August 23, 2024

Submitted Electronically via www.regulations.gov

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1805-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, et. (CMS-1805-P)

Dear Administrator Brooks-LaSure:

We are writing as advocates for older Americans who need affordable access to quality care to maintain their health and wellbeing, particularly when they are challenged by serious chronic illnesses. On January 1, 2025, CMS is scheduled to alter coverage of Phosphate Lowering Therapies (PLTs) for Medicare beneficiaries with End Stage Renal Disease (ESRD) by moving these treatments from the Medicare Part D coverage system to the ESRD Prospective Payment Systems. We believe this shift will be severely detrimental to aging ESRD patients and we urge you to refrain from implementing this change.

Access to PLTs is critical for patients undergoing dialysis treatment. Without these therapies, dialysis leads to excessively high levels of phosphorous in the body and a heightened risk of health emergencies, disability or death. More than a quarter of ESRD patients are Medicare-eligible seniors.

Moving these treatments into an ESRD payment bundle that is already stretched thin has serious ramifications for patients. It can place financial considerations between the patient and doctor and their shared decision-making. It can result in seniors being kept on cheaper, less effective classes of therapies even if novel treatments are developed and determined to be better for patient health. And in moving PLTs out of the Medicare Part D program, seniors lose important benefits like Part D's cap on out-of-pocket drug costs, exacerbating the risk that these therapies may become too expensive for seniors on fixed incomes.

There are other important practical considerations. Approximately, one of every 10 dialysis patients resides in a skilled nursing facility (SNF). These patients tend to be the most vulnerable to health decline, suffering high rates of morbidity and mortality. Most of these patients receive their PLTs through the contracts their nursing facilities maintain with area pharmacies. By moving PLTs into the ESRD payment bundle, SNF residents would no longer be able to receive these treatments through pharmacy delivery because only dialysis facilities would be allowed to dispense them. This creates unnecessary complexity and increases the risk that these drugs would be inaccessible to the patients who need them the most.

We also cannot be certain that dialysis facilities will carry a full range of PLT options because of storage considerations and the uncertainty as to whether they would be compensated for this additional logistical burden.

For these reasons, Administrator Brooks-LaSure – the possibility of higher out-of-pocket costs, impaired access to treatments, financial considerations interfering in doctor-patient decisionmaking, an unnecessary burden placed on residents of skilled nursing facilities – we feel strongly that CMS should pause the implementation of this change and leave PLTs within the Medicare Part D program. In this case, the status quo is serving ESRD patients well and changing it will place their health at unnecessary risk.

Thank you for your consideration of our request. We look forward to working with you in maintaining access to lifesaving and life-improving treatments for seniors.

Sincerely,

Robert B. Blancato
Executive Director, National Association of Nutrition and Aging Services Programs (NANASP)

Michael Ward
Vice President of Public Policy and Gov't Relations, Alliance for Aging Research

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