The Honorable Alex M. Azar, II  
Secretary  
Department of Health and Human Services Centers for Medicare & Medicaid Services  
200 Independence Avenue  
Washington, DC 20201

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
SW 7500 Security Boulevard  
Baltimore, MD 21244

September 9, 2019

Re: Comments on the Proposed Rule in CMS/CMMI-5527-P Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures and the Executive Order on Advancing American Kidney Health, July 10, 2019

Dear Secretary Azar and Ms. Verma:

Home Dialyzors United (HDU) is pleased to have the opportunity to comment on the Health and Human Services and Centers for Medicare and Medicaid Services (CMS/CMMI) notice of proposed rule entitled “Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures” published in the Federal Register on July 18, 2019. This proposed rule includes provisions based on an Executive Order, signed by the President on July 10, 2019. HDU was proud to be included at that historic event. We have been a proponent of home dialysis for over ten years, and to see the benefits of home dialysis recognized by the President of the United States was an incredible experience. HDU applauds the Administration’s commitment to the 37 million patients with chronic kidney disease (CKD) and the more than 726,000 with end stage renal disease (ESRD) on dialysis. The success of any demonstration models depends on balancing incentives for doctors and dialysis facilities; to provide home dialysis treatment where appropriate; provide adequate support to those patients who perform in home treatments; and minimize the unintended consequences for existing dialysis patients of any proposed changes to the current treatment models.

As always, HDU stands ready to work with the Administration towards final design and implementation of its plans. To that end, we offer the following comments as the Administration continues to improve the model of care for kidney patients.

The Executive Order mandated:

Sec. 1 Purpose. The Administration is dedicated to advancing American kidney health. The state
of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

HDU supports CMS/CMMI in its efforts, first and foremost, to improve the patient’s ability to access the highest quality of dialysis therapy, and to preserve the ability of nephrologists to provide, and patients to receive, individualized care. HDU believes it is critical that home hemodialysis (HHD) be supported as a treatment modality, both because of data supporting improved long-term outcomes, and because of the growing burden of dialysis on the CMS/CMMI budget. Despite studies showing that long-term outcomes on HHD can be equal to or better than deceased donor transplants, we know that HHD has grown to less than 2% of the total dialysis population during the last 10 years.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. Currently, only 11.6 percent of dialysis patients receive treatment at home. Since only a little over 11% of all patients receive a home dialysis therapy and less than 2% of those patients receive home hemodialysis, this modality is clearly underutilized and falls short of meeting the congressional mandate. HDU wants to thank the President, HHS and CMS/CMMI (hereafter referred to as CMS/CMMI) for recognizing the benefits of home dialysis, and at the same time, caution you that moving patients home is NOT about achieving numbers, but about improving the health and quality of life of those patients.

HDU is pleased that this proposed rule contains a vision for the evolution of dialysis delivery with respect to home dialysis and transplants and remains committed to working with CMS/CMMI to achieve that vision.

Sec. 2. Policy. It is the policy of the United States to:

(a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;

HDU recognizes that too many patients with undiagnosed CKD advance needlessly to ESRD and commends CMS/CMMI on advancing patient education and awareness of early detection. This needs to be expanded to include general practice, internal and pediatric practitioners. CKD awareness is needed at all levels of patient care. Detection is simple and inexpensive but ignoring it is costly and

2 United States Renal Data System (USRDS), 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States.
leads to unnecessary and often avoidable CKD progression.

As CMS/CMMI strive to improve the quality and efficiency of dialysis care in the Medicare ESRD Program by reflecting a broader Administration-wide strategy to relieve regulatory burdens for providers, HDU cautions that they also support the patient-doctor relationship in healthcare, and promote transparency, flexibility, and innovation in the delivery of care. While HDU applauds CMS/CMMI in its commitment to, in theory, transform the healthcare delivery system, we caution you to set realistic and achievable expectations and goals. HDU has consistently advocated for the majority of patients receive the benefits of home dialysis, but for reasons stated below, we feel that setting a goal of 80% by 2025 is not only unrealistic, but places patients at risk of being moved to the home dialysis setting without the proper infrastructure and support in place for them to succeed.

(b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and

Section 1861(ggg)(1)(A) of the Act, establishes that in order for the KDE services to be covered by Medicare, the services must be furnished to an individual with Stage IV CKD, who, according to accepted clinical guidelines, will require dialysis or a kidney transplant. However, all other stages of CKD are ineligible for KDE; perhaps most problematic is the fact that Stage V CKD patients are ineligible and these are the patients closest to needing dialysis or transplant. CKD V patients have an urgent need for KDE as they are likely to start dialysis imminently, and CMS/CMMI should encourage CMMI to allow Stage V patients to receive KDE under the CEC Model.

HDU also encourages CMS/CMMI to be diligent and continue seeking and removing the remaining barriers to patient access to home dialysis treatments. Among these barriers, HDU believes extending the pre-dialysis Kidney Disease Education (KDE) beyond Stage 4 CKD patients, as it is imperative to ensure that all patients are fully cognizant of their dialysis choices while still healthy enough to properly evaluate and choose a modality choice that bests fit their lifestyle.

Further, CMS/CMMI must encourage and allow for the dialysis treatment to fit the patient, and not the one-size-fits all treatments that are currently promoted. This will become critically important as clinics move more patients home. The need for a customized treatment program, anywhere from 1-7 days per week, for anywhere from 2-8 hours should be patient driven, and not protocol driven. For home patients to succeed, they must see and feel the benefits of their treatments. For some this may mean every other night dialysis of 6-8 hours, others may only need 2.5 hours 5x per week; some need less, others need more. Just like any medication, like insulin for example, dialysis needs to be properly dosed and titrated. Home patients are not going to do the work, if they don’t feel better. Eric Weinhandl, et al, addressed this recently:

3 74 Fed. Reg. at 61896 (Nov. 25, 2009) (Defining Stage IV CKD as kidney damage with a severe decrease in glomerular filtration rate (GFR) quantitatively defined by a GFR value of 15-29 ml/min/1.73 m2, using the Modification of Diet in Renal Disease (MDRD) Study formula).
Get the prescription right for the individual patient. Treatment frequency, session duration and dialysate volume were prescribed based on a holistic assessment of the patient’s clinical needs and lifestyle. HHD prescriptions were adjusted using the NxStage Dosing Calculator as a patient’s clinical and lifestyle needs changed.⁴

CMS/CMMI must insure, in their payment models, that they allow for variation, frequency and amount of dialysis, per physician prescription. When the Medicare Administrative Contractors (MACs) tried to restrict payment for dialysis treatments to 3x per week, the extent of the patient pushback overwhelmed CMS, and the proposals were all but abandoned by the majority of MAC’s. Patients want a treatment that works for them, whether that be 1x per week or 7. No one does more dialysis because they want to; they do it because they feel healthier. Any payment model must NOT place restrictions on the physician prescription for appropriate dialysis treatment.

While HDU’s mission is to create an extraordinary quality of life for the home dialysis community, we would not be fulfilling that mission if we did not support innovation in renal replacement therapy. To that end, we support many current research projects by providing the patient perspective during their research and development. One such partnership is with The Kidney Project, at UCSF and Vanderbilt, who are developing an implantable kidney for renal replacement therapy. Of grave concern is that no pathway exists for a) funding this type of innovation, and b) adding these new devices to the bundle.

In the absence of guidance and clarity concerning reimbursement pathways, investors and industry are understandably wary of investing in the development of new devices for patients. Companies with existing products in this space that are not currently in use in the United States, but are used elsewhere, also experience confusion regarding how to bring these products to Americans with kidney failure. For example, Redsense manufactures a blood leak detector, specific to the home dialysis community. This valuable tool alerts a patient to a potentially fatal venous blood leak, and yet CMS/CMMI has no reimburse pathway for clinics to use this device in home patients. Redsense currently has the next-stage device in testing, abroad, which will not just detect the leak, but stop the blood pump, thus potentially saving lives, and providing an additional level of security to home dialysis patients. Yet they have no pathway for reimbursement for their device once they receive FDA approval.

In each case, patients are potentially deprived of access, whether today or in the future, to devices that could improve their quality of life or longevity. Additionally, this lack of competition drives the cost of dialysis up, and quality of therapies down.

HDU joins other groups in urging relevant policymakers to prioritize the development of a clear pathway to add new devices to the bundle. Similar to our view concerning the addition of new drugs to the bundle, HDU feels strongly that new money must be made available to appropriately reflect the

cost of new devices added to the bundle.

(c) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

Since HDU’s mission is to inform, inspire and advocate for an extraordinary quality of life for the home dialysis community, we will leave the comments on the transplant system to organizations that are far more qualified to do so. HDU does however support any initiative that increases access to kidney transplants and improves the care and support of living donors, who selflessly donate life-saving organs, and yet receive little or no protection from job loss and insurance discrimination.

Sec. 3. Announcing an Awareness Initiative on Kidney and Related Diseases.
Within 120 days of the date of this order, the Secretary of Health and Human Services (Secretary) shall launch an awareness initiative at the Department of Health and Human Services (Department) to aid the Secretary’s efforts to educate patients and support programs that promote kidney disease awareness. The initiative shall develop proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease; to improve kidney transplantation; and to share information with patients and providers to enhance awareness of the causes and consequences of kidney disease.

While HDU is not a research organization, we believe that patient education is key to the successful management of CKD and ESRD. Research has shown that patients who received CKD education were more likely to choose home dialysis. To that end, we address the ability to share information with patients. Over the years, in collaboration with the Medical Education Institute (MEI), HDU has developed a series of patient education programs, designed to help patients choose a dialysis treatment modality that works for them, at that specific moment in time. Studies show that lobby days, chairside visits in center, and clinic run patient education programs do not work. Why? Because a clinic is not conducive to making life-altering decisions. Entering a dialysis clinic, whether for the first time or the 100th, is a traumatizing event and patients can’t learn, absorb knowledge, or make decisions when they are overwhelmed with fear.

HDU and MEI have developed a curriculum which we have launched around the country, in conjunction with the ESRD Networks. With the collection of pre/post meeting data, we hope to substantiate by the end of 2020, and the completion of at least 15 patient education meetings, that our curriculum is successful in providing patients with the information they need to make a transition to a home modality and/or the transplant list. Since we have been working in collaboration with the


6 https://meiresearch.org/
ESRD Networks, to ensure that we reach ALL clinics in a given region, we would hope that CMS/CMMI might establish, through the Networks, a demonstration model that will allow us to continue this vital and important project.

One way that CMS/CMMI could support new education concepts for CKD education such as the one HDU proposes, is to not focus on who is providing the education, i.e. restricting it to clinic staff, but to pay the KDE to a vetted curriculum, more along the lines of what has made diabetic education so successful. It’s not the WHO that is important, it is the WHAT and HOW. Ultimately, it is not how fast we can move people to home dialysis, but about providing patients with the proper education, at the right time, so they can make an educated choice about what treatment is right for them. No one wants to choose any form of dialysis nor can they when they are paralyzed with fear. First and foremost, patient education must address that fear and then help patients understand which dialysis treatment modality, including the benefits of home and transplant, will best suit their life goals. We recommend the My Dialysis Choice tool in all our patient education programs, and recommend that CMS/CMMI adopt this tool in all its educational and promotional materials it disseminates, including via NEPOP, the NCC/LAN and the Networks.

Sec. 4. Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development. Within 30 days of the date of this order, the Secretary shall select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis. The selected model shall include options for flexible advance payments for nephrologists to better support their management and coordination of care for patients with kidney disease.

Sec. 5. Payment Model to Increase Home Dialysis and Kidney Transplants. Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider’s attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis and may eliminate the need for dialysis altogether for many patients.

Again, while HDU thanks the Secretary and CMS/CMMI for bringing awareness to the importance of the benefits of home dialysis, we have some concerns about the proposed initiative. First and foremost, the goal of having 80% of incident patients either dialyzing at home or receiving a transplant by 2025 is overly optimistic, and leaves patients vulnerable to becoming statistics instead of improving
their quality of care. While HDU fully supports adequate reimbursement to implement this goal, we nevertheless have concerns that providing payment incentives will result in an immediate push by the dialysis companies to maximize their profits, at the possible expense of patient care.

Not every clinic can and should deliver home based therapies. Studies have shown that the larger clinics perform better in training and retaining home patients. If home dialysis is being offered in every single dialysis facility, for the sole purpose of obtaining the add on payment, then patients will suffer. We recommend randomly selecting ESRD facilities from facilities that are already certified to provide home training and support.

This initiative also presents a nursing workforce issue. Due to many factors, including regulatory issues, there aren’t enough nurses available to be educated as home training nurses. Additionally, there are a limited number of experienced home training nurses in the U.S. today. Dialysis facilities report difficulty recruiting. Using this model to increase the number of facilities offering home dialysis would intensify competition and might encourage facilities to recruit less experienced RNs for open home training positions. Limited home training experience can reduce the RN’s ability to troubleshoot problems which could reduce home dialysis retention and adversely affect patients’ health and survival. Once again this puts the burden of care squarely on the backs of those least prepared to do so – the patient – for clinics to maximize profits. Better to support a system in which home dialysis is delivered in a subset of qualified facilities so that staff and resources can be concentrated.

Historically physicians have referred a limited number of patients for PD and/or home HD. One barrier may be their medical training in and comfort with dialysis. Only about 11% of questions on the nephrology board exam are on dialysis, ESRD complications, and medical director responsibilities under the ESRD Conditions for Coverage. Research has shown that inadequate training in home hemodialysis in medical school and postdoctoral training may adversely affect physician referral to and utilization of home hemodialysis. A survey of nephrologists found that those who said they were very well trained in dialysis at the time of certification or they had sought additional training in dialysis were significantly more likely to treat PD patients. Unless this barrier is addressed, clinicians may fall short in offering home dialysis options.

HDU recognizes and strongly encourages solo HHD. However not every patient is capable or comfortable with a solo option. Solo dialysis should be subject to patient choice and capability. Therefore, another program that HDU would like to see CMS/CMMI resurrect and support, in its move to bring patients home, is staff assisted home dialysis. Many patients that could thrive on a home dialysis treatment regime are denied the ability to do so because they simply cannot manage all of their treatment alone (solo). If it is acceptable to treat patients with trained technicians in center, HDU sees no reason why technicians can’t be utilized in the home for qualifying patients. Satellite Health Care is already employing in their home program without the appropriate compensation, and with great success, and maintains a home dialysis program of 25% or more patients. In-center self-care dialysis should be seen as a stepping-stone to home dialysis and compensated as such in the ETC.

Model.

We propose expanding the definition to read as follows:

“Dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in §494.100(a) of this part. At a minimum, a self-care patient, with the dialysis machine turned toward them should:

- Set up and take down the equipment used in the treatment
- Touch the machine during treatment and respond to alarms
- Manage access site pre- and post-treatment, with or without self-cannulation
- Take and record their own weight and vital signs.

We believe that self-dialysis in center is an important modality that increases choices for patients and serves as
1. an option for patients who don’t have a suitable home environment,
2. as a bridge to home for patients who may initially decline home dialysis,
3. as a model to transition patients who can no longer be on peritoneal dialysis and
4. to enable beneficiaries to more likely stay on home dialysis when needing respite care.

More specificity on what constitutes self-dialysis is necessary for both providers and regulators to clearly understand what does and doesn’t qualify.  

Sec. 6. Encouraging the Development of an Artificial Kidney.
Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology.

HDU was the first patient organization to partner with The Kidney Project in 2017 to promote awareness for the implantable kidney, as well as provide important feedback on risk/benefits analysis of what patients want. As recently as last week, HDU and The Kidney Project met with senior officials at HHS to discuss how to get the implantable kidney to market. Additionally, HDU has partnered with other innovative technology companies as they develop new products to bring to market, such as

8 Outset Medical letter to Secretary Azar, 9/13/2019

Diality and Outset Medical. It is critical that these innovative technologies be vetted early on by patients in order to avoid costly mistakes during research and development, only to get a product to market to discover that it is not something patients will tolerate or want. For example, the single needle developed by Medisystems, although great for patients, was not proven to be efficacious. The V-Wing, another vascular access innovation, did not catch on because patients did not want a metal implant. We applaud innovators like Outset Medical and The Kidney Project for working with patient organizations from the beginning.

Sec. 7. Increasing Utilization of Available Organs.

(a) Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.

(b) Within 180 days of the date of this order, the Secretary shall streamline and speed up kidney matching and delivery to reduce the discard rate. Removing process inefficiencies in matching and delivery that result in delayed acceptance by transplant centers will reduce the detrimental effects on organ quality of prolonged time with reduced or cut-off blood supply.

Sec. 8. Supporting Living Organ Donors.

Within 90 days of the date of this order, the Secretary shall propose a regulation to remove financial barriers to living organ donation. The regulation should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

The mission of HDU is to promote an extraordinary quality of life for the home dialysis community, however this does not preclude supporting patient’s in their transplant process. While HDU does not include transplant issues in its immediate platform, we support all of the above efforts to improve the transplant process, including increasing living donors thru better protections, and increasing the availability and usability of organs.

Conclusion

Far too many dialyzors are needlessly suffering. We cannot expect more people to opt for HHD treatments if their outcomes are or may be poor, and improvement in quality of life proves to be minimal or non-existent. Likewise, dialysis patients will NOT continue home treatments if they deem the downsides to overshadow the benefits. Therefore, resolving the specific barriers to optimal, person-centered treatment goes together with identifying the overall clinical barriers to sustaining HHD.
To date, little has been done to identify these clinical endpoints that are central to the problem of patient retention on HHD, nor to identify the causes of attrition due to technique failure, and thus limiting the clinical effectiveness of the modality. Without the appropriate infrastructure in place to address the specific clinical needs of this population, patients will continue to abandon their home therapy and return to in center at a rate of 23% or higher.

Descriptive research reveals that patients want and need more disease specific clinical knowledge to support self-care behaviors, and that lack of effective provider communication is seen as a barrier to receiving and understanding this information, and more importantly, to receiving optimal patient care in the home setting. Education and communication among all members of the patient’s care team is critical to sustaining a HHD therapy. Any improvement to the dialysis delivery model MUST include these elements.

Foremost should be the ability to stay employed, attend school, participate in family events and pursue their self-defined life goals. Unemployment in the 18-54-year-old dialysis population is close to 80%. Maintaining employment helps fulfill the original intent of the Medicare ESRD legislation and could save Medicare money and raise revenues in Social Security and Medicare through taxes if program models would promote efforts to help CKD and ESRD patients maintain or obtain employment. HDU encourages CMS/CMMI to look toward incorporating pathways to obtaining, retaining, and continuing employment in any proposed delivery model.

The overarching goal of these proposed programs should be to initiate measures which truly reflect patient centric outcomes as defined by the patient. Home dialysis, coupled with multifaceted holistic rehabilitation allows patients to live a normal life and be productive citizens, including maintaining their job or re-entering the work force. Comprehensive rehabilitation programs exist for almost every chronic condition, such as cardiac and pulmonary rehabilitation, except CKD and ESRD. Most centers also lack scheduling flexibility that permit in-center dialyzors to continue or pursue gainful employment.

While HDU is pleased that the Executive Order has resulted in an enhanced vision for the evolution of dialysis delivery, especially with respect to home dialysis, we are also pleased to note the continuing CMS/CMMI shift toward incorporating the patient voice as it establishes new rules and regulations.


We look forward to working with CMS/CMMI going forward and would be happy to provide further input to help improve quality of life for the growing ESRD population and help CMS/CMMI create a visionary program of home dialysis delivery.

HDU, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated to home dialysis. Our mission is to inspire, inform, and advocate for an extraordinary quality of life for the home dialysis community. We know from personal experience that, with the right dialysis treatment, patients with ESRD (and their families and care partners) can lead a normal life that may include employment, education, family involvement, socialization, volunteerism and leisure activities. We also know that studies have repeatedly shown that patients who dialyze at home have better treatment outcomes.

HDU currently interacts with all relevant stakeholders and has the advantage of being the “boots on the ground” patient organization for home dialyzors. HDU is the little organization that CAN! We have an educated and committed group of individuals who work tirelessly to improve home dialysis for the patients and their community across all platforms. HDU is the voice of the home dialysis patient, and that voice needs to be heard.

Respectfully,

Home Dialyzors United

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