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 inspecting of clinical labs and regulation and licensing of laboratory personnel. The major conclusions of the report were:

- They failed to inspect almost 2,000 state labs and 91 out-of-state labs either upon original licensure or upon renewal.
- Lack of sufficient policies and procedures regarding PT testing.
- Lack of LFS policies to prioritize, track and initiate investigations.
- 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 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 performing 2,001 or fewer tests with the highest at $4,960 for 1,000,000 tests per year.

SB 744 would also establish specific requirements for clinical lab accrediting organizations such as the 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 for accrediting organizations.
CSP President’s Message
S. Robert Freedman, M.D.

As president of the California Society of Pathologists, it was indeed an honor to attend the inauguration of CAP President, Stephen Bauer, MD at CAP 09 in Washington, D.C. in early October. As California pathologists, we are proud of Dr. Bauer and his many years of dedicated service to pathology at the State level, as a former President of the CSP, and now as President of one of the leading national organizations representing pathologists. We are indeed pleased to have a colleague of Steve’s caliber in such an important leadership role at this critical time for our Country in the discussions of the many facets of healthcare reform.

CAP is very interested in what happens at the state level, and regularly follows issues in state legislature through a forum of State Society Presidents and CAP States Issues staff members. There is special interest in the CSP and what happens here in California because of the extent of the legislative and regulatory activity affecting pathologists in all types of practice.

The CSP continues to monitor legislative and regulatory activities affecting pathologists and clinical laboratories, as well as activities of the CMA, Medical Board of California, payers and their fiscal intermediaries, and the laboratory industry relevant to the practice of pathology in California. Members can look forward to the latest updates on important issues before the legislature in our CAL Path Facts email messages. In addition, our Practice Management associate members follow important policies related to billing and coding unique to pathology.

The CSP will host the annual educational meeting “Seminars in Pathology”, December 2-5, 2009 at the Hyatt Regency in San Francisco. Please join us at what will be a program of interesting topics to enhance the practice of pathology including the opportunity to participate in SAMS courses, as well as new activities for resident and fellows.

I look forward to your continued support and participation in the activities of our organization.
The CSP met with CDPH and the lab community to discuss our perspective and concerns. We supported SB 744 with the following changes:

1. Technical amendments to the new provisions regarding responsibilities of recognized accrediting bodies. Though LFS has recognized CMS approved accrediting organizations such as the College of American Pathologists 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 ensure 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 passed both Houses with those changes and was signed by the Governor. We encourage you to watch for advisories from Lab Field Services that implement these changes.

"Red Flag” Identity Theft Rules - Another Delay

The Federal Trade Commission’s “Red Flag Rules” require financial institutions and “creditors” to develop and implement identity theft detection and prevention programs by May 1, 2009. Despite objections from CMA, AMA, 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 originally by May 1, 2009 deadline. That deadline has been delayed a fourth time and with a new deadline of June 1, 2010.

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. Physicians should begin to plan their compliance programs until further notice.

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.

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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 up to 20 physicians to be employed by district hospitals that met certain criteria, i.e. rural, financial operating losses, and have at least 50% Medi-Cal patient base. That pilot program also required the Medical Board of California to issue a report on the pilot, which they did last October. That report was inconclusive since the number of actual physicians employed by district hospitals under the pilot was only five.

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 believe 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 five. 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.

Both AB 646 and 648 did pass the Assembly but did not pass their initial Committee hearings in the Senate Business and Professions Committee and thus have become two year bills, meaning they can be taken up next year and are alive.

In the meantime SB 726 was substantially amended in the Senate Committees prior to its passage by the Senate. It would have limited the total number of physicians that could be employed by district hospitals to 20 statewide, no more than two per hospital, after there was proof of the inability of the hospital to recruit that type of physician for at least 1 year. It would have also limited the physicians who could be employed to “core” specialties such as internal medicine, surgery and ob-gyn and not radiology. With those amendments SB 726 passed the Senate over the author’s real reluctance to accept these restrictive amendments. The CMA thought this was a reasonable compromise and the CSP agreed with that assessment.

When SB 726 was heard in the Assembly Health Committee there were amendments to delete the restrictions and limits on the number of physicians who could be employed and the “core specialties” limitation. It would allow employment of physicians by both district and rural hospitals. Organized medicine now opposes the amended SB 726. It is on the Assembly floor and becomes a two year bill. This issue will continue since the need to change the employment restriction is strongly supported by district hospitals, the California Hospital Association, unions, and a growing number of individual physicians who are testifying at hearings that they want to be employed for economic security.

There is no doubt that some district and many rural hospitals do have problems in recruiting physicians. Many of these hospitals have a large census of Medi-Cal and Medicare patients which result in lower revenues for both hospitals and physicians and creates financial stability problems. Providing greater autonomy to hospitals by allowing them to employ physicians is not the answer.
The CSP has joined with the CAP in raising serious concerns over the provision of SB 482 (Padilla) regarding entities that provide bioinformatics services directly to consumers via genetic testing.

SB 482 amended after its introduction attempted to set up a new regulatory structure for entities like the bill sponsor 23&Me which would be outside the current clinical laboratory structure. LFS had previously examined entities such as 23&Me and concluded that they were providing clinical lab services and had to be licensed as such. SB 482 would have allowed companies that use CLIA certified and licensed clinical labs to obtain and perform the testing on biological specimens to in turn use data generated by those tests to provide post CLIA informatics.

The pathology community argued that such companies should not be exempt from clinical lab and that SB 482 would undermine current California law and CLIA that regulate clinical lab genetic testing. There is need to ensure the reliability of the conclusions provided to consumers or patients and though not described as medical information it definitely has impacts on how consumers will deal with this information.

There are also major issues regarding privacy and confidentiality issues since consumer/patient information would be utilized for research issues. There would have to be assurances that individual patient information could not be compromised or shared.

SB 482 was referred to the Senate Judiciary Committee earlier this year but was never heard by the Committee. It is a two year bill that would have to move out of the Senate by January 2010. The CSP continues to review potential revisions and work with the sponsors. To date we have not been satisfied with the bill revisions and have been opposed to SB 482.

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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 Court agreed and concluded that the dispute over the level of payment had to be resolved between the physician and the plan or delegated medical group. The regulation took effect on October 15, 2008. A legal challenge to the authority of DMHC to issue the regulation was not successful.

Recently the DMHC has sent a letter to all its regulated health plans and their delegated medical groups seeking information on their rate methodologies for non-contracted hospital based physicians providing emergency services in the hospital setting. It also asked if those reimbursement rates have been altered during the last six months. It is believed that DMHC is gathering this information to be better positioned to arbitrate a reimbursement dispute and to perhaps establish some benchmark as to what is “reasonable” payment for plans and delegated medical groups. The data is to be collected in October. We will keep you informed on developments in this area.

In the meantime, if you or your group manager have legal questions related to billing of non-contracted patients, check the CSP website at www.calpath.org. We have posted a link to the toolkit the CMA has prepared to address these issues.

This year AB 1126 (Hernandez), which would extend the ban on balance billing for emergency services to patients enrolled in CalPERS PPO plans, has been introduced. Many physicians are concerned that this balance billing ban would be extended beyond HMO enrollees. AB 1126 was never heard in Committee and the author appears to have abandoned the bill.

Self Assessment Module (SAMS) Available Onsite at the CSP Annual Convention

For the first time, the CSP is offering a self assessment module (SAM), which can earn a registrant 1 unit of SAM credit (for the American Board of Pathology's Maintenance of Certification MOC). This SAM will be based on the workshop on "Ancillary Techniques in Surgical Pathology" by Drs. Hunt and Leslie. The SAM will be available online for all registrants of the annual meeting--both workshop registrants and those who elect not to register for the workshop. A $35.00 fee will be applied to this SAM test. The test will consist of 15-20 multiple choice questions, and a passing score will be 80% correct. Certificates will be sent out after the CSP Annual Convention.
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For information on sponsorship and exhibits go to www.calpath.org or contact the CSP office at (916) 446-6001 or ttyler@amgroup.us.
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;

Please visit the site here: www.cmanet.org/hit/