

## State Society Presidents Quarterly Conference Call

Thursday, August 27, 2009

### Health Care Reform

*As background information for the State Pathology Society Presidents' Quarterly Conference Call please find attached excerpts of letters sent by the College to the House of Representatives and Senate during their deliberations on health care reform.*

#### **Now Agenda:**

##### *SGR*

Unless Congress acts, on January 1, 2010 Medicare physician payments will be cut by 21.5 percent next year and by more than 40 percent over the next decade. The CAP applauds your efforts to offer more than a short-term fix to address this problem. As you know, Congress has had to use a financing mechanism over the last several years that results in deeper and deeper projected cuts for each subsequent year, making each legislative fix more costly. We support replacing the current SGR with a stable payment system that includes positive updates and accurately reflects increases in medical practice cost. Specifically, we support reforms in your proposal to remove physician-administrated drugs and clinical diagnostic laboratory tests from the update calculation. While the two-tiered update structure allows for greater growth for primary care services, this initiative represents an improvement over provisions considered in the last Congress to establish multiple update buckets with the potential for pathology service to be placed with fast growing services and resulting in steep reductions.

##### *Primary Care Bonuses*

Primary care physicians play an important role in our health care system. The CAP recognizes the need to increase access to primary care services and supports the 5% payment increase provided in the Tri-Committee proposal. At the same time, the CAP would oppose a budget neutral payment increase that would reduce payments to other physicians.

The CAP strongly urges the Committees to make clear that payment increases for primary care would be paid through new funding rather than penalizing other members of the health care team. Pathologists have already sacrificed to increase funding for primary care services. In 2007, similar budget neutral increases to evaluation and management services reduced reimbursement to pathologists by eight percent. The continued shifting of dollars from specialty medicine to primary care medicine will only undermine the collaborative, coordinated care model that is dependent upon primary care providers and specialty physicians working together on behalf of the patient and the system.

##### *PQRI – P4P*

While the CAP supports the extension of the PQRI program, we urge the Committees to require CMS to further define the measures review process and also allow for quality

measure alternatives. Furthermore, although the proposal makes no specific mention of penalties, we would not support the imposition of financial penalties for providers who fail to participate in the PQRI program by a date certain because through no fault of their own, the lengthy and cumbersome measures approval process has not yet produced standards for their participation.

While the draft legislation creates a feedback mechanism that emphasizes timeliness, there is continued heavy reliance on the National Quality Forum (NQF) for the identification and development of measures. We believe that this revision will not be sufficient to ensure that once submitted, PQRI measures will be approved in a timely manner. The CAP has been working to develop quality measures since 2006. Of the 11 measures developed, only two have been approved, leaving nine measures stuck in the pipeline. We believe the PQRI program's current one-size fits all approach continues to be a major roadblock, making it difficult to develop measures for specialties such as pathology that have unique characteristics, exacerbating the already burdensome process.

The CAP is also concerned with the tie between electronic health records (particularly meaningful use) and the PQRI program. The draft requires the Secretary to develop a plan to integrate clinical reporting on quality measures to include reporting requirements on meaningful use. It also calls for the development of new measures to demonstrate meaningful use and the electronic collection of health data to identify deficiencies in care coordination and quality. Currently, pathologists use Laboratory Information Systems (LIS) and Anatomic Pathology Information Systems (APIF) that provide electronic patient information needed for laboratory services, but not the full patient medical record. However, under the American Recovery and Reinvestment Act (ARRA), hospital-based pathologists were excluded from receiving financial incentives tied to meaningful use, whether to modernize existing systems or to purchase interfaces with electronic health record systems. We are concerned that if the definition of "meaningful use" does not include use of an LIS or APIS pathologists may again be excluded from PQRI measures due to lack of access to an electronic health record.

#### *Self-Referral*

In addressing the "hospital exception" under the "Stark" law, the CAP recognizes the Committees' interest in ensuring that exceptions under this law are not abused. The CAP supports the disclosure of physician ownership and investment information and urges the Committees to include additional provisions to address abuses of the "in office ancillary services exception" (IOAS) under the "Stark" law with respect to diagnostic tests provided by pathologists. Specifically, the CAP urges that anatomic pathology be removed from the IOAS exception altogether to close loopholes that give physicians an incentive to increase utilization of pathology services and drive up Medicare costs.

The pathology community has seen a continued proliferation of certain contractual joint ventures that allow a physician practice, typically a large dermatology, gastroenterology or urology group, to share in the revenue generated by pathology services for the group's patients. These arrangements are not subject to certification under the Clinical Laboratory

Improvement Amendments of 1988 (CLIA) and they violate the intent, and in some cases, the letter of the law.

Both Congress and CMS have recognized that when physicians who order diagnostic testing also have an economic interest in billing and collecting payment, the result is often over utilization, higher costs, and incentives to base testing referrals on profit rather than quality. CMS' most recent regulatory efforts have not resolved the problem of abusive pathology arrangements. With each change, physician groups have found a new loophole through which to maintain a revenue stream from anatomic pathology services not performed by the billing physician. Therefore, if such practices are allowed to continue, CAP stresses at a minimum that in office histology laboratories must be required to secure CLIA certification, similar to the requirement under the Medicare Improvements for Patients and Providers Act (MIPAA) whereby imaging providers, regardless of practice setting, must be accredited.

#### *TC Grandfather*

The CAP strongly supports the extension of the TC grandfather for two years through 2011 to ensure that laboratories can continue to ensure access to critical pathology services provided to hospital inpatient and outpatients. Without this provision, independent laboratories would be forced to seek payment from already cash-strapped hospitals that would receive no new funds from Medicare to compensate for the increased costs. The burden would fall especially hard on small and rural hospitals, which typically cannot afford in-house pathology services and rely heavily on independent laboratories to provide these services

#### **Future Agenda:**

##### *Demonstration Project - Test Selection and Therapy Management*

The CAP strongly urges the Committees to include in their health care legislation a directive to the Center for Medicare and Medicaid Services (CMS) to conduct a demonstration project that would evaluate the role of pathologist-initiated consultations on test selection and assisting in therapy management as a method to improve patient care and control costs. The project would assess whether this model provides for cost-effective utilization of tests, increased quality and reduced costs. It would focus on complex genetic and other diagnostic tests that will continue at a rapid pace to create powerful new, but costly tests that not only assist in the diagnosis and management of disease, but also delineate an individual's unique responsiveness to preventive and therapeutic interventions.

Personalized health care will rely heavily on laboratory-derived, genotypic information interpreted by pathologists, correlated with a patient's family history and which enable and benefit from collaborative consultations on diagnosis and therapy between pathologists and physicians, both primary care and specialists. There have already been significant success stories where pathologists have improved outcomes and saved dollars through proper genetic testing and interpretation. For example, with respect to colorectal cancer, pathologists using genetic tests are able to determine if a specific oncogene, referred to as K-RAS, has activated. If activation has occurred, the cancer cells will not

respond to Erbitux, a common therapy for colorectal cancer. If K-RAS has not activated, Erbitux can indeed be an effective therapy. Thus, pathologists can help improve patient care to produce the best possible outcome while saving the health care delivery system hundreds of thousands of dollars per patient, not to mention the side effects that typically accompany these therapies.

Breast cancer is yet another example. A woman can be tested for an overexpression of HER2/neu, an oncogene which signifies higher rates of aggressiveness for specific types of breast cancer. Some patients with HER2/neu respond favorably to Herceptin, which can stop the cancer cells from growing. However, if an overexpression of HER2/neu is not present, women aren't likely to benefit from this therapy. Again, by determining whether or not Herceptin is a good therapy option for women, pathologist consultations with physicians are crucial to determining the best possible outcome for the patient while preventing the use of ineffective, costly and potentially harmful therapies.

The development of these pharmacogenomic tests is accelerating at an exponential pace. Pathologists are in a unique position to assist physicians as they integrate these tests into mainstream practice, ensuring that patients get the right test, improving outcomes, and reducing inappropriate testing and cost.

The CAP supports moving toward a coordinated care model based upon the concept of the medical home and Accountable Care Organizations (ACOs) as outlined in the draft proposal. However, the CAP believes that to facilitate the success of these coordinated care models, policy makers should also pilot a model to realign outmoded Medicare payment policy to promote collaborative partnerships between clinicians and laboratories to provide appropriate test selection and guide effective therapy options for the patient, particularly as we move into the age of personalized health care.

This recommendation may not be obvious since one might reasonably question what prevents such collaboration from occurring today. However, current payment policies do not adequately recognize the pathologist's contribution to managing this critical aspect of patient care, potentially leading to overuse, misuse and under use of medical testing by ordering physicians. Medicare payment policies restrict consultations between physicians and pathologists in a way that impedes collaborative consultations that may well benefit the patient and reduce inappropriate testing and unnecessary costs. Specifically, under current policy, pathologists are not compensated if they initiate a consultation with a clinician. The consultation must be formally requested by the attending physician. As a practical matter, this impedes the two-way collaboration fundamental to a coordinated care and value-based system. The current policy may have made sense in an era where laboratory test results were considered routine, understood by most clinicians, but this clearly is not the case today with the evolution of complex testing, such as molecular and genetic testing.