November 21, 2024

The Honorable Charles Schumer Majority Leader United States Senate The Capitol Washington, D.C. 20510

The Honorable Mike Johnson Speaker United States House of Representatives The Capitol Washington, D.C. 20510 The Honorable Mitch McConnell Minority Leader United States Senate The Capitol Washington, D.C. 20510

The Honorable Hakeem Jeffries Minority Leader United States House of Representatives The Capitol Washington, D.C. 20510

Dear Majority Leader Schumer, Speaker Johnson, Minority Leader McConnell and Minority Leader Jeffries,

On behalf of the more than 600,000 Medicare beneficiaries with End Stage Renal Disease (ESRD) we serve, we urge you to pass HR5074/S4510, the Kidney PATIENT Act to keep oral-only drugs out of the Medicare Part B ESRD Prospective Payment System (PPS) bundled payment. This legislation will continue the current policy of keeping phosphate lowering therapies in Part D and ensure that all dialysis patients have reliable and flexible access to critical treatments tailored to best suit their needs.

Phosphate lowering therapies (PLTs) treat hyperphosphatemia – or high phosphate levels in the blood –a condition present in the vast majority of dialysis patients. Hyperphosphatemia can lead to vascular calcification, cardiovascular complications, and death if left untreated. For years, and up until present day, Medicare beneficiaries with kidney failure who needed PLTs accessed their medication through local or preferred mail order pharmacies. However, on June 27, 2024, the Centers for Medicare & Medicaid Services (CMS) proposed a policy requiring dialysis patients to receive these therapies through dialysis clinics, instead of pharmacies, starting on January 1, 2025.

CMS has proposed this policy to require dialysis facilities to supply PLTs, even though these pills are taken outside of the facility with meals, rather than during a dialysis session. Most patients take between three and 10 pills per day (or approximately 100-300 pills per month). With the majority of ESRD patients taking these therapies, and recognizing the large volume of pills that must be supplied, inclusion of these drugs in the bundle will place a significant burden on dialysis facilities. Many facilities, particularly small, rural and urban providers, lack the resources and infrastructure to meet the new mandate which would require stocking massive quantities of products (where state law permits) or contracting with a specialty mail order pharmacy.

According to the Medicare Payment Advisory Commission (MedPAC), ESRD providers experienced an aggregate fee-for-service Medicare margin of -1.1 percent in 2022, and the current projected margin for 2024 is 0 percent. While some large dialysis chains may be able to afford

¹ Medicare Payment Advisory Commission. (2024). March 2024 Report to the Congress: Medicare Payment Policy, Chapter 5: Outpatient Dialysis Services, *MedPAC*,

the additional costs associated with this delivery system change, many mid-sized and small community dialysis providers simply cannot. This policy change risks creating a two-tiered Medicare benefit and needlessly threatens patient access to the standard of care that currently exists.

Further complicating a change in policy, roughly half of Medicare beneficiaries with ESRD are enrolled in a Medicare Advantage (MA) plan. MA plan contracts do not readily account for products that are new to a payment bundle until contracts are updated or renegotiated, which can take up to 12 months or more to complete. As a result, many of these beneficiaries may not only be unable to access the product that has proven to be the most effective option for them, but also may not be able to access a prescribed product at all. This is clinically very problematic for these vulnerable patients.

This new policy also presents a serious health equity challenge, as a disproportionate number of patients with ESRD are minorities residing in rural and low-income communities. Black, Hispanic, and Native American populations face significantly higher rates of ESRD. Additionally, outdoor workers and those exposed to extreme heat are disproportionately impacted by the condition. Including PLT coverage in the ESRD bundle will only exacerbate the existing health disparities among these underserved groups.

In March, the House Energy & Commerce and Ways & Means Committees favorably reported bipartisan legislation that would extend the current policy of keeping oral-only drugs out of the ESRD bundled payment for an additional two years. Companion bipartisan legislation has been introduced in the Senate. We respectfully urge you to pass this legislation through your respective chambers at your earliest convenience to provide ESRD Medicare beneficiaries with the certainty and comfort of knowing that their lifesaving dialysis care will not be disrupted next year.

Sincerely,

Renal Healthcare Association
Nonprofit Kidney Care Alliance
Renal Physicians Association
American Society of Nephrology
American Nephrology Nurses Association
Independent Dialysis Foundation
Northwest Kidney Centers
Central Florida Kidney Centers
Atlantic Dialysis Management Services
Puget Sound Kidney Centers
Dialysis Clinic Inc.
BlackDoctor.org

Patients

American Kidney Fund Renal Support Network Kidney Champion Foundation

Rogosin Institute

Chronic Care Policy Alliance

National Minority Quality Forum

US Hispanic Business Council

Arizona Chronic Care Together Coalition

New York State Black, Puerto Rican, Hispanic & Asian Legislative Caucus

Black Nurses Association of Central Illinois

Florida Renal Association

African American Diabetes Association

Teamsters Local 623 (Philadelphia)

Florida State Hispanic Chamber of Commerce

National Hispanic Construction Alliance (NHCA)

Hispanic Chamber of e-Commerce

National Kidney Foundation of Florida

Alliance for Aging Research

Alvin Stokes, Kidney Dialysis Patient (Detroit, MI)

Renal Coalition

Cornerstone Community Baptist Church - Pastor W. L. Lawson (Atlanta, GA)

Antioch Missionary Baptist Church - Pastor Q. E. Hammonds (Birmingham, AL)

Breaking The Sickle Cell Cycle Foundation

Arizona Blood Alliance

Advocates for Responsible Care

Bethesda Baptist Church - Pastor Michael Thompson (Washington, DC)

Judge Derek Mosley, Kidney Transplant Warrior (Milwaukee, WI)

National Forum for Heart Disease & Stroke Prevention

Peer Plus Education and Training Advocates

Kidney Foundation of Central PA

Coalition of Black Trade Unionists (MA Chapter)

Lupus and Allied Diseases Association, Inc.

Deborah Spooney, Sickle Cell Disease Patient Advocate (Stone Mountain, GA)

Rev. Dr. E. Dewey Smith, The House of Hope Atlanta (Atlanta, GA)

Looms for Lupus

Pastor Earnest Gillespie, III, Pearly Gate Baptist Church (Memphis, TN)

Pennsylvania Avenue Baptist Church - Rev. Dr. Kendrick Curry (Washington, DC)

Redmoon Project

Reverend Alvin Love, Lilydale First Baptist Church (Chicago, IL)

National Consumers League

Richard Hooker, Jr., Secretary, Treasurer & Principal Officer, Teamsters Local 623 (Philadelphia, PA)

Faith Advisory Council for Community Transformation - Pastor George Lamb (San Bernardino, CA)

Intelatin

Kindness for Kidneys International

Mapillar Dahn, MTS Sickle Cell Foundation, Inc. (Jonesboro, GA)

The EPIC Foundation

Victor Waters, MD, Chief Medical Officer, Dignity Health (Phoenix, AZ)

Illinois Public Health Association

Lupus And Community Empowering Support (LACES)

Salathiel DeLoach, CEO, DeLoach Lupus Foundation (Savannah, GA)

Lupus Foundation of America, Wisconsin Chapter

Michael Bryant, CEO, New Life Community Alliance (Atlanta, GA)

Michigan Lupus Foundation

Utah Hispanic Chamber of Commerce

Sickle Cell Thalassemia Patients Network

Taura Brown, Kidney Dialysis Patient Advocate (Detroit, MI)

Greater Young Zion Baptist Church - Pastor William H. Blount, Sr. (Augusta, GA)

HEAL Collaborative

Pastor Brian Kennedy, Mt. Zion Church of Ontario (Ontario, CA)

Pastor George Britt, Mount Teman AME Church (Elizabeth, NJ)

Minister Timothy Smith, New Life Church (Decatur, GA)

Rita Littlefield, Past Member of Texas Chronic Kidney Disease Task Force and Founder of Texas

Ruby A. Neeson Diabetes Awareness Foundation, Inc.

Shenika Smith, Lupus Patient Advocate (Atlanta, GA)

Sickle Cell Association of Kentuckiana

Pastor Walter Fields, St. Paul Church of God in Christ (Milwaukee, WI)

Lisa Parker, Hyperphosphatemia Patient Advocate (Decatur, GA)

Texas Renal Coalition

Kidney Champion Foundation - Crystal King, Founder and Executive Director

NAACP NY Conference

Respectfully,

Rob S. Bomstad, M.S., B.S., RN

President Renal Healthcare Association