New Jersey, Rhode Island, Montana, Iowa, South Carolina, Nevada, and California (the latter limited to gynecologic cytology, though a bill has been introduced to expand it to anatomic pathology).

States that prohibit physician markup of laboratory services include Florida, Michigan, Oregon, Washington, and California, according to a College of American Pathology listing. States that require disclosure of lab charges include Arizona, Connecticut, Delaware, Florida, Louisiana, Maine, Maryland, North Carolina, Pennsylvania, Texas, Vermont, New Jersey, and Tennessee, according to the listing.

California: Under a new law signed April 17, clinical laboratories and other providers will have to switch to a patient-name-based reporting system to track HIV infections. Had the state stuck with the old code-based system, it could have faced a loss of up to "$50 million in federal funding [via the Ryan White CARE Act] to support HIV prevention and critical healthcare services," said the Office of Gov. Arnold Schwarzenegger.

The switch aligns HIV reporting with rules for all communicable and non-communicable diseases, state officials noted. The old code-based system often led to duplication of data and other difficulties that impeded information sharing among state and federal agencies to track HIV infections, critics said.

The California law also increases penalties for willful or malicious disclosure of any confidential public health record. Disclosure through negligence would result in a civil penalty not less than $2,500; for willful or malicious disclosure, $5,000 to $10,000.

Massachusetts: The Democratic House on April 25 overrode GOP Gov. Mitt Romney's veto of an employer assessment under the state's new healthcare reform law to cover uninsured residents. Under the assessment provision, employers of more than 10 workers that do not provide health insurance coverage will pay a yearly assessment of up to $295 per full-time employee. This would raise an estimated $45 million initially to help finance the reform program.

The Senate is expected to override the veto, but at press time, the issue was not yet on the calendar, a spokesperson for the Senate President's office confirmed to *NIR*. The reform law includes a requirement that all individuals purchase coverage, similar to auto insurance rules the state applies to motorists (*NIR, 27, 13/Apr 24 '06, pp. 1, 4-5*).

OIG Touts Provider Self-Disclosure, *from p. 3*

Self-disclosure can also help the OIG determine whether the provider qualifies for a certification-of-compliance agreement—less detailed and onerous than a corporate integrity agreement.

Providers can expect reduced penalties when they self-disclose. "Because multiple OIG authorities are implicated, a provider's liability falls along a continuum," Levinson noted. CMPs for Stark violations, for example, are based on the number and dollar value of improper claims. CMPs for kickbacks are based on the number and dollar value of improper payments or remuneration. Depending on the facts and circumstances of each case, "the OIG generally settles SDP matters for an amount near the low end of this continuum," he said.

Civil Monetary Penalty Liability

- **Stark self-referral statute**
  - ❑ CMPs of up to $15,000 for each service billed in knowing violation of the statute, and
  - ❑ Assessments of up to three times the amount claimed for such services.
- **Anti-kickback statute**
  - ❑ CMPs of $50,000 for each kickback, plus
  - ❑ An assessment of not more than three times the total amount of remuneration offered, paid, solicited, or received.

Note: In addition, the OIG has authority to exclude providers and suppliers from Medicare, Medicaid, and other federal healthcare programs for violating these statutes.

Washington G-2/IOMA is inviting nominations of individuals who have made a significant contribution to the public interest through accomplishments that directly enhance patient care or the laboratory professions.

The Lab Public Service Award is presented annually by Washington G-2 Reports/IOMA. Recipients are chosen by an independent selection committee. This year's recipient will be announced September 28 during the annual Lab Institute program, to be held September 27-30 at the Crystal Gateway Marriott Hotel in Arlington, VA.

The award, inaugurated in 1993, honors an individual's contributions in one or more of the following categories: advancing the lab professions; basic or applied research; business creativity and innovations; public policy; lifetime achievement; or performance of a special service, task, or project benefiting the lab community.

Deadline to submit nominations: June 15. To obtain the nomination forms and related materials, go to *http://www.surveymonkey.com/s.asp?u=194482041792*.

Submit completed form and related materials to: Lab Award, Attn Perry Patterson, Washington G-2 Reports/IOMA, 3 Park Avenue, 30th Floor, New York, NY 10016. Or fax to 212-564-0465.

washington WATCH

Update On Preparedness For Pandemic Influenza

Government officials sounded a sobering note on readiness for pandemic influenza, including avian bird flu, in conjunction with the release this month of the Bush Administration's implementation plan for a national strategy to combat such a crisis.

A pandemic would quickly overwhelm federal and state resources to respond, so local communities, including hospitals and labs, both public and private, must be prepared to tackle local outbreaks with their own resources.

Hospitals and labs are urged to have plans to handle surge capacity, provide needed services (especially stat work), and address worker absenteeism and disruption to the supply chain due to the pandemic.

To download the plan, go to *www.whitehouse.gov/homeland/nspi_implementation.pdf.*

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