



October 9, 2009

The Honorable Max Baucus
United States Senate
Washington, DC 20510

Dear Senator Baucus:

As you work to finalize health care reform legislation for Senate floor consideration, the Association for Molecular Pathology (AMP), Association of American Medical Colleges (AAMC), Association of Pathology Chairs (APC), American Society for Investigative Pathology, and College of American Pathologists (CAP) urge you to drop or significantly modify a Wyden-Carper amendment accepted by the Finance Committee that would change current law with respect to payment for certain molecular laboratory tests.

Our organizations represent physician pathologists, medical schools and teaching hospitals, university chairs of pathology departments, scientists and laboratory professionals who perform molecular testing and render diagnoses in the laboratory. The amendment was accepted by the 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 laboratory organizations do not support the amendment and we write today to reiterate our concerns.

While appropriate reimbursement for complex molecular testing is a concern, the amendment, in its current form, would single out commercial reference (i.e., “independent”) 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 to cease or limit the use of these important tests. Unless modified, the amendment 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 the Center for Medicare and Medicaid Services (CMS).

The amendment would allow direct payment from Medicare, but only for independent laboratories that develop and perform qualifying molecular tests. Hospital-based laboratories, medical schools and teaching hospitals would not qualify, even if they were 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 amendment 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 remove the Wyden-Carper Amendment #D10 unless modified to apply to all laboratory settings.

Thank you for your consideration,

Association for Molecular Pathology
Association of American Medical Colleges
Association of Pathology Chairs
American Society for Investigative Pathology
College of American Pathologists