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Lab Bidding Demo Stalls, Drive to Repeal It Intensifies

Everything has been controversial about the Medicare bidding demo, the latest being the selection of San Diego County as the first of two launch sites. And with the demo design calling for both sites to be located within a single state, who could be next in California? See the Focus, *pp. 4-6.*

The California wildfire emergency temporarily stalled plans by the Centers for Medicare & Medicaid Services to kick off the lab competitive bidding demonstration in San Diego, but there has been no abatement in the lab and pathology lobbying campaign to get Congress to repeal the demo in the short time left on the already crowded legislative calendar before members adjourn in December.

CMS had planned to hold a bidder's conference October 31 in San Diego to explain the demo to affected labs, but because of the emergency, postponed it, saying a new date will be set shortly. At press time, it was yet to be rescheduled. CMS last month announced its selection of the San Diego-Carlsbad-San Marcos metropolitan area as the first of two sites for the bidding project.

On Capitol Hill meantime, House and Senate bipartisan bills to repeal the lab bidding demo have attracted additional co-sponsors since our last coverage (*NIR, 29, 2/Oct 22 '07, pp. 1, 4-5*). The legislation is not expected to pass as a stand-alone bill, so lab and pathology supporters are working to get it attached to a broader Medicare bill that Congress is expected to take up later this year.

Pathology Quality Reporting Measures On Track for 2008

Two pathology pay-for-performance (P4P) measures, based on breast and colon cancer protocols, may be applicable for physicians who report quality measures with their 2008 Medicare claims, the College of American Pathologists announced October 23.

The measures are:

❑ #1: Breast cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.

❑ #2: Colorectal cancer reaction pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.

The measures have received final approval from AQA, a multi-stakeholder payer-supported organization, and will be included in the final 2008 Medicare physician payment rule. This would make pathologists eligible for Medicare's Physician Quality Reporting Initiative, which offers a bonus for those who voluntarily submit specified quality data (*NIR, 28, 18/Jul 16 '07, p. 3*).

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Pathology Quality Reporting Measures, *from p. 1*

"Although payment allocations for 2008 are uncertain, the College will continue to proceed with cautious optimism while it develops further measures for consideration," said CAP president Jared N. Schwartz, MD, PhD, FCAP.

Under the Medicare initiative, which debuted July 1 of this year, a bonus of 1.5% was available from a $300 million pool for reporting through December 31, 2007.

CAP developed the new pathology measures—posted at *www.ama-assn.org/ama1/pub/upload/mm/370/pathologyws062707.pdf*—in conjunction with the American Medical Association's Physician Consortium for Performance Improvement. In 2006, AMA designated CAP to take the lead in development of pathology measures. Work continues, CAP says, on developing additional measures for 2009.

Lab Test Pricing Still Under the OIG's Microscope

How Medicare payment rates for clinical laboratory services compare to other payers is a topic that remains on the scrutiny list of the HHS Office of Inspector General, according to its recently released work plan for fiscal 2008.

The OIG said it will continue to review Medicare payments for certain lab tests in light of the rates of other federal, state, and private plan payers. In 2006, the OIG noted, lab payments exceeded $3 billion. In previous work, the OIG found that Medicare paid significantly higher prices than other payers for certain lab tests. As part of the lab pricing review, the OIG will scrutinize rate variances among contractors for the most commonly performed tests.

In other lab areas, the OIG will:

- ❑ Study whether Part B payments for tests furnished during inpatient stays were appropriate. Lab services to inpatients are generally included in the hospital's Part A payment.
- ❑ Ensure that dialysis providers correctly bundle and bill for lab tests included in the composite rate and not bill Part B separately for these services. In addition, the OIG will review separately billable clinical lab tests that are regularly provided to ESRD beneficiaries.

Meantime, in a new report released October 31, the OIG published its findings of a survey of state public health lab officials on lab readiness for pandemic influenza. Eight critical tasks are required. Four involve coordination with clinical labs. All states reported that their public health labs met the first two critical tasks: (1) to conduct year-round influenza testing and (2) detect and subtype influenza viruses. Although not specifically required, all states reported on public health lab capability to subtype H5 influenza.

Forty-four states said they have no clinical labs to perform H5 subtyping. Another four states reported they did not know if clinical labs in their state had H5 influenza subtyping capability. The H5 strain normally infects birds, but has the potential to cause a human pandemic.

The OIG's report (OEI-04-07-00670) is posted at *http://www.oig.hhs.gov/oei/reports/oei-04-07-00670.pdf*.

Two New Awards Announced for Medicare Part A/B Contractors

The new MAC awards will impact clinical laboratory, pathology, and other Medicare provider claims in seven states, the District of Columbia, and three U.S. territories. The prior three MAC awards have impacted providers in 10 western and four midwestern states.

The Centers for Medicare & Medicaid Services announced October 26 that it has contracted with two more entities to combine Part A/B claims processing and payment as Medicare Administrative Contractors (MACs).

Congress established MACs in the 2003 Medicare reform law to replace the current system that splits claims functions between Part A fiscal intermediaries and Part B carriers. And for the first time, Congress allowed companies other than health insurers to compete for Medicare business.

The two new awards represent the fourth and fifth MACs to be named by CMS and are among the largest, in terms of claims volume, of the 15 MACs that CMS plans to establish by 2011.

New MAC Awards

- **Highmark Medicare Services Inc.** (Camp Hill, PA):
  Jurisdiction 12—Delaware, Maryland, New Jersey and Pennsylvania, as well as the District of Columbia. Full responsibility for Part A/B work no later than September 2008.
- **Palmetto GBA** (Columbia, SC):
  Jurisdiction 1—California, Hawaii, Nevada, American Samoa, Guam, and the Northern Mariana Islands. Full responsibility for Part A/B work no later than June 2008.

Previous MAC Awards

- **Noridian Administrative Services, LLC** (Fargo, ND). Contract awarded in July 2006.
  Jurisdiction 3: Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming.
- **TrailBlazer Health Enterprises** (Richardson, TX). Contract awarded August 3, 2007.
  Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas.
- **Wisconsin Physicians Health Insurance Corp.** (Madison, WI).
  Contract awarded September 4, 2007.
  Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska.

The MACs were selected in open competition under federal procurement rules. The Highmark and Palmetto contracts include a base period and four one-year options, with an opportunity to earn award fees based on their ability to meet or exceed performance requirements set by CMS. These include enhanced provider customer service, increased payment accuracy, improved provider education and training leading to correct claims submissions, and cost savings from efficiencies and innovation.

For beneficiaries and providers in the various jurisdictions, the MAC is intended to give each a single point of contact with the Medicare program. When operational, the MACs will be the contact for all Medicare providers and physicians in the states included in their jurisdiction, while beneficiaries will pose their claims-related questions to a Beneficiary Contact Center. MAC contracts must be reopened for competitive bidding every five years. For more information, see *http://www.cms.hhs.gov/MedicareContractingReform/*

focus on: Lab Competitive Bidding

For Lab Bidding Pilot, It's a Struggle to Start—and to Stop

Though it cancelled the October 31 bidder's conference for the lab competitive bidding demonstration in San Diego County, the Centers for Medicare & Medicaid Services says it will set a new date shortly, and there has been no official change in the project's previously announced tentative timeline.

The timeline, presented at the July 16 open-door forum, called for bids to be collected and winning labs to be announced by the end of this year, with the demo to begin its three-year run in the initial site in the spring of 2008. A second pilot is to be launched a year later in another site within the same state.

Legislation to repeal the demo has been introduced in the House and the Senate, but to get passed, industry supporters acknowledge, it will have to be attached to a broader Medicare bill that the Senate Finance Committee is working on. Lab lobbyists have briefed committee staff on the repeal provision and report getting a sympathetic ear, so at press time, there is cautious hope that the demo repeal could make it into the Medicare legislation.

The purpose of the demonstration, required by the Medicare Modernization Act of 2003, is to see if competitive bidding can be used to pay for Part B lab services to Medicare fee-for-service beneficiaries at rates below the current lab fee schedule and yield program savings, without sacrificing quality or access. The Congressional Budget Office has scored savings from the bidding project at $10 million to $20 million.

CBA Market Characteristics

The San Diego-Carlsbad-San Marcos area is the 16th largest metropolitan statistical area in the United States, with a population of 3,083,038. It is a clinical laboratory market where:

- LabCorp, Quest Diagnostics dominate.
- LabCorp has a regional lab, plus 20 patient service centers (PSCs) in San Diego.
- Quest's Nichols Institute, located about 35 miles north of San Diego, has 22 PSCs in the area.
- The largest hospital lab outreach program is run by Scripps Health, which includes five hospitals, plus the Scripps Clinic.
- Sharp Memorial Hospital in San Diego also has a lab outreach program.
- No independent labs do significant business in San Diego. Those with a small presence include Westcliff Medical Labs (Santa Ana), Prime Clinical Labs (Winchester), Physicians Automated Lab (Bakersfield), Advanced Medical Analysis (Monrovia), and Bio-Date Medical Lab (Montclair).

Source: *Laboratory Economics*.

Critics Fault Site Selection

CMS's choice of the San Diego-Carlsbad-San Marcos metro area as the initial competitive bidding area (CBA) drew immediate flak from critics who said it is not representative of the lab market nationally—one of the criteria for site selection under the demo's design. This was one of three criteria used in selecting San Diego, said Elizabeth Hall, director of the CMS Office of Legislation, in an October 16 letter to Senate and House committees having jurisdiction over the demo. The other criteria were (1) the CBA must have enough labs to allow for effective bidding and multiple winners, and (2) the CBA must allow for potential Medicare savings.

Industry sources told *NIR* that the San Diego area is not even typical of other Metropolitan Statistical Areas (MSAs) that could be considered potential site candidates, based on the demo's design criteria. The CMS contractor for the project, RTI International, had previously said about 23 MSAs could meet the criteria, but declined to identify them.

If the locale is not representative, critics ask, how can the government generalize from results there to a nationwide lab bidding program, as the Bush administration has advocated? Design flaws notwithstanding, the demo could become a fait accompli, critics say, if not stopped in Congress this year.

Alan Mertz, president of the American Clinical Laboratory Association, voiced the same concern: "What conclusions can you draw from the project's pilot in such a site?" ACLA and other lab and pathology groups in the Clinical Laboratory Coalition have long opposed the demo, saying it will result in less competition, lower quality, and reduced access. CMS's choice of the initial site "in no way changes our legislative strategy nor does it detract from our support in Congress," Mertz told *NIR*. "In fact, it makes it even more imperative that Congress intervene sooner rather than later," before the demo gets rolling.

Political Buzz on Site Selection

There has been speculation that CMS could have chosen San Diego County in part to reduce the local political fallout. No independent lab has been identified as having a major chunk of business there, thus reducing the threat to small businesses—a major issue raised by lab industry opponents in House hearings on the demo. Moreover, the congressional representatives for the area—Republicans Bruce Bilbray, Darrell Sisal, and Duncan Hunter, and Democrat Susan Davis—don't sit on any House committee that has jurisdiction over the demo.

Pundits also speculate that by locating the demo in a site where the two lab giants—LabCorp and Quest Diagnostics—dominate and compete, CMS could ascertain a "bottom price" for covered lab tests, which could be tapped to "rebase," that is, lower, the Part B lab fee schedule nationally.

Required Bidders

Estimates of the number of independent labs that would be "required bidders" in the San Diego CBA vary at this point. It is likely to be 10 to 13, CMS said in a letter to Small Busi-

After San Diego, Who's Next in California?

CMS has said previously that it plans to conduct the Medicare lab bidding demo in two sites within a single state. Assuming the agency sticks with San Diego as the first pick, the following MSAs in California could be candidates for the second demo launch, based on the project's site selection criteria.

- Riverside-San Bernardino-Ontario, CA
- Sacramento—Arden-Arcade—Roseville, CA
- San Jose-Sunnyvale-Santa Clara, CA

An estimated 23 Metropolitan Statistical Areas (MSAs) could be considered potential sites for the lab bidding demo, based on the demo design's criteria for site selection, the CMS contractor for the project has said in public forums. Though project officials at RTI International in Research Triangle Park, NC, declined to speculate on which MSAs would likely make the final cut, industry sources came up with their own short list:

- Austin-Round Rock, TX
- Birmingham-Hoover, AL
- Buffalo-Niagara Falls, NY
- Cleveland-Elyria-Mentor, OH
- Columbus, OH
- Denver-Aurora, CO
- Jacksonville, FL
- Las Vegas-Paradise, NV
- Milwaukee-Waukesha-West Allis, WI
- Nashville-Davidson-Murfreesboro, TN
- New Orleans-Metairie-Kenner, LA
- Oklahoma City, OK
- Orlando-Kissimmee, FL
- Phoenix-Mesa-Scottsdale, AZ
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- Rochester, NY
- Sacramento—Arden-Arcade—Roseville, CA
- San Antonio, TX
- San Diego-Carlsbad-San Marcos, CA
- San Jose-Sunnyvale-Santa Clara, CA
- Seattle-Tacoma-Bellevue, WA
- Tampa-St. Petersburg-Clearwater, FL

ness Committee chairwoman Nydia Velázquez (D-NY), who has introduced a bill to repeal the demo (H.R. 3453). CMS previously told the Office of Management & Budget that any site to be selected could involve up to 70 required bidders. Industry sources think the number affected in the San Diego area could be as high as 50.

Required bidders are defined as labs with $100,000 or more in annual revenue from "demo tests" furnished to beneficiaries residing in the CBA. Labs below that threshold are exempt from bidding, but will be paid at the competitively set rate. Only winning labs and those that are exempt will be paid for Medicare Part B lab services during the three-year duration of the demo. Labs that bid and lose or labs that must bid but opt not to will be paid nothing by Medicare for demo tests during the demo.

Required bidders must submit prices for 303 HCPCS codes on the demo's test menu. The codes represent 99% of volume and payment for tests paid under the Part B lab fee schedule. Excluded from the demo tests are Pap smears, colorectal cancer screening, and new lab codes added to the fee schedule during the run of the demo.

Bills To Repeal Lab Bidding Demo Gather More Co-Sponsors

On Capitol Hill, there is a "narrow window of opportunity," Mertz said, to get demo repeal legislation passed. Bipartisan repeal bills are pending in the House, H.R. 3453, and in the Senate, S. 2099 (*NIR, 29, 2/Oct 22 '07, pp. 1, 4-5*), and have recently gathered more co-sponsors.

At press time, H.R. 3453 had 15 co-sponsors. Democrats Mike Capuano (NY) and Kathy Castor (FL) were the latest additions, signing up on October 22, and Democrat Mazie Hirono (HI) followed suit on October 25. S. 2099 had five co-sponsors, with Democrats Dianne Feinstein (CA) and Daniel Inouye (HI) signing up on October 25.

Site Selection Not the Big Issue

To Mark Birenbaum, who heads the American Association of Bioanalysts and the National Independent Laboratory Association, it doesn't matter where the pilot is located. No site, he told *NIR*, could be representative of the lab industry nationally, since the demo excludes physician office labs and hospitals (though their outreach work would be covered). At least 60% of the local lab market would be exempt from having to bid and win, he said, and could continue to be paid at higher rates under the lab fee schedule.

The project favors national and regional labs, creating a "slanted playing field," Birenbaum said. "A big lab with other significant business outside the CBA can afford the risk of bidding. It's only a small percent of its overall business. The big lab can bid lower than a smaller lab with a much higher percent of its business concentrated in the CBA." And typically, he noted, the local labs are the only ones serving nursing home, homebound, and dialysis patients.

Lawmakers and policymakers should not discount the danger that competitive bidding could pose to small business labs, Birenbaum said. Now more than ever, he pointed out, it is important to maintain and strengthen the local lab infrastructure to respond to emergencies such as natural disasters, infectious disease outbreaks, and bioterrorism.

Lab Spending Fingered in 2008 Medicare Premium Increase

Growth in Medicare fee-for-service spending for independent lab and physician office lab services is singled out by the Centers for Medicare & Medicare Services as one of the cost drivers contributing to the 3.1% increase in the standard Medicare Part B monthly premium in 2008.

The premium will rise to $96.40, up $2.90 from $93.50 for 2007, CMS has announced. Beneficiaries with yearly income above $82,000 will pay more under "means-testing" that began with 2007 premiums.

The 3.1% rise in the standard monthly premium is the smallest percentage increase since 2001, the agency said, and is $2.10 less than the premium increase for 2007. The Part B deductible also will rise next year, from $131 to $135.

Other spending growth areas that factored in to the premium increase were home health services, physician-administered drugs, ambulatory surgical center services, durable medical equipment, and the Medicare Advantage program.

NPI Update: Key Deadlines for Claims Processing Changes

The National Provider Identifier is one of a series of unique standard identifiers required by the Health Insurance Portability & Accountability Act to facilitate electronic health data exchange.

JANUARY 1, 2008: As of this date, the Centers for Medicare & Medicaid Services has announced, contractors will reject 837I electronic claims and UB04 paper claims without a National Provider Identifier (NPI) in fields identifying the primary provider (billing and pay-to). Legacy identifiers paired with NPIs in the primary provider fields will still be acceptable, as will legacy-only numbers in secondary provider fields.

CMS has not yet announced the date by which an NPI will be required for primary provider fields on 837 professional electronic claims and 1500 paper claims processed by carriers, Part A/B Medicare Administrative Contractors (MACs), and DME MACs. This will occur prior to May 23, 2008; a date will be announced once available.

MAY 23, 2008: In keeping with CMS's NPI contingency plan, this is the deadline to complete the transition to NPIs only on all HIPAA electronic transactions (837I, 837P, NCPDP, 276/277, 270/271 and 835), paper claims, and SPR remittance advice. This includes all secondary provider fields on the 837P and 837I. The reporting of legacy identifiers will result in the rejection of the transaction.

CMS cites some common claims problems/errors that trigger rejection when claims contain incompatible NPI/legacy pairs:

- ❑ The type of NPI you use (Entity Type 1 or Entity Type 2) must match your Medicare enrollment PIN (individual or organization).
- ❑ Those who are enrolled with Medicare as individuals but obtained an Organization (Entity type 2) NPI through NPPES (or vice versa) need to ensure their enrollment records are correct and their NPIs were obtained appropriately.
- ❑ On professional claims (837P and CMS-1500), the NPI/PIN combination should identify the Billing, Pay-to, and Rendering Provider (the Pay-to Provider is identified only if it is different from the Billing Provider). This includes claims from corporations that physicians and non-physician practitioners have formed or from physicians and non-physician practitioners who bill Medicare directly.

California Adopts Expanded Pathology Direct Billing Law

According to CAP, 13 states now have direct billing statutes for pathology services. In addition, six states have anti-markup provisions affecting pathology, and 14 require disclosure of physician charges, including pathology (NIR, 28, 22/Sep 24 '07, p. 5).

California Republican Gov. Arnold Schwarzenegger on October 13 signed into law legislation expanding the scope of state direct billing requirements to include anatomic pathology services. The measure, SB 661, had broad bipartisan support, clearing the state Senate unanimously and the Assembly by a vote of 86-2.

The law prohibits clinicians from billing patients and third-party payers for anatomic pathology services not performed or directly supervised by the clinician. Current state law already bans direct billing for cytopathology, including Pap smears, and bars physicians from marking up all other clinical lab services.

The drive to get the law enacted was led by the California Society of Pathologists and supported by the College of American Pathologists and the American Society for Clinical Pathology, among others.

The definition of anatomic pathology in the law is consistent with model CAP legislative language, including histopathology, cytopathology, hematology, subcellular pathology, surgical pathology, and blood banking services performed by a pathologist.

Upcoming G2 Events
Plan Now to Attend!

LAB LAW & LIABILITY SUMMIT
December 5-7, 2007
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Fort Lauderdale, FL

LABCOMPETE 2008
February 6-8
Loews Ventana Canyon Resort
Tucson, AZ

MOLECULAR DIAGNOSTICS 2008
April 30-May 1
Hyatt Regency Cambridge
Cambridge, MA

LAB OUTREACH 2008
June 18-20
The Bellagio Hotel
Las Vegas, NV

LAB INSTITUTE 2008
September 17-20
Crystal Gateway Marriott Hotel
Arlington, VA

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