



March 28, 2023

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN) thank the Biden-Harris Administration for its dedication and commitment to combatting the COVID-19 pandemic. The ASN members, leadership, staff, and I also appreciate the administration's efforts to guide the nation through an extremely challenging period.

While the COVID-19 pandemic may not represent the threat it once did for many Americans, it still presents a health risk for some members of the population. For those Americans with kidney diseases—especially those with kidney failure who are either on dialysis or who have kidney transplants and experience chronic immunosuppression—an ongoing risk exists of more severe COVID-19 illness and fatality.

The impact of the COVID-19 pandemic on the 37 million Americans with kidney diseases has been dramatic. The rates of infection and mortality in kidney patients were far greater than the general Medicare populationⁱ. For the first time in the 50-year history of the Medicare End-Stage Renal Disease (ESRD) program, the population of patients treated by maintenance dialysis decreased in 2020ⁱⁱ. Sadly, the difference is attributable to the disproportionate impact of pandemic-related mortality in this vulnerable population rather than advances in preventing kidney failure. Kidney transplant recipients with COVID-19 affected by underlying comorbidity and chronic immunosuppression also demonstrated higher morbidity and mortality than non-transplant patients with COVID-19ⁱⁱⁱ.

Therefore, on behalf of the 37 million Americans with kidney diseases, ASN urges the Biden-Harris Administration to:

- Seek clarity on final ACIP recommendations for annual adult and pediatric COVID-19 immunizations. While current ACIP recommendations include COVID-19 bivalent vaccines, they also refer to CDC interim guidance, causing confusion.
- Eliminate pre-authorization requirements for anti-viral drugs. Antivirals must be administered shortly after infection is diagnosed, particularly in immunosuppressed patients with kidney diseases. Pre-authorization requirements can delay treatment beyond the effective treatment window.

- Deploy single dose vials of COVID-19 vaccines to continue disbursement of the vaccine in dialysis facilities. Dialysis facilities need an efficient way to disperse COVID-19 vaccines. Current multi-dose vials often result in unused doses, causing waste and increased cost.
- Assure continued access to large-scale COVID-19 testing for dialysis facilities and transplant centers. This immunocompromised population must continue to have easy access to COVID-19 tests to remain safe and receive timely lifesaving treatment.

In thanking the Biden-Harris Administration for making vaccines available to Americans with kidney failure in their dialysis facilities during the public health emergency (PHE), ASN also appreciates the many other steps the federal government undertook for the health of the nation during the PHE. However, when the PHE ends in May 2023, there will be changes in health insurance coverage affecting availability of and access to vaccines, diagnostic tests, and treatments for COVID-19. When funding for COVID-19 diagnostics and therapeutics is exhausted, the risks for Americans with kidney diseases will be great.

Beyond their compromised immune systems, a disproportionate share of these individuals are from historically marginalized communities. The pandemic has caused loss of employment or housing, disruption of educational systems, and increased rates of food insecurity. These challenges are felt disproportionately in historically marginalized communities with limited social and economic reserves. The end of the PHE threatens to widen these disparities unless urgent action is taken to mitigate these anticipated untoward consequences that threaten to exacerbate underlying inequities.

These Americans often do not have secondary insurance coverage and, therefore, may be subject to co-pays and deductibles for vaccines (once the allotment purchased by the federal government is exhausted), diagnostic testing, and therapeutics. Vaccines recommended by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) are a covered preventive health service for most insurance plans. However, COVID-19 vaccinations are not currently recommended by ACIP.

Americans with commercial plans—including Medicare Advantage plans (which now represent approximately 50 percent of dialysis patients)—will likely face increased prior authorization from those plans before they can receive treatment for COVID-19 through anti-viral therapeutics. Prior authorizations are resource intensive, creating a further barrier for this population. Prior authorizations require time that is not available to patients requiring treatment for COVID-19, since treatment must begin within five to seven days of symptom onset. This timing means that patients may be effectively denied appropriate care. Notably, certain anti-viral therapeutics are the only line of defense against COVID-19 available to many immunosuppressed populations, such as kidney transplant recipients.

For those Americans with state-based Medicaid insurance coverage, notably many children with kidney diseases, wide variations in coverage exist for costs related to COVID-19. These variations are likely to increase after September 30, 2024, when states will be able to choose to end PHE Medicaid flexibilities, including the number of individuals served, provider qualifications, and access to free over-the-counter COVID-19 tests^{iv}.

ASN's members, leadership, staff, and I urge the Biden-Harris Administration policymakers to adapt these four recommendations on behalf of the 37 million Americans with kidney diseases.

Again, thank you for your leadership during the COVID-19 pandemic. To discuss this letter further, please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org.

Sincerely,



Michelle A. Josephson, MD, FASN
President

CC:

The Honorable Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329-4027

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20933

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

ⁱ Silberzweig, J, Bhat, JG, Dittrich, M, Druvasula, R, Guillain, J, Himes, J, Johnson, D, Schiller, B, Spech, R, Spry, L, Walker G, Watnick, S, Yee, J and Freedman, B, "Collaboration between dialysis providers." *JASN* 2022; 33(8): 1440-1444.

ⁱⁱ Silberzweig, J, Wu, S, Sinclair, M, Watson, T, Welder, N, Concepcion, D, Yee, J, Speed, F, Cukor, D, Schiller, B and Weiner, D, "Response to COVID-19: The outpatient dialysis setting." *CJASN*, 2023.

ⁱⁱⁱ Vinson AJ, Agarwal G, Dai R, Anzalone AJ, Lee SB, French E, et al. COVID-19 in Solid Organ Transplantation: Results of the National COVID Cohort Collaborative. *Transplant Direct*. 2021;7(11):e775

^{iv} *Ibid*