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November 27, 2017

The Honorable Eric D. Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Hargan:

I am writing on behalf of the Society for Women's Health Research (SWHR[®]) to express our serious concerns regarding the 2018 Clinical Laboratory Fee Schedule (CLFS) that the Centers for Medicare and Medicaid Services (CMS) published on November 17, 2017. SWHR, a national nonprofit based in Washington, DC, is widely recognized as the thought leader in promoting research on biological differences in disease and eliminating imbalances in care for women through science, advocacy, and education.

SWHR is concerned that these CLFS payment rates—if implemented—will have significant impact on patient care. Over the last decade, tremendous advancements have been made in our knowledge of how diseases and illnesses impact women differently, disproportionately, or exclusively from men. Through research and innovation in personalized medicine, scientists have developed cutting-edge diagnostic tools and technologies that expedite health care decisions and improve patient care. Having access to new technologies is critical to advancing care for patients and their providers and towards achieving better outcomes. These tools and technologies provide physicians with specific information for diagnosing and managing the care of patients with complex conditions that have disproportionately broad impact on women, such as cancer, cardiovascular disease, and rheumatoid arthritis.

Implementation of the *Protecting Access to Medicare Act of 2014* (PAMA) [Pub. L. 113-93] requires CMS to update the way clinical laboratories are paid under the Medicare program through the creation of a new mandatory reporting system and revised fee schedule. It is our understanding that CMS relied on a significantly deficient data collection process to establish new payment rates for clinical laboratory tests, resulting in unreliable and unsustainable rates that fall short of Congress' goal of establishing a



market-based system. Before CMS proceeds with implementation of the CLFS payment rates on January 1, 2018, SWHR strongly believes the agency must: a) first address data integrity concerns, b) ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market, and c) provide a transparent process to allow for the validation of the data collected by CMS.

Therefore, we urge HHS and CMS to suspend implementation of the modified CLFS until these deficiencies can be addressed. We strongly encourage CMS to work with Congress and stakeholders to ensure that the clinical laboratory payment system under PAMA truly reflects a market-based approach.

If you have any questions, please contact Sarah Wells Kocsis, Vice President of Public Policy at SWHR at swellskocsis@swhr.org or 202.496.5003. Thank you for your prompt attention on this important matter.

Sincerely,

A handwritten signature in black ink that reads "Amy M. Miller". The signature is written in a cursive, flowing style.

Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research