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CMS Forging Ahead with Lab Bidding Demo in San Diego

CMS timeline for demo launch: Bids due February 15, winning labs to be announced in April, demo to start July 1 in San Diego-Carlsbad-San Marcos metro area.

The Centers for Medicare & Medicaid Services took another big step toward the launch of its Part B lab competitive bidding demonstration with a December 5 bidder's conference for clinical labs in San Diego, the first of two sites for the pilot project.

Several days later, members of Congress who represent the San Diego site called for an end to the demo. Reps. Brian Bilbray (R), Susan Davis (D), Bob Filner (D), and Duncan Hunter (R) sent a letter on December 11 to the House and Senate health leadership urging that demo repeal be included in any must-pass Medicare bill this year. Senators Dianne Feinstein (D) and Barbara Boxer (D) made a similar appeal. Lawmakers cited the harm the project would pose to small labs, local competition, and patients' access to services.

Also in the wake of the bidder's conference, lab industry critics said the meeting did little to assuage their concerns *Continued on p. 2*

Time Running Out for Physician Fee Fix

Prospects for congressional action to block a 10% cut in Medicare payments to pathologists and other physicians next year are murky at press time, as House and Senate negotiators remain at odds over a fee fix and how to pay for it. Though blocking the cut could be attached to an omnibus spending bill, Senate Finance chairman Max Baucus (D-MT) has raised the possibility that the pay issue may even be put off until January.

Finance leaders, unable to get committee members to agree on markup of a legislative fee fix and other Medicare policy reforms, have been meeting directly with their House counterparts to resolve key sticking points. One is whether to grant a one- or two-year fee increase; another is how much to cut Medicare managed care to finance the increase. The House has approved a 0.5% raise in 2008 and 2009 and a reduction of managed care rates to 100% of fee-for-service levels. Complicating the picture is the President's threat to veto any cuts to the Medicare Advantage program.

Also hanging in the balance before Congress adjourns for the year is the House-passed extension, through 2009, of the "grandfather" protection for independent labs that bill Part B for the technical component of pathology services to hospital patients. This expires December 31 of this year, and Medicare intends to eliminate such billings as of January 1 unless Congress says otherwise.

INSIDE *NIR*

Lab lobbyists are pushing hard to get the repeal of the lab bidding demo attached to Medicare legislation or an omnibus spending measure Congress is expected to pass before adjourning for the year. Bipartisan bills for repeal have been introduced in the House (H.R. 3453) and in the Senate (S. 2099).

Lab Bidding Demo, *from p. 1*

over such issues as low-ball bids, the specific terms and conditions that participating labs must agree to, and the impact on Medi-Cal lab fees (now pegged at 80% of the Medicare lab fee schedule).

The fact that major questions raised by the industry remain unanswered at this late stage "only reinforces the need to repeal the demo," said Alan Mertz, president of the American Clinical Laboratory Association.

Bidder's Conference: Key Payment & Billing Rules

At the bidder's conference, officials from CMS and the project contractor, RTI International (Research Triangle Park, NC), provided a section-by-section breakdown of the bidder's package, then opened the floor to the audience, estimated at upwards of 100, including local and national labs and lobbyists.

The purpose of the demo, required by the Medicare Modernization Act of 2003, is to see if competitive bidding can be used to provide Part B lab services at rates below the current lab fee schedule while maintaining quality and access to care.

As designed by CMS and RTI, the project covers Part B "demo tests" for fee-for-service (FFS) beneficiaries residing in the competitive bid area (CBA) during the three-year run of the pilot. One competitively bid fee schedule will be used to pay for these tests, which include independent lab services, but *not* testing by physician office labs and hospitals for their patients. However, outreach and/or non-patient testing by a hospital or a POL is covered when the lab is functioning, in effect, as an independent lab.

Of special note to labs are the following operational details discussed by CMS and RTI officials at the bidder's meeting:

- ❑ Labs must bid on approximately 300 test codes representing approximately 99% of tests paid under the current lab fee schedule. Exempt tests are Pap smears, colorectal cancer screens, and new codes added to the lab fee schedule during the three-year demo.
- ❑ Multiple winning labs will be selected, based on price and non-price elements (such as quality, capacity, and geographic coverage). Winning labs must also be CLIA-certified, enrolled in Medicare, and agree to the terms and conditions of the demo in order to participate. CMS has already noted that one of the terms will be use of standardized performance measures for turnaround, transport, and processing time, turnaround on stat tests, reporting time for critical values, log-in error rates, and lost or unusable specimens.
- ❑ Labs, physicians, and beneficiaries will have the choice of selecting from any of the participating labs regardless of where the lab is based. Beneficiaries who travel outside the CBA during the demo period may obtain demo tests from most labs in the U.S., according to CMS; however, these labs will be paid at the CBA rate.
- ❑ All labs that bill or plan to bill for demo tests are either:
  - —Required bidders: Labs that expect to bill Medicare for at least $100,000 annually for demo tests during any year of the three-year project.
  - —Non-required bidders: Small businesses below the $100,000 threshold, as well as labs that exclusively provide covered tests to ESRD and nursing home/home health beneficiaries residing in the CBA.
- ❑ Whether bidding or not, all labs that bill or plan to bill for demo tests must complete the demo application. Bidding labs must

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focus on: Genetic Testing

Advisory Panel Prescribes Changes for CMS, FDA in Genetic Test Oversight

As genetic testing becomes more widely embedded in clinical practice and as technological advances transform the way the testing is performed, what adaptations are needed in federal oversight policy to address quality and safety concerns, and what value for patients would be gained by additional and/or revised government regulation?

For two key players, a top HHS advisory panel has some new answers. It recommends that the Centers for Medicare & Medicaid Services should beef up CLIA quality and enforcement safeguards, and the Food & Drug Administration should follow a more broadly consultative course in regulating lab-developed tests (LDTs).

The recommendations are contained in the new draft report that the HHS Secretary's Advisory Committee on Genetics, Health & Society (SACGHS) has released for public comment through December 21. SACGHS prepared the report for HHS Secretary Michael Leavitt in support of his Personalized Health Care Initiative. The Initiative aims to advance the use in general healthcare of genomic technologies that tailor treatment and prevention strategies to each patient's unique genomic characteristics and needs.

The initial reaction of the American Clinical Laboratory Association and the College of American Pathologists to the SACGHS recommendations for CMS and the FDA was generally favorable, but with some caveats. Both groups insist that CMS should be the lead federal agency to oversee genetic testing services, and both contend the FDA should take a "go slow" consultative approach to regulating genetic test products.

General Advice to HHS

In what SACGHS dubs its "overarching recommendation," the panel calls for new and enhanced federal-state-private partnerships to address the many complexities associated with genetic testing oversight, including gaps in knowledge regarding clinical validity and clinical utility (*see table, p. 5*). For example, SACGHS says target more resources and expertise to assess LDTs that are not reviewed by the FDA and to develop incentives for a central and accessible registry of genetic tests, their uses, and limitations.

In a separate broad recommendation, SACGHS advises Leavitt that CMS and the FDA need to work closer together and coordinate their efforts with other federal agencies such as the Federal Trade Commission (on advertising and marketing issues) and with researchers at the Centers for Disease Control & Prevention and the National Institutes of Health.

New Advisory Panel Report

The draft report from SACGHS, *U.S. System of Oversight of Genetic Testing*, responds to HHS Secretary Michael Leavitt's directive to study potential harm to patients due to gaps in government and private oversight systems; whether these gaps are linked to issues of analytic validity, clinical validity, and/or clinical utility; and how to fill these gaps.

Leavitt requested the report to help guide the Personalized Health Care (PHC) Initiative he announced last March. Because the PHC dovetailed with work underway at SACGHS since 2006 to assess oversight systems, he asked the panel "to develop a comprehensive map of the steps needed for evidence development for genetic and genomic tests and to consider questions about the scientific information and the regulatory structures needed to ensure that tests are properly developed and used and the transparency of oversight systems."

The 192-page draft report is posted at *www4.od.nih.gov/oba/sacghs.htm*.

Specific Advice to CMS

CMS last year scrapped its efforts to create a CLIA genetic testing specialty, saying additional requirements were not necessary nor was it clear how more rules on top of the high complexity standards that now apply to genetic testing could address related issues such as counseling, informed consent, confidentiality, and liability. In lieu of more regulation, CMS said it would provide guidance on inspecting labs that perform genetic testing, technical training of inspectors, and provider education aids (*NIR, 28, 1/Oct 9 '06, p. 1*).

SACGHS agrees with CMS's decision, but says the agency needs to follow through on its alternative action plan, including additional training of CLIA lab inspectors by subject matter experts. Specific steps also are needed to address inadequacies in proficiency testing (PT). SACGHS recommends:

- ❑ HHS should fund studies of the effectiveness of other types of performance assessment methods to determine whether they are as robust as PT.
- ❑ The list of CLIA regulated analytes should be updated to include genetic tests for which PT products are available.
- ❑ HHS should develop incentives to expand PT products for those tests.

Of added concern to SACGHS are certain types of health-related genetic tests that are marketed directly to consumers and appear to skirt CLIA's boundaries—for example, some nutrigenomic tests (e.g., for caffeine metabolism) and tests to determine the gender of a fetus. SACGHS advises that the CLIA rules, and the CLIA statute if necessary, should be expanded to encompass the full range of health-related genetic tests, as defined in consultation with relevant agencies.

Advice to the FDA

Around the same time that CMS pulled the plug on a CLIA genetic testing specialty, the FDA tightened its rules for lab-developed tests. In a draft guidance document, the FDA said it will require premarket review for a set of gene- or protein-based tests that combine assays and algorithms to produce results tailored to a specific patient (In Vitro Diagnostic Multivariate Index Assays, or IVDMIAs). Examples include tests for breast and prostate cancer, cardiovascular disease, and Alzheimer's. What makes IVDMIAs different, the FDA said, is that the algorithms are proprietary, making it difficult for physicians to interpret results and validate them independently (*NIR, 27, 22/Sep 25 '06, p. 1*).

While SACGHS supports the FDA's regulation of lab-developed tests and "the flexible risk-based approach the agency is taking to prioritize the type of LDTs that will be subject to premarket review," it concludes that lack of clarity on the agency's role in regulating LDTs is an oversight gap. As a result, SACGHS "suggests that further analysis, deliberation, and consultation are needed to determine whether the appropriate weight has been apportioned to the risks associated with the novelty and complexity of the testing platform and technology." The panel calls on HHS to convene relevant federal agencies and stakeholders to gather further input on a risk-based framework for regulating LDTs.

In a statement to SACGHS, the College of American Pathologists said genetic testing as now practiced in the U.S. "is safe and effective, even for tests that are not FDA-cleared or

Regulatory Status of Currently Available Genetic Tests

More than 1,100 genetic tests are currently offered in 1,167 clinical labs, according to data submitted voluntarily to Genetests.org.

The FDA has cleared or approved several dozen genetic tests to date—*e.g.*, tests for Leiden factor, cystic fibrosis, UGT1A1, CYP450 2D6 and 2C19, breast cancer prognosis gene expression tests, bladder cancer fluorescence in situ hybridization (FISH), prenatal aneuploidy FISH, and HER2 FISH. This number refers to molecular genetic tests; when biochemical assays for genetic conditions (mainly newborn screening) are added, the figure approaches 100.

According to a 2003 survey of U.S. molecular diagnostics labs, testing for inherited diseases was the second largest testing activity, representing 15% of the total volume. Of the labs surveyed, 85% reported using at least one lab-developed test.

Key Elements of Genetic Testing Oversight	
• **Regulation of clinical labs and testing services**	**Federal:** CMS CLIA, with involvement of other federal agencies (*e.g.*, FDA in categorization of tests and FTC in oversight of marketing). **Some states** (*e.g.*, New York, Washington, California)
• **Medical product regulation**	**Federal:** FDA regulation of genetic tests and therapies used in conjunction with genetic tests, with oversight of marketing shared with FTC
• **Regulations affecting reimbursement and access**	**Federal:** CMS Medicare. **State:** State health programs and insurance regulations affecting private insurers. **Informal/private sector:** Medical necessity and utilization review practices, contracts.
• **Clinical practice regulation** (when, whom to test; physicians' claims and disclosures about tests)	**State law:** Medical practice and pharmacy regulations, consent laws, genetic privacy acts, tort law. **Informal regulation:** Voluntary guidelines and professional standards.
• **Regulation of specific uses and misuses of test results** (*e.g.*, privacy and data security; discrimination in employment and insurance	**Federal:** ERISA, HIPAA, Americans with Disabilities Act, etc. **State:** Statutes and tort law.
• **Standards of patient responsibility**	**State tort law:** Determines when patients are responsible for protecting themselves vs. when they are entitled to rely on protection by others (*e.g.*, manufacturers, physicians).

approved, thanks in large part to CLIA regulations combined with medical oversight of every clinical lab by a physician… Not all LDTs are genetic tests and different rules for genetic LDTs would be inappropriate, given the high quality testing already in place." Requiring FDA approval for every LDT would be harmful to patients, CAP said, because it would stifle innovation, limit access to beneficial tests, and slow development of new tests.

Reliance on CLIA standards does not mean the FDA has no role to play, ACLA said in its statement to SACGHS: "It should have a clearly defined consultative role in providing comment to the CLIA program on clinical validity and promotional claims for certain high-risk genetic LDTs."

ACLA elaborated on what that role should be in additional comments submitted December 11 to the FDA regarding its IVDMIA guidance. ACLA advocates a regulatory model for IVDMIA oversight that addresses industry concerns "while avoiding overlapping and potentially conflicting regulation." A key aspect of the model is "an interagency Memorandum of Understanding (MOU) defining a significant consultative role for the FDA while maintaining CMS and CLIA as the exclusive regulatory authority for lab test services." The FDA role would include defining a risk classification for IVDMIAs and validity criteria.

The model also includes:

- ❑ "CLIA enhancements … to identify any gaps in CLIA quality programs" and to resolve overlaps between CLIA quality control rules and the FDA's quality system requirements.
- ❑ A mandatory IVDMIA test registry of standard data maintained by CMS or a public-private entity and accessible by the public.
- ❑ Independent review of clinical validity and use claims by CMS/FDA or by a third-party review funded through user fees.

The model "can be implemented under current law through the MOU process and use of interpretive guidelines," ACLA said. "If regulatory changes are needed, the industry would be committed to making consensus standards happen in a timely fashion."

Defining Genetic Tests

CAP believes that genetic tests are not unlike many of the other lab tests that have been successfully introduced into medical practice and warns against an overly broad definition of genetic tests that could "capture many non-genetic tests that have not raised public concern—for example, serology assays that detect and measure proteins encoded by genes undergoing rearrangement and somatic mutation. We do not believe that all serology assays like those used to determine prior exposure to rubella or those used for blood typing in transfusion medicine warrant the term 'genetic test.'"

ACLA also warns against an overly broad regulatory definition "that could sweep in many tests which have some genetic component but not necessarily an inherited one, including routine cholesterol or glucose checks, basic blood counts, and DNA-based tests for non-inheritable abnormalities."

Coverage & Reimbursement of Genetic Tests

There is a continuing need for appropriate coverage and payment of genetic tests to spur innovation and patient access, SACGHS points out, noting that healthcare payers are increasingly requiring evidence of clinical utility before they will pay. The panel last year outlined for the Secretary a series of steps to tackle this issue (*NIR, 27, 13/Apr 24 '06, p. 8*).

In the new draft report, SACGHS urges HHS to act on those recommendations. They include more consistent coverage decisions by Medicare and other third-party payers, adding more Medicare screening services, and higher fees to align genetic test prices with actual costs. Also, until the five-year freeze on lab fees expires at the end of 2008, the Secretary should direct CMS to use its inherent reasonableness authority to increase Medicare fees for genetic tests. Under this authority, CMS can adjust fees up or down by 15% if they are "grossly excessive" or "grossly deficient."

Oversight at the State Level

Twenty-six states have some degree of statutory authority over the practice of clinical laboratory medicine, and most rely on CLIA rules to regulate genetic testing.

New York has the most stringent oversight system. All labs that solicit and receive specimens must obtain approval prior to offering a genetic test in a clinical setting, including genetic tests that are FDA-approved, use analyte-specific reagents, or any lab-developed test. An estimated 75% of all cytogenetic and genetic specimens tested in the U.S. are subject to New York oversight.

California reviews genetic tests used in newborn and prenatal screening, based largely on the published literature that establishes an association of the marker to be tested (*e.g.*, deletions detected by FISH, gene mutation, enzyme level) and the disease of interest.

Washington State has a program that evaluates clinical validity on an as-needed basis when there is doubt about a specific test.

New Jersey applies some personnel standards of the American Board of Medical Genetics to labs that perform genetic testing.

Clinical use of genetic tests is primarily regulated at the state level via a complex web of statutes, regulations, and liability rules that affect whom to test, when to test, which test to use, and what should be done in response to specific test results (*see table, p. 5*).

Next Step: A Final Report to the HHS Secretary

SACGHS says it is on track to deliver a final report to the HHS Secretary well before a July 2008 deadline set in the FDA user fee reauthorization bill signed into law last September (*NIR, 29, 2/Oct 22 '07, p. 1*). That deadline is part of a modified version of the genetic testing study advocated by Sen. Barack Obama (D-IL) to provide a decision matrix for federal risk-based ranking of genetic tests.

The provision states that if the SACGHS report is not submitted by the July deadline, "the Secretary shall contract with the Institute of Medicine for recommendations on oversight of genetic/genomic testing, taking into account relevant work by SACGHS." Even if the deadline is not met, the Secretary still has discretion to contract with the IOM if needed to help further guide federal policy on genetic test regulation.

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complete the entire form. Non-bidders must complete only certain sections.

- ❑ In the bid evaluation process, test code volumes, based on Medicare 2006 claims data, will be used to determine test code weights. For an individual demo test, the weight is the volume of that code divided by the volume of all demo codes. For example, CPT 36415, Routine venipuncture:
  - —Volume for the code = 260,271
  - —Total volume for all test codes = 1,724,727
  - —Test code weight = 260,271 divided by 1,724,727 or 0.15091
- ❑ After bids are evaluated, labs will be designated by CMS as winners, non-winners, or passive labs (small business, ESRD, nursing home/home health services exclusively). Non-winning labs cannot bill Medicare directly, but can subcontract with winning or passive labs.
- ❑ Bid prices must be provided for all demo tests whether performed in-house or through a reference lab. The bidding lab must identify which labs will be providing reference testing and show evidence that it has in place contractual or other relationships with the reference labs for performing work under the demo. Current Medicare rules on billing for referred work (70/30 rules) apply.
- ❑ Palmetto GBA will process and pay demo test claims. Palmetto (headquarters in Columbia, SC) is the Medicare A/B contractor for the San Diego site and will run a hotline, 1-866-613-9438, and provide other help to labs in the demo.

Initial Industry Reaction

The day after the bidder's conference, Mark Birenbaum, head of the National Independent Laboratory Association, faulted CMS for "not answering the most critical of questions: how the potential for market manipulation will be prevented. There is still a possibility that a low-ball bid will obliterate the competitive landscape, leaving many local community labs bankrupt and out of business."

Birenbaum urged local labs to lobby their elected officials to oppose the demo. "Plain and simple, competition is working right now in Southern California," he said. "The government's definition of 'competition' is not what you learned in high school economics. The number of labs available to service the community will actually be drastically cut. The worst part is the government bureaucrats almost 3,000 miles away will make these critical decisions, leaving local residents with no choice of their own."

In other reaction, local labs, while fearing they could be shut out of Medicare if they lose a bid, also note that the demo puts them at a disadvantage by requiring them to obtain bids from labs that handle their reference work, and these labs like Quest Diagnostics and Lab Corp will be submitting bids of their own as well.

♦ MEDICARE CLAIMS *Advisory*

January 1—Key Deadline for Use of National Provider Identifier

Effective January 1, 2008, Medicare 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.

Medicare Improper Claims Payment Continues to Drop

Citing stepped-up oversight, the Centers for Medicare & Medicaid Services said the error rate for Medicare fee-for-service (FFS) claims continued to fall this year, to 3.9% from 4.4% in 2006 and 14.2% in 1996, when the improper payment rate was first reported.

The continued reduction is due, CMS said, to efforts by its contractors to use detailed data analysis to isolate areas of erroneous claims processing, inaccurate billing, and provider error. Insufficient documentation is one area targeted in particular, declining from 4.1% of the error rate in 2004 to 0.4% in 2007. During the past three years, error rate reductions have led to approximately $11 billion less in improper payments, CMS said. Medicare pays more than one billion fee-for-service claims each year.

CMS reports its Medicare FFS improper payment findings in an annual report. The complete report contains additional error rate information along with more specific improper payment estimates. It is posted at *www.cms.hhs.gov/cert*.

washington WATCH

At press time, Medicare had yet to officially release the final lab fee schedule for 2008. Typically, the schedule is out in November each year. CMS has been mum so far about why there has been a delay this year.

Virtually all lab codes and the national minimum payment for Pap smears remain frozen at 2003 levels, but several new fee schedule codes need to be priced. They include a new code for a basic metabolic panel (ionized calcium), three in chemistry, two in immunology, and two in microbiology as well as a proposed "G" code for hemoglobin A1c. CMS reportedly is likely to adopt the crosswalk method for pricing the new codes *(NIR, 29, 2/Oct 22 '07, p. 7)*.

In tandem with the 2008 fee schedule, CMS sets the Medicare travel allowance. While the personnel portion is expected to remain frozen, the mileage portion can change based on the rate set by the Treasury Department.

For updates on lab fees for 2008, check "Today's News" on our Web site, *www.g2reports.com*.

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