August 11, 2020

The Honorable Chuck Grassley
Chairman, Finance Committee
U.S. Senate
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member, Finance Committee
U.S. Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Grassley and Ranking Member Wyden:

On behalf of our organizations, representing device manufacturers, physician specialty societies, clinical and patient associations, wound care clinics, tissue banks/processors, and distributors, **we would like to express our concern over S. 4295, legislation that would allow the Secretary of Health and Human Services to extend the period of Medicare pass-through status in the hospital outpatient setting to any product with that status during the COVID public health emergency.** We want to bring to your attention the fact that, as written, the legislation would allow products that have already had well over the statutory period of two-to-three years to have extended pass-through time. **For some products, such an extension would permit the product to have six or more years of pass-through status, more than double the statutory limit.**

Our organizations are particularly concerned about the impact such a pass-through extension would have within the cellular and/or tissue-based product market for skin wounds (CTPs) also known as skin substitutes. CTPs are used in the treatment of non-healing chronic wounds, including diabetic foot ulcers and leg ulcerations. The CTP market is diverse with significant competition. The CTP products that currently hold pass-through status have held such status since 2015, generating significant data that has already resulted in adjustment to APCs. Further extension of this product category at this time would be extremely detrimental to market competition at a time when all product manufacturers are trying to get their businesses back up and running to provide technologies used for elective surgical procedures.

As wound care stakeholders, we want to ensure access to all CTP products in the market to support clinical choice and patient value. Extending the pass-through term of CTP products well beyond the normal pass-through period drastically detracts from that effort. We believe this skews patient access as it incentivizes use of these CTP pass-through products over others in an otherwise established market.

While we appreciate that products currently on pass-through with less than three years of that status may not be fully benefitting during the PHE due to reduced surgical procedures, we strongly believe that CTPs that have had more than three years of pass-through status *prior* to the start of the public health emergency have maximized the full benefit of that status, have generated significant data for the Centers for Medicare and Medicaid Services, and are not in need of further pass-through time. Our organizations ask that you not move this legislation forward without further effort to address these concerns. Please don't hesitate to contact Julie Allen (Julie.Allen@PowersLaw.com) or Joe Nahra (Joseph.Nahra@PowersLaw.com) with any questions.

Sincerely,

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