KIDNEY CARE PARTNERS

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KCP Comment on Section 232 Investigation of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices
Docket No. 250924-0160; ID BIS-2025-0258; XRIN 0694-XC134

I. Introduction

Kidney Care Partners ("KCP") is grateful for the opportunity to submit a comment in response to the Notice of Request for Public Comments on the Section 232 National Security Investigation of Imports of Personal Protective Equipment ("PPE"), Medical Consumables, and Medical Equipment, Including Devices (the "Notice") by the Bureau of Industry and Security ("BIS") within the Department of Commerce ("Commerce"), published on September 26, 2025. This comment addresses the reasons why the imposition of tariffs or other trade measures related to PPE, Medical Consumables, and Medical Equipment (together, "Medical Supplies") that are critical in the treatment of End Stage Renal Disease ("ESRD") are not necessary for U.S. national security and would have severe adverse impacts, including threatening the lives and health of ESRD patients. Trade remedies, such as tariffs, would restrict access to life-saving ESRD Medical Supplies for an equipment-dependent patient population and would significantly undermine the efficacy of Medicare programs designed to benefit this unique population. In addition, KCP notes that ESRD patients often have complex conditions and require access to other ESRD Medical Supplies, and trade remedies that restrict access to these ESRD Medical Supplies could be detrimental to the lives of ESRD patients and those outside of the ESRD population. Accordingly, we respectfully request that any tariffs or other trade measures imposed pursuant to this investigation exclude the ESRD Medical Supplies identified in Appendix A.

II. Kidney Care Partners

KCP is a non-profit, non-partisan coalition of more than thirty organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

III. End Stage Renal Disease and the Patient Population

ESRD is the last stage of chronic kidney disease ("CKD") and is characterized by permanent, irreversible kidney failure. Patients with ESRD include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. According to the U.S. Renal Data System (USRDS), in 2024, approximately 831,000 Americans were living with ESRD.[1]

Due to the limited number of kidneys available for transplantation and the variation in patients' suitability for transplantation, about seventy percent of patients with ESRD undergo maintenance dialysis. Dialysis replaces the filtering function of the kidneys when they fail. Although improvements launched by President Trump's first Administration in 2019[2] are underway to promote in-home treatment options and transplantation, most patients on dialysis travel to a treatment facility to undergo hemodialysis three times per week for approximately four hours per treatment. Hemodialysis uses an artificial membrane encased in a dialyzer (which serves as an artificial kidney) to filter the patient's blood. In addition to a dialysis machine, this process involves several ESRD Medical Supplies including, but not limited to: (1) the dialyzer; (2) blood tubing sets, to connect the patient's blood vessels to the dialyzer; and (3) fistula needles and catheters, to access the patient's bloodstream. Other ESRD Medical Supplies are also often required to deliver medications and treat related co-occurring conditions such as anemia and bone disease that result from the loss of kidney function.

The ESRD population is unique among those that rely on ESRD Medical Supplies. In 1972, Congress expanded Medicare to cover individuals diagnosed with ESRD regardless of age, including for costs associated with the purchase of ESRD Medical Supplies. This marked the first time that Congress allowed individuals to enroll in Medicare based on a specific medical condition rather than on age. Congress extended Medicare coverage to individuals with ESRD due to the lethality of the disease, the then-prohibitive cost of paying for dialysis, and the "indirect [economic] costs" that the disease inflicts on the nation.[3] To this day, ESRD remains one of only

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[1] Nat'l Inst. of Diabetes and Digestive and Kidney Diseases, ESRD Quarterly Update (May 2025), https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/esrd-quarterly-update (select Prevalent Count Line Charts tab).

[2] On July 10, 2019, President Trump issued an Executive Order on Advancing American Kidney Health. *See* Trump White House, *Executive Order on Advancing American Kidney Health* (July 10, 2019), https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-advancing-american-kidney-health/. This landmark policy commitment incentivizing kidney patient choice and quality improvement, modernizing Medicare systems to promote in-home treatments and transplantation, and implementing new delivery models designed to accelerate value-based care is a major milestone for kidney patients, their families and the community of providers, nephrologists, nurses, social workers and drug and device manufacturers that support them. **The Advancing American Kidney Health Executive Order (2019) remains today the most profound investment by any President in patients with this devastating disease.**

[3] S. Rep. No. 92-1230, at 1243–44 (1972) (statement of Sen. Hartke).

two diseases that makes an individual eligible for Medicare regardless of age or other disability. In extending coverage to this population, Congress acknowledged that special measures were necessary to ensure ESRD patients would receive the life-saving dialysis treatment necessary to stay alive.

IV. Scope: ESRD Medical Supplies

KCP has prepared a list of ESRD Medical Supplies, attached as Appendix A, that are critical to long-term treatment of ESRD, including dialysis treatment and treatment following a kidney transplant. Appendix A is broken into two sections. The first section lists ESRD Medical Supplies that are specific to the treatment of ESRD, including, but not limited to dialysis and kidney transplant. The second section lists ESRD Medical Supplies that are also necessary for the treatment of ESRD but may also be used in other health care contexts. Without the ESRD Medical Supplies in Appendix A (including both Sections I and II), ESRD patients would be unable to manage their condition.

For the following reasons, KCP respectfully requests that BIS carefully consider the life-saving ESRD Medical Supplies included in Appendix A and recommend excluding ESRD Medical Supplies from any future trade action, including tariffs. In the event that BIS is unwilling to consider relief for all products in Appendix A, we respectfully request relief for ESRD Medical Supplies listed in Section I of Appendix A.

KCP would also like to note that there are many Americans living with ESRD who have comorbidities that require access to other non-ESRD Medical Supplies. As such, KCP respectfully requests that BIS consider the ramifications that tariffs on non-ESRD Medical Supplies will have on those living with ESRD and the broader American patient populace.

V. Exclusion of ESRD Medical Supplies is necessary to save lives.

If ESRD patients lose access, even temporarily, to ESRD Medical Supplies, many will face severe health consequences, including death. ESRD dialysis patients require a variety of ESRD Medical Supplies that are administered during dialysis to filter the patient's blood and prevent the buildup of toxins and fluids that is fatal. Many ESRD Medical Supplies are also necessary to provide dialysis and prevent severe, adverse complications related to ESRD, including anemia,[4] mineral

[4] Anemia is a reduction in hemoglobin that occurs when the body does not have enough red blood cells or when the body's red blood cells do not function properly, affecting oxygen delivered to the body. Ninety-one percent of U.S. dialysis patients have been diagnosed with anemia and require a variety of Medical Supplies to manage the condition.

and bone disorders,[5] such as hyperphosphatemia,[6] and secondary hyperparathyroidism,[7] among others.

ESRD kidney transplant patients require ESRD Medical Supplies not only to undergo a successful kidney transplant surgery but also to continue monitoring and treating their condition to prevent rejection of the transplanted kidney. Additionally, during their transplant course, kidney transplant recipients also require ESRD Medical Supplies needed for induction therapy and infection prevention. ESRD Medical Supplies protect the transplant patient and the donated kidney from rejection and related complications.

Most ESRD treatments are administered multiple times per week and rely on these ESRD Medical Supplies so that patients do not miss any doses or treatments—whether the result of unaffordability or supply chain disruption—that can have grave consequences for patients. The United States should not impose trade measures that would significantly limit or effectively wall off access to critical ESRD Medical Supplies. The importance of this access is paramount to the American ESRD patient population and therefore overcomes any perceived or potential national security concerns.

VI. Exclusion of ESRD Medical Supplies would be an appropriate form of relief for this vulnerable population.

Granting an exclusion to ESRD Medical Supplies from a broader Medical Supplies trade measure would be appropriate and would not hollow out the effect of said trade action. More than 831,000 Americans (or 0.24 percent) live with ESRD. In other words, ESRD patients comprise less than one quarter of one percent of the total U.S. population.[8] As a very small subset of the population, a carve-out specially designed for the vulnerable and treatment-dependent ESRD population will not negatively impact national security or U.S. policy goals. Additionally, an ESRD exclusion would not undermine the overall efficacy of a trade action, including a Medical Supplies tariff, that is imposed on the Medical Supplies industry more broadly.

[5] In patients with ESRD, mineral and bone disorder occurs when there is an imbalance in the blood levels of calcium and phosphorus. This mineral imbalance affects bones, the heart, and blood vessels.

[6] Hyperphosphatemia is a condition characterized by elevated levels of phosphate in the blood. In patients with ESRD, the kidneys lose the ability to excrete phosphate effectively, leading to its accumulation in the blood. Phosphate lowering therapies are used in nearly 80 percent of dialysis patients.

[7] In ESRD, the kidneys' inability to filter waste products leads to decreased levels of calcium and elevated levels of phosphate. This triggers the parathyroid glands to produce excessive PTH, which further disrupts calcium and phosphate levels, causing secondary hyperparathyroidism.

[8] Nat'l Inst. of Diabetes and Digestive and Kidney Diseases, ESRD Quarterly Update (May 2025), https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/esrd-quarterly-update (select Prevalent Count Line Charts tab); U.S. Census Bureau, U.S. and World Population Clock, https://www.census.gov/popclock/ (last visited Oct. 16, 2025).

VII. The importation of ESRD Medical Supplies does not present a national security risk, and therefore, no special trade measures are required to protect national security.

A. Foreign supply chains are required to meet U.S. demand for ESRD Medical Supplies, but many countries that produce such ESRD Medical Supplies are U.S. allies.

A small portion of all critical ESRD Medical Supplies is manufactured in the United States with many ESRD Medical Supplies exclusively produced abroad. For example, dialysis machines and dialyzers are commonly produced in Germany, Mexico, Japan, and Singapore while component parts are often manufactured in Italy, Mexico, France, and elsewhere. Fistula needles, another critical tool in ESRD treatment, often come from Thailand and other countries. Lastly, although some peritoneal dialysis fluid for home dialysis is manufactured in the United States, ESRD patients also rely on production in Germany, Ireland, Mexico, Spain, and Turkey.

KCP recognizes the importance of increasing domestic production, including within the Medical Supplies industry, but the capacity needed to support U.S. demand is not practical in the short or medium-term. Several kidney care institutions are committed to bringing more ESRD manufacturing capabilities into the United States and plans to increase the domestic footprint of ESRD Medical Supplies. Further expanding these capabilities requires significant time and investment, particularly in an industry that is subject to strict regulatory scrutiny. ESRD patients rely on these life-saving ESRD Medical Supplies on a daily basis and cannot wait for treatment if trade barriers to life-saving ESRD Medical Supplies are imposed while waiting for domestic manufacturing to be more readily available.

Furthermore, although foreign supply chains are necessary to meet domestic need for ESRD Medical Supplies, any national security risks are effectively mitigated where these ESRD Medical Supplies are produced in countries with which the U.S. has favorable relations. The U.S. has favorable political and trade relations with many of the key manufacturing countries for ESRD Medical Supplies (*e.g.*, Mexico, Germany, Japan, France, etc.). It is therefore unlikely that these nations would restrict ESRD Medical Supplies as a foreign policy aim; however, the consequences of tariffs would pose significant risk to domestic supply and U.S. patients.

B. U.S. imports of ESRD Medical Supplies come from a diverse group of suppliers from various countries, limiting any potential national security threat.

For most ESRD Medical Supplies, there is a diverse pool of suppliers that produce these articles in several different countries. Many ESRD Medical Supplies can currently be procured from a variety of countries, such as Germany, Mexico, Japan, Singapore, Italy, Thailand, Switzerland, and the United Kingdom, among others. In KCP's assessment, no single country could restrict exports of ESRD Medical Supplies to gain leverage over U.S. foreign policy or national security. Global supply chain diversification protects U.S. access to life-saving ESRD Medical Supplies.

Moreover, protecting this diversity of suppliers, rather than erecting barriers such as tariffs, ensures that supply chains critical to ESRD treatment remain available at all times. Tariffs and other trade

actions often foreclose supply chains by making procurement prohibitively expensive, which would in turn limit the available options of ESRD Medical Supplies in the United States. Faced with a limited list of suppliers and tariffs on many U.S. trading partners, the U.S. market would be unable to pivot to a different foreign supplier in response to supply chain disruptions or price increases in a particular market.

Furthermore, by limiting accessible markets through trade restrictions, manufacturers, providers, and patients would become more dependent on a smaller number of suppliers, creating greater risk that the U.S. would not have access to alternative suppliers when needed—for instance, in the event of a natural disaster or other catastrophic event. Additionally, because ESRD Medical Supplies are a relatively small market with limited domestic supply, trade restrictions could dramatically reduce competition, creating incentives for domestic suppliers to raise prices while reducing incentives to increase production. It is imperative to protect the flexibility of both foreign and domestic ESRD supply chains.

C. Foreign governments do not subsidize/ have predatory trade practices in the ESRD industry.

Unlike in industries such as lumber, aluminum, and carbon, the International Trade Administration ("ITA") has not investigated or identified any dumping practices related to ESRD Medical Supplies. To the best of our knowledge, there are no antidumping/countervailing duty ("AD/CVD") cases related to ESRD Medical Supplies, which implicitly acknowledges that Commerce, the ITA, and domestic producers have not identified state-sponsored overproduction concerns. Further, these government organizations have not investigated ESRD Medical Supplies for these state-sponsored concerns, indicating that the American Medical Supplies industry has not raised these concerns with Commerce and ITA.[9]

VIII. Tariffs or other trade measures would significantly disrupt the Medicare programs set up for ESRD patients by Congress and disrupt access to ESRD Medical Supplies.

ESRD patients are one of two unique patient populations eligible for Medicare regardless of age due to the severe and costly nature of the treatments required. The ESRD population accounts for approximately 1% of the Medicare population yet spending on all of their Part A and B care accounts for 7% of Medicare spending.[10] Accordingly, both ESRD patients and Medicare would be uniquely impacted by trade measures imposed on the ESRD Medical Supplies industry.

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[9] International Trade Administration, AD/CVD Search, https://access.trade.gov/ADCVD_Search.aspx (last visited Oct. 16, 2025).

[10] Paulette C. Morgan, *Medicare Advantage (MA) Coverage of End Stage Renal Disease (ESRD) and Network Requirement Changes* (2021), https://www.congress.gov/crs-product/R46655; *see also* Nat'l Inst. of Diabetes and Digestive and Kidney Diseases, 2022 Annual Data Report, End Stage Renal Disease: Chapter 9, Healthcare Expenditures for Persons with ESRD, https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd.

In 2011, Congress modernized how Medicare pays for dialysis care by creating a broad payment bundle called the "ESRD Prospective Payment System (PPS)."[11] Under the ESRD PPS, facilities receive a single adjusted payment that includes services, drugs, laboratory tests, medical equipment, and supplies. Medicare payments to dialysis facilities are then adjusted each year based on the ESRD market basket input price index which tracks the price increases for goods and services that facilities purchase to provide patient care.[12]

At the time Congress and CMS were developing the ESRD PPS, the Government Accountability Office[13] and others who supported the new policy had emphasized that, when CMS implements such payment changes, it is important for the bundled payment rate to accurately reflect the *expected* costs of beneficiaries' care to ensure that efficiencies are not realized at the expense of beneficiaries' access to and quality of care. However, the potential introduction of *unexpected* ESRD Medical Supplies tariffs into a payment system that forecasts reimbursement based on the lagged prices of goods and services could immediately and irreparably harm the ability of dialysis providers to provide care to vulnerable beneficiaries and could have longer term consequences for Medicare outlays.

In the short term, dialysis providers would be required to absorb the price increases resulting from the imposition of tariffs, other trade measures, or onshoring the production of ESRD Medical Supplies. Although dialysis providers always seek to avoid any disruption to patient access, purchasing ESRD Medical Supplies at a loss is <u>not</u> financially sustainable, which could result in major provider shortages and reductions in treatment capacity for the entire treated population. The impact of these outcomes would cascade across Medicare as individuals with ESRD who cannot receive routine dialysis experience avoidable complications that result in greater utilization of physician and hospital care.

In the long term, the Medicare program would likely feel the effects of rising costs of ESRD Medical Supplies in its market basket updates, which would further strain the U.S. Treasury accounts used to fund Medicare. Higher costs caused by tariffs could result in private insurers forcing ESRD patients onto Medicare, which would result in significant cost increases to the U.S. government.

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[11] Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494, https://www.congress.gov/110/statute/STATUTE-122/STATUTE-122-Pg2494.pdf.

[12] The government's base payment rate for each dialysis treatment is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatments. In 2025, the base payment rate is approximately $291 per treatment. *See generally* Medicare Payment Advisory Commission, Report to Congress at 168 (March 2025), https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_MedPAC_Report_To_Congress_SEC.pdf.

[13] *See*, for example, U.S. Gov't Accountability Off., GAO-11-365, End-Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data (2011); U.S. Gov't Accountability Off., GAO-10-295, End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System (2010).

IX. If the BIS is inclined to recommend trade measures, KCP urges BIS to consider domestic incentives as an alternative to tariffs.

In the event BIS determines that trade measures on Medical Supplies, including ESRD Medical Supplies, are necessary to protect U.S. national security, KCP respectfully submits that the U.S. government should consider alternatives that would not risk disrupting the supply of life-saving treatment to ESRD patients, as would the imposition of tariffs. These alternatives could include:

- Implementing subsidy or grant programs to incentivize domestic production of completed ESRD Medical Supplies and parts thereof;
- Implementing tax incentives for companies that manufacture ESRD Medical Supplies in the U.S.;
- Spearheading a preferential treatment program or relief fund for U.S.-manufactured ESRD Medical Supplies to include manufacturer rebates and discounts through CMS; or
- Investing in workforce development to spur onshore production of ESRD Medical Supplies.

X. Conclusion

For the reasons stated above, Kidney Care Partners urges the Bureau of Industry and Security to exclude the ESRD Medical Supplies identified in Appendix A from any tariffs or other trade measures imposed as a result of this Section 232 investigation, or in the alternative, to exclude the ESRD Medical Supplies identified in Section I of Appendix A. ESRD Medical Supplies are critical, life-saving, and necessary to the survival of Americans living with ESRD, which is a chronic, permanent condition. Loss of access to these ESRD Medical Supplies for even a short period of time could result in severe health consequences for ESRD patients, including death. Imposing tariffs or other trade measures on ESRD Medical Supplies would not support U.S. national security or foreign policy interests. Moreover, the relief requested by KCP—namely, excluding ESRD Medical Supplies from any trade action—is narrowly tailored and necessary to protect the ESRD population. Due to the importance of this issue for ESRD patients, KCP respectfully requests a meeting with BIS officials before any action is taken that would impact access to life-saving ESRD Medical Supplies.

Sincerely,

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Chair 2024-2025
Kidney Care Partners

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KIDNEY CARE PARTNERS

Appendix A: ESRD Medical Supplies

Section I: Medical Supplies Specific to ESRD Treatment, including Dialysis and Kidney Transplant Treatment

Medical Consumables	Bicarbonate
	Biomed Solutions
	Bloodlines
	Continuous Renal Replacement Theory (CRRT)
	Crit-Lines
	Dialysis Concentrates
	Dialysis Solutions (including premixed hemodialysis and peritoneal dialysis solutions)
	Dialysis Tubing
	Dialyzers
	Dialysate Water Filters
	Fistula Needles
	HHD Disposables
	Parts of dialysis water treatment systems
Medical Equipment and Devices	Biomed Meters
	Dialysis Machines (including hemodialysis/ hemodiafiltration and peritoneal dialysis, such as CRRT Machines)
	NxStage Machines
	Reverse Osmosis Equipment
	Spare Parts for Dialysis Machines
	Sterilizers
	Surdial DX
	Device Parts, Components, and Accessories (*e.g.*, cords, plugs, clamps, motors, etc.) to the extent covered by this investigation

Section II: Medical Supplies Necessary for ESRD Treatment and Broader Use in Health Care

Personal Protective Equipment	Face Shields
	Gloves
	Hand sanitizer
	Hand soap
	Infection Control Products
	Lab Gowns
	Masks
Medical Consumables	Alcohol
	Bandages
	Betadine
	Biopatch
	Blood tubing sets
	Catheter Caps
	Catheter Kits
	Chlorhexidine
	Dental Hand Instruments
	Diagnostic Tools
	Dialyzer Connectors
	Disposable Exam Room Products
	Gauze
	Hazards Bag
	Hypodermic Supplies
	Incontinence Products
	Infectious Waste Management
	Infusion Ports
	Infusion Tubes
	Iodine
	Irrigation Products
	IV Bags
	IV Kits
	Lab Coats
	Medical tapes
	Medical Wraps
	Needles
	Nutritional and Feeding Supplies
	Orthopedic Products
	Mineral and Bone Disease Management Supplies
	Prefilled Saline Syringes
	Procedure Tools
	Reverse Osmosis Membranes and Accessories
	Saline Flushes
	Surgical Kits

	Surgical Packs
	Surgical Tools
	Surgical Trays
	Syringes
	Tego caps
	Tubing, Connectors, Valves, Clamps, and Related Accessories
	Wound Care Products
Medical Equipment and Devices	Blood Pressure Cuffs
	Cardiac Monitoring and Treatment Devices
	Code/Crash Carts
	Durable Medical Equipment
	Imaging Equipment
	IV Poles
	Magnetic Resonance Imaging Machines
	Medical Lighting
	Medical Sensors and Related Accessories
	Medication Refrigerators
	Optical Encoders
	Patient Beds
	Patient Room Equipment
	Pumps (including IV, Blood, and Dialysate)
	Respiratory Equipment
	Supply Carts
	Surgical Table
	Vitals Monitors
	Wheelchairs
	X-Ray Machines
	Device Parts, Components, and Accessories (*e.g.*, cords, plugs, clamps, motors, etc.) to the extent covered by this investigation

Appendix B: KCP Signatories

Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
Atlantic Dialysis Management Services, LLC
CorMedix, Inc.
CSL Vifor
DaVita, Inc.
Diality, Inc.
Dialysis Care Center
Dialysis Patient Citizens, Inc.
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
Nephrology Nursing Certification Commission
North American Transplant Coordinators Organization
Pathalys Pharma, Inc.
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
The Rogosin Institute
U.S. Renal Care
Unicycive Therapeutics, Inc.