In the January Medi-Cal Bulletin there was an announcement that effective February 1, 2010 Medi-Cal would no longer recognize modifiers, such as -26 professional component only, on a wide variety of clinical pathology codes. There was no explanation provided as to the reason for the change, but the effect of the prohibition would be to eliminate the ability of hospital-based pathologists to bill the professional component for clinical pathology services.

Under current Medi-Cal hospital contracting, hospitals are paid a per diem amount for a range of covered services. The contracts will specify what services are bundled under the per diem payment and the professional component of anatomic or clinical pathology can be included or excluded from the per diem payment amount. These contracts are not public documents but we believe that the PC of anatomic pathology is seldom included and in many contracts the PC of clinical pathology is also excluded from the per diem payment. When the PC is excluded the hospital based pathology group is able to bill the Medi-Cal program directly for the PC for hospital in or out-patients.

The CSP worked with the then Department of Health Services many years ago to establish the ability of hospital based pathologists to bill for the PC of clinical pathology services. When we became aware of the proposed change, we immediately contacted the Medi-Cal Rate Development Branch of DHCS to determine the reasons for the change and to indicate the impact on the pathology community.

The DHCS policy was promulgated to make Medi-Cal conform to current Medicare policy which does not recognize a PC

(Continued on page 3)
As President of the California Society of Pathologists, it has been indeed gratifying to see how effectively our organization can benefit pathologists in the different aspects of their practices in the State of California, and the impact it can have on the rest of the Country. It is said “The future begins in California,” and the recent events declare it so.

When Medi-Cal decided to pattern the professional component (PC) of clinical laboratory reimbursement on the Medicare model, considering the pathologists payment to be contained within the hospital payment for clinical laboratory services, the CSP argued that this would have a substantial impact on pathologists’ revenues, especially on those practices with a major proportion of Medi-Cal patients.

When Anthem Blue Cross decided to reduce GYN Pap smear payments to levels less than production costs, the CSP was able to convince them to maintain the current fee schedule.

When Palmetto, fiscal intermediary for Medicare, once again decided to impose limitations on flow cytometry, the CSP, spearheaded by Dr. Gerald Hanson, a member of the Board of Directors and Chair of the CAP Professional Affairs Committee, was able to create an understanding of the value of using this diagnostic technology as a cost effective modality for patient care.

When a plaintiff challenged the ability of a forensic pathologist serving as Medical Examiner to retain tissue for diagnostic purposes, the CSP participated in an amicus brief in defense.

As pathologists, we rely on well-trained and dedicated laboratorians including clinical laboratory, cytology and histology personnel, but are concerned about their decreasing numbers and the inability to fill these positions in the future, as detailed by Dr. Tim Hamill, Director of Laboratories at UCSF, member of the Board of Directors, and Chair of the Clinical Laboratory Technical Advisory Committee (CLTAC) for the California Department of Health. Students need opportunities for practical experience, so open up your laboratories to your local training programs. You might find a capable new addition to your laboratory.

The Education Committee, chaired by Dr. Palaram Puligandla, is busy making arrangements for the next California Seminars in Pathology in San Francisco on December 1 through the 4th, 2010, which promises to be an outstanding educational opportunity as usual.
CSP Successful in Reversing Medi-Cal - Continued from page 1

component under Part B for most clinical pathology services, but instead classifies the pathologist effort and responsibility as a Part A service payable through the hospital. We informed DHCS that the Medicare payment system is different than Medi-Cal and that Medi-Cal in its contracts with hospitals either includes or excludes the PC of clinical pathology in their per diem payment to the hospital. When it is excluded, the pathologist is able to bill that PC for Medi-Cal patients and it is the only source of compensation for their services. They indicated that they had not considered that fact when revising the policy and will make that change. The prohibition on separate billing for these services on a -26 basis outside the hospital will continue.

We are pleased to report that after a series of discussions with the Rate Development and Medical Policy branches of the Department of Health Care Services (DHCS), they have informed us that they are rescinding the policy announcement that would have denied -26 or professional component billing for most clinical pathology codes in the hospital setting. The policy change did take effect in time to change the edits now in place to deny claims with the -26 modifier. Many groups will see denials for the time being for hospital claims with dates of service on or after 2/1/10.

The Department will inform the CSP on how long it will take EDS/HP to make the systems changes to restore -26 payments for these codes. As of publication we had not yet received an effective date for the change back. Any claims that do get denied would be reprocessed and paid via an Electronic Payment Correction (EPC), so whether you hold your claims or not they will eventually be paid correctly.

We are pleased with the ability to have this discussion and the willingness of DHCS to make this prudent change. We will provide more information as it becomes available.
We were contacted by several pathology groups that have noted substantial proposed reductions from Anthem Blue Cross in their PPO reimbursement of gynecologic cytopathology codes for manually screened and imaged liquid based preparations effective January 1, 2010.

Specifically, reimbursement to some providers for CPT 88142 (cytopathology, cervical or vaginal, collected in preservative fluid, automated thin layer preparation, manual screening under physician supervision) and 88175 (cytopathology, cervical or vaginal, collected in preservative fluid, automated thin layer preparation, with screening by automated system, and manual rescreening or review, under physician supervision) would be reduced to levels below Medicare and Medi-Cal. The specifics of reimbursement may vary based upon region or the provider.

The CSP contacted Blue Cross to indicate our concerns with the magnitude of these reductions. We also stated that this level of reimbursement will impede the ability of pathology groups and independent labs to make this important service available to their members. In discussions with their Chief of Provider Contracting, they promised to look into our concerns. However, with the dialogue occurring in December, they will not be able to make changes to the fee schedule effective January 1, 2010. The 2010 fee schedule amounts were as follows;

88142- $24.39  
( was going to be reduced to $20.71)

88175- $31.90  
( was going to be reduced to $27.08)

Those levels were well below Medicare and even Medi-Cal payment amounts. The fee schedule amount may vary by area in California.

The CSP sent an email blast to its members requesting data on the costs of providing liquid based pap smears. We collected the data and presented it to Blue Cross while protecting the identity of individual providers who submitted the data. Conversations with Blue Cross continued in January and February on a sporadic basis but no real progress occurred.

We were contacted by phone and a follow-up letter from Blue Cross indicating that our concerns had been considered and that they would be reverting to the 2009 fee schedule amounts for those services. That would eliminate the reductions in payment for those codes. In addition they would implement two additional changes;

* There are 12 payment regions in California for Blue Cross whose fee schedule amounts for various services can vary. Blue Cross will utilize the highest payment level for 88142 and 88175 and apply that rate to all of the regions. Some areas will actually see an increase in the payment amount for these codes from 2009 to 2010.

* In addition, Blue Cross will make this price change retroactive to 1/1/10. Pathology groups can re-bill for the difference in paid claim amount from the effective date of the change, March 2010.

We are very pleased with the willingness of Blue Cross to consider the concerns of the pathology community and to revert to reimbursement for these procedures that will ensure availability to their enrollees.
CSP Files Comments with Palmetto on Draft LCD Policy for Flow Cytometry

Palmetto is the Medicare Part B Carrier for California and from time to time will issue Local Carrier Determinations (LCDs). An LCD establishes specific policy in this region for the coverage and payment of a specific medical procedure. The CSP filed comments with Palmetto in late February on a draft Local Carrier Determination (LCD) policy on flow cytometry. The LCD made available in draft form last year contained an effective date of May 1, 2010 which allowed time for comment and revision. The proposal would have limited the number of flow cytometry procedures that could be provided to a patient without submission by the provider of additional medical documentation and limited coverage to certain conditions. The carrier has continued to express concerns that some providers are routinely providing 20 or more flow cytometry procedures for all of their patients.

Years ago the CSP engaged with the then Medicare Carrier NHIC on an LCD for flow cytometry and IHC. That policy, after revision based upon our comments, established numerical thresholds of 10 and 20 respectively for IHC and Flow cytometry. A Medicare provider who submitted a claim for any quantity greater than this would have to submit documentation as to why it was necessary to exceed that quantity.

This new draft LCD was developed based upon continued concerns from Palmetto that some laboratories were routinely providing flow cytometry markers in greater quantities than necessary.

We have included a portion of the comments submitted by the CSP to Palmetto.

(Continued on page 6)
* There is a consistent and strongly expressed concern regarding the statement on page 7, “Palmetto GBA will not pay for more than 10 markers unless the diagnosis is NHL or Acute Leukemia.” The FCM evaluation of several of the other listed categories under “indications” in the draft, such as MDS and Chronic Lymphocytic Leukemia regularly requires a set of markers more comparable to NHL and Acute leukemia. Thus, we believe the “no more than 10” statement to be erroneous and unworkable.

* Testing methods for PNH are changing with the recognition that the disorder involves more than just the red cell lineage. Suggest modifying and incorporating the following: “This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing both the red and white blood cells by flow cytometry for the absence of these antigens. In general staining both the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and/or with antibodies to some of the missing GPI anchored antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

* Page 6, HIV, Organ Transplants, Primary Immunodeficiency

For clarification it may be of value to include a comment related to the following issue which is made in the context of HIV but may also be relevant for organ transplants, and primary immunodeficiency syndromes when the study is just for quantitative cell enumeration.

There has been confusion over the use of codes 88184-89 in HIV. In reading the LCD, it appeared that the discussion was based on peripheral blood flow cytometry. When flow is being used for lymphocyte subset quantification, these codes should not be used. Quantitative codes within the immunology section of CPT should be considered:

* Page 6, Carcinoma

Suggest make the heading DNA Analysis (88182) and under this include two parts. The first category: Carcinoma/non-hematolymphoid tumors. The current narrative is satisfactory.

Suggest adding a second category for:
Molar Pregnancy

* Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles, which are triploid, can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

Add ICD-9 associated with Molar pregnancy (ICD-9 630)

* Mission: Flow Cytometry Analysis of Primary Platelet Disorders

Suggest adding a section for non-neoplastic primary platelet disorders. There is no mention of primary non-neoplastic constitutional platelet disorders in the draft.

Flow cytometry has been utilized for analysis of platelets in quantitative and qualitative disorders such as Glanzmann Thrombasthenia (GT) and Bernard-Soulier Disease (B-S).

GT is a rare inherited or acquired platelet disorder that derives from a defective GPIIa/GPIIIb receptor normally involved in platelet cross linking by serving as a receptor for fibrin, thereby creating the initial platelet plug at the site of endothelial injury. Absence of this receptor results in increased susceptibility to bleeding. As demonstrated by Jennings, platelets with decreased expression or absence of the GPIIa/GPIIIb receptor can be easily distinguished in patients with GT by flow cytometry. Demonstration of decreased surface expression provides evidence as to the presence of hereditary GT. Acquired GT is more of an
autoimmune phenomenon with the presence of GPIb/GPIIIa blocking antibodies. Giannini et al, recently reported the ability to use flow as a rapid test to determine both the functional effect and identity of the molecular targets of these antibodies.

Bernard-Soulier (B-S) Disease is another rare inherited disorder that prevents the initial binding of platelets at the site of endothelial injury by absence of or presence of abnormal surface GPIa/V/IX receptor. Abnormalities of this receptor thereby prevent attachment of platelets to subendothelial or free von Willebrand’s factor with subsequent tendency to bleed. Flow cytometry can be used to measures antibodies directed at specific loci of the GPIa/V/IX receptor which include GPIb (CD42b), GPIX (CD42a), and GPV (CD42d). Another characteristic of B-S Disease that can be utilized in the initial evaluation of the flow cytometric data is the size of platelets. In B-S disease platelets are generally larger than normal and may demonstrate an increase spectrum of size that can be distinguished from fragmented RBCs and debris by specific binding of antibodies directed to the GPIb/IX/V receptor, as previously mentioned.

Add ICD-9: 287.1 platelet defects.

* Omission: Flow Cytometry Analysis of Non-neoplastic Red Cell and White Cell Disorders.

There is no mention in the draft of the use of FCM in the diagnosis of 1.) hereditary spherocytosis and eliptocytosis; and 2.) hereditary persistence of fetal hemoglobin (HPFH) in the context of compound hemoglobinopathy syndromes where the co-existence of HPFH with Hgb S for example has great prognostic and therapeutic importance, and in quantifying fetomaternal hemorrhage; 3.) neutrophil defects such as CGD and CD11b deficiency; and, 4.) HLA B27 testing. FCM is an efficient and usually more sensitive and/or specific method of diagnosis for these conditions.

Corresponding ICD-9 codes to be added:

* 282.0 Hereditary spherocytosis
* 282.1 Hereditary eliptocytosis
* 282.5, 282.60-282.69 Sickle cell
* 282.7 HPFH
* Conditions associated with gene HLA B27
* Reiter’s syndrome (ICD-9 099.3)
* Uveitis (ICD-9 364.3)
* Psoriatic arthritis (ICD-9 696.0)
* Juvenile arthritis (ICD-9 714.30)
* Ankylosing spondylitis (ICD-9 720.0-720.9)
* Inflammatory bowel disease (ICD-9 555.0-556.9)

There is concern that the dynamic nature of flow cytometry applications requires that the LCD can be updated on a periodic basis for evolving clinical practice standards including addition of ICD-9 edits. We request that the LCD acknowledge with a statement such as: “Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.”

Our thanks to Dr. Gerald Hanson for his assistance in coordinating the input from a variety of pathologists and sources to develop these comments. Dr. Hanson serves as the CSP representative to the Medicare CAC, is a CSP Board member and Past President. We will review the final draft LCD once it is available. Palmetto may still implement a new LCD on flow cytometry effective May 1, 2010.

We have already been contacted by the Medical Director of Palmetto expressing their appreciation for the quality of the comments and acknowledging that the changes will be incorporated into revisions to the draft. We will let you know when the final LCD policy is available for review. The draft can be found on the Palmetto website at www.palmettobga.com under Region 1 Part B.
The CSP was contacted by the National Association of Medical Examiners (NAME) regarding a case currently on appeal with the California Court of Appeals. The case Picon vs. County of San Mateo involved an autopsy by the county coroner’s office and the sending of the deceased’s heart for consultation to Stanford University Medical School as part of the coroner’s investigation. During the course of the trial plaintiff’s expert alleged that the whole organ need not have been retained by Stanford and that only the tissue used for the consultation should have been retained.

Plaintiff alleged that the diagnosis of congenital heart disease was already known and that the heart was submitted for non-coroner training, education and research purposes.

The brief filed by NAME and CSP described the importance of the autopsy as the primary tool of medicolegal death investigation. Coroners properly rely on pathologist physicians to perform autopsies and obtain necessary diagnoses to determine the cause of death. The retention of biological specimens is an important and necessary component of autopsy practice. Whole organs and large tissue blocks may necessarily be retained for further examination and consultation in some cases.

Forensic pathologists often consult with a variety of specialty pathologists, e.g. neuropathologists, molecular pathologists, or a variety of clinical colleagues. The wrong ruling by the lower court could impede the ability to utilize such consultants if there is not consent obtained for the tissue or whole organ to be sent out for consultation. The need for consent could further be an impediment if the person with the right to control that decision, i.e. father of deceased, is in fact the main suspect in the cause of death.

The amicus brief further argued that discretion regarding autopsy procedures is properly that of the autopsy pathologist and serves as a presumption of correctness of the pathologist’s decision to retain tissues and organs.

We will keep you informed on how this appeal progresses.
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As many pathologists involved with laboratory testing are probably aware, California is in the midst of a technologist workforce crisis. What you may not realize is that this problem will likely get much worse before it gets any better.

In recognition of this problem the Hospital Council of Northern and Central California, in conjunction with the California Hospital Association, spearheaded the creation of the Healthcare Laboratory Workforce Initiative (HLWI; http://www.hospitalcouncil.net/cgi-bin/default.asp?AID=100) to find innovative solutions to the laboratory workforce shortage. The Initiative’s advisory group is composed of a broad coalition of statewide and regional hospital associations, major healthcare systems, laboratory manufacturers, independent laboratories, professional associations, government entities, and the California community college and state university systems. The goal of the HLWI is to increase the number of licensed Clinical Laboratory Scientists (CLS) and Medical Laboratory Technicians (MLTs) in California in order to meet the demand for such workers across industry sectors.

In 2009 the HLWI published a whitepaper entitled: California’s Other Healthcare Crisis: The Clinical Laboratory Workforce Shortage (see link on HLWI homepage). Based on data from government, industry and a survey of California laboratories it paints a bleak picture:

- In 2001, California had 76 clinical laboratory workers per 100,000 population compared to 102 nationally, and was ranked 43rd among the 50 states on this measure.
- The average age of a CLS in California is above 50. There are not enough new CLSs in the pipeline to equal the numbers currently working but planning to retire.
- A 2007 report from the Campaign for College Opportunity found that the supply of laboratory personnel in California would have to increase by 559% in order to meet current demand or approximately 800 new CLSs a year.
- In 2007, there were a total of 119 CLS graduates in California. In 2008, the number is expected to only increase to 125 -- a significant shortfall compared to projected needs.
- The number of CLS training programs in California has dwindled. Today there are just 13 programs in the State -- 4 academic programs and 9 hospital-based.

What can pathologists do to help? First and foremost, get involved in technologist education. One of the largest impediments to expanding the number of trainees is a lack of clinical sites where students can get the hands on experience they require. All the California college based training programs indicate they could take more students if they had access to more clinical training positions, however, only 21% of hospital laboratories offer these positions. A significant benefit of becoming a training site is the ability to hire the trainees after they graduate and have their license. These individuals will already know your laboratory operations, computer systems and staff, and can become productive staff members in a very short time. Data from the HLWI survey indicates that most training sites retain the bulk of their graduates.

Secondly, consider hiring Medical Laboratory Technicians (MLTs) into open positions. California recently finalized the regulations to allow MLTs to perform waived and most moderately complex tests. Unfortunately, job openings for people graduating from the state’s fledgling MLT training programs have been hard to find. Without the

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For more information about CyberGuard, please visit www.thedoctors.com/cyberguard.

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The California Laboratory Workforce Shortage (Continued from page 10)

ability of these graduates to find employment there is concern that the MLT training programs will be abandoned. This would have a long-lasting negative impact on the laboratory workforce shortage. In an effort to educate laboratory managers and directors about the potential use of MLT’s, the HLWI has put on their website an MLT ‘Toolkit ‘that answers FAQ’s about these licensed laboratory professionals as well as a sample job description of their duties (http://www.hospitalcouncil.net/cgi-bin/default.asp?AID=325).
The CSP is pleased to Announce its Second in a Series of Webinars

Please see page 9 for details.