

## Laboratory Field Services Releases Regulation Package on Personnel Licensing

Last year LFS previewed a set of proposed changes to the clinical lab personnel standards. You can find the statement of reasons and full text of the package by going to [www.cdph.ca.gov](http://www.cdph.ca.gov) then clicking on Decisions Pending and Opportunity for Public Participation, then Proposed Regulations.

Many of these changes are long overdue and needed to address the evolution of genetic molecular testing, the standards for multiple types of examinations, and the scope of testing for cytotechnologists, among many more.

Public comment closed on September 27, 2010. CSP did submit comments that focused on:

- The proposed definition of molecular pathology tests.
- Alterations to the types of degrees required to be licensed as a cytotechnologist.
- Suggested changes to the types of molecular pathology or biology tests that a cytotechnologist would be authorized to perform.
- Supported a number of changes to existing personnel requirements that will update the licensure process to be more reflective of current standards.

There is no indication as of yet as to what, if any action LFS will take on this regulation package. There were comments suggested by a number of organizations and LFS is obligated to issue responses to those comments. They could adopt the regulations as proposed or reissue the regulations for another public comment period with proposed revisions.

### *The California Society of Pathologists 64th Annual Convention*

Our thanks to Dr. Balam Puligandla and the Education Committee for their continuing efforts in providing a most excellent program.

CSP was very active this year on the legislative front and we had some significant accomplishments on behalf of our specialty. We appreciate the support of our members and will continue to explore ways to better serve the pathology community and benefit the patients that you serve.

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## President's Message

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### SOCIETY MEMBERSHIP

Applications for membership can be obtained by writing: CSP Central Office, One Capitol Mall, Suite 320, Sacramento, CA 95814. The Society offers four categories of membership. You can access membership information on-line at [www.calpath.org](http://www.calpath.org).

Thank you for the privilege of serving as your President. As I begin my second year I wanted to express our appreciation for your support as a member. As you will see from the articles in this Bulletin CSP is engaged on behalf of the pathology community on a variety of issues. The CSP Board just concluded its annual planning session and the Board is working very diligently on making CSP a relevant and active organization. In addition to our continued interaction with the State Legislature and related regulatory agencies, I also wanted to highlight some of our recent initiatives:

CSP will provide quarterly webinar meetings for our members that hopefully provide a unique California perspective. In the Bulletin you will see the announcement for the February 16, 2012 webinar by Jane Pine Wood, Esq. on important marketing/legal issues for pathology groups. Watch for the announcements on the other upcoming webinars.

CSP has been in active discussions with Palmetto, the Medicare Part B carrier for California on new policies for the coverage and reimbursement of molecular pathology services. Our thanks to Dr. Gerald Hanson as our Medicare CAC representative for his tireless efforts in communicating the concerns of the pathology community on the impact of these proposed changes. We will provide tools to our members to help understand the nature and impact of the final policies.

The CSP Education Committee led by Dr. Balaram Puligandla is working to finalize the program for the 2012 meeting set again for San Francisco from November 27-December 1, 2012. The program has a standard of excellence that draws pathologists from around the country. A number of our members continue to volunteer their time to serve in other important capacities including the LFS Clinical Laboratory Advisory Committee, CMS Specialty Society Delegation and Commission on Legislation.

If you have an interest in serving as a volunteer for CSP on one of our committees or as a representative to other organizations please contact the Sacramento office. There is plenty of work to be done. We also encourage you to help us build the CSP membership base by making sure all the members of your group belong to CSP. Thank you for your support.

Peter Kolbeck, MD  
President



## Bill to Allow Optometrists to Perform Waived Tests and be Lab Director

**A**B 761 (Hernandez) is sponsored by the California Optometric Association and would allow optometrists to act as Lab Directors and allow them to supervise the performance of waived tests for conditions that are within their scope of practice. In initial conversations with the sponsors they indicate the desire to perform waived tests beyond conditions involving the eye. They have indicated a desire to perform glucose testing for the detection of diabetes, urinalysis, and sedimentation rate.

CSP has indicated their concerns with both the education/training and need for optometrists to perform the broad range of waived testing. We will be in discussions with the author and sponsor in the coming weeks. It has been double referred to both the Assembly Business and Professions and Health Committees.

## Legislative Activities

**C**SP continues its legislative advocacy. Following is a highlight of some of the issues that have been monitored. Also, the Legislative section of the CSP website, [www.calpath.org](http://www.calpath.org), provides access to CSP's entire legislative bill tracking activity throughout the year.

### *Medi-Cal 10% Provider Rate Reduction*

DHCS has notified provider groups that they intend to implement the 10% provider rate reduction retroactive to June 1, 2011. They indicated that by the end of this month they would be able to inform individual providers what the total amount of the recoupment would be and provide a schedule for the take backs to occur, i.e. not recouping the total amount in one check write. We will provide additional information as it becomes available.

In the meantime a lawsuit was filed by the CMA and other provider groups to enjoin implementation of the 10% provider rate reductions.

On 1/31/12 Judge Snyder made final her tentative ruling that would enjoin the DHCS from implementing the 10% provider rate reduction. In the Judge's order she also states that DHCS is prohibited from applying the 10% reduction back to June 1, 2011, but is not prohibited from applying the reduction to services performed from that date until the date of the order, 1/31/12, if the services have not yet been reimbursed. This part of the ruling needs to be clarified by counsel but appears to protect providers from any recoupment effort if they have already been reimbursed for the services. This pertains to a legal argument under the 11th Amendment providing state immunity and whether a federal court can retrospectively impact state action.

Meanwhile the U.S. Supreme Court heard oral argument on the appeal by DHCS on the previous Federal Court injunction that was issued against the Medi-Cal provider rate reductions that were supposed to take effect in 2008. You will recall that those cuts were stopped in August 2008 for many providers including physicians. For pathologists it meant that the cut did not impact you unless you billed as a clinical lab. The 10% cut ended for clinical labs as of Feb. 28, 2009 and transitioned to a 1% reduction that then applied to almost all types of providers. This is a case that questions the abilities of providers to have legal standing to bring a legal action to challenge Medicaid program reductions. This is an important case that has drawn the support of the Obama administration for the position of DHCS and against the provider community. A decision is not expected until next spring. ■

# 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 through 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. The report issued in 2009 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 successful and no change was adopted in 2010.

In 2011 there were two new bills, AB 1360 (Swanson), AB 684 (Chesbro) introduced to allow district hospitals to employ a limited number of 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 five. We believe so for the following reasons:

*The existing prohibition is important for patients and quality of care to maintain physician independence.*

- *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.*

Neither of these bills moved out of the Assembly or house of origin this year. There was an actual compromise reached with Assemblyman Swanson on a limited ability for district hospitals to employ a small number of physicians with advice and consent of the medical staff. The unions that are sponsoring his bill however did not support the changes and the bill stalled in the Assembly Health Committee. Both bills are now two year bills, meaning they can be taken up in 2012 and are alive

This issue will continue since the need to change the employment restriction is strongly supported by district hospitals, the California Hospital Association, unions, and even 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 have difficulty 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, causing financial stability problems. Providing greater autonomy to hospitals by allowing them to employ physicians is not the answer. ■

## New Medicare Carrier for California

**C**SP continues an active liaison with Palmetto Medicare, carrier for California. My thanks to Dr. Gerry Hanson who monitors and attends the Medicare CAC committee meetings for California to advocate for the interests of the pathology community.

CSP submitted substantial comments on a new policy on flow cytometry that had been adopted. Those changes recommended by CSP will ensure that pathologists can provide the range of testing appropriate for quality patient care without the need for extensive additional documentation.

Last November, CSP also submitted comments on a draft article on molecular testing that includes coding guidance, potential edits, and coverage guidance for new testing. This type of input is crucial for the pathology community and the future of our specialty.

## Membership Update

**T**he financial resources provided by members' dues drive the activities and services of CSP. CSP, like most medical associations, is struggling with sagging membership numbers. CSP cannot survive if only a small number of pathologists in a group belong to the organization on behalf of the entire group. We encourage senior members of practice groups to discuss joining CSP with junior members. If you are not currently a member or have colleagues in your group who do not belong, we would encourage you to join and participate in the Society's services.

### *2011 CSP 64th Annual Convention Recap*

**T**he CSP 64th Annual Convention held on November 29 – December 3, 2011 was a huge success. Over 300 pathologists from California and across the country gathered at the Hyatt Regency Embarcadero in San Francisco, California. CSP presented its annual educational program "California Seminars in Pathology" which brought distinguished faculty from outstanding institutions throughout the country.

Leaders in pathology – the 2011 Convention Faculty – designed a program to enhance your practice by providing seminars in relevant and new information to practicing pathologists, while introducing important, innovative concepts useful in day-to-day practice. The CME courses, video tutorials and lectures represented diverse topics in lymphoma, breast, kidney and prostate, soft tissue and GI pathology. The Special Lecture provided a current prospective on Lung Carcinoma, and the clinical pathology lecture discussed important updates in Microbiology. Additional courses providing SAMS credit were offered.

CSP designated the educational activity for a maximum of 26 AMA PRA Category 1 Credits™ accredited by the Institute for Medical Quality/California Medical Association (IMQ/CMA) to provide continuing medical education for physicians. Attendee evaluations appreciated the CME course information just as much as the networking opportunities and the beautiful waterfront convention site. Please join us this year, November 27th – December 1st, 2012 for the CSP 65th Annual Convention.

# Medicare Palmetto Policies on Molecular Diagnostics

Over the past 6 months CSP has been in dialogue with Palmetto, The Medicare Part B Carrier for California and the Western region. They have been developing Local Carrier Determination (LCD) policies that would dramatically impact the coding and claims submission process for many molecular pathology tests. CSP's Palmetto Carrier Advisory Committee representative, Dr. Gerald Hanson, has submitted extensive comments to Palmetto on behalf of the CSP regarding the proposed LCD policies that could take effect on March 1, 2012. We have included below a recent article for CAP Statline that describes the efforts of the CAP to stop the implementation in March. CSP will be sending an email communication to our members in February to update you on the status of these changes.

Reprinted from CAP Statline:

*Representatives from the College met with the Centers for Medicare and Medicaid Services (CMS) last week to express the CAP's concerns regarding the Molecular Diagnostics (MolDx) reporting program announced by Palmetto GBA in November 2011, and asked CMS to delay or revoke the program.*

*Last November, Palmetto GBA, the program administrator for Medicare in Jurisdictions 1 and 11, informed providers that beginning on March 5, 2012, all claims for molecular tests in Jurisdiction 1, (encompassing California, Hawaii, and Nevada), must include a unique "Z-Code" in order to be paid. Palmetto GBA said it will use the Z-Codes to "identify the billed test, determine reasonable and necessary services, and apply appropriate reimbursement."*

The Z-Codes are generated and managed using the McKesson Diagnostics Exchange, a proprietary system developed and owned by McKesson Corporation. Since each test must have a unique Z-Code, providers are required to apply for and attain a Z-Code for each test from McKesson.

As of March 5, 2012, Palmetto said it will reject any claim for an affected test submitted without a Z-Code. A rejected claim would not be accepted for adjudication unless the lab submits the test to McKesson for review and a Z-Code was assigned to the test by March 1, 2012.

Before new codes were developed for 2012, labs used molecular diagnostic "stacking" codes for their component procedures when billing CMS. One problem with this approach is that not all labs use the same component procedures, so Medicare potentially paid different amounts for essentially the same test.

But Palmetto's adoption of the Z-Codes amounts to the creation of a local coding system, which violates the Health Information Portability Act (HIPAA), CAP leaders told CMS during the meeting. "By statute, local codes are not permitted," said Jonathan Myles, MD, a pathologist at the Cleveland Clinic, and Chair of CAP's Economic Affairs Committee, who together with Stephen Black-Schaffer, MD, led the CAP delegation at the meeting. "Palmetto's creation and use of its Z-Codes would circumvent the process of stakeholder input into changes prior to implementation," he added.

## The Palmetto Plan

Palmetto's program, should it move forward, requires several steps before labs could receive payment for molecular tests covered by Z-Codes, including those that currently use multiple methodology-based molecular diagnostic "stacking" CPT codes to identify the service as well as micro-array CPT codes, cytogenetic CPT codes, and pathology and laboratory Not Otherwise Classified (NOC) codes.

In order to obtain a Z-Code, labs must submit to Palmetto a dossier of information that includes information to support clinical tests' validity and utility. A panel of "subject matter experts" chosen by Palmetto will assess this information and decide whether to cover the test. If the panel decides to cover a test, it will assign the test a Z-Code. If the panel decides not to cover a test, that test will not be eligible for reconsideration for six months. The CAP is also concerned about the lack of transparency

*Continued from page 6...*

in how the panel members are chosen, and that Palmetto's process may not be compliant with the Federal Advisory Committee Act, which covers advisory committees and conflicts of interest. In addition, the CAP believes that Palmetto's proposed modified gap-fill payment policy is inconsistent with existing payment rules and that the existing payment mechanisms should be used instead to develop payment amounts for laboratory services.

## New Molecular CPT Codes

In response to concerns about variation in billing and payment for molecular tests, the American Medical Association's CPT Editorial Panel developed and issued single CPT codes for the vast majority of molecular pathology tests.

In contrast to the Z-Codes, which are to be developed privately without input from stakeholders, the new CPT Codes for Molecular Pathology were devised during a 2½ year process that included CMS, other

payers, providers, and several organizations including CAP. The more than 100 codes cover 90% of existing molecular tests. However, CMS delayed implementation of the new molecular codes for Medicare use until it decides whether they should be placed on the physician fee schedule or on the clinical laboratory fee schedule. "CAP continues to advocate that there is professional work involved in molecular pathology and the codes should be placed on the physician fee schedule," Myles said. The College urged CMS to publish the developed relative value units on the physician fee schedule and allow them to gain momentum.

CMS is expected to respond to CAP's request to revoke Palmetto's Molecular Diagnostics program in the next couple of weeks. Statline will continue to follow and report on this issue. ■

## Practice Management Members

**T**he Practice Management Committee has continued to confer on Medicare and Medi-Cal claims processing issues.

CSP has begun to develop some additional webinar programs to provide information to practice managers and pathologists. We offered programs this year on hospital contracting issues and Maintenance of Certification. We hope to continue to expand those offerings.

The CSP continues its efforts to build a database of individual pathology practice managers. If you would like to have your group manager become involved as an Associate Member simply call the CSP office or go the CSP website at [www.calpath.org](http://www.calpath.org). The membership information is available on the website under the membership section. ■

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## **Save the Date 2012**

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