



August 23, 2013

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Tavenner:

The undersigned organizations are writing to express our deep concerns with the reimbursement cuts to pathology services proposed by CMS in the Physician Fee Schedule Proposed Rule for CY 2014. The proposal includes changes that will adversely impact a broad array of diagnostic pathology tests which are critical in the diagnosis and treatment of many patients each year. Finalization of this proposal could compromise the access of hundreds of thousands of patients to needed testing. Many organizations signing this letter will be submitting more detailed comments on this issue prior to the expiration of the comment period on September 6, 2013.

The policy proposed by CMS would tie payment rates for some pathology services on the Physician Fee Schedule to rates paid to hospitals' outpatient departments. By the agency's own estimate, the change would cut payment rates by an average of 26%, and some of the most common services would be cut by nearly 75%, including flow cytometry, immunohistochemistry, and fluorescence *in situ* hybridization.

Hospitals and labs have completely different cost structures, and payments to hospital outpatient departments are from aggregate lab cost reporting from hospitals. Medicare charge-based hospital data are not an accurate proxy for individual services provided by pathologists and independent laboratories. Particularly troubling, CMS would set reimbursement rates using this flawed information even in situations where only 5% of these pathology services are provided in the hospital setting.

Basing payment rates on nebulous data from hospitals, particularly when only a fraction of services are provided in this setting, is a faulty approach that could threaten patient access to diagnostic care and fails to apply the statutory requirement that payments to physicians be resource-based. This misguided approach, if finalized, would in many cases result in reimbursement below the cost to even purchase the components necessary to run the tests.

Due to the inherent flaws in the use of hospital data, the absence of a resource-based standard as required by statute, and the threat to patient access to care, we strongly believe this proposal should not be finalized. We are committed to working with CMS, Congress and other stakeholders on payment policies that recognize the vital role of diagnostic services in health care delivery, and preserve patient access to care.

Sincerely,

AdvaMedDx  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Society for Clinical Pathology  
Association for Molecular Pathology  
Association of Pathology Chairs  
College of American Pathologists  
Coalition to Preserve Access to Cancer Diagnostic Services

cc: The Honorable Max Baucus  
The Honorable Orrin Hatch  
The Honorable Fred Upton  
The Honorable Henry Waxman  
The Honorable Dave Camp  
The Honorable Sandy Levin