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California Sues 7 Clinical Labs for Overcharging Medi-Cal

The broader issue posed by the case is whether it will prompt other states with similar laws to follow suit to scrutinize lab charges and curb rising costs in their Medicaid programs.

The state of California is suing seven clinical laboratories, including national giants Quest Diagnostics and LabCorp, to recover hundreds of millions of dollars in illegal overcharges to its Medicaid program, known as Medi-Cal.

State attorney general Edmund G. Brown Jr. announced March 20 that his office is joining a whistle-blower suit filed against the labs by Chris Riedel, the CEO of Hunter Laboratories in Campbell, Calif.

The *qui tam* suit filed under the state's False Claims Act seeks triple the amount of California's damages, civil penalties of $10,000 for each false claim, and recovery of costs, attorneys' fees, and expenses. Under the state's FCA, the whistle-blower receives a share of the recovery if statutory requirements are met.

"In the face of declining state revenues, these medical labs have siphoned off hundreds of millions of dollars from programs intended for the most vulnerable California families," Brown said. "Such a pattern of massive Medi-Cal fraud and kickbacks cannot be tolerated, and I will take every action the law allows to recover what is owed."

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CAP Urges CMS to Take a Different Tack on CLIA Cytology Proficiency Testing

The College of American Pathologists has asked the Centers for Medicare and Medicaid Services to withdraw its proposed revisions to proficiency testing (PT) requirements for pathologists and cytotechnologists who perform Pap testing and to consider a continuing medical education (CME) alternative.

In a letter to CMS, CAP president Jared N. Schwartz, M.D., Ph.D., FCAP, said "CAP believes the current regulation and recently proposed revisions … continue to demonstrate problems with embedding professional standards into federal regulations…. CMS's efforts to regulate in this manner have resulted in a program that fails to measure competency, is not supported by science, and does not support improved health outcomes."

Advocacy, an independent office within the U.S. Small Business Administration, is also urging CMS to consider

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— Webinar, April 2: Optimizing Your Molecular Diagnostic Test Menu: Lessons From Lab Leaders
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In a statement, Brown noted that under California law, "no provider shall charge [Medi-Cal] for any service … more than would have been charged for the same service … to other purchasers of comparable services … under comparable circumstances."

Yet, the defendant labs charged Medi-Cal up to six times as much as they charged some of their other customers for the very same tests, he continued. For example:

- *Complete blood count (CBC), one of the most frequently ordered blood tests*. Quest Diagnostics charged Medi-Cal $8.59; some of its other customers, $1.43.
- *Hepatitis C antibody screening*. LabCorp charged Medi-Cal $30.09; some of its other customers, $6.44.
- *HIV antibody screening*. Health Line Clinical Laboratories charged Medi-Cal $12.65; some of its other customers, $1.75.

'Pattern' of Abuse

These are not isolated examples, Brown said. "They are part of a pattern of fraudulent overcharging and kickbacks that developed over the past decade." Here's how it worked:

- The labs provided deep discounts when paid directly by doctors, patients, or hospitals. Prices were often below the lab's cost and sometimes free.
- In exchange for these discounts, the labs expected customers to refer all of their other patients (where the lab was paid by an insurance company, Medicare, and Medi-Cal) to its lab. Under California law, this amounted to an illegal kickback.
- These sharply reduced prices were not made available to Medi-Cal. In effect, the labs shifted the costs of doing business from the private sector to Medi-Cal.
- Additionally, the labs offered their clients who paid them directly (not through Medi-Cal or other insurance) deeper discounts to get a larger share of the lab testing business. This created an unfair playing field, and laboratories that followed the law could not effectively compete and sometimes were forced to sell or close down.

Open to Dispute

The Medi-Cal case is not cut-and-dried, say industry sources. The "lowest rate" argument is subject to dispute, attorney Patric Hooper, with Hooper, Lundy, and Bookman in Los Angeles, told *NIR*. While he could not comment on the specifics of the case, he could discuss the law in general, which he said allows discounts to physicians.

This was affirmed in a state appellate court ruling in the *People v. Duz-Mor Diagnostic Laboratory, Inc.*, which found that the lab's practice of charging discounted fees to physicians' private-pay patients did not violate the state's unfair competition law. The court held, "In our view, the practice of negotiating discounts for physicians' private-pay patients benefits health care consumers. The lower prices are by law passed on to consumers. The evidence established that if discounts were not negotiated, private-pay patients would

Labs Named in the Lawsuit

The *qui tam* suit contends that the following medical labs systematically overcharged Medi-Cal over the past 15 years.

- Quest Diagnostics Inc., Madison, N,J.; its affiliate Specialty Laboratories Inc., in Valencia, Calif.; and four other Quest affiliates.
- Health Line Clinical Laboratories Inc., now known as Taurus West, Inc., in Burbank.
- Westcliff Medical Laboratories Inc., in Santa Ana.
- Physicians Immunodiagnostic Laboratory Inc., in Burbank.
- Whitefield Medical Laboratory Inc., in Pomona.
- Seacliff Diagnostics Medical Group, in Monterey Park.
- Laboratory Corporation of America, Burlington, N.C.

pay more for services than Medi-Cal pays on behalf of its beneficiaries or than HMOs pay for their members. We can see no public policy benefit in such a result."

Nor are discounts unfair to the public because Medi-Cal is not offered similar discounts. The court noted that the amount Medi-Cal pays for a test is governed by state regulations and can be no more than the lesser of the amount billed, the charge to the general public, Medicare's allowance, or scheduled amounts. "Medi-Cal, not Duz-Mor, controls the amount the program will pay," the court said.

A previous ruling by a California court in a separate case came to a different conclusion on discounts. In *Physicians & Surgeons Laboratories, Inc. v. Department of Health Services*, which is cited in the *qui tam* suit, the court held that the defendants could charge any other purchaser any fee for their services as long as Medi-Cal obtained the best price available to other customers under comparable circumstances.

Industry Reaction

Mike Arnold, who represents the California Clinical Laboratory Association, told *NIR* that "the lab industry feels the [whistle-blower] case is not well-founded and the industry plans to defend itself to the fullest extent. Once the facts are know, the defendant labs say they will be exonerated." CCLA will not be involved in the litigation, he said, but will continue to act as a clearinghouse to transmit to its members all the case materials in the public domain.

Meantime, Nancy Ogan, the chief executive of Seacliff, one of the labs charged in the case, was quoted in the *Los Angeles Times* as saying, "Though we believe our inclusion in this suit is not justified, we plan to conduct an investigation into the allegations, cooperate fully with the authorities, and vigorously defend Seacliff against these charges as we believe we will be vindicated in a court of law."

Court Rules in Lab Competitive Bidding Demo Lawsuit

In a long-awaited ruling, a federal district court in San Diego on March 25 granted the government's motion to dismiss the lawsuit filed by local labs to stop the launch of the Medicare competitive bidding demo for independent lab services, but the court denied the government's motion to dissolve the preliminary injunction and vacate the interlocutory opinions.

The preliminary injunction stopped the demo from going forward on July 1 of last year and barred the Centers for Medicare and Medicaid Services from disclosing or using the bid information the labs previously submitted. Congress then repealed the authority for the demo, but CMS declined to return the bids. The lab plaintiffs—Sharp Healthcare, Internist Laboratory, and Scripps Health—feared CMS would use the bid information to lower rates and demanded that CMS return and not use the information (*NIR, 29, 21/Sep 15 '08, p. 8*). Judge Thomas Whelan opted not to hold a hearing last Sept. 22 on motions from the plaintiffs and CMS, saying he would decide the matter based on briefs they submitted.

The judge's March 25 ruling gives the lab plaintiffs 30 days to amend the existing complaint to raise the document retention issue directly but urges the parties to work out the dispute. Most importantly, said the labs' attorney Patric Hooper, the judge refused to vacate the previous orders, suggesting that the court has substantial concerns about CMS's continuing use of the bid data. Hooper is with Hooper, Lundy, and Bookman in Los Angeles.

CMS to Suspend Phase VIII MUEs for Lab, Pathology Codes

Scrutiny of clinical laboratory and pathology claims under Phase VIII of the medically unlikely edit (MUE) program will be suspended, the Centers for Medicare and Medicaid Services has announced in response to industry concerns.

In a March 13 conference call, the director of the agency's program integrity office, Kim Brandt, said this will give CMS and the industry time to work out problems with the Jan. 1 implementation of the Phase VIII edits, which involve more than 100 CPT/HCPCS lab and pathology codes. In a follow-up e-mail, she said a meeting would be set up between CMS medical officers and industry representatives to discuss the specific issues.

Carrying through on the suspension may take several weeks, she cautioned, because of the systems changes needed. Tests affected include, but are not limited to, flow cytometry, histology, immunohistochemistry, and fluorescent in situ hybridization.

The American Clinical Laboratory Association organized the March 13 conference call. Joining in were representatives from the College of American Pathologists and ACLA associate members representing medical device manufacturers and lab management interests—among them, Abbott Molecular, Roche, Siemen, and Xifin.

Denial of claims, lack of transparency, economic disincentives, the criteria used for establishing the MUEs, and process issues were all presented as concerns that affect patient care and thus need immediate resolution.

Background on the Medically Unlikely Edits

Medically unlikely edits (MUEs) are limits on the units of service that can be billed for a particular CPT/HCPCS code per Medicare beneficiary per day. Claims exceeding the limits are automatically rejected.

Their purpose is to weed out improper Medicare fee-for-service payments and lower the paid claims error rate. The CMS contractor for the program is Correct Coding Solutions, LLC, in Carmel, Ind.

MUEs have been controversial since being developed as part of Medicare's Correct Coding Initiative (*NIR, 27, 7/Jan 23 '06, p. 1*). The Centers for Medicare and Medicaid Services implemented the MUE program as of Jan. 1, 2007 (*NIR, 28, 5/Dec 15 '06, p. 5*).

The program, as described by CMS, seeks to identify claims with obvious or negligent errors, such as typographical or transcription mistakes and duplicative services. It initially targeted "anatomical" edits (for example, billing for multiple appendectomies or for a vasectomy for a female or a hysterectomy for a male). But it since has expanded to clinical conditions more open to scientific debate, prompting critics to say the MUEs are set too low and often clash with medical necessity determinations when testing is required.

CMS declined to establish an advisory committee on the MUEs, as advocated by the industry (*NIR, 28, 11/Mar 26 '07, p. 3*). But it continues to invite comments on any new round of proposed MUEs.

In response to industry requests, CMS agreed to MUE disclosure. Reversing its long-held "restricted distribution" policy, the agency began publishing most of the MUEs on Oct. 1, 2008, withholding only those it said were primarily designed to detect fraud (*NIR, 30, 1/Oct 13 '08, p. 2*).

A big concern about Phase VIII is CMS's decision not to disclose to ACLA and other commenters the final MUEs of four or more, David Mongillo, ACLA's vice president of policy and medical affairs, told *NIR*.

Providing comments is a resource-intensive, thoughtful effort, he said, and "if you don't know the final MUE, there is no way to challenge it." Labs and pathologists also will have no idea why their claim was denied and whether they will be paid at all for tests deemed medically necessary by the ordering provider, he noted.

It is difficult, Mongillo continued, to set a finite cap on many of the codes subject to Phase VIII. The units of service provided for the same patient on the same day are driven by clinical conditions, he pointed out. The MUEs should recognize that the lab will have to perform the same service for the same patient many times in specific cases. In flow cytometry, for example, where the lab is looking for distinct changes in individual cells, numerous probes may be required to arrive at a diagnosis. So, it is not "unlikely" that the lab will bill for many different levels of units of service based on the clinical findings and good medical practice.

'It is difficult to set a finite MUE cap on many of the Phase VIII lab and pathology codes. The units of service provided for the same patient on the same day are driven by clinical conditions, which can vary widely from patient to patient'
—David Mongillo, ACLA vice president for policy and medical affairs.

ACLA member labs noticed a significant increase in claim denials starting in January, Mongillo said. ACLA did a quick survey and found 23 codes at issue, equating to about a $1 million loss to the labs that month. The survey tapped only a small sample, he noted, so it is hard to know what is going on nationwide.

Among the issues raised by ACLA regarding Phase VIII:

- It includes a number of codes that allow for multiple units of service appropriately billed for the same patient the same day based on the clinical circumstances. It is therefore very important to either recognize that these codes should not be subject to an MUE or that the MUE should be set at a level high enough to accommodate major variations in clinical circumstances.
- It includes CPT codes where the AMA description states its use is "each" and, therefore, should not be restricted to a specific number of units of service. It would be very difficult (if not impossible) to set a limit of how many of this type of CPT code would be applicable to testing on a single date of service.
- CMS's MUE appeal process and Medicare billing requirements do not represent viable options for appeal or billing resolution. Labs will have to resubmit and appeal thousands of claims, based on the expected level of service, to numerous different carriers or Medicare Administrative Contractors. That process is slow, expensive, and the delay will severely affect a laboratory's cash flow. "Also, under Medicare requirements, all providers are to bill for the services they provide. It is wholly improper to require that labs bill for [these] services and then penalize them by not paying for any of those services because some (but not all) exceeded the MUE."

Under the current CLIA cytology PT program, there are two approved national PT providers: the College of American Pathologists and the American Society for Clinical Pathology. The state of Maryland runs a separate PT program for those testing specimens of state residents.

CLIA Cytology Proficiency Testing, *from p. 1*

concerns raised by CAP and the Cytology Improvement Coalition representing more than 60 organizations.

In a letter to CMS, Advocacy said it was concerned about the rulemaking's compliance with the Regulatory Flexibility Act. Under the rulemaking, most cytology labs and cytology PT programs are considered small businesses. Advocacy called on CMS to analyze the impact of the proposed rule on them as well as alternatives that would reduce the regulatory and cost burden while protecting the public health. Advocacy noted that as an independent office, its views do not necessarily reflect those of the SBA or the administration.

CMS released its long-awaited cytology PT proposal in January (*NIR, Vol 09, Iss 2/Jan 26, p. 1*). The agency proposed to increase the number of Pap test challenges from 10 to 20 per test, decrease test frequency from once each year to once every two years, change the grading scheme, require validation of cytology challenges before use in testing, and allow for new technologies, for example, digital images, as they become available.

While CMS did not agree to drop different scoring grids for pathologists and cytotechnologists in favor of the same scheme for both, as recommended by the Clinical Laboratory Improvement Advisory Committee, it did invite further comment on this issue.

The CME alternative backed by CAP, along with others in the Cytology Improvement Coalition, was contained in legislation that passed the House and garnered 43 co-sponsors in the Senate last year before the 110th Congress ended. But this alternative could be achieved through regulatory changes if CMS desires to do so, CAP said. Under this alternative:

- ❑ All individuals involved in screening and interpreting Pap tests must participate in a federally mandated annual CMS testing program in gynecologic cytology.
- ❑ All CMS PT programs must be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.
- ❑ All cytology testing programs must incorporate the interpretation of Pap tests with glass slides (or equivalent technologies).
- ❑ Each lab must maintain a record of each individual's cytology test results.
- ❑ Each lab director must use results from the annual test, along with other CLIA-required metrics, to assess individual performance and, if necessary, take appropriate action for remedial training or further continuing medical education.

CMS Cytology PT Proposals

Current rule	***Proposed rule***
10 slides/test	20 slides/test
2 hours/test	4 hours/test
Annual test	Biennial testing
Test Composition:	*Test Composition:*
• 1 unsatisfactory challenge	1 unsatisfactory challenge
• 1 normal challenge	1 normal challenge
• 1 low grade (LSIL) challenge	1 low grade (LSIL) challenge
• 1 high grade (HSIL) or cancer (CA) challenge	2 high grade (HSIL) or cancer (CA) challenge
1 missed HSIL/CA = automatic failure	2 missed HSIL/CA = automatic failure
Glass slide test	Glass slide test and opportunity for new technologies
Field validation of slides not required	Continuous field validation required
Appeals process not required	Appeals process required
Different scoring grids for pathologists, cytotechnologists	Same

- ❑ Each lab director must share individual testing results with the lab's accrediting organization so that it can review and monitor individual performance on an ongoing basis.
- ❑ Accrediting organizations must review the testing results as part of conducting laboratory inspections and accreditation under CLIA.
- ❑ Each lab director must transmit assessment results and improvements to the accrediting body of the lab for quality assurance.

Obama Names His Picks for Top FDA Posts

Strengthening FDA's regulatory oversight is an administration priority in the wake of controversies over drug and device approvals and the agency's response to a series of outbreaks of food-borne illness.

President Barack Obama has selected Dr. Margaret Hamburg to be commissioner of the Food and Drug Administration and Dr. Joshua Sharfstein to be the principal deputy commissioner.

Hamburg, if confirmed by the Senate as expected, would succeed Bush appointee Andrew von Eschenbach, who resigned in December. Hamburg was New York City's health commissioner for six years and drew praise for an initiative to control the spread of tuberculosis, reducing infant mortality rates, and boosting child immunizations. She later served as the Nuclear Threat Initiative's founding vice president for the biological program. Before joining NTI, she was the assistant secretary for planning and evaluation at HHS during the Clinton administration.

Sharfstein, a pediatrician by training, is commissioner of health for the City of Baltimore. He led the Obama transition team's assessment of the FDA. He also has worked as an aide to Rep. Henry A. Waxman (D-Beverly Hills), a leading critic of the pharmaceutical industry. He is a member of the board on Population Health and Public Health Practice of the Institute of Medicine.

Blumenthal Named to Head HIT Office at HHS

The Obama administration on March 20 announced its choice of Massachusetts physician David Blumenthal as national coordinator for health information technology (HIT) at the U.S. Department of Health and Human Services. He replaces Robert Kolodner, M.D.

In this position, Blumenthal will lead the implementation of HIT systems as required under the American Recovery and Reinvestment Act (Pub. L. No. 111-5). The measure includes $19 billion for HIT, including Medicaid and Medicare payment incentives to help physicians and hospitals adopt IT systems (*NIR, Vol 09, Iss 4/Feb 23, p. 1*). The law also formally established the HIT coordinator's office.

Blumenthal most recently has been director of the Institute for Health Policy at the Massachusetts General Hospital/Partners HealthCare System and a professor at Harvard Medical School. Before that, he was senior vice president at Boston's Brigham and Women's Hospital and executive director of the Center for Health Policy and Management.

"As a primary care physician who has used an electronic record to care for patients every day for 10 years, I understand the enormous potential of this technology," Blumenthal said in a statement. "President Obama has laid out a vision of health reform that is both inspiring and long overdue. We cannot make that vision a reality without the help of our most advanced computer technology."

CMS Considers Medicare Coverage of HIV Screening

The Centers for Medicare and Medicaid Services has taken the first step toward covering screening for HIV infection in the Medicare population. After reviewing various preventive services recommended by the U.S. Preventive Services Task Force, the agency has decided to initiate a national coverage analysis of HIV screening, according to a CMS tracking sheet notice. The task force strongly supports HIV screening of all adolescents and adults at increased risk for infection and all pregnant women.

Since Jan. 1 of this year, CMS no longer needs congressional approval to add to the Part B preventive services benefit. It now has the authority to add services on its own under the Medicare Improvements for Patients and Providers Act (Pub. L. No. 110-275).

CMS will use the national coverage determination process to see whether the HIV screening is rated grade A (strongly recommends) or grade B (recommends) by the task force and meets certain other requirements. The public may comment until April 12. A proposed decision is due Sept. 13. The national coverage analysis is expected to be completed by Dec. 12.

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