January 31, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC, RIN-0938-AU55
P.O. Box 8010
Baltimore, MD 21244-8010

Submitted electronically to www.regulations.gov

Re: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities; RIN-0938-AU55

Administrator Brooks-LaSure:

Innovate Kidney Care (IKC) welcomes the opportunity to respond to the Request for Information (RFI) issued by the Centers for Medicare & Medicaid Services (CMS) related to End-Stage Renal Disease (ESRD) facilities, transplant programs, organ procurement organizations, and related issues. We appreciate CMS's responsiveness to IKC's advocacy encouraging the agency to gather additional information from stakeholders regarding ways to modernize the Conditions for Coverage (CfC) for ESRD facilities.[1] We support CMS's goal of incentivizing the creation of new treatments and technologies that will accelerate the adoption of home dialysis. We believe that updating the CfC regulations and guidance is critical to achieving the aims of better patient outcomes, improved patient experience, improved health care practitioner experience, lower costs of care, and a more equitable health care delivery system for all patients with kidney diseases.

IKC is a group of forward-thinking organizations that seek to improve kidney care for the more than 700,000 Americans with ESRD. We are dedicated to fostering innovation, expanding access to kidney care at home, and improving patients' options for receiving dialysis training and support. Our efforts are guided by three key goals:

- Modernizing federal regulations and guidance to keep pace with the innovations in self-care, home dialysis, and telehealth for dialysis patients;
- Expanding patient access to home dialysis and self-dialysis by removing unnecessary regulatory barriers and right-sizing regulations and guidance for home-focused providers; and
- Reducing administrative burdens on clinicians and focusing more attention toward patient outcomes, empowerment, and safety.

The CfCs have not been revised since 2008. This regulatory framework is long overdue for a refresh to keep pace with technological developments, innovation, and a changing health care

[1] Medicare and Medicaid Programs: Conditions for Coverage for End-Stage Renal Disease Facilities, 73 Fed. Reg. 20,370, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf.

landscape. Today, a single set of rules applies to all dialysis settings, with no distinction between a facility and a patient's home. This creates barriers to access for home dialysis. As CMS revises the requirements for ESRD facilities, we urge the agency to modernize its standards for coverage and prioritize patient safety and choice. With this perspective in mind, we offer the following comments to the RFI.

To summarize, our recommendations in response to the RFI are as follows. Each of these are described in greater detail below:

- Revise the definition of "dialysis facility" at 42 CFR § 494.10 to include two types of offerings: in-center dialysis facilities, and home dialysis training and support facilities.
- Eliminate inapplicable survey requirements for home dialysis and support facilities, such as the requirements related to water treatment rooms.
- Revise regulatory language to clarify that Registered Nurses (RNs) are required to oversee and participate in home training, rather than requiring that RNs conduct home training.
- Update the definition of "self-dialysis" by adding the specific functions that a person who performs self-dialysis should be able to complete, and clarify that self-dialysis patients capable of the specific self-dialysis functions listed in the updated definition do not need to be "in the view of staff" during treatment.
- Modify the training requirements for RNs, either by replacing current time-based requirements with a competency requirement, such as completion of a home training program, or allow for modality experience to be developed concurrently with nursing experience.
- Add new patient protection requirements to promote patient autonomy and expand access to home dialysis.
- Modernize telehealth regulations to:
    - Allow home dialysis patients to access their multidisciplinary care team virtually (either through audio and video or audio-only), provided that the Medical Director or a clinician maintains oversight.
        - Allow certain aspects of home dialysis training to be conducted virtually.
    - Allow for members of the multidisciplinary team, other than the RN, to conduct the pre-home dialysis visit with an RN engaged virtually as needed.
- Revise the governance requirements at 42 CFR § 494.180 to update the joint venture reporting requirements to CMS and disclosure to patients if the physician has a financial interest in the referral facility. Also urge CMS to do a detailed annual analysis of the JV information.

In addition, we offer some comments on improvements that CMS at large can make to ensure improved care transitions and outcomes for people with kidney disease

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B. Kidney Health and ESRD Facilities[2]

[2] RFI, at 68,599.

1. Background[3]

The agency indicates that it would like to learn what patient, clinician, and system factors would help patients maintain or improve their health, and what factors would help identify those at risk of developing Chronic Kidney Disease (CKD). The agency is also interested in ways to improve CKD detection rates. In addition, the Administration is interested in actions to close health equity gaps in CKD detection, education, and care.

It is clear that home dialysis offers people autonomy, which in turn allows them to pursue economic opportunities and a better quality of life. It also allows for more flexible and personalized care, including personalized ultrafiltration rates, dialysis duration, and treatment frequencies, which impact both patient clinical outcomes, symptom burden, and quality of life outcomes. In addition, studies indicate that in the initial 5 years of therapy hemodialysis conducted more frequently at home is associated with similar survival rates as transplantation, suggesting that when preemptive and living donor transplantation is not an immediately available option home dialysis can serve as a bridge to transplantation.[4]

Though home dialysis offers high-quality care and an additional option for a large majority of patients, we know that there are clear disparities, particularly in communities of color, in access to home dialysis and preemptive transplantation. Black patients are 1.5 times less likely to receive a kidney transplant or conduct dialysis at home. Hispanic Americans are also 1.2 times less likely to receive home dialysis.[5] By expanding treatment opportunities, CMS can begin to close the gaps we see today in access and health outcomes.

We believe that modernizing the CfCs aligns not only with the Administration's broader goals around health equity, but also with its goals to enhance competition. Today's kidney care market is very concentrated and dialysis care has remained largely unchanged for decades. The area of health care is ripe for innovation, and refreshing outdated requirements is one way to facilitate greater competition.

Our comments that follow contain specific recommendations for modernizing outdated coverage requirements, particularly as they pertain to increasing equitable access to home dialysis.

2. Home Dialysis[7]

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[3] RFI, at 68,599.
[4] Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. Am J Transplant. 2018;18(5):1168-1176. doi:10.1111/ajt.14702.
[5] Norton JM, Moxey-Mims MM, Eggers PW, et al. Social Determinants of Racial Disparities in CKD *JASN* (2016), 27 (9) 2576-2595; DOI: https://doi.org/10.1681/ASN.2016010027.
[6] Childers CP, Dworsky JQ, Kominski G, Maggard-Gibbons M. A Comparison of Payments to a For-profit Dialysis Firm From Government and Commercial Insurers. JAMA Intern Med. 2019;179(8):1136–1138. doi:10.1001/jamainternmed.2019.0431.
[7] RFI, at 68,600.

Under the current CfCs described in 42 CFR § 494.70(a)(7), patients have the right to be informed about all treatment modalities and settings, including home dialysis modalities, in-facility hemodialysis, transplantation, and more. However, once patients are stable on a particular modality, they are often unaware of other options or otherwise discouraged from changing modalities. Below, please find our recommendations regarding how CMS can modernize this system to improve care, transparency, and patient autonomy.

1.What are patient barriers to dialysis modality choice? How can we overcome barriers to ensure patients understand their options and have the freedom to choose their treatment modality?

It is widely accepted that home dialysis improves health and quality of life outcomes. However, today, less than 14%[8] of ESRD patients are treated by home dialysis or preemptive transplantation. This is a clear consequence of significant and unique market barriers to innovation in the kidney care space.

Outdated CfCs are one barrier to modality choice that the agency can address swiftly. Modernizing the CfCs to provide distinct regulations for Medicare certification of home dialysis programs versus facility programs is critically important. Home dialysis is not simply in-center dialysis done at home, and home programs should not be unnecessarily burdened with regulations that only make sense for in-center care, as this creates an economic disadvantage to establishing home programs outside of a conventional in-center model. Unfortunately, while clinics are required to present patients with all of their options, doing so is simply not enough to help patients truly understand the pros and cons of each option specific to their lifestyle and preferences, and there is little incentive for an in-center facility to do more than inform. Creating distinctive guidance will make it more feasible and attractive to develop home dialysis programs and will enable clinicians to become more confident in empowering their new and existing patients to consider home dialysis.

2.What are reasons for differing rates of home dialysis by race/ethnicity? How can we address any barriers and improve equity in access to home dialysis to improve equity in access to home dialysis?

There is little literature on the reasons for differing rates of home dialysis by race/ethnicity. Experts agree that barriers are related to socioeconomic status, housing conditions (including the need for sufficient space to store multiple boxes of supplies and need for landlord approval), and payment necessary for minor home modifications to connect equipment to electricity and water. Additionally, unconscious and conscious bias regarding who is a candidate for home dialysis creates selectiveness in the population that disproportionately impacts non-white patients. Non-white patients are also more likely to start dialysis urgently, and most patients who start dialysis in a hospital are immediately referred for in-center dialysis upon discharge. To solve these issues, CMS could allow for providers and home dialysis device manufacturers to pay for minor home

[8] Weinhandl ED, Gilbertson DT, Wetmore JB, Johansen KL. Recent trends in utilization of home dialysis modalities, overall and by duration of ESKD. Presented at: Kidney Week 2021, November 2-7, 2021. Abstract PO0956.

mitigations for patients. In addition, as more new machines come to market, it is imperative that manufacturers be able to train patients on how to use such machines. It is impractical to expect training nurses to know the mechanics of multiple machines.

3.With regard to home dialysis, how can CMS ensure that adequate safety standards such as appropriate infection control behaviors and techniques are enforced?

Infection control success at home is largely a matter of appropriate clinician education of patients and their care partners on prevention techniques. Initiatives such as the Making Dialysis Safer For Patients coalition have developed many useful resources for hemodialysis catheter infection prevention measures, but little has been developed to date on peritoneal dialysis (PD) infection prevention protocols. In addition, measures in the Quality Incentive Program (QIP) only measure infection reporting and events in hemodialysis patients. CMS should consider creating similar measures for PD. (Please see additional comments below on recommended changes to the QIP).

4.What can CMS do to increase availability and use of home support resources with regard to home dialysis as described in 42 CFR § 494.100(a)(3)(iv)? Given the increase in home dialysis patients, is there a need to revise the current standards § 494.100, including but not limited to updating and revising training and care delivery requirements?

Bold action from the agency is required to increase the availability and use of home dialysis. Our specific recommendations are provided below.

Revise applicable regulations to account for facility type and size. Currently, dialysis facilities are not defined to reflect differences in size and type of facility. This means that a facility primarily intended to support home dialysis is subject to the same rules, regulations, and guidance that apply to in-center dialysis facilities. The one-size-fits-all framework stunts innovation and makes it challenging for facilities of different scopes to operate within the same regulatory environment.

To better capture the range of types and sizes of centers and home programs, we propose that CMS revise the definition of "dialysis facility" at 42 CFR § 494.10 to include two types of offerings: in-center dialysis facilities, and home dialysis training and support facilities. This revision would allow CMS to differentiate requirements across provider types, rather than grouping all sites of care as a single category.

Creating this differentiation would allow greater flexibility for the agency to regulate dialysis care by setting requirements that match the site of care more appropriately and foster innovation. Enabling this differentiation in the regulatory framework will ultimately encourage greater development of these sites of care offerings, because requirements for home programs can be tailored as appropriate to ensure patient safety.

Differentiation thereby encourages the growth of home dialysis training and supports facilities to make more choices available to patients, allowing them to decide which site of care best meets their needs. For example, some patients who ultimately decide not to return home may instead desire to remain in a small care setting and conduct only the aspects

of care that they feel comfortable performing themselves. Regulatory differentiation would also encourage investment in home programs for patients who prefer to dialyze at home.

We propose that CMS update the definition of "dialysis facility" to differentiate two types of facilities/programs at 42 CFR § 494.10:

i. In-center dialysis facility means a facility that conducts traditional dialysis treatments in a clinical setting;
ii. Home dialysis training and support program means a program which provides training and support services to patients intending to self-dialyze after completing an appropriate course of training.

Create guidance specific for home dialysis and support facilities. Current regulations apply in-center regulations to home through exceptions set forth in various guidance documents, creating confusion among potential new home providers and surveyors, and resulting in discouragement to providers and delays in certification. Ambiguity in the guidance leads to policies that adopt the most stringent interpretation to avoid risk, resulting in practices that inadvertently rob patients of the largest benefits of self-care at home—patient autonomy and independence. By differentiating between facility types, as described above, CMS can modify the standards that apply to home dialysis and support programs, making the applicable requirements more appropriate to the facility type. Such changes would increase the number of patients that are able to receive high-value care in the comfort and convenience of their home.

Surveyors and facilities need regulations and guidance specific to home dialysis that allow providers the flexibility necessary to support, improve, and innovate care in the wide variety of home environments that exist. Some home programs may offer training in traditional brick-and-mortar clinics, but others may wish to create home dialysis programs within existing health care settings convenient to patients. In some countries, self- dialysis models have developed that allow for patients to conduct their own hemodialysis treatments in-home on their own schedule.[9] This should be permissible in the U.S. as long as the home location has appropriate remote monitoring, emergency response, and infection protocols in place.

Specifically, with regard to home dialysis and support facilities CMS should:

- Eliminate the survey requirements that relate to water treatment rooms.
- Allow water and equipment testing according to manufacturer instructions. Most home dialysis equipment technology does not require separate water treatment equipment. CMS has previously issued memoranda and guidance noting to test water and equipment according to the manufacturer instructions, which is appropriate as the FDA regulates water specifications to ensure that quality and safety standards are met. Therefore, all of the guidance regarding water treatment need not apply to home programs.

[9] Walker et al., "Patients' Experiences of Community House Hemodialysis: A Qualitative Study, Kidney Medicine, Volume 1, Issue 6, November–December 2019, Pages 338-346.

- Eliminate the requirement for an isolation room, as long as the facility has a backup plan for training or providing respite care at another facility with an isolation room or in the patient's home.
- Eliminate the requirement that emergency medications be stocked to reduce waste. Home dialysis and support facilities should be required only to have oxygen-O^2, antiepileptic drugs, bag valve mask (e.g., Ambu bag), airway, and suction. Given the small number and transient nature of patients coming through a home dialysis facility for back-up care, other emergency medications and equipment are unnecessary, potentially harmful if used by staff with little to no experience in their administration, and costly if unused medication expires and must be discarded.
- Allow home programs to subcontract with community-based health care settings for home patients to be able to meet with their multidisciplinary care team, as this convenience and access to care for patients will help them succeed on this modality. The home program would remain responsible for the care provided, and all patient encounters must be documented in the patient's facility medical record.

These regulations and guidance changes will create clarity for home dialysis and support facilities, giving stakeholders the confidence to invest in these types of care settings and giving providers the confidence to deploy these new options for their patients.

5.If more patients choose home dialysis, would there be systems and infrastructure in place to support this? Were more patients to choose home dialysis, what other supports, systems, or infrastructure might be necessary?

Yes, if more patients choose home dialysis, stakeholders can rapidly deploy the systems and infrastructure to support this choice, provided that the regulatory and subregulatory landscape keeps pace with innovation. There are steps CMS should take to further ensure that systems and the workforce are prepared to meet expanded demand. Well-trained nurses and nephrologists are critical to initiate and maintain patients on home modalities.

When nephrologists are surveyed, 94% would prefer either PD or Home hemodialysis (HHD) for themselves.[10] Nephrology nurses show similar preferences. This discordance between nephrologists' personal preferences for home treatment and the in-center hemodialysis modality most commonly used by patients can in part be explained by training experience. In one study, 87% of nephrology fellowship program directors reported training in PD to be inadequate in our country and a major factor limiting PD utilization.[11]

In a survey of recently graduated nephrologists, 84% did not feel competent managing HHD patients, and 44% did not feel competent managing PD patients.[12] There is, however, evidence

[10] Merighi JR, Schatell DR, Bragg-Gresham JL, Witten B, Mehrotra R. 2012. Insights into nephrologist training, clinical practice, and dialysis choice. Hemodial Int. 16(2): 242-251.
[11] Wadhwa NK, Messina CR, Hebah NM. 2013. Does Current Nephrology Fellowship Training Affect Utilization of Peritoneal Dialysis in the United States? OJNeph 3:109-114.
[12] Berns SJ. 2010. A Survey-Based Evaluation of Self-Perceived Competency after Nephrology Fellowship Training. CJASN 5(3):490-496.

that fellows want better training. A 2016 ASN survey found that HHD and PD were the top two topics in which graduating fellows most desired additional instruction.[13] These results point to a window of opportunity to increase utilization of home therapies through more comprehensive physician education.

Leverage the skills of members of the multidisciplinary care team for home dialysis training. Current regulations require that home dialysis patient training be conducted by an RN who meets the applicable regulatory requirements.[14] We appreciate and share the agency's commitment to ensuring that patients dialyzing at home are properly trained by qualified professionals. We think this goal can be achieved with requiring RN participation and supervision over training, rather than requiring that an RN conduct all aspects of the training.

Specifically, to expand capacity for home training and support, CMS should remove the words "be conducted" from the home training CfC and instead insert language requiring that the training "have oversight and participation" by an RN. CMS also should clarify that an RN does not need to be physically present for all aspects of the training, provided that other members of the multidisciplinary care team conduct those aspects of training and that the patient is in the line of site of any RN (often a facility nurse manager) if non-RN care team members actively provide treatment during the training sessions. The home RN and nephrologist should be responsible for signing off that the trained patients are competent in self-dialysis and able to dialyze at home.

This approach will ensure safety and quality for patients and support RNs involved in ESRD treatment and training—helping to combat some of the burnout these professionals face. Patients will benefit from stronger relationships with the multidisciplinary care team, a goal that CMS has also articulated. This minor clarification will help to reinforce that sentiment while promoting CMS's goal of improving both the patient and practitioner experience.

Empower independence for dialysis patients. Self-dialysis in-center can be a meaningful pathway to independence for patients who seek to eventually dialyze at home but are not yet ready to do so. It can also provide an alternative for patients who have trained for self-dialysis but ultimately decide not to dialyze at home. Today, rigid definitions and interpretations of requirements serve as barriers to self-dialysis in the U.S. We recommend that CMS modernize the requirements related to patients engaged in in-center self-care.

Specifically, CMS should add to the definition of "self-dialysis" to empower patients to be engaged in activities related to their dialysis care such that they can become more independent over time. We propose that CMS update the definition of "self-dialysis" by adding the specific functions a person who performs self-dialysis should be able to complete. The new language is shown below in italics.

42 CFR § 494.100 Definitions

[13] Rope R, Pivert K, Parker MG, Sozio S, Merrell SB. 2017. Education in Nephrology Fellowship: A Survey-Based Needs Assessment. J Am Soc Nephrol. 28(7): 1983–1990.
[14] 42 CFR § 494.100(a)(2).

> Self-dialysis means 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 person who performs self-dialysis should:*
>
> *i. Have the machine set up for favorable orientation toward the patient;*
> *ii. Be able to set up the equipment required for treatment;*
> *iii. Be allowed to touch the machine during treatment and respond to alarms;*
> *iv. Be able to manage the access site pre- and post-treatment, with or without self-cannulation; and*
> *v. Be able to take and record their own weight and vital signs, as relevant.*

Once the patient can perform self-dialysis pursuant to this new definition, CMS should clarify that self-dialysis patients do not need to be "in the view of staff" during treatment.[15] CMS standards do not distinguish between trained in-center self-care patients and patients that are largely dependent on clinical staff to deliver their treatment. CMS standards currently require ESRD patients who are conducting in-center self-care to be in the line of sight of an RN, even when the patient is fully trained in self-dialysis. This creates an unnecessary burden for patients, who must schedule times for availability when they can be within the line of sight of an RN. This dynamic can make it difficult for patients to manage care on top of other important, competing demands, including professional and personal responsibilities. In addition, home dialysis training and support programs should be permitted to allow patients to conduct self-dialysis in a clinic certified as a home training and support program without having to seek separate certification as an in-center dialysis facility.

Modify the requirements for home training RNs. Today, CMS requires that the nurse responsible for overseeing self-care and/or home care training must be an RN and must have at least 12 months experience providing nursing care and an additional three months of experience in the specific modality for which the nurse will provide self-care training.[16] Given the strains on the nursing workforce and the increased demand for home dialysis and self-care, we recommend that CMS consider replacing the time-based requirement with a competency-based requirement (such as completion of a home RN training program deemed appropriate by the Medical Director of the facility, as is required for patient care technician competency) or allow for modality experience to be developed concurrently with the 12 months of nursing experience, i.e., the 12 months of nursing experience inclusive of the three months of modality experience. Modifying these criteria will likely result in an increased number of specialized dialysis nurses, helping to address the ongoing and challenging reality of personnel shortages.

Encourage classroom-style training. Some of the training on the machine and basics of dialysis can be done in a classroom-style learning setting. Today most training is done while the patient is dialyzing, which can be burdensome. This change would increase capacity and decrease RN and patient fatigue experienced during current training sessions. While classroom-style training should not be a required training model, the guidance documents should allow for flexibility in training models.

[15] 42 CFR § 494.60.
[16] 42 CFR § 494.140(b)(2).

Increase patient protections. In anticipation of more patients choosing home dialysis, CMS should ensure that certain supports, systems, and standards are in place to promote patients' autonomy and to increase care and financial protections. Specifically, CMS should work to ensure the following:

- Patients receiving dialysis at home should have the right to discuss their treatment with the multidisciplinary care team in person or via teleconference according to their preference.
- Patients should not be charged a fee for accessing a copy of their medical record.
- Patients receiving dialysis at home should have the ability to choose whether to participate in initial and annual care planning with the multidisciplinary care team at home via teleconference (via audio and video or audio-only communication) or face-to-face in the clinic.
- If the patient chooses, and if permitted according to the FDA's labeling of the medications, self-administration of medications at home should be permitted (including by a care partner).
- Clinic policies should not prohibit home patients from dialyzing on specific days of the week (i.e., Sundays), and clinics should be prohibited from unduly restricting hours for patients to dialyze at home (with appropriate remote monitoring, emergency response, and infection protocols in place)
- The name of the facility's Medical Director responsible for ensuring the quality of care in the in-center facilities and home programs should be posted prominently in the clinic, and this information should be available on CMS's Dialysis Facility Compare website.

These measures will help to support and empower patients who choose home dialysis and will convey the benefits and feasibility of home care.

6.To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection and uptake of home dialysis as a modality? What are best practices in this area that would facilitate the delivery of safe and quality care?

We strongly support the use of telehealth and remote monitoring technology and believe that additional flexibilities should be allowed for dialysis. Telehealth access is a natural complement and advantage for patients who choose home dialysis.

Allow dialysis patients to access their care team via telehealth. CMS should specify that members of the multidisciplinary care team can provide services virtually, so long as a Medical Director maintains oversight. This would enable nurses, social workers, dietitians, and other care team members to provide services via telehealth and would allow patients increased flexibility to access their care team at home, while ensuring consistent quality care and essential oversight. This approach is practical and patient-friendly and promotes greater integration of the multi-disciplinary care team, thus sharing and dividing responsibilities among the most appropriately experienced and trained professionals.

Allow certain aspects of home dialysis training to be conducted via telehealth. Based on the home RN's assessment of the patient and their ability to use telehealth, CMS should allow portions of home dialysis training to be conducted virtually, with a few exceptions for portions of the training

that would not apply or that would need to be conducted in person. Such exceptions should include cannulation training and initial physical assessment. Care partners involved in the patient's treatment plan should also be permitted to engage in trainings virtually. With virtual access to training, it is important that the focus remains on the patient being the one doing as many aspects of the training as physically capable. Too often when full responsibility is delegated to a care partner, they burn out, and the dialyzor returns in-center. Therefore, we encourage a focus on the patient and care partner experience.

Allow for non-RN members of the multidisciplinary team to conduct the pre-home-dialysis visit. In some instances, a member of the multidisciplinary team may provide support services, including coordination of the home patient's care. However, the training of home dialysis patients, patient assessments, and in-center oversight largely falls to RNs. CMS should expand this scope to allow Licensed Practical Nurses or patient technicians to conduct home visits with an RN engaged virtually, as needed. Expanding the scope of professionals able to complete this assessment will help increase the speed at which facilities can approve patients for the self-dialysis modality of their choice and may lead to increased uptake of home dialysis options.

Allow qualified employees of home dialysis device manufacturers, who meet their state licensing requirements and the CfC staffing requirements, to train patients for home dialysis, including cannulation. Manufacturers also employ trained dialysis nurses with the requisite experience in home dialysis. Given the current nursing shortage, providers are struggling to find enough qualified nurses to establish or expand home programs, creating a backlog of patients. Home dialysis manufacturers are experienced and willing to help fill this gap. Nurses employed by a home device manufacturing company are the most knowledgeable and experienced on the device that their company manufacturers, making them uniquely suited to train patients. Manufacturers of other devices that treat chronically ill patients are already allowed to train and support patients in using the device, making ESRD an anomaly.

D. Nephrology Joint Ventures[17]

1.Would it be helpful for CMS to collect information on joint venture arrangements as part of Medicare enrollment in order to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries?

Yes, it would be helpful for the agency to collect and analyze information on joint venture arrangements. Such information is collected at Medicare enrollment but is not updated afterwards. CMS should require qualified dialysis facilities to disclose to CMS all individuals and entities with a financial interest in the facility, facility subsidiary, and/or joint venture partnerships to which it or its subsidiaries are a party, and to inform CMS of any changes. This reporting to CMS should include the national provide identification (NPI) number of such individuals, the NPI for providers that are party to such an entity, and any other changes as CMS sees fit. CMS should also commit to do a detailed analysis of the updated JV information on an annual basis.

2.Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients for improved transparency?

[17] RFI, at 68,607.

CMS should require physicians who make self-referrals to dialysis facilities where they have a financial interest to disclose this to their patients consistent with the requirements of the American Medical Association Code of Medical Ethics, Physician Self-Referral, 9.6.9, adopted in 2008.

The following suggested language captures our recommended changes related to joint ventures:

3. Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so, please describe how joint venture arrangements affect resource use, patient care, or choice of modality.

While there is some evidence to suggest that joint ventures may have an impact on patient care, resource use, and choice of modality, substantially more information is needed to fully understand the scope of the impact of these relationships.[18] CMS should analyze these arrangements to inform the answers to these questions and take action, as appropriate, to address any effect on patient access, choice, and outcomes.

Promoting Kidney Health and Safe Transitions

CMS is accountable for a significant at-risk population of kidney patients, and CMS has a unique ability to manage kidney disease across the spectrum of care. CMS comparatively across payers is accountable for the most high-expenditure, at-risk populations, and the disease burden is particularly placed on underserved and minority populations. Traditional Medicare is responsible for covering 61.4% of the ESRD population in 2019, a large majority of ESRD patients.[19] As CMS well knows, Medicare expenditures on ESRD exceed 7% of spending on fee-for-service .

The burden of CKD prevalence rates, which are approximately 25% higher in the uninsured population,[19] falls disproportionately on certain populations, particularly communities of color. For instance, African Americans comprise 13% of the U.S. population, but they represent 30% of the ESRD population. We know that access to health care directly impact CKD progression and ESRD. Additionally, research shows that states with more robust Medicaid coverage exhibit significantly lower incidence rates of kidney disease.[20] As evident, poorer access to health care contributes to CKD disproportionate burden particularly in systemically disadvantaged population.[21]

Additionally, the nature of CKD means that the condition first must be detected and classified before it can be appropriately managed. Unfortunately, CKD is underdetected. A recent study of 28 million at-risk patients found that 80.3% did not receive guideline-concordant CKD detection.[22] Studies also have found that C-SNPs achieve better outcomes by providing targeted care to address chronic conditions. Yet today, although C-SNPs serve ESRD patients, these specialized care plans

[18] *See e.g.,* Glickman A, Lin E, Berns JS. Conflicts of interest in dialysis: A barrier to policy reforms. *Semin Dial*. 2020;33(1):83-89. doi:10.1111/sdi.12848.

[19] 2021 Annual Data Report. https://adr.usrds.org/2021.

[20] Kurella-Tamura M, Goldstein BA, Hall YN, Mitani AA, Winkelmayer WC. State Medicaid Coverage, ESRD Incidence, and Access to Care. J Am Soc Nephrol. 2014;25(6):1321-1329.

[21] Evans K, Coresh J, Bash LD, et al. Race differences in access to health care and disparities in incident chronic kidney disease in the US. Nephrol Dial Transplant. 2011;26(3):899-908. doi:10.1093/ndt/gfq473.

[22] Alfego D, Ennis J, Gillespie B, et al. Chronic Kidney Disease Testing Among At-Risk Adults in the U.S. Remains Low: Real-World Evidence From a National Laboratory Database. Diabetes Care. 2021;44(9):2025-2032. doi:10.2337/dc21-0723.

are not able to serve patients who have CKD but have not yet progressed to ESRD. The care coordination offered by MA SNP plans could help patients with CKD better manage their disease and delay or even avoid progression ESRD. Therefore, we encourage CMS to expand the list of C-SNP conditions to include patients with CKD Stages 3, 4 and 5.

On the provider side, dialysis providers are incentivized to meet minimum adequacy and other clinical metrics. However, the nephrology community has become increasingly aware of patients' frustrations over a lack of focus on their desired outcomes for dialysis. Dialysis patients value reducing symptom burden, optimizing their functional status, and improving their ability to maintain their preferred lifestyle.[23,24] For example, providers commonly note difficulties reconciling a patient's defined quality of life goals with CMS's metrics required minimum adequacy. Financial incentives via measures in the ESRD QIP de-emphasize the patient's defined quality of life goals to avoid a financial penalty.

With the aligned vision of empowering patients through self-directed goals of care, flexibility must also be allowed for more progressive concepts of "adequacy standard." Clinical quality metrics derived from population health must be balanced with individual goals. Common deterrence from home dialysis include incident patients adjusting to the new demands of dialysis on their schedules, patients' desire to preserve residual renal function, and frail patients desiring to maximize time with family. However, the financial penalty of not meeting minimum "adequacy standards" serves as a deterrent to deviating from conventional and overly burdensome prescriptions, particularly for home dialysis patients. Clinical assessment and patient choice should be given weight in determining individual dialysis adequacy goals. We recommend that CMS significantly revisit the structure and metrics within the QIP and also work with the kidney patients to design metrics that are most meaningful to them.

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Within the last decade, kidney care has seen innovations that improve patients' lives and have the potential to reduce the costs of care. These improvements in the value of kidney care are only sustainable, however, when standards and conditions support treatment breakthroughs. Through the COVID-19 pandemic, we have seen the benefits of public support in fostering home care capabilities by leveraging remote patient monitoring and telehealth technologies. We believe that lessons learned during this period can help drive further innovation in home care, ultimately meeting patients where they are and delivering care in the most appropriate setting. Kidney care requires similar changes, and CMS should modernize outdated standards and conditions for coverage to keep pace with industry innovations.

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[23] Urquhart-Secord et al. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study. AJKD. 2016:68(3).

[24] Himmelfarb, J Vanholder, R Mehrotra, R et al. The current and future landscape of dialysis. Nat Rev Nephrol 2020:16(573-585).

IKC appreciates the opportunity to provide feedback on CMS's RFI on health and safety requirements for ESRD facilities. We look forward to working with the agency on additional guidance and revisions related to ESRD treatment. If you have any questions or wish to discuss our comments further, please contact Tonya Saffer at tsaffer@outsetmedical.com.

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