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California Cancels Medicaid Lab Contracting Initiative

In pulling the plug before awarding any contracts, Medi-Cal told independent labs to keep on billing as usual

The state of California has cancelled the independent lab contracting initiative under its Medi-Cal program, becoming the second major state this year to abandon plans to change how Medicaid pays for clinical laboratory testing. Florida earlier this year yanked its Medicaid bidding competition for independent lab services (*National Intelligence Report, 26, 10/Mar 7 '05, p. 3*).

In announcing the cancellation on September 19, the Office of Medi-Cal Procurement said the Department of Health Services took this action in "its best interests" but is looking at changes that could achieve the original contract goals—namely, quality services at competitive rates and prevention of lab fraud and abuse.

In commenting on the move, a DHS spokesperson would only say that "based on the broad range of labs that responded to a request-for-applications (RFA), the Department decided that contracting is not the best option." For now, all clinical labs should "continue to do business with the Department as usual." ➥ *p. 2*

INSIDE *NIR*

Labs Edgy Over Possible Medicare Cuts

Clinical laboratory lobbyists are keeping an anxious eye on any budget reconciliation maneuver that could open Medicare to spending cuts, tempting Congress to consider Part B lab fee reductions or revival of a 20% lab co-pay.

While Hill budget leaders have not put Medicare off the table, their main target has been Medicaid, slated for $10 billion in cuts. But after Hurricane Katrina, it's unclear how the GOP majority will proceed, especially since the Bush Administration has pledged to fully reimburse state Medicaid services to evacuees and has also called for massive federal aid for relief and recovery, now upwards of $200 billion.

House and Senate budget leaders have postponed markup of reconciliation bills till late October and have suggested that any Medicaid cuts would likely be confined to such areas as reducing drug costs, restricting asset transfers to qualify for nursing home care, and flexibility to impose co-payments.

Katrina has also delayed action to avert a cut in Medicare physician fees in 2006. A fee increase would cost billions and is problematic, Hill sources say, given what the Gulf Coast needs.

The effort to alter Medi-Cal payment methods for lab services has historically been triggered by a state budget crisis, said CCLA's Mike Arnold. It began with a 1991-92 crisis, lagged for a long while, then got revived when another budget crunch hit in 2003

Medicaid Lab Contracting Initiative, *from p. 1*

DHS launched the initiative early last year, requiring independent clinical labs to obtain contracts with DHS if they wanted to continue to provide and get paid for Medi-Cal services. In April, the state issued an RFA for two-year contracts to provide services at reduced prices (80% below the Medicare rate), then revised the RFA and send it out again around the end of September. Only labs with an active Medi-Cal provider number for performing tests of CLIA moderate or high complexity were required to apply (*NIR, 25, 13/ Apr 19 '04, p. 7*).

"Juice Not Worth The Squeeze"

The cancellation is in the "best interests" of the laboratory community too, said Mike Arnold, who lobbies for the California Clinical Laboratory Association in Sacramento. He thinks DHS realized the initiative would cost more than it would save. "The juice wasn't worth the squeeze," he told *NIR*.

This was just the first installment of the contracting drive, he noted. Next in line after the independent labs were the hospital labs and the physician office labs. So, DHS had big cost issues if it decided to move forward, he pointed out.

Labs did respond to the RFA, Arnold said, "at great cost, I might add." Of the 416 labs that could apply, 243 did so. He thinks the information proved useful to DHS, offering more insight into the services the labs provide and allaying some major concerns about potential fraud and abuse.

In Arnold's view, Medi-Cal has reached the lab contracting goals in other, less disruptive and less potentially litigious ways. In terms of savings, Medi-Cal has already reduced lab rates to 80% below the Medicare rate. More active enforcement has cut into fraud, bolstered by a moratorium on new Medi-Cal provider numbers, in place for up to two years now, he noted. And finally, to assure quality testing, DHS has a lab licensing program, plus state and federal inspections.

COLA Gets CLIA Okay For Anatomic Pathology

COLA has received federal approval to accredit laboratories for anatomic pathology specialties under CLIA (the Clinical Laboratory Improvement Amendments), paving the way for the organization to extend its accreditation program to full-service hospital laboratories and specialized pathology labs. The approval, announced September 20, is effective as of last August 31.

COLA is based in Columbia, MD, and the majority of labs it accredits under CLIA (some 6,800, according to COLA sources) are physician office and group practice labs. But as COLA's CEO Doug Beigel said in a statement, "We are now poised to offer a full range of services to hospital labs, physician office labs, and independent labs. With the integration of these capabilities, we now offer clients one source for accreditation, which saves time and money."

He also noted that COLA accreditation is recognized by the Joint Commission on Accreditation of Healthcare Organizations. This allows JCAHO-affiliated hospitals and networks to bring all of their labs under a single accreditation program.

CMS Approves CAP's Cytology Proficiency Testing Program

Enrollees in an approved PT program must stay for one calendar year, but may switch to another approved program thereafter. So, a MIME enrollee who passes the testing this year has the option to switch to CAP's or any other approved program in 2006

Beginning in 2006, the College of American Pathologists will compete on the federal playing field for gynecologic cytology proficiency testing, a field that the Midwest Institute for Medical Education (MIME) has all to itself this year.

The CAP PAP program has been approved by the Centers for Medicare & Medicaid Services as a national PT provider and may be used by laboratorians to meet federal requirements under CLIA (the Clinical Laboratory Improvement Amendments of 1988). The American Society for Clinical Pathology has filed for approval too; its application is under review.

The CAP program offers field-validated slides; 22 testing sessions; two educational mailings, each with five glass slides and two online cases; and inter-laboratory comparison data with color images; plus 10-12 CMD/CE credits for all cytology staff. Because program slides must be field-validated, this limits the number of new 2006 customers that can be accommodated, so CAP urges all current CAP PAP customers to enroll promptly.

CAP Still Wants PT Overhaul

While CAP president Mary Kass, MD, noted in a "Dear Colleague" letter that the College is pleased with CMS's approval, "this decision does not alter our fundamental position that the existing PT requirements should be suspended and re-evaluated in the context of modern science and practice."

The requirements were published in 1992, but not enforced until last year when CMS announced that MIME had qualified as the first national PT provider for gynecologic cytology, as of January 1, 2005 (*NIR, 26, 5/Dec 16 '04, p. 1*). CAP and ASCP quickly responded by filing for approval of their programs, and they and other pathology groups have been lobbying the HHS Secretary and Congress for an overhaul of the requirements (*NIR, 26, 17/Jun 20 '05, p. 3*).

CLIAC Approves PT Workgroup

In response to the continuing controversy, the Clinical Laboratory Improvement Advisory Committee, at its meeting earlier this month, approved creation of a special workgroup to examine the regulatory requirements and see what changes might be made. Earlier this year, CLIAC advised CMS to consider revising the cytology PT rules, based on updated comments from professional groups and the public, evidence-based guidelines, and anticipated changes in technology.

Waived Lab Test Scrutiny To Continue

Quality remains a problem in laboratories that operate with a certificate of waiver under CLIA (Clinical Laboratory Improvement Amendments), and the Centers for Medicare & Medicaid Services will continue to survey these labs in 2006, said Judy Yost, the top CLIA official at CMS.

In a presentation to the Clinical Laboratory Improvement Advisory Committee, which met September 7-8 in Atlanta, Yost said the data show that quality issues in these settings are ongoing, though follow-up visits reflect sustained improvement.

CLIA Stats Update

Total enrollment: 192,533

Certificate Type	*# of Labs*	*POLs*
Waiver	111,338	51,792
PPM	39,088	32,265
Compliance	20,607	13,627
Accreditation	15,544	5,835
Exempt states (NY, WA)	5,956	

Labs by Self-Selected Types	
POLs	104,994
Nursing homes	14,741
Hospitals	8,617
Home health agency	9,051
Community clinics	6,522
Independent labs	5,239

Accreditation Organization Enrollment	
COLA	6,260
CAP	5,246
JCAHO	3,153
American Osteopathic Assn	49
American Assn of Blood Banks	214
American Society for Histocompatibility & Immunogenetics	129

Source: CMS CLIA office

According to the most recent data (from 2004), CMS visited 1,742 labs and issued 860 letters of compliance, 719 letters of recommendation, and 42 statements of deficiency. Some 20% of the labs surveyed were not performing quality control, 11% were not following the test manufacturer's instructions, and 4% were testing beyond the scope of their certificate of waiver.

The surveys are "educational visits to ensure that labs that perform only waived tests are doing their testing correctly and understand the principles of basic good laboratory practice," Yost told *NIR*.

Quality control in CLIA-certified labs has been and remains a big problem since the regulatory oversight program began in 1992. The most frequently cited deficiencies have been in the areas of test method verification, calibration, calibration procedures, and quality control procedures.

CLIAC recommended support for development of a "companion document by the Clinical Laboratory & Standards Institute containing guidance for labs on quality control practices," Yost said. "It will parallel the Option 4 CLSI document that is under development for manufacturers and the Food & Drug Administration. These would both be an outgrowth of the March 18 CLSI meeting on quality control" (*NIR, 26, 12/Apr 11 '05, pp. 4-5*).

Pathologists Get Boost From AMA On PC Lab Test Payment

Pathologists often report the PC of clinical lab tests because they oversee the lab and are responsible for the results, the AMA notes

Pathology groups across the country have been battling with private health insurers over denial of reimbursement for the professional component (PC) of clinical laboratory services. The latest fight involves the United HealthCare subsidiary, Ingenix, in Salt Lake City, UT. And the latest salvo supporting the pathologists comes from the American Medical Association in the form of new, pointed guidance on CPT coding.

In correspondence in December 2004 and in June of this year, the AMA challenged a change in policy at Ingenix, which said that separate PC payment would not be made for laboratory oversight services because it is part of the facility payment and a pathologist must generate a written report in order to use the modifier 26 for pathology and lab codes.

In the August *CPT Assistant*, the AMA emphasizes: "The use of modifier 26 is required for CPT codes 80048-89356 in those instances where the physician is only billing for the PC of the laboratory tests (e.g., medical direction, supervision, or interpretation). This reporting method is appropriate when the technical and the professional components are performed by different providers. A written report for an individual patient is not a requirement for having performed a PC service."

The last sentence is key, since CPT is clear that use of modifier 26 is not limited to a procedure that may generate a written report, but is broader and applies to medi-

cal direction and supervision, attorney Jane Pine Wood told *NIR*. Wood is in the Cleveland office of McDonald Hopkins Co., which represents many of the pathology groups objecting to the Ingenix policy.

A number of private insurers, including such giants as United HealthCare, Blue Cross, and Aetna, have argued that they are following Medicare's lead in denying separate payment for PC lab services. Medicare generally rolls the PC payment into its Part A hospital prospective payment and leaves it up to the hospital and the pathologist to agree on the details.

Groups representing pathologists do not buy the argument. Private insurers do not have an analogous payment mechanism, they point out. Moreover, says Wood, many of these payers' contracts with hospitals and pathologists do not support the position that the payers include payment for the PC services in their payments to hospitals. The policy change at Ingenix, she added, comes after decades of allowing pathologists to report and bill for PC lab services. While no lawsuits have been filed, her firm is tracking the dispute, she said. Meantime, there has been no response from, or sign of a change at, Ingenix.

CDC Award To CLSI Targets HIV Testing

The Clinical Laboratory & Standards Institute has secured a $365,000 cooperative agreement from the Centers for Disease Control & Prevention for capacity-building aid for global HIV/AIDS laboratory guidelines and standards development.

The year-long agreement is funded by the President's Emergency Plan for AIDS Relief—a five-year, $15 billion multifaceted approach to combating the disease in more than 100 countries around the world.

Through the agreement, CLSI will develop partnerships with health leaders in nations most afflicted by HIV/AIDS and work with them to build an infrastructure to develop long-term testing capacity—using, in particular, sound laboratory practices for HIV screening. These include quality systems for treatment, surveillance, prevention of mother-to-child transmission, and blood safety.

CLSI, based in Wayne, PA, is a global standards development organization formerly known as the National Committee on Clinical Laboratory Standards, with 4,000 organizations from the industry, government, and professional sectors worldwide participating as members and volunteers.

Medicare Expands Online Hospital Quality Data

The additions bring the quality measures on the Website to 20, including 17 related to heart attack, heart failure, and pneumonia

Consumers can get new information online to help them see how well their local hospitals are performing at *www.hospitalcompare.hhs.gov* (and at *www.medicare.gov*). Medicare this month posted two new quality measures for preventing surgical infections and one more measure for pneumonia patients.

The surgical infection prevention measures are "prophylactic antibiotic received within one hour prior to surgical incision, and prophylactic antibiotics discontinued within 24 hours after surgery end time." The new measure for pneumonia patients is "appropriate initial antibiotic selection."

These data are in addition to the 10 "starter" measures that acute-care hospitals are required to voluntarily report to obtain the full annual update to their Medicare reimbursement. Hospitals that don't report get 0.4% less. The pay differential was established under the Medicare Modernization Act of 2003. The Centers for Medicare & Medicaid Services has since added to the "starter" list (*NIR, 26, 13/Apr 25 '05, p. 5*).

The HospitalCompare Website is updated by the Centers for Medicare & Medicaid Services and the Hospital Quality Alliance, a public-private collaboration. The two new measures to prevent surgical infection are the first of a larger set of patient safety measures on which data will be collected in the Surgical Care Improvement Project. Its goal is to reduce the incidence of post-operative complications in U.S. hospitals by 25% by 2010.

Comparing A Hospital's Performance: *Quality Measures On The Website*

- **Heart attack (acute myocardial infarction)**
  - — Aspirin at arrival
  - — Aspirin at discharge
  - — Beta-blocker at arrival
  - — Beta-blocker at discharge
  - — ACE inhibitor for left ventricular systolic dysfunction (LVSD)
  - — Percutaneous transluminal coronary angioplasty (PTCA) within 90 minutes of arrival*
  - — Thrombolytic agent (clot buster) within 30 minutes of arrival*
  - — Smoking cessation counseling*
- **Heart failure**
  - — Left ventricular function (LVF) assessment
  - — ACE inhibitor for left ventricular systolic dysfunction (LVSD)
  - — Smoking cessation counseling*
  - — Discharge instructions*
- **Pneumonia**
  - — Initial antibiotic received within 4 hours of hospital arrival
  - — Pneumococcal vaccination status
  - — Oxygen assessment
  - — Smoking cessation counseling*
  - — Blood culture performed before initial antibiotic received*
  - — Appropriate initial antibiotic selection**
- **Surgical Infection Prevention**
  - — Prophylactic antibiotic received within one hour prior to surgical incision**
  - — Prophylactic antibiotics discontinued within 24 hours after surgery end time**

* One of the seven measures added by CMS earlier this year.
**Measure displayed for the first time in September 2005.

Virtually all eligible hospitals are reporting the required data and will get the full Medicare update in 2006, says CMS. More than 90% of the 4,048 participating hospitals are reporting at least the 10 starters. Over 70% (2,903) are reporting these plus seven others introduced in April 2005, an almost threefold increase (967 hospitals). Just over 80% (3,291) publicly reported the new pneumonia measure. CMS administrator Mark McClellan commented, "Certain processes appear to be well grained in U.S. hospitals—rates for aspirin at arrival and discharge and beta blocker at discharge for heart attack patients and assessment of blood oxygen levels for pneumonia patients remain high."

HHS Secretary Picks Advisory Panel On E-Health Records

Health & Human Services Secretary Michael Leavitt has selected 16 commissioners to serve on the American Health Information Community, a federally chartered panel that will advise the Department on how to make patients' health information digital and interoperable. The panel's first meeting is set for October 7 in Washington, DC, and will be open to the public.

Lab industry sources are disappointed that nominees from their ranks were passed over in the final selection. They wanted a seat on the panel for direct input, noting that lab testing data comprise the bulk of most patients' records and contribute to 70% of medical decisions

Selection of the commissioners kicks off a national strategy Leavitt unveiled earlier this year to create a national electronic health record system whose aims are to reduce medical errors, minimize paperwork, lower costs, and improve the quality of care. The strategy envisions using federal muscle as a dominant healthcare purchaser and provider to get the private sector involved in a collaborative effort to meet President Bush's call for most Americans to have e-health records within 10 years (*NIR, 26, 17/Jun 20 '05, p. 4*).

Leavitt will chair the panel, and the commissioners will serve two-year terms. Eight of the members are from federal agencies, including the heads of the Centers for Medicare & Medicaid Services and the Centers for Disease Control & Prevention. The other appointees include representatives of payer and provider interests, such as the Blue Cross Blue Shield Association, the American Academy of Family Physicians, and the Federation of American Hospitals; state agencies and consumer groups; and executives from PepsiCo, SureScripts, and Intel Corp.

The panel "will adhere to an aggressive timetable that focuses on areas of critical need—such as adverse drug event reporting and biosurveillance—as we get about the work of developing, setting, and certifying standards," Leavitt said.

"The public-private nature of the panel is designed to ensure that the nationwide transition to e-health records, including common standards and interoperability, occurs in a smooth, market-driven way," added Dr. David Brailer, MD, PhD, the national coordinator for information technology.

♦ QUESTION *of the* M·O·N·T·H

Prior determination is not required for submission of a claim, CMS officials emphasized. It is a voluntary process

As I understand it, physicians and beneficiaries will be able to know in advance if Medicare will cover and pay for certain physician services, under a rule that the Centers for Medicare & Medicaid Services recently proposed. Does the rule apply to clinical laboratory services when furnished by a physician and/or to any pathology services?

The answer is no to both questions, CMS officials told *NIR*. The "prior determination" process, required by the Medicare Modernization Act of 2003, applies only to services reimbursed under the Medicare physician fee schedule, not to the lab fee schedule. Nor are any pathology codes being considered in the agency's initial workup of the services for which an advance coverage decision may be requested.

CMS proposes to create an initial pool of eligible services from among the 50 physician services with the highest allowed average charges that are performed at least 50 times a year. Most will be non-emergency services in an inpatient setting, the agency says. The pool will then be culled for services for which there is a local or national coverage decision. Local Medicare contractors will get a list of the remaining services, plus plastic and dental surgeries that Medicare may cover and that have an average allowed charge of at least $1,000. Contractors must make a decision on coverage no later than 45 days after getting a request, but must respond faster in urgent circumstances. CMS published the advance notice rule in the August 26 *Federal Register*.

Providers To Rate Satisfaction With Medicare Payers

Starting next year, clinical laboratories, pathologists, and other healthcare providers can rate their satisfaction with the local contractor that processes their Medicare fee-for-service claims.

In January, the Centers for Medicare & Medicaid Services will begin measuring provider satisfaction with local contractors. The agency completed a pilot of the survey in June and used the results to refine the survey, data collection procedures, and analysis and reporting of the results.

When the program goes national in 2006, about 30,000 providers will have the chance to rate fee-for-service contractors, including fiscal intermediaries, carriers, durable medical equipment regional carriers, and regional home health intermediaries. Providers can respond online or by mail or fax.

CMS will use the results to create custom reports for the contractors measuring overall satisfaction scores from providers. The information is expected to help contractors identify improvements they could make.

The survey research firm Westat, whose main campus is in Rockville, MD, has been awarded the contract to run the provider satisfaction survey program.

KATRINA Relief & Recovery

CDC Opens Hotline For Labs

The Centers for Disease Control & Prevention has opened a toll-free hotline that clinical laboratories may call for help in the wake of Hurricane Katrina, 1-800-232-4636.

The agency will help labs locate supply and reagent sources, volunteer staff, courier services, and useful contacts at state and local public health departments.

The hotline handles many inquiries, the CDC notes, so "you will need to identify yourself as a clinical lab and indicate your specific need for assistance."

Once a request is received from a lab impacted by Katrina, it will go to a CDC response team for follow-up in finding the relevant contacts and assistance.

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