

Congress of the United States
Washington, DC 20515

October 9, 2013

Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Tavenner:

We are writing this letter to support the Centers for Medicare and Medicaid Services' (CMS) efforts to promote efficiency in the delivery of healthcare services and long-term cost containment by packaging payment for skin substitutes used in advanced wound care in the 2014 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule. As stewards of our taxpaying constituents' dollars, we are committed to ensuring public programs such as Medicare are administered in the most efficient manner. We believe this proposal will reduce waste, extending the solvency of the program.

Under the current system, CMS reimburses skin substitutes on a per square centimeter basis. The use of "size appropriate" skin substitutes should have minimized cost. However, some manufacturers of the products in the skin substitute category have taken advantage of this reimbursement system by offering their products in only one size, which is fifteen to twenty times larger than that needed to cover the average size wound. In the hospital outpatient setting alone, this has resulted in an estimated \$75M in wasted product and lost taxpayer dollars in CY2011. In the physician setting, considerable waste also occurs. Your proposal represents an important step in reducing this waste by removing the incentive to use skin substitutes significantly larger than the size needed to care for a Medicare beneficiary's wound.

Other comments from industry stakeholders may propose a payment structure based on how a product is regulated by the Food and Drug Administration (FDA). However, the FDA regulates all of the skin substitutes covered by Medicare in some way. The regulatory pathway that a particular product takes to market should not be relevant for payment. The FDA determines how a product is to be regulated. The pathway taken does not necessarily correlate with clinical effectiveness. For example, some products regulated as tissues have been shown to heal wounds more rapidly and more effectively than other products regulated as devices. Therefore, no product should be exempted from the packaging proposal based on its regulatory status.

We further understand that some stakeholders have expressed concerns that the proposed packaging policy would undermine the provider's ability to treat large and complex wounds. With only one adult bundled price, hospital outpatient centers may opt to use

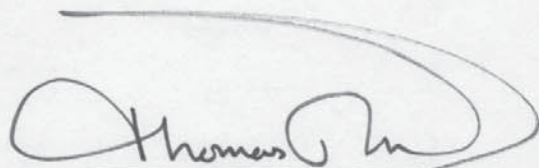
less effective products that are offered at a lower price, particularly if the wound is large and difficult to treat. In order to address these concerns, we urge you to create a tiered packaging structure based on wound size that would adequately reimburse providers for the treatment of larger wounds, such as advanced venous leg ulcers.

At this time in history, with continuing financial challenges and an aging population, it is more important than ever to act now to eliminate wasted dollars from our healthcare system, a system that is already overburdened. We support you in your efforts to promote efficiency and cost-containment in the delivery of healthcare services and maximize the effectiveness of taxpayers' contributions to Medicare. As you finalize the CY2014 OPPS rule, we ask that you continue these efforts while also taking into account the need to protect beneficiaries' access to the most appropriate treatment for large and complex wounds. Tiered packaging based on wound size is a more refined approach that will allow for the most effective product to be used on each wound, while significantly reducing waste in the Medicare program.

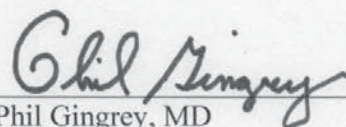
Due to the substantial and ongoing nature of the wastage that has occurred with certain skin substitutes over the years, it is imperative that you make these proposed payment changes as soon as possible. Thank you for your attention to this important matter.

We look forward to your positive response.

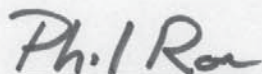
Sincerely,



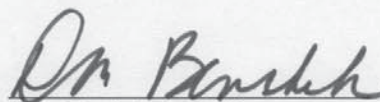
Tom Price, M.D.
Member of Congress




Phil Gingrey, MD
Member of Congress



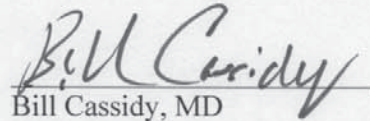
Phil Roe, MD
Member of Congress



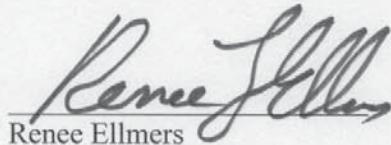
Dan Benishek, MD
Member of Congress



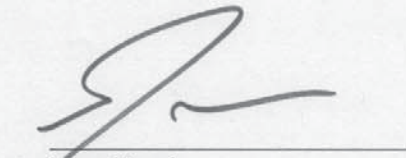
Andy Harris, MD
Member of Congress



Bill Cassidy, MD
Member of Congress



Renee Ellmers
Member of Congress



Tom Reed
Member of Congress



NOV 19 2013

Administrator
Washington, DC 20201

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding Medicare payment for total knee and total hip replacements under the Physician Fee Schedule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The CMS is reviewing payment for total and hip and knee replacements under the potentially misvalued code initiative. This initiative was developed in response to concerns raised by Congress, the Medicare Payment Advisory Commission, and other stakeholders. We identified these services as potentially misvalued in our calendar year (CY) 2012 Medicare PFS final rule, along with many other services, because these are high expenditure services that had not been reviewed since CY 2006. Under the potentially misvalued code initiative, CMS reviews recommendations made to us by American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC) as well as recommendations made by other stakeholders when available. For codes being reviewed under the potentially misvalued code process, we typically do not receive AMA RUC recommendations in time for us to fully review them and include our proposals in the proposed rule.

We have adopted a process to consider and, as appropriate, revise values for all codes considered under the potentially misvalued codes initiative. Under that process, we establish values for misvalued codes on an interim basis in the final rule subject to public comment. We consider public comments received on the interim values in the final rule and respond to those comments in the final rule for the following year.

Although CMS did not include the AMA RUC's recommended values or its own proposed values for hip and knee replacements in the CY 2014 PFS proposed rule, CMS has met with physicians representing hip and knee replacement surgeons in order to understand their concerns about the AMA RUC recommendations. CMS is considering the issues they have raised to us as we consider interim values for these surgical services for CY 2014.

I appreciate your interest in this important issue as we work toward our mutual goal of strengthening the Medicare program. I will also provide this response to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink that reads "Marilyn Tavenner". The signature is fluid and cursive, with a large loop at the end.

Marilyn Tavenner