



Alex M. Azar, II, JD  
Secretary, Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

March 19, 2020

Dear Secretary Azar,

On behalf of the American Society of Nephrology (ASN), thank you for your leadership advancing the care of the 37 million Americans with kidney diseases. The society is grateful for your efforts to improve the health and safety of these Americans, and more recently, is appreciative of your efforts to address the spread of the novel coronavirus and COVID-19. People with kidney diseases—particularly the approximately 500,000 on dialysis and 222,000 with kidney transplants—are among the most vulnerable to COVID-19, and ASN is focused on ensuring the highest quality of care for them in the context of the coronavirus outbreak.

ASN recognizes the COVID-19 situation is evolving quickly, and we are grateful for the information and resources the administration has provided to educate and support health professionals. Working closely with the Centers for Disease Control and Prevention (CDC), the society is diligently sharing this information and guidance with the ASN membership, and the nephrology community in general, on a daily basis and will continue to do so. ASN has also identified several additional actions we believe are also necessary to continue to optimize the care and safety of kidney patients and health professionals. This letter delineates these additional actions.

ASN commends President Trump's declaration of a national emergency on Friday, March 13, and appreciates the continued announcements from Vice President Pence and numerous leaders within the administration regarding the status of public-private efforts to address the situation. The emergency declaration is particularly promising because it opens the possibility of issuing Status 1135 waivers, which ASN believes is a crucial step for the administration to take at this time. The society urges you to take additional action—including issuing 1135 waivers—to support those with kidney disease and enable the healthcare system to respond optimally to the COVID-19 outbreak. The ASN leadership, staff, and more than 22,000 members stand ready to assist the administration in any way possible with this effort.

In summary, ASN recommends that the administration:

- Establish flexibility to improve the safety of and access to dialysis care by rapidly bringing new outpatient dialysis units online and re-designating certain inpatient units to allow outpatient dialysis.
- Expand access to care via telehealth by temporarily:
  - Permitting telephonic interactions when video, two-way technology is not available (and count towards reimbursement).

- Adding codes for the care of patients with chronic kidney disease, on in-center dialysis, and awaiting kidney transplant or donation to the list of Medicare-approved telehealth services.
- Encourage that health professionals temporarily be allowed to provide care across state lines regardless of state-based certification via telehealth or in-person.
- Increase the supply of, and prioritize access to, testing kits for dialysis patients and transplant care.
- Pause Quality Assessment and Performance Improvement (QAPI) requirements mandating that home patients go into dialysis units for routine testing and suspend QAPI reporting requirements on a temporary basis.
- Issue immediate guidance addressing the continuation of regular medication regimens, such as angiotensin-converting-enzyme inhibitors (ACEis) and angiotensin II receptor blockers (ARBs), for COVID-19 patients.
- Pursue innovative technology solutions, now and in the future.
- Issue 1135 waivers as necessary to enable to above actions.

**Establish flexibility to improve the safety of and access to dialysis care:** As noted, patients on dialysis are particularly susceptible to COVID-19. Accordingly, extra caution to ensure their safety, and the safety of the health professionals caring for them, is imperative. Dialysis units not currently licensed as outpatient dialysis units (for example, units that are currently designated as inpatient units) could be optimal pls to dialyze a cohort of possible COVID-19 patients away from patients with no symptoms of COVID-19—especially as the testing kit shortage remains a challenge.

ASN recommends establishing temporary regulatory flexibility to skip the current designation and certification steps to make this possible. Other flexibility, such as opening new dialysis facilities for patient care that are functionally ready but have not yet been certified for operation by the Medicare Program, would help ensure patient and health professional safety and reduce the likelihood of further spread of COVID-19.

Additionally, ASN encourages CMS to examine ways to expand financial support for care partners supporting patients transitioning to home dialysis or who are already on home dialysis (including family members, nurses, home health aides, etc.). Care partners can be critical to success when patients make the transition to home, as well as to help them stay at home long-term, but at present the system offers too little support for this vital role. Besides the well-documented quality of life and outcomes benefits of home dialysis, the more patients who are dialyzing at home during a pandemic like COVID-19, the less they are exposed to the virus or putting strain on the brick-and-mortar healthcare infrastructure. Expanding financial support for care team members would enable more patients to go home and stay at home, making the nation's dialysis infrastructure overall more resilient in future emergencies.

**Expand access to care via telehealth:** ASN thanks the Trump Administration for the bold steps it has already taken this week to expand telehealth options for patients and clinicians. As the number of suspected and confirmed COVID-19 cases grows, the traditional healthcare system will become increasingly challenged to meet demand in a safe and efficient manner. Patients with kidney diseases are likely to be disproportionately represented amongst these



suspected and confirmed cases. To maximize capacity as well as ensure patient safety, ASN urges the administration to permit the broadest possible use of telehealth on a temporary basis during the COVID-19 outbreak.

ASN recognizes that permanent changes to telehealth use would require statutory changes to section 1834(m). However, ASN encourages the administration to utilize the president's emergency declaration to create the greatest number of options for health professionals and patients especially for those without access to video, two-way technology. Home dialysis patients are already permitted to communicate with their nephrologist through telehealth for purposes of the monthly capitated payment (MCP) visit, regardless of location or geography, should they choose. However, many of the individuals who are eligible do not currently have the complete technology to enable two-way, synchronous video communication.

ASN recommends that the rule to utilize two-way, synchronous video communication be temporarily relaxed, allowing patients to communicate telephonically with physicians (and allowing physicians to be reimbursed for this care).

Additionally, ASN encourages that all patients on dialysis temporarily be permitted the option to interact with their nephrologist for purposes of the MCP during the COVID-19 outbreak (recognizing those who dialyze in-center will still have to go in-center to obtain dialysis care), including waiving the requirement that they do one face-to-face visit per month for the in-center hemodialysis MCP and instead can conduct that visit via telehealth.

ASN also recommends CMS temporarily remove the requirement that home dialysis patients and their nephrologists meet in-person, face-to-face visits one out of every three-months and remove the requirement mandating three months of face-to-face visits post initiation of home dialysis for telehealth, during the crisis for home dialysis patients.

Besides the MCP, ASN urges CMS to temporarily add the E/M codes for care of patients with advanced chronic kidney disease as well as pre-transplant workup, post-transplant care, and living donor evaluation to the list of Medicare-approved telehealth services. The care needs of patients with chronic kidney disease, who are poised to receive a transplant, who recently received a transplant, or who are poised to donate a kidney, will not diminish despite the spread of COVID-19. Permitting these patients, donors, and their care teams the option to interact via telehealth will ensure continuity of care, minimize unnecessary exposure to COVID-19 in brick-and-mortar healthcare environments, and ease the strain on the health system infrastructure as more patients with COVID-19 overwhelm facilities.

ASN also thanks the administration for guidance stating that health professionals are allowed to provide care via telehealth across state lines during the COVID-19 outbreak, which some state licensing requirements currently prohibit. The society also recommends that health professionals be able to provide care across state lines in-person, regardless of whether they are licensed in that state, during the COVID-19 outbreak. While the federal government may not be in a position to override state law, sending an unequivocal signal that temporarily easing state licensing requirements would emphasize that the administration is doing everything possible to help patients, their health professionals, and the public health during this unique moment in



history. Creating this flexibility will help ease strain on the healthcare system created by the influx of COVID-19 patients at brick-and-mortar institutions and assist health professionals who are overburdened or themselves infected.

**Increase the supply of, and prioritize access to, testing kits for dialysis patients and transplant care:** ASN is encouraged by the announcement that ADM Brett P. Giroir, MD, will lead efforts to expand COVID-19 testing and form a broad public-private partnership to improve and hasten access to testing, regardless of geographic location. The society strongly supports these and all other efforts to accelerate testing kit production and patient access. Despite the administration's efforts, at this time, the shortage of testing kits remains a challenge.

People on dialysis are particularly at-risk for contracting COVID-19. Dialysis patients depend on receiving dialysis therapy (the majority of patients receive it thrice-weekly in an outpatient dialysis center), have an associated risk of being exposed to COVID-19 or exposing patients and healthcare professionals if they have contracted the virus, and have compromised immune systems. Until the important steps the administration is taking to ameliorate the testing kit shortage take full effect, ASN recommends that dialysis patients who have COVID-19 symptoms be given priority status for testing and urges the administration to issue guidance or recommendations along these lines.

Transplant candidates and donors also have unique and important COVID-19 testing needs. Ideally, *all candidates* should be tested pre-transplant surgery to ensure they are not positive for COVID-19 as they prepare to initiate an immunosuppressive drug regimen. Additionally, *all* deceased donors should be tested to ensure no COVID-19 positive organs are transplanted into immunosuppressed patients (tests specifically designed for deceased donors are available), and *every* living donor be screened before donation. ASN recommends that transplant patients and donors be given priority access to currently available tests and urges the administration to issue guidance or recommendations along these lines.

Similar to the challenges presented by the present shortage of testing kits, the lack of sufficient personal protective equipment (PPEs) is a challenge for all healthcare professionals, but particularly for those caring for patients on dialysis. PPE production should be accelerated if at all possible and health professionals as well as care partners serving dialysis patients be given priority status—ideally conveyed through guidance from the administration—to access the PPE supplies that do exist.

**Pause QAPI requirements mandating that home patients go into dialysis units for routine testing:** At present, home dialysis patients must travel to an in-center unit once a month for routine testing and assessment. ASN is concerned about unnecessary patient exposure to COVID-19 that would come with patients leaving home to travel to places where gatherings of 10 or more people take place (such as most dialysis units) as well as non-essential demands on healthcare professionals. Because the lab tests that are done are not essential to patient survival, ASN recommends that the administration waive the requirement that dialysis facilities must conduct these tests on home dialysis patients until the COVID-19 outbreak has been brought under control.



Additionally, ASN recommends that the administration suspend QAPI reporting requirements in order to allow staff to spend their time in direct patient care, particularly with the complex care requirements of COVID-19 care.

**Issue immediate guidance addressing the continuation ARBs and ACEis:** There has been concerning misinformation online regarding speculation of a possible connection between certain medications, such as angiotensin-converting-enzyme inhibitors (ACEis) and angiotensin II receptor blockers (ARBs), and COVID-19. While a possible connection between ACEis/ARBs and COVID-19 is still being assessed by the international research community, there is no current evidence to suggest that such a connection exists, and adherence to these medications is critical for the health of patients for which they are prescribed.

We ask that the federal government issue immediate guidance that, in the absence of compelling clinical data in humans to show that ACEis/ARBs either improve or worsen susceptibility to COVID-19 infection or affect the outcomes of those infected, it is strongly recommend that the routine use of ACEis/ARBs as prescribed by a physician should continue and should not be influenced by concerns about COVID-19 infection.

**Pursue innovative technology solutions, now and in the future:** In addition to the above recommendations, ASN has identified a suite of unmet technology and product development gaps, the society believes would greatly enhance health professionals' ability to address the spread of COVID-19, listed below. The KidneyX Steering Committee is actively discussing how KidneyX (a public-private partnership between HHS and ASN) can assist or partner to bring forward the necessary technology. ASN is also engaging with other stakeholders in the private sector to explore avenues to advance possible solutions.

ASN believes that both rapid-cycle, short-term opportunities exist for innovation to support patients and health professionals during the COVID-19 pandemic, as well as longer-term opportunities to enhance our nation's capacity to meet the unique needs of kidney patients in future emergency situations. Preventing the need for dialysis altogether and helping more patients with kidney failure obtain a kidney transplant, dialyze at home, or access a novel technology, such as an artificial kidney, will make America more resilient in the future. ASN recommends that both the private and public sector commence work on developing the following:

- **Novel "molecular point-of-care" testing kits** that reveal test results immediately (similar to flu) and can be easily administered and developed quickly for broad distribution; as discussed, the testing kit shortage is particularly problematic for the vulnerable dialysis patient population. The administration's effort to swiftly tackle this challenge in partnership with the private sector, led by ADM Giroir, is a major advancement towards this objective.

The need for novel testing kits is particularly relevant for patients on in-center hemodialysis. Many dialysis unit staff do not have the training/skills to properly administer the deep respiratory culture necessary for traditional reverse-transcriptase polymerase chain reaction (RT-PCR) COVID-19 testing, which may result in inadequate



samples that lead to false negative results, significant delays in patients getting access to proper testing, and the unnecessary exposure of additional patients and staff to possible COVID-19.

However, we also seek to avoid having to send all dialysis patients with flu-like symptoms to the emergency room, which itself carries exposure risks and creates additional burden on the patient and the healthcare system. The development of a molecular point of care test, for example, would enable testing in the dialysis units that is significantly faster and safer than the current test. While a molecular point of care test may slightly increase the risk of error in the analytic phase of testing, the ability to quickly administer a test with minimal infrastructure and triage patients- such as when a kidney patient is waiting in their car outside of a dialysis unit - would outweigh this risk.

As mentioned above, the urgent need to minimize exposure of kidney patients receiving dialysis to COVID-19 is such that the prioritization of tests that can quickly be brought to market is of paramount importance, regardless of the specific testing platform. This includes the utilization of existing tests and testing protocols that may have increased rates of false positives: in a setting where missing cases is much more concerning than identifying too many cases, ASN believes that tradeoff is a small price to pay. The society applauds the administration's decision to allow local public health labs and academic centers to develop their own tests, and efforts to engage the private sector in the development and deployment of novel COVID-19 tests. ASN encourages the administration to do everything possible to ensure the appropriate resources and inputs are available to support this work.

- **Infection prevention** capabilities (that need to be continually evaluated and updated based on the changing landscape from COVID-19). For instance:
  - **New mask** designed to replace the N95 to offer health professionals protection without the need to fit test.
  - **Portable isolation pods** for use in dialysis facilities to reduce the spread of COVID-19 from infected patients to non-infected patients (and staff) in the dialysis unit, which is a major concern at present.
  - **Anti-fog face shield** to address the fact that the masks that health professionals currently use fog rapidly, making performance of basic patient care tasks cumbersome and inefficient.
- **Data collection** system that captures pertinent data from electronic medical records (EMR) [protocol or standard operating procedure] of kidney patients with COVID-19. ASN is partnering with dialysis companies to collect and ultimately analyze COVID-19-related data for dialysis patients. The American Medical Association's creation of a CPT code for COVID-19 reporting, as well as the CMS Interoperability and Patient Access Proposed Rule, may also help facilitate this goal.

Again, thank you. ASN appreciates your and the administration's leadership on behalf of kidney patients, and in addressing the COVID-19 outbreak, and the society hopes that the



recommendations included in this letter are helpful. If you have any questions, or if ASN can offer any further information or assistance, please contact ASN Director of Policy and Government Affairs Rachel N. Meyer at [rmeyer@asn-online.org](mailto:rmeyer@asn-online.org) or 202-640-4659.

Sincerely,

A handwritten signature in black ink, appearing to read "Anupam Agarwal", with a long horizontal line extending to the right.

Anupam Agarwal, MD, FASN  
President

CC: Eric D. Hargan, JD, Deputy Secretary, Department of Health and Human Services  
Seema Verma, Administrator, Centers for Medicare and Medicaid Services  
Robert R. Redfield, MD, Centers for Disease Control and Prevention  
Ambassador Deborah L. Birx, MD, Coronavirus Response Coordinator  
ADM Brett P. Giroir, MD, Assistant Secretary, Department of Health and Human Services  
Jim Parker, Senior Advisor to the Secretary, Department of Health and Human Services  
Nicholas Uehlecke, Advisor to the Secretary, Department of Health and Human Services