



**Position Paper:  
Recommended Changes  
to Conditions for Coverage  
to Improve and Modernize  
Kidney Care**

Innovate Kidney Care

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# Innovate Kidney Care Position Paper: Recommended Changes to Conditions for Coverage to Improve and Modernize Kidney Care

**For many patients with end-stage renal disease (ESRD), lifesaving treatments and life-changing technologies exist, but are too often out of reach. The Conditions for Coverage (CfC) for ESRD facilities have not been updated in more than a decade, presenting barriers to expanding access and optimizing the way that kidney care is delivered today and in the future.**

## Executive Summary

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On April 15, 2008, the Centers for Medicare & Medicaid Services (CMS) finalized the ESRD CfC Rule, which sets the minimum health and safety standards and requirements that all Medicare and Medicaid participating dialysis facilities must meet. In other words, this rule determines the conditions facilities must satisfy to participate in the Medicare and Medicaid programs. At the time, the ESRD CfC Final Rule was intended to modernize “Medicare’s ESRD health and safety conditions for coverage” and update “CMS standards for delivering safe, high-quality care to dialysis patients.”

Since 2008, there have been groundbreaking innovations and improvements to kidney care and healthcare administration, especially in home dialysis. **Yet the CfCs remain unchanged, and the requirements present barriers to expanding access and optimizing the way that kidney care is delivered today and in the future.**

[Innovate Kidney Care](#) is a group of forward-thinking organizations seeking to improve kidney care for the more than 700,000 Americans with ESRD. In this position paper, Innovate Kidney Care recommends CfC modifications under the following broad themes that will expand patient access to kidney care at home and foster innovation:

1. **Alleviating the Nursing Shortage via Multidisciplinary Care Teams:** Maximize the ability of all care team members to support home dialysis patients, which in turn will allow healthcare professionals to foster more attention toward patient outcomes, empowerment and safety.
2. **Promoting Competition and Patient Choice:** Expand care options and patient access to home dialysis and self-dialysis by encouraging new providers and delivery models in kidney care and reducing consolidation.
3. **Furthering Patient Centricity:** Modernize regulations and guidance to keep pace with the innovations in home dialysis and telehealth for dialysis patients. Leverage telehealth to create more customized, patient-centered options for both training and support.

The COVID-19 pandemic has highlighted the power of innovation and the urgent need for a coordinated national response to make available high-quality dialysis care delivery at home. Twenty-first-century technology has made this evolution possible, and patients and providers have benefited from high-value care through remote patient monitoring and telehealth services, as well as improved dialysis equipment.

In order to sustain this era of improved dialysis care and prepare for future ESRD population growth, the kidney community requires policy support to modernize outdated guidance, regulations and legislation to keep pace with innovation and assist stakeholders who work to improve care and access for patients in need.

## Landscape for Kidney Care

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Kidney disease causes significant quality of life and cost burden on the US patient population. More than 37 million Americans are affected by chronic kidney disease (CKD). Total expenditures for Medicare and Medicaid totaled \$49.2B in 2018, with expenditures for beneficiaries with ESRD accounting for 7.2% of overall Medicare FFS expenditures.<sup>1</sup>

ESRD patients are among the most vulnerable patient populations, requiring costly and high-intensity healthcare treatment. The progression of the disease begins with Stage 1 CKD, characterized by normal to high function of the kidneys. ESRD is the most severe, characterized by total and permanent kidney failure, requiring patients to undergo transplantation and/or live dependent on consistent dialysis. More than 700,000 people in the U.S. today suffer from ESRD, with incidence rising levels each year by about 21,000 cases.<sup>2</sup> Additionally, Medicare spending on patients with ESRD is \$37 billion annually; approximately \$67,000 a year for each beneficiary.<sup>3</sup>

We know that the disease burden falls disproportionately on minority populations, particularly Black and Brown communities. According to the US Renal Data System (USRDS) 2020 Annual Data Report, for every white person who develops ESRD, three Black people develop the condition, and for every three non-Hispanic people who develop ESRD, four Hispanic people develop it.<sup>4</sup> While African-Americans comprise 13% of the U.S. population, they represent 30% of the ESRD population.

More than half a million Americans depend on dialysis treatments three or more times per week to live. And, while there are few physical limitations on who can receive home dialysis treatment, only 13% of people who dialyze currently do, despite data indicating more favorable outcomes with home compared to in-center hemodialysis. Receiving in-center dialysis can create a significant burden on patients, impacting their quality of life, ability to maintain employment and adherence to their dialysis treatment regimen.

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 five 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.<sup>5</sup>

Modern technologies and care delivery models provide an avenue to address the high costs and burdens to patients and the healthcare system. Traditional in-clinic dialysis imposes substantial financial, physical and emotional burdens on patients with kidney failure, as well as their care partners. Today, safe and effective options exist for patients facing kidney failure to self-dialyze at home. State-of-the-art technology and connectivity confers numerous benefits to patients compared to in-clinic dialysis, improving overall quality of life and value of care.

## Obstacles to Treating Today's ESRD Patient Population

**Barriers due to socioeconomic status:** Though home dialysis offers high-quality care and is an empowering 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 than white patients to receive a kidney transplant or conduct dialysis at home. Hispanic Americans are also 1.2 times less likely to receive home dialysis.<sup>6</sup>

While health equity has been a major issue in ESRD treatment, there is little literature on the reasons for differing rates

<sup>1</sup> United States Renal Data System (USRDS), [Healthcare Expenditures for Persons with ESRD](#), 2020.

<sup>2</sup> National Kidney Foundation, [Kidney Disease: The Basics](#), 2021.

<sup>3</sup> USRDS, [Healthcare Expenditures for Persons with ESRD](#), 2020.

<sup>4</sup> USRDS, [Annual Data Report: ESRD](#), 2020.

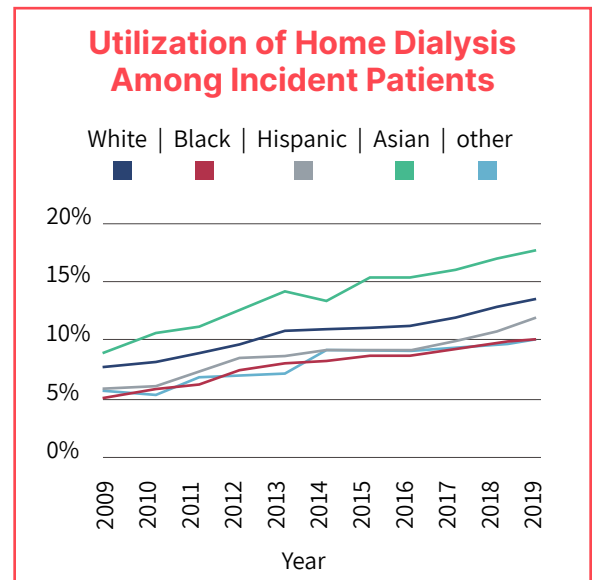
<sup>5</sup> Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. *Am J Transplant*. 2018;18(5):1168-1176. doi:10.1111/ajt.14702.

<sup>6</sup> 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>.

## Obstacles to Treating Today's ESRD Patient Population

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 payment and landlord approval necessary for minor home modifications to connect equipment to electricity and water. Additionally, clinician 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.

By creating flexibility in home dialysis program regulations, CMS can encourage providers to overcome socioeconomic barriers to home dialysis and deliver more personalized, patient-centered care to begin to close the gaps we see today in access and health outcomes:



**Nursing shortages:** The U.S. is facing a rapidly increasing shortage in nurses, and the outlook for nephrology nurses is especially troubling. According to the USRDS and the Chronic Kidney Disease Surveillance System, the number of full- and part-time dialysis center staff in the U.S. has shown an increase from 2017 to 2018. However, as noted in the American Journal of Kidney Disease Policy Forum, approximately 5-7% of nursing positions have remained unfilled at outpatient dialysis facilities since 2004. High turnover is problematic because competent nephrology nurses require between three and nine months of additional experience.<sup>7</sup>

In addition, existing regulations require that nurses conduct home dialysis training, leading to the interpretation that the nurse must deliver all aspects of training, despite other care team members having applicable skills and training. This situation places an additional burden on nurses, making the shortage an additional challenge for expanding home dialysis.

“The dialysis crisis of the COVID-19 pandemic is a cautionary tale, and a reminder that the nephrology nursing pool is a limited resource in providing lifesaving therapies to a vulnerable population. Current projections suggest there will be fewer nephrology nurses at a time of steadily increasing need.”<sup>1</sup>

**Nephrologist joint ventures:** Nephrologists play a crucial role in guiding and informing their patients' treatment decisions. Yet current business models, specifically nephrology joint venture arrangements, are opaque and can create conflicts of interest, which may prevent critical patient populations from gaining access to the most current and efficacious renal replacement modalities – and allow them to successfully pursue treatment at home.

According to the Medicare Payment Advisory Commission (MedPAC), “the concern is whether providers with financial interests in dialysis facilities initiate patients on early dialysis when it is of questionable value, steer patients to in-center dialysis instead of home dialysis or transplantation, steer patients to the dialysis facilities in which they are investors even if another one might be more convenient to the patient or provide higher quality of care, and over-furnish profitable separately billed services or under-furnish bundled services (to the extent clinically possible).”<sup>8</sup>

<sup>7</sup> S. Boyle, R. Washington, P. McCann, S. Koul, B. McLarney, C. Gadegbeku, "The Nephrology Nursing Shortage: Insights From a Pandemic", *AJKD Policy Forum Editorial*, VOLUME 79, ISSUE 1, P113-116, JANUARY 01, 2022.

<sup>8</sup> MedPAC, Letter to CMS Administrator Chiquita Brooks La-Sure, January 28, 2022.

The prevalence of these arrangements adversely impacts vulnerable patient populations:

Dialysis patients are a vulnerable population, with low health literacy, high mortality and hospitalization rates, and considerable comorbidity burdens. Furthermore, dialysis treatment involves numerous preference-sensitive choices regarding transplantation and dialysis modality—necessitating significant physician consultation and shared decision-making. Therefore, even small influences from financial or non-financial incentives may have inappropriate effects on care decisions. Financial conflicts of interest may lead to harm when such interests conflict with the aim of providing optimal care for patients, aligned with their personal preferences and goals of care. As such, recent and future payment changes for dialysis treatment require close monitoring of their effects on financial conflicts.<sup>9</sup>

Today, there is high consolidation of dialysis providers with a few large dialysis organizations caring for the majority of patients. When combined with the opaqueness of joint ventures between dialysis companies and nephrologists, patients are facing a landscape where choice is limited. While it's widely accepted that home dialysis improves health and quality of life outcomes, the significantly entrenched and unique market barriers in the kidney care space create little incentive for innovation – leaving dialysis care largely unchanged for decades.

## The Need for Change: Modernizing the Conditions for Coverage (CfCs) Rule for ESRD Facilities

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Successive administrations have worked to change the landscape for ESRD patients, from the introduction of the ESRD bundled prospective payment system (PPS) in 2011, the Executive Order on Advancing American Kidney Health in 2019 (which sought to increase access to home dialysis) and the introduction of an innovation add-on payment to dialysis reimbursement. The Biden Administration has also begun to make its mark through policy changes and to improve equitable access to home dialysis and kidney transplants through modifications to the ESRD Treatment Choices (ETC) Model in 2021. This payment model is intended to incentivize providers for improving the rates of home dialysis and kidney transplants for lower-income beneficiaries, and it led to the first approval of a substantially improved home hemodialysis machine technology to qualify for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

These actions to date have begun to transform kidney care for patients. Additional bold action can build on this momentum to continue to spur innovation and improve patient care.

Ultimately, the CfCs must accelerate adoption of home dialysis, which will drive better patient outcomes, improve patient experience, improve healthcare practitioner experience, lower costs of care and create a more equitable healthcare delivery system for all patients with kidney diseases.

### 1. Alleviating the Nursing Shortage via Multidisciplinary Care Teams

Investing in education and training is needed to take full advantage of new advancements in kidney care and home dialysis. However, to accommodate the growing demand for home dialysis, we must re-imagine who we train and how we train them.

**Leverage the Skills of the Multidisciplinary Care Team.** We must expand beyond only Registered Nurses for training and support them by sharing responsibilities with other members of the care team and the patients, to meet market demand and to reduce the burnout RNs face.

- CMS should allow for shared responsibilities of a multidisciplinary care team to conduct training. More specifically, CMS should remove the requirement that RNs “conduct” the training, replacing it with “have oversight and participation by a” RN who can then determine readiness.

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<sup>9</sup> Glickman A., Lin E., Berns J, Conflicts of Interest in Dialysis: A Barrier to Policy Reforms, [Semin Dial. 2020 Jan; 33\(1\): 83–89. 2020](#)

- CMS should clarify that the home dialysis training RN does not need to be physically present for all aspects of training, if other members of the multidisciplinary care team are conducting aspects of training (given that the patient is in the line of sight of the home nurse manager if they are actively treating during the training sessions). In both cases, the training nurse and nephrologist should be responsible to sign off that trained patients are competent in self-dialysis to go home.
- CMS should permit home dialysis device manufacturers to directly train patients, under the oversight of the dialysis facility nurse. 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.
- CMS should specify self-care definitions to ensure patients are empowered to engage in as many activities of their dialysis care as they desire. The definition should be modified to include certain requirements related to self-dialysis. Furthermore, CMS should make explicit in guidance and regulation that patients who are fully trained for self-dialysis and are conducting in-center self-care do not need to be in line of sight of an RN.

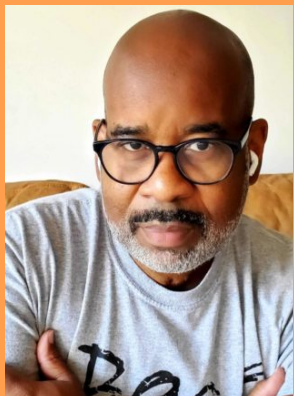
**Rethink Nurses’ Training for Greater Efficiency.** Currently, CMS requires that the responsible nurse be registered, have at least 12 months experience providing nursing care and have an additional three months of experience with the specific dialysis modality. This cadence of timing has no evidence showing that it improves patient outcomes at home.

- Instead, CMS should permit the dialysis modality experience to either be developed concurrently with the 12 months of nursing experience or allow for a training program that tests competency in home dialysis training and support as the requirement. This would increase the number of specialized dialysis nurses, directly addressing the challenges of personnel shortages while ensuring patients and their care partners are safely trained and supported at home.

## 2. Promoting Competition and Patient Choice

Dialysis providers should have to compete for patients by delivering personalized and patient-centered care options. Unfortunately today, patients have limited options. In many areas of the country, there may be only one (if any) option of technology, training and support available to patients.

Here are just a few examples of real patients who have experienced the repercussions of limited choice:



John: No local access to HHD training.

**John** is a veteran of all modalities of dialysis treatments. When his kidneys failed, he struggled with in-center dialysis, and when he first made the decision to transition to home hemodialysis (HHD), he found that his options were limited. Even though he lived in an urban area, he found there were few dialysis centers that offered HHD training.

With the assistance of his nephrologist, John was able to identify a center that met his needs, but it was 45 minutes away, and not conveniently located near public transportation, which he is dependent upon. John persevered, selected the center and eventually was able to complete his HHD training, and experienced great success with HHD.



Gwenie: Uninformed and then misinformed about home modalities.

**Gwenie** lives on a ranch in rural Montana. She is not new to the healthcare arena, but she had no idea that she had CKD when she “crashed” into dialysis in November 2020. With no major medical center near her small town, Gwenie drove over 400 miles to Billings to seek treatment. Like many others who crash into dialysis, she woke up with a CVC catheter on dialysis in the hospital.

Upon discharge, Gwenie was sent to her closest dialysis facility for outpatient dialysis, 60 miles away on an Indian reservation. She received no information on home modalities at that clinic, and only learned about her options on the internet. When she approached her clinic about this option, it required that her husband be in attendance for her entire dialysis training, three days a week for 4-6 weeks, despite no regulation requiring a care partner for the machine she would be using at home. Gwenie and her husband operate a working ranch with livestock, so one of them has to be present on the farm at all times. The clinic would make no accommodations for this. So, Gwenie did more online research. She found a clinic in Fargo, ND that would train her for solo dialysis. In the Spring of 2021, Gwenie relocated 500 miles away to Fargo for 4-5 weeks to begin her training for solo home dialysis.



Vy (left): Uninformed about range of treatment options.

**Vy** is an avid Muay Thai boxer and sandwich blogger living in Orange County, CA. While he had done some of his own research on dialysis, he started in-center dialysis without fully understanding all the options.

Vy joined a new kidney-specialized care management program three weeks after starting in-center hemodialysis. He engaged with his new care team and outlined what his goals were, both for treatment and his lifestyle. It was very important to him to keep up his active lifestyle and get back to Muay Thai boxing 3-4 times a week.

After receiving in-depth, customized education on all of his treatment options and talking it through with his dedicated nurse, Vy decided to switch to peritoneal dialysis. This decision allowed Vy to get back into the ring and live his best life.

An expanded market will help provide people like Gwenie, John and Vy with more choices, that fit their particular lifestyle and personal situation. It is important that patients are informed about nephrologists’ relationships and financial interests that are tied to specific dialysis facilities and modalities when weighing their own options.

- CMS should require qualified facilities to disclose to CMS and patients all individuals and entities with a financial interest in the facility, facility subsidiary and joint venture partnerships that it or its subsidiaries are a party to. While some of this information is collected at the time the provider enrolls in Medicare, it is not updated afterwards. This reporting to CMS should include the National Provider

Identifier (NPI) of such individuals, and also the NPI for any providers that are party to such an entity, and the information should be updated annually. CMS should also commit to perform a detailed analysis of the updated information annually.

- Additionally, in accordance with the American Medical Association’s ethics, nephrologists should also disclose to patients any financial interests in dialysis facilities where they refer their patients.
- The Medical Directors who have clinical and quality oversight of the dialysis clinic should also be listed publicly within the facility and on the CMS Dialysis Facility Compare website.

These disclosure requirements provide patients with clear information on clinic ownership and Medical Director leadership. Additionally, disclosure allows for CMS and researchers to further study the impact that these financial agreements have on patient choice of facility, provider and availability of home dialysis. This research could help shed more light on patient choice, access and quality of care.

### 3. Furthering Patient Centricity

Creating separate and distinct regulations for home dialysis versus in-center dialysis is critical to providing a roadmap to innovators who are seeking to better personalize patient care, and support patients at home. Home dialysis is not simply in-center dialysis moved home. The technology and care delivery model is distinctly different, and CMS regulations and guidance must be updated to acknowledge these innovations in order to foster accessibility to home dialysis.

Home dialysis, remote patient monitoring and telehealth work in tandem to bring care to where the patient is. To sustain the anticipated benefits of home dialysis and new technologies to create more personalized options, we need to incorporate and promote telehealth and at-home programs to support patient training, monitoring and ongoing care.

- CMS should specify that members of the multi-disciplinary care team can provide services virtually. This would mean that social workers, dietitians and other care team members can provide care and support services as an option to dialysis patients via telehealth, as proven in kidney disease care and across healthcare during the COVID-19 public health emergency.
- CMS should allow portions of home dialysis training to be conducted virtually, with few exceptions in portions of training that would not apply, based on RN assessment of patient ability to use telehealth and patients’ willingness to participate in remote training. These exceptions should include cannulation training and initial physical assessment.
- CMS should allow home programs to subcontract with community-based healthcare settings, enabling home patients to meet with all members of their multidisciplinary care team, and to provide patients with convenient access to home training. This convenience for patients will improve access to home dialysis support services, and also help patients succeed on this modality. The home program would remain fully responsible for the care provided in community-based healthcare settings, and all patient encounters must be documented in the patient’s facility medical record.

## Conclusion

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Within the last decade, kidney care has seen innovations that have improved patients’ lives and potentially reduced costs of care. Real-world experience during the COVID-19 pandemic accelerated public support for home care capabilities, by leveraging remote patient monitoring and telehealth technologies.

The recommendations outlined in [IKC’s response to the CMS Request for Information](#); Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities; provides additional detail on how and where Congress and CMS can modernize kidney care policy.