



Congress of the United States  
House of Representatives

August 26, 2015

The Honorable Sylvia Burwell  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Burwell,

I appreciate your response to the letter my colleagues and I sent regarding the “minimal self-adjustment” definition for orthotic and prosthetic services. I have constituents who care deeply about providing these important products for those in their community and there are a few areas in which they would appreciate greater clarification.

The focus of the original letter was to reiterate that Congress has previously defined “minimal self-adjustment” and that the agency’s attempt to redefine it is in clear violation of statute. In your July 1 letter, you state that the “regulatory definition recognizes this level of adjustment that an average beneficiary could perform but allows a caretaker or supplier of the device to make adjustments the beneficiary otherwise could make on their behalf.” I believe you fail to recognize the unique role that these caretakers and suppliers have and the specific skills relating to these devices that far exceed that of the “average beneficiary.”

I have heard directly from constituents that many of these devices are not appropriate for beneficiary self-adjustment. It is my understanding that industry representatives met with CMS personnel in July 2011 and demonstrated a number of devices that CMS had believed were off the shelf (OTS), but were shown not to be suitable for self-adjustment by the average beneficiary. As this meeting occurred prior to your tenure as Secretary of Health and Human Services, I hope that you will consider conducting a follow-up meeting with industry representatives to discuss these specific devices and the potential limitations and dangers of self-adjustments conducted by a beneficiary.

I also appreciate your acknowledgment of program vulnerabilities due to the inaction of CMS in response to the passage of the Beneficiary Improvement and Protection Act of 2000.

Fifteen years have passed without the promulgation of rules pursuant to the law, and I believe it is important that the agency act quickly. I would appreciate an update as to when the notice of proposed rulemaking will be issued.

Those beneficiaries who depend on orthotic and prosthetic services are a unique patient population, and access to appropriate care and products help them lead full and productive lives. I appreciate your attention to these issues and look forward to hearing from you.

Sincerely,

A handwritten signature in blue ink that reads "Brett Guthrie". The signature is written in a cursive style and is positioned above a horizontal line.

BRETT GUTHRIE  
Member of Congress