Clinical Lab Licensing Reform

Last year the independent Bureau of State Audits issued a report that critically evaluated the performance of Laboratory Field Services in their task of licensing and inspection of clinical labs and regulation and licensing of laboratory personnel. The major conclusions of the report were:

- They had failed to inspect almost 2,000 in state labs and had failed to inspect 91 out-of-state labs either upon original licensure or upon renewal.
- A lack of sufficient policies and procedures regarding PT testing.
- A lack of LFS policies to prioritize, track and initiate investigations.
- A failure to appropriately approve and use outside accrediting organizations to provide lab oversight.

The Department of Public Health has sponsored the introduction of SB 744 (Strickland) to reform the clinical lab licensing fee structure to provide sufficient funding to complete their licensing and oversight responsibilities. Clearly funding has been a problem for LFS in completing its inspection obligations.

The current lab license fee is $1,032 and SB 744 would replace the flat fee with a sliding-scale fee schedule based upon the volume of testing by the lab, which is similar to the CLIA fee schedule. The lowest fee would be $270 for a lab performing 2,001 or fewer tests per year with the highest at $4,960 for 1 million tests per year.

SB 744 would also establish specific requirements for clinical lab accrediting organizations, like the College of American Pathologists (CAP), to be recognized for California inspection purposes. The CAP has been unofficially given deemed status by LFS, but LFS never finalized regulations to establish approval.

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CSP President’s Message
S. Robert Freedman, M.D.

It is an honor and privilege to serve as President of the California Society of Pathologists. As a general pathologist in hospital practice in the San Jose area, and a member of the CSP Board of Directors for over 10 years, I am well aware of the issues specifically affecting pathologists in various modes of practice in this State. I am proud of the accomplishments of the Society not only providing excellent educational opportunities, but also representing the interests of pathologists to the Legislature, Laboratory Field Services, the Medical Board, and various payers including Palmetto, the Medicare fiscal intermediary. I welcome your suggestions and participation in the activities of the organization and look forward to continuing to insure the success of pathologists and the California Society of Pathologists.

Clinical Lab Licensing Reform
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for accrediting organizations. The CSP has participated in several meetings with DPH and the lab community to discuss our perspective and concerns. We support SB 744 but have suggested the following changes:

(1) Technical amendments to the new provisions regarding responsibilities of recognized accrediting bodies. Though LFS has recognized CMS approved accrediting organizations like the CAP for inspection purposes there have not previously been these specific detailed elements of responsibility.

(2) The proposed fee schedule should also contain language to allow license fees to be capped at the amount necessary to administer the program. New provisions will insure that all fees shall remain in the Clinical Laboratory Improvement Fund for use only for those purposes. We believe it is reasonable to limit fees to the amount necessary to conduct the program.

(3) Existing law since 1992 has allowed LFS to assess an additional fee to clinical labs that perform cytology services, mostly Pap smear evaluations. That additional fee assessed on a volume basis was to provide funding for special inspections and development of a Proficiency Testing program for cytology services. That program was never developed yet the fees have continued to be paid for many years. We request that this separate assessment be eliminated.

SB 744 will be heard in numerous committee hearings as it makes its way through the legislative process. We will keep you informed on the progress of the bill and our efforts to obtain changes.
CSP Launches New Online Career Center

In May, the California Society of Pathologists (CSP) will launch its interactive job board, the CSP CAREER CENTER. With its focus on the pathology profession, the CSP CAREER CENTER will offer members—and the industry at large—an easy-to-use and highly targeted resource for online employment connections.

Both members and non-members can use the CSP CAREER CENTER to reach qualified candidates. Employers can post jobs online, search for qualified candidates based on specific job criteria, and create an online resume agent to e-mail qualified candidates daily. They also benefit from online reporting that provides job activity statistics.

For job seekers, CSP CAREER CENTER is a free service that provides access to employers and jobs in the pathology profession. In addition to posting their resumes, job seekers can browse and view available jobs based on their criteria and save those jobs for later review if they choose. Job seekers can also create a search agent to provide e-mail notifications of jobs that match their criteria.

As a registered employer or job seeker you also have access to the National Healthcare Career Network (NHCN), a network of over 60 top healthcare associations and professional organizations. CSP’s alliance with NHCN increases your reach to over 7,000 resumes and over 1,500 job postings — giving you more control over your career advancement and a one-stop-shop to find targeted and quality candidates.

FTC Says Physicians Must Comply with “Red Flag” Identity Theft Rules
New August 1 Deadline

The Federal Trade Commission’s “Red Flag Rules” require financial institutions and “creditors” to develop and implement identity theft detection and prevention programs by August 1, 2009. This is a delay from the previously established May 1 deadline.

Despite objections from CMA, AHA, and others in organized medicine, the FTC insists that physicians who regularly bill their patients for services (including copayments and coinsurance) are considered “creditors” and must develop and implement written identity theft prevention programs for their practices by the May 1 deadline.

The original purpose of these regulations was aimed at financial institutions and based upon objections from physicians and others the regulation implementation was delayed last year.

CMA and AMA continue to urge the FTC to reconsider its interpretation of physicians as “creditors.” CMA believes the Red Flag Rules could impose an unnecessary burden on physician practices, which often already operate under severely strained conditions. CMA also believes the new rules are unnecessary for most physicians because the Health Insurance Portability and Accountability Act (HIPAA) imposes strict requirements to safeguard the confidentiality and security of electronic patient information. Until further notice, however, physicians should begin to plan their compliance programs.

CMA is also preparing a written toolkit to help physicians develop and implement identity theft detection programs. The toolkit will be posted on the CMA website as soon as it is completed.

Spring 2009
Brown Sues to Recover Hundreds of Millions of Dollars Illegally Diverted from Medi-Cal

The following is an excerpt of a press release from the Ca. Attorney General on a lawsuit over Medi-Cal Lab Payments

LOS ANGELES - Responding to a whistle-blower's allegation of "massive Medi-Cal fraud and kickbacks," Attorney General Edmund G. Brown Jr. joined legal action against seven private laboratories to recover hundreds of millions of dollars in illegal overcharges to the state's medical program for the poor.

"In the face of declining state revenues, these medical laboratories have siphoned off hundreds of millions of dollars from programs intended for the most vulnerable California families." Attorney General 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," Brown added.

According to whistle-blower Chris Riedel, the CEO of Hunter Laboratories, "I confirmed with the California Department of Health Care Services that these practices were illegal. We then had a choice--either join the other labs in violating the law or be unable to compete for business. We choose to suffer the financial consequence, and follow the law."

The lawsuit, which is pending in San Mateo Superior Court, contends that the 7 medical labs systematically overcharged the Medi-Cal program over the past 15 years.

The defendants include: Quest Diagnostics, Inc.; its affiliate Specialty Laboratories, Inc.; and 4 other Quest affiliates; Health Line Clinical Laboratories, Inc.; West, Inc.; Westcliff Medical Laboratories, Inc.; Physicians Immunodiagnostic Laboratory, Inc.; Whitefield Medical Laboratory, Inc.; Seacliff Diagnostics Medical Group.; Laboratory Corporation of America.

California law states that "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, these medical laboratories charged Medi-Cal up to six times as much as they charged some of their

Important Court Decision on Liability of Lab Director for Medi-Cal Payments

A Sacramento Superior Court Judge has issued a final ruling on a petition filed by a pathologist to overturn a determination by an Administrative Law Judge that found the pathologist laboratory director responsible for repayment to Medi-Cal totaling over $6 million dollars. The judge ruled in favor of the pathologist by ruling that he is not liable for the repayment.

The case involved a pathologist who had been the director of two independent labs that were audited by the Medi-Cal program in 2002 for clinical lab services billed and reimbursted in the prior three year period. At the time of the audit the labs had been closed and the owners of the labs could not be found. Since there were no records for the services that had been reimbursed DHCS sought restitution of those payments. In the absence of the owners DHCS then attempted to find the pathologist liable for repayment as the lab director. The pathologist was not an owner of the labs and had not billed in his name or been paid any of those funds, but for a nominal payment as lab director. He was listed as the director of the lab on both the state licenses and CLIA certificates.

The pathologist appealed the auditor's determination beginning in 2003 through a hearing before an Administrative Law Judge and discussions with DHCS but to no avail. The ALJ decision did find the pathologist responsible for $6 million dollars in payments and sought restitution. The ruling was based on the provisions in the Business and Professions Code that state that the laboratory director is jointly and severally responsible for the overall operation and administration of the laboratory. The ALJ decision was ultimately ratified by the Director of DHCS. Last year the pathologist sought a Writ of Mandate in Sacramento Superior Court to overturn the ALJ decision. The Writ argued that the pathologist was not the "provider" under state law, had received none of the disputed payments, had no oversight or responsibility for the billings to Medi-Cal, and under the law of restitution the action can only be against a party that had received the disputed funds.
Bills to Allow District Hospitals to Employ Physicians

Current California law prohibits hospitals from employing physicians with exceptions for some county hospitals and purely charitable institutions. This is the bar on the corporate practice of medicine intended to allow physicians to practice without interference from business interests though an employment situation. It allows the medical staff to function independently in the best interests of the patient.

Several years ago legislation was adopted to create a program for about 20 physicians to be employed by district hospitals that met certain criteria, i.e. rural, operating at a financial loss, and has a patient base of at least 50% Medi-Cal. That pilot program also required the Medical Board of California to issue a report on the pilot, which they did October 2008. That report was inconclusive since only five physicians were employed by district hospitals under the pilot.

Last year there were three bills introduced to modify the current prohibitions for either district hospitals only or all acute care hospitals. None of those bills were ultimately successful but we did support one of the bills that would have continued the current pilot with a slight level of expansion.

This year there are three new bills, AB 646 (Swanson), AB 648 (Chesbro) and SB 726 (Ashburn), introduced to either allow district hospitals to employ a limited number or any number of physicians or to allow any acute care hospital to employ physicians. District hospitals cite the difficulty in recruiting physicians to rural and poor performing hospitals and that being able to employ physicians will make that easier. We oppose any change to the current prohibition except one that focuses on certain types of troubled hospitals and only expands the number of employed physicians to 5. We believe so for the following reasons:

- The existing prohibition is important for patients and quality of care to maintain physician independence.
- The real problem for some of these district hospitals is inadequate reimbursement from Medi-Cal and others that does not provide sufficient practice revenue to allow a physician to practice.
- Some hospital based specialties like radiology and pathology need a group practice in order to provide adequate hospital coverage. Hiring individual physicians will not solve that issue.

We fight frivolous claims. We smash shady litigants. We overprepare, and our lawyers do, too. We defend your good name. We face every claim like it’s the heavyweight championship. We don’t give up. We are not just your insurer. We are your legal defense army. We are The Doctors Company.

The Doctors Company built its reputation on the aggressive defense of our member physicians’ good names and livelihoods. And we do it well: Over 80 percent of all malpractice cases against our members are won without a settlement or trial, and we win 87 percent of the cases that do go to court. So what do you get for your money? More than a fighting chance, for starters. To learn more about our medical professional liability program, call (800) 862-0375 or visit us at www.thedoctors.com.
Court Decision Ends Balance Billing By Non-Contracted Hospital Based Physicians

In January the California Supreme Court issued a unanimous decision in the Prospect Medical Group case involving non-contracted hospital emergency room physicians and a delegated medical group. The Medical Group argued that there was an "implied" contract between the emergency room physician and the HMO enrollee in the case of emergency services that prohibited the ER physician from balance billing and requires them to seek any payment recourse from the plan or delegated medical group. The CSP has joined the CMA and other impacted medical specialties in fighting this issue in the Courts and in the Legislatures. This decision only applies to emergency services in the hospital setting but does apply to other then just ER physicians.

Late last year the Department of Managed Health Care (DMHC) had filed a third version of a regulatory package that would ban the ability of non-contracted hospital based physicians to balance bill enrollees of plans or delegated medical groups that have contracts with their hospitals. It would apply to emergency services and would define balance billing as an unfair billing practice. This regulation version would ban balance billing, establish an arbitration system, but with no interim payment standard. The CSP submitted comments in opposition to this regulation. The regulation took effect on October 15, 2008. A legal challenge to the authority of DMHC to issue the regulation was not successful.

We realize that non-contracted HBPs will have questions as to what they can do legally in terms of billing patients prior to a Court determination of the validity of the prohibition on balance billing. The CMA has prepared a tool kit that answers these practical issues and we have placed a link to that material on the CSP website at www.calpath.org.

This year AB 1126 (Hernandez) has been introduced that would extend the ban on balance billing for emergency services to patients enrolled in CalPERS PPO plans. One of the concerns of all physicians was that this balance billing ban would be extended beyond HMO enrollees. AB 1126 has not yet been set for hearing. We have informed the Assemblyman that physicians need to be ensured that they will be fairly compensated by non-contracted plans and that the ability of physicians to negotiate with plans is severely limited if plans can make “take it or leave it” offers.

One of the concerns of all physicians was that this balance billing ban would...

Funds to be Available to all Physicians for Health Information Technology

The 2009 federal economic stimulus package includes $19 billion for health information technology (HIT), the vast majority of which will be directed to physicians to subsidize the purchase and usage of Electronic Health Records (EHR) systems. Beginning in 2011, qualifying Medicare providers stand to receive up to $44,000 under the program; qualifying Medi-Cal providers stand to receive as much as $65,000. These funds are predicated on physicians using EHRs, so practices and groups that already have purchased EHR systems can also qualify for funds. The CMA has made available some background information and tools applicable to all physicians.

You can access this information on the CMA web site at: www.cmanet.org/hit/.
CONVENTION SCHEDULE

WEDNESDAY, DECEMBER 2
8:30 am - Noon
Distinctive Blood and Bone Marrow Lesions: Practical Tips to Paradigm Practice Changes
M. Kathryn Foucar, MD

1:30 - 5 pm
Timely Topics in Dermatopathology
Scott Binder, MD
Jeffrey J. Gottlieb, MD

5:30 - 7 pm
Microscope Tutorials: Routine to Esoteric: Clues to Reactive and Neoplastic Bone Marrow Disorders
M. Kathryn Foucar, MD

Abnormal Products of Conception: A Practical Approach to Molar Pregnancy and Other Trophoblastic Entities
Joseph T. Rabban, MD, MPH

Video Tutorials:
Diagnostic Challenges in Head and Neck Pathology
Jennifer L. Hunt, MD

THURSDAY, DECEMBER 3
8:30 am - Noon
Ancillary Techniques in Surgical Pathology: Current Applications of Molecular Diagnostics in Surgical Pathology
Jennifer L. Hunt, MD
Kevin O. Leslie, MD

THURSDAY, DECEMBER 3 (con’t)
1:30 - 5 pm
Epithelial Neoplasms of the Ovary
Debra A. Bell, MD
Teri A. Longacre, MD

5:30 - 7 pm
Microscope Tutorials: Update on Renal Tumors with Emphasis on New and Evolving Entities
Shikha Bose, MD

Diagnostic Problems in Pulmonary Pathology
Kevin O. Leslie, MD

Video Tutorials:
Diagnostic Problems in Pancreatic Pathology
Ricardo Lloyd, MD, PhD

A Pattern-Oriented Approach to Soft Tissue Tumors
John R. Goldblum, MD

Friday, December 4
8:30 - 9:50 am
Clinical Lecture: No Need to Panic: Critical Values in Your Laboratory
Elizabeth A. Wagar, MD

5:30 - 7 pm
Microscope Tutorials
Pathology of the Pleura
Kirk Jones, MD

Practical Neuropathology for Practical Pathologists
Tarik Tihan, MD, PhD

Video Tutorials:
Mucinous Ovarian Tumors: Primary and Metastatic...And How to Tell the Difference
Debra A. Bell, MD

Grading and Staging of Chronic Hepatitis and Steatohepatitis
Sanjay Kakar, MD
Linda Ferrell, MD

California Society of Pathologists
62nd Annual Convention
“Seminars in Pathology”
December 2 - 5, 2009
Hyatt Regency San Francisco

Visit calpath.org for the latest convention information
Brown Sues
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other customers for the very same tests.

The sited examples were determined not to isolated incidences, but rather part of a pattern of fraudulent overcharging and kickbacks that developed over the past decade. Here's how it worked:

- The defendant labs provided deep discounts when they were being paid directly by doctors, patients, or hospitals. Prices were often below the lab's cost and sometimes free.

- In exchange for these steep discounts, the defendants expected its 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 providing an illegal kickback.

- These sharply reduced prices, however, were not made available to Medi-Cal. Instead of charging the discounted prices, the defendants charged Medi-Cal up to 6 times more than the defendant charged others for the same tests.

In effect, defendants shifted the costs of doing business from the private sector to Medi-Cal.

- Additionally, defendants offered their clients who paid them directly (not through Medi-Cal or other insurance) deeper and deeper discounts in order 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. These law-abiding companies were sometimes forced to sell or go out of business completely.

The case was filed under seal in San Mateo Superior Court under California's False Claims Act by a whistle-blower and qui tam plaintiff Hunter Laboratories, which processes blood tests. Hunter Laboratories had found that it could not compete in a significant segment of the marketplace where many of the major players were offering referring doctors, hospitals, and clinics far lower rates than they were charging Medi-Cal.

After the whistle-blowers filed the complaint, the Attorney General's Bureau of Medi-Cal Fraud and Elder Abuse investigated the allegations and Attorney General Brown intervened under seal. The case became public this week.

Under California's False Claims Act, anyone who has previously undisclosed information about a fraud, overcharge, or other false claim against the state, can file a sealed lawsuit on behalf of California to recover the losses. They must notify the Attorney General as well.

Such a case is called a "qui tam" case. If there is money recovery, the law provides that the qui tam plaintiff receives a share of the amount recovered if the requirements of the statute are met.

The lawsuit asks for relief in the amount of triple the amount of California's damages, civil penalties of $10,000 for each false claim; and recovery of costs, attorneys' fees and expenses. It is estimated that damages could amount to hundreds of millions of dollars.