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San Diego Labs Seek Injunction Against Bidding Demo

Labs that must bid and are not selected as winners will be barred from billing Medicare for demo tests furnished to fee-for-service beneficiaries in the San Diego-Carlsbad-San Marcos metro area for the three-year run of the project.

The three labs in San Diego County that are suing to block the Medicare competitive bidding demonstration in their locale have again asked a federal court to stop the project from going forward.

The labs—Sharp Healthcare, Scripps Clinic, and Internist Laboratory—filed for a preliminary injunction to halt the demo prior to April 11, when the Centers for Medicare & Medicaid Services plans to announce the labs that have submitted winning bids.

The labs also seek to require CMS to return to clinical labs any bid applications that have been submitted. These contain confidential and proprietary information, the labs argue, and CMS should not be allowed to use any information in the bids for any purpose, including but not limited to setting Medicare payment rates for lab services.

In response, the judge has ordered a hearing on the case for April 7, said the attorney representing the labs, Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles. *Continued on p. 2*

Bill to Overhaul CLIA Cytology PT Clears House Health Subcommittee

The House Energy & Commerce health subcommittee on March 11 passed, with no opposition, legislation that would revamp the current program for gynecologic cytology proficiency testing under CLIA (the Clinical Laboratory Improvement Amendments). And at press time, the full committee is expected to pass the measure before Congress recesses March 14 for two weeks.

The bipartisan bill that cleared the Energy & Commerce health panel—H.R. 1237, the Cytology Proficiency Improvement Act—was introduced February 28, 2007, with Rep. Bart Gordon (D-Tenn.) as lead sponsor and is widely supported by pathology groups. It scraps the existing CLIA cytology PT program for testing individuals and replaces it with a continuing medical education alternative for pathologists and others who screen for cervical cancer.

The bill includes requirements that each clinical lab:

- ❑ Ensure that all individuals who screen and interpret cytological preparations participate annually in an approved continuing medical education program that provides each participant with gynecologic cytologic preparations designed to improve locator, recognition, and interpretive skills; and
- ❑ Maintain a record of program results.

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Bidding Demo, *from p. 1*

The Medicare demo, required by Congress, is intended to see whether competitive bidding can be used to pay for independent lab services at rates below the current Part B lab fee schedule. The San Diego-Carlsbad-San Marcos metropolitan area is the first of two sites to be selected for the project. CMS plans to begin paying San Diego winning labs for demo tests for fee-for-service beneficiaries in the area under a competitively derived fee schedule July 1.

Judge Thomas Whelan of the U.S. District Court for the Southern District of California previously denied the labs' request for a temporary restraining order prior to the February 15 deadline for submitting bids, basing his ruling on jurisdictional and other objections raised by CMS. However, since the labs did not have the opportunity to review the government's arguments prior to this ruling, the judge gave the labs added time to submit counterarguments.

Forging Ahead With the Lawsuit

The three labs in San Diego County argue that if the government goes ahead with the demo, it will cause their businesses and thousands of beneficiaries irreparable harm, loss, and damage. For Internist, losing the bid and thus its ability to bill Medicare will drive the family-owned lab out of business, the lawsuit alleges, while Sharp and Scripps will have to scale back operations and make significant changes to the way lab services are delivered within their respective hospital system, with adverse impact on access to urgent and emergency care services.

The demo design covers Part B lab testing furnished by independent labs and by hospital and physician office labs when they are in effect functioning as independent labs. Tests excluded from the demo are Pap smears, colorectal cancer screening, and new codes added to the fee schedule during the run of the project in the demo site.

The labs contend that Medicare law does not override the court's jurisdiction to hear their case, that the administrative remedies the government says have not been exhausted are in fact not available, and that the government is violating federal law by moving forward with the demo without following the Administrative Procedures Act's public notice and comment requirements.

"As illustrated by the fact that plaintiffs have now already all submitted bids, the current policies in the demo impose obligations and carry legal consequences. That is all that is required for these policies to be subject to judicial review at this time," concluded the labs' brief.

CMS to ACLA: 'No Demo Delay'

Meantime, CMS has told the American Clinical Laboratory Association that it sees "no basis" for delaying the bidding demo. ACLA had written to the HHS Secretary on February 13, requesting an immediate halt to the demo for at least 180 days. Replying for the Secretary, CMS official Timothy Love said in a February 27 letter, "We believe it is appropriate to continue to carry out the requirements of the law." And that includes obtaining market-based prices for Medicare, he noted. Love said CMS has made modifications to the project design to address concerns about the impact on local small business labs, especially those that serve niche markets such as beneficiaries receiving nursing home, home health, and ESRD services.

One major concern ACLA raised is that required bidders, including niche and esoteric labs, must bid on all 303 codes from the Part B lab fee schedule that are included in the demo, even though many of these labs use as few as 10 of the codes.

"Further, and inexplicably," ACLA said, "they must provide winning bids on those codes in order to participate, an almost impossible challenge since they have no experience with a vast majority of these tests nor relationships with laboratories that perform them." CMS said it had analyzed claims data and the market structure of potential demo areas and found only a few labs that bill only a few codes under the entire lab fee schedule.

Timeline: Long-Running Battle Over Medicare Lab Bidding Demo

2007	
July 16	CMS holds open-door forum on draft bidder's package for the demonstration project and invites public comment.
July 25	House Committee on Small Business holds hearing on lab industry concerns about the demo's impact on small local labs and niche markets (nursing home, home health, and ESRD fee-for-service beneficiaries).
August 4	Small Business Committee chairwoman Nydia Velazquez (D-N.Y.) introduces H.R. 3453 to repeal statutory authority for the demo.
September 26	Sen. Ken Salazar (D-Colo.) introduces companion bill to repeal the demo (S. 2099).
October 17	CMS selects first demo site, San Diego-Carlsbad-San Marcos metro area.
October 31	Bidders' conference for labs in San Diego postponed due to wildfires in the region. CMS says it will reschedule soon.
December 5	CMS holds bidders' conference in San Diego to explain demo's operational details.
2008	
January 29	San Diego labs file suit in federal court for immediate halt to the demo, including the February 15 deadline for submitting bids. The suit seeks to require CMS to follow public notice and comment procedures for the demo in accord with the Administrative Procedures Act.
February 4	The President's budget request for fiscal 2009 advocates nationwide Medicare lab competitive bidding program, with estimated savings of $110 million in FY 2009 and $2.3 billion over FY 2009-2013.
February 13	House Small Business Committee chairwoman Velazquez and ranking Republican Steve Chabot (Ohio) urge HHS Secretary to delay the demo until the Committee has a chance to re-examine it. Separately, ACLA asks the Secretary to suspend demo activity for at least 180 days to address concerns about niche and esoteric labs.
February 14	Court denies San Diego labs' motion for a temporary restraining order to stop the demo prior to the February 15 bid submission deadline, based on jurisdictional and other issues raised by the government. However, the court gives plaintiffs until February 29 to file counterarguments and CMS until March 14 to respond.
February 27	CMS denies ACLA's request for 180-day suspension, saying it has modified the project to address concerns about local small labs and beneficiary access.
February 28	San Diego labs file counterarguments to CMS request to dismiss the lawsuit.
March 10	Labs seek preliminary injunction to halt the demo before CMS-scheduled date of April 11 to announce winning bidders. The judge orders a hearing for April 7 on the case. Meantime, CMS plans to disclose winners April 11 and begin Medicare payment for demo tests under a competitively derived fee schedule July 1. Medicare will pay nothing to losing labs for demo tests during the three-year run of the project. CMS plans to launch the demo in a second site (yet to be selected) in July 2009.

focus on: Clinical Laboratory Workforce

Alarm Sounded Once Again Over Shrinking Supply of Lab Personnel

The current and projected personnel shortage in the nation's clinical laboratory workforce is back in the policy and political spotlight once more, as national lab and pathology organizations raised new warnings to senators and to members of a top federal advisory panel about the crisis this poses for patient access to quality care.

The groups sounded the alarm in remarks to the Senate Committee on Health, Education, Labor & Pensions (HELP) and in briefings of the Clinical Laboratory Improvement Advisory Committee (CLIAC):

- ❑ Demand continues to outpace the supply of medical lab technologists and technicians, as their numbers in the workforce continue to dwindle and as the number of training programs continues to decline.
- ❑ Clinical labs are reporting that it is getting harder to recruit and retain qualified testing personnel—and this has a direct bearing on CLIA compliance, since CLIA sets specific licensure, certification, training, and experience requirements for personnel who perform moderate and high complexity testing.
- ❑ Federal funding for allied health professions training (a small portion of which goes to programs for lab technologists and technicians) is on life support, and the Bush administration proposes to pull the plug and end it.

CLIAC Briefed on the Personnel Shortfall

In a briefing of CLIAC, which advises the government on CLIA scientific and technical issues, during its February 20-21 meeting in Atlanta, the Coordinating Council on the Clinical Laboratory Workforce presented its outlook on the labor shortage and what can be done about it, based on discussions at the council's strategic planning session held in January. The council is a coalition of representatives from lab professional and accrediting organizations, diagnostic test manufacturers, and federal agencies, among others.

Outlook Bleak for Lab Labor Market

- ❑ By 2016, the U.S. will need 92,000 additional medical technologists and technicians to replace retiring staff and fill newly created positions, according to projections by the Bureau of Labor Statistics. The median age of the workforce is 48 years.
- ❑ With fewer than 4,700 individuals graduating each year from accredited training programs, including only 260 cytotechnologists, the number of graduates would need to increase more than threefold to meet the estimated demand.
- ❑ The capacity to train new laboratory personnel has declined substantially over the past 10 years. According to the National Accrediting Agency for Clinical Laboratory Science:
  - The number of accredited medical technology programs dropped from 709 in 1975 to 222 in 2007.
  - For cytotechnologists, the number of training programs has been reduced 40 percent; from 65 programs in 1994 to 39 active programs in 2008.

Source: American Society for Clinical Pathology.

The council has developed a draft plan, "Vision Elements, 2008-2011," that spells out specific actions being taken or planned to implement its strategic directions. These directions include:

- ❑ "Drive the business case internally and externally" to create local and national awareness of the critical role lab personnel play in health care.
- ❑ "Improve the professional profile" by promoting the integration of lab personnel as members of the patient's health care team.
- ❑ "Align the scope of practice" by standardizing credentials, improving the career ladder, working with pathologists to shape and expand

consulting roles for lab personnel, and updating curricula as the scope of practice evolves.

- ❑ "Create effective recruitment and retention" through collaborative strategies that target science faculty and aim to diversify career pathways.

Also at the CLIAC meeting, the American Society for Clinical Pathology charted the dimensions of the current and projected workforce shortage (*see box*) and raised its special concern over recent closures of cytotechnologist education programs. ASCP also briefed CLIAC on its lobbying campaign to get a funding increase for Title VII allied health education programs that train lab professionals and for a separate title specifically for clinical laboratory science.

Senate Committee Gets An Earful Too

ASCP also aired these issues to the Senate HELP Committee at a February 12 hearing on health care workforce issues and called on senators to adopt a series of program authorization and funding remedies to help alleviate part of the shortage crisis.

ASCP president Lee H. Hilborne, MD, told the committee, "For many years, our nation's clinical laboratories have faced a critical and growing shortage of qualified laboratory technologists and technicians, with the shortfall evident in almost every state in our country. This shortage hampers the ability of clinical labs to meet patient testing demands, which compromises patient health and welfare."

In its 2005 Wage & Vacancy survey, ASCP found that nearly 44 percent of responding labs across the country reported difficulty filling lab personnel positions, and it is becoming increasingly difficult in rural areas and smaller hospitals, Hilborne said. Moreover, "medical labs reported special problems in finding personnel for evening and night shifts at 72 and 82 percent, respectively, and on average, it was taking more than two months to fill medical technologist, histotechnologist, and cytotechnologist openings. The current vacancy rate for histotechnologists is exceptionally high at 30 percent."

Current vacancy rates for medical technologists and cytotechnologists are high, and "for histotechnologists, it is exceptionally high at 30 percent," ASCP president Lee Hilborne, MD, said in testimony before the Senate HELP Committee. "Furthermore, the impending retirement of thousands of baby boomers threatens to transform a serious personnel shortage into nothing less than a national health care crisis."

Rural areas are hit hard by the reduction in the number of training programs, Hilborne said, because many potential lab practitioners seek training avenues near their homes. But many urban areas have also been affected, he said. "The cities of Los Angeles and Miami do not have any medical technologist or medical laboratory technician training programs. Moreover, there are no cytotechnologist training programs in Florida. Now, students who *are* [sic] interested in pursuing a career as a laboratory professional face limited opportunities to do so."

Lobbying for Federal Relief

To address these problems, funding mechanisms are needed to encourage students to consider careers in clinical labs and encourage the development and enhancement of lab training programs, Hilborne said. ASCP called on the HELP Committee to support restoring funding for Title VII allied health programs to at least their fiscal 2005 level of $300 million. The President's budget request for FY 2009 proposes to eliminate all health professions training funds except for nursing programs, for an estimated savings of $557 million.

ASCP also advocates creation of an independent title (outside Title VII) that is dedicated to the clinical laboratory field, Hilborne noted. Further, he called on senators to

co-sponsor the Allied Health Reinvestment Act, S. 605, a bipartisan bill introduced by Maria Cantwell (Washington) on February 15, 2007 and referred to the HELP Committee. Discussions are underway on a House companion bill, he said.

S. 605 authorizes funding for Title VII programs to promote careers in allied health and to educate and train allied health personnel, especially in critical shortage areas. Support would include grants to facilitate and expand student enrollment and to develop internship and resident programs; loans for faculty development; and scholarships for students who agree to provide service in rural and other medically underserved areas. The bill specifically includes clinical lab sciences, medical technology, and cytotechnology as eligible programs (*NIR, 28, 13/Apr 23 '07, p. 5*).

The Act builds on "important contributions of the Title VII allied health professions programs," Hilborne said, citing the University of Nebraska as one of the innovative programs that received grants under this title. "According to data from the Health Resources & Services Administration, Nebraska has more than 128 laboratory professionals per 100,000 residents—almost twice the number of Wyoming and one of the highest concentrations of laboratory personnel per capita in the country." But due to cuts in allied health and other discipline grants, funding for the Nebraska program and others supporting clinical lab science have been eliminated, he said.

Special Concern Over Cytotechnologist Training

Hilborne also briefed the committee about the concerns raised by the cytotechnology school consortium, composed of eight leading pathology organizations, over the fact that many prominent cytotechnologist training programs are closing or slated to close this year, "under the mistaken belief that cytotechnologists only perform gynecologic cytology (Pap smears)."

In January, a letter signed by all eight organizations involved in the consortium went to higher education and hospital administrators at schools under threat to inform them of the need to keep these programs open and active. The consortium noted that "sensational sources have wrongly touted the end of the Pap test due to the advent of the HPV vaccine. Administrators have redirected funding for schools and facilities have been closed or told they will be terminated at the end of the academic year."

The consortium noted that HPV vaccines do not protect the currently infected population that needs to be screened for cervical cancer (over 50 million women) nor do they protect the young girls who receive the vaccine from the entire spectrum of viruses that cause cervical cancer—"thus the Pap test will continue to be a preventive health care imperative for many decades to come. Moreover, the belief that cytotechnologists perform only Pap smears belies their true role in patient care. Cytotechnologists are also vitally important in interpreting all body sites—from lung to breast cancer, from lymphoma to fine needle aspiration biopsies. The damage caused by these program closures cannot be easily reversed and the potential consequences for patient care will be profound."

Key Issues in the Lab Workforce

The personnel shortage has multiple dimensions and solving it requires a multifaceted approach to key issues, lab and pathology groups agree. These issues include:

- Recognition of the critical role that lab personnel play in assuring quality care for patients, with as much as 70 percent of medical decisionmaking based on lab test results.
- Power: Expanding the role for consulting with pathologists and for being integrated as a member of the patient's health care team.
- Work environment, characterized by little opportunity for career advancement, long work hours, the risk of infectious disease, and stress related to all these conditions.
- Wages/salaries not commensurate with education and competency requirements.
- Intense competition for clinical lab scientists from pharmaceutical companies and industry.

Sources: ASCP and CLIA program presentation to CLIAC.

CLIA Cytology, *from p. 1*

In the Senate, a similar bipartisan bill was introduced December 19, 2007—S. 2510, the Cytology Proficiency Improvement Act, with Mary Landrieu (D-La.) as lead sponsor. It is pending before the HELP Committee (*NIR, 29, 6/Jan 14 '08, p. 3*).

The College of American Pathologists is working in concert with the 66-member Cytology Improvement Coalition to muster additional support on Capitol Hill for H.R. 1237 and S. 2510.

In discussing the recent legislative movement on H.R. 1237, a spokesperson for the College told *NIR* that it is "definitely progress, not the end-all and be-all, but promising," adding that "once the bill clears the full committee, it is ready to go to the House floor on the suspension calendar as a non-controversial item."

CAP is pushing for congressional approval of cytology PT overhaul, arguing that the "current cytology PT requirements, based on regulations written more than a decade ago, do not promote quality and cannot effectively assess the competency of individuals examining Pap tests." In a statement in support of the Senate bill, CAP said its approach "would be an improvement over the current PT approach because it would challenge screening and interpretation skills in a constructive learning environment and, over time, keep pace with advances in science and technology."

The legislation would further clarify, CAP noted, how CME results would be incorporated into the lab's quality assurance activities. "The lab director would utilize CME testing results, along with other CLIA established metrics, to assess individual performance and, if necessary, require remedial training or further continuing medical education. CME results would be shared with the lab's accrediting organization as part of its inspection and accreditation process."

♦ Medicare Coding & Billing *Advisory*

Fee Change for Panel Code 80047 Equals Less Pay

Clinical laboratories nationwide will see a sharp reduction in their Medicare reimbursement for the new CPT metabolic panel code 80047, effective July 1. As of that date, Medicare will pay for the code—Basic metabolic panel (ionized calcium)—at the rate for 80048, Basic metabolic panel (total calcium). CPT 80047 was added to the 2008 Part B lab fee schedule, effective January 1.

Components of CPT 80047

Basic metabolic panel (calcium, ionized)
- Calcium, ionized, 82330
- Carbon dioxide, 82374
- Chloride, 82435
- Creatinine, 82565
- Glucose, 82947
- Potassium, 84132
- Sodium, 82495
- Urea nitrogen (BUN), 84520

In making the fee crosswalk to 80048, the Centers for Medicare & Medicaid Services is considering CPT 82330, ionized calcium—which is part of panel code 80047—as an automated chemistry test for payment purposes subject to Medicare rules for 23 automated multichannel chemistry codes.

Currently, CPT 80047 is paid as the sum of the rate for a seven-test panel (reimbursed by most contractors at $11.42) and the rate for 82330 (capped at $19.09), or a maximum of $30.51. Under the change effective July 1, payment for 80047 will be pegged to the rate for an eight-panel code, which translates to $11.83 in most regions of the country. In some areas, however, the rate will be lower—from $11.20 to a low of $8.93 to anywhere in the $9 to $10 range, according to CMS-maintained local fee schedules in states such as New York, Indiana, Ohio, Kentucky, Tennessee, North Carolina, Wyoming, and Washington.

Lab Groups Team Up For Congressional Lobbying Blitz

For registration and other information on the event, go to www.ascls.org.

On March 17-18, the American Society for Clinical Laboratory Science, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association will hold their annual Capitol Hill Day/Legislative Symposium in Washington, D.C.

Members of each organization from throughout the country will fan out across the Hill to visit their respective House representatives and senators to discuss the issues that affect their daily practice. Participants in the symposium also will receive "how to" training in lobbying and education about the roles of congressional committees and staff.

As of March 6, 129 had registered and more are expected as the event date approaches, ASCLS executive vice president Elissa Passiment told *NIR*. The list of major issues they will raise include Medicare reimbursement (frozen at the 2003 level for five years, through 2008), competitive bidding, lab personnel shortages, and increased funding for allied health training programs. Passiment emphasized that ASCLS is strongly committed to legislative repeal of the lab bidding demo scheduled to start July 1 in San Diego County (*related story, p. 1*).

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