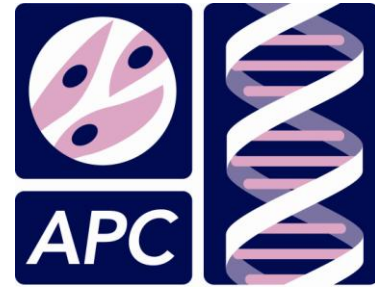
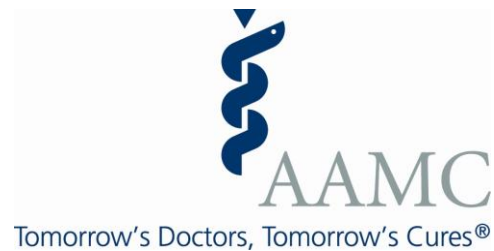




*Advancing Excellence*



Association of Pathology Chairs



November 2, 2009

Dear Senator:

As you work to finalize health care reform legislation for Senate floor consideration, the College of American Pathologists (CAP), Association for Molecular Pathology (AMP), Association of Pathology Chairs (APC), Association of American Medical Colleges (AAMC), American Society for Investigative Pathology (ASIP) and the American Hospital Association (AHA), **urge you to drop or significantly modify to apply to all laboratory settings, Section 3114 of the Senate Finance Committee's *America's Healthy Future Act*, that would change current law with respect to payment for certain molecular laboratory tests.**

Our organizations represent physician pathologists, medical schools, **community** and teaching hospitals, university chairs of pathology departments, scientists and laboratory professionals who perform molecular testing and render diagnoses in the laboratory. This provision was originally **adopted by the Finance Committee** with the understanding that the laboratory community was united in its support of the amendment. That is not the case. A variety of health care providers

as well as experts in laboratory medicine do not support the amendment and we write today to reiterate our concerns.

While appropriate reimbursement for complex molecular testing is a concern, **Section 3114, in its current form, would continue to single out commercial reference laboratories for special reimbursement treatment,** while excluding hospital-based laboratories, medical schools and teaching hospitals that also provide these services to Medicare beneficiaries treated in their facilities. Independent laboratories that have arrangements with hospitals to provide an array of testing, including molecular testing, would also be excluded. This unlevel playing field could reduce beneficiary access to complex molecular testing as resulting payment inequities cause hospital-based laboratories and others not covered by the provision to cease or limit the use of these important tests. Unless modified, the provision will also potentially ease direct marketing of such tests to patients, without sufficient assurances of appropriate utilization.

Often, blood or tissue samples are collected from patients while they are a hospital inpatient or during an outpatient visit and stored for future testing. Under current Medicare regulations, if a laboratory performs testing on such a specimen within 14 days of a patient's discharge, the date of service for payment purposes is the date on which the specimen was collected from the patient while he or she was an inpatient or outpatient in the hospital. This means that payment for the laboratory performing the test within 14 days of discharge must come from the hospital through its existing DRG, rather than a direct payment from Medicare.

**Section 3114 would allocate \$100 million from Medicare (outside of the DRG) for direct payments to laboratories for qualifying molecular tests, but only for commercial laboratories.** It excludes hospital-based laboratories, medical schools and teaching hospitals, even if they are performing the very same tests or a less costly but equally effective alternative. These laboratories would continue to be subject to the 14 day rule, creating the same barriers to testing and payment that the provision seeks to address.

Ultimately, patient care will suffer. Hospitals, medical schools, and teaching hospitals could be pressured to outsource sophisticated molecular testing to laboratories that are independent of the hospital in order to remove costs for these tests from the DRG. Similarly, innovation will be stymied as such facilities will be discouraged from developing the in-house capability to perform these tests. Opportunities in hospital and academic settings for important clinician-laboratory consultation on these tests and the oversight of their clinical validity, utility, safety, and effectiveness will be diminished.

Again, we urge you to exclude this provision in any healthcare reform legislation unless modified to apply to all laboratory settings.

Thank you for your consideration,

College of American Pathologists  
Association for Molecular Pathology  
American Society for Investigative Pathology

Association of Pathology Chairs  
Association of American Medical Colleges  
American Hospital Association