



July 6, 2021

The Honorable Shalanda Young
Acting Director
Office of Management and Budget
725 17th St., NW
Washington, DC 20503

***Re: Response to the Office of Management and Budget (OMB) request for information (RFI):
Methods and Leading Practices for Advancing Equity and Support for Underserved
Communities Through Government***

Dear Acting Director Young:

The Alliance for Home Dialysis (Alliance) is a coalition of kidney community stakeholders representing patients, clinicians, providers, and industry. Since the March 2012 National Summit on Home Dialysis Policy, Alliance members have come together to identify policy opportunities and regulatory actions that can increase and improve utilization of home dialysis, because we believe that all patients deserve the opportunity to dialyze at home. Through our efforts, the Alliance promotes and advances policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis. Tragically, these barriers and the ensuing inequity for low-income patients and communities of color have been both revealed and exacerbated by the COVID-19 pandemic. In our comments to this RFI, we offer some insights into how these systemic inequities in healthcare impact kidney disease patients, especially their access to home dialysis therapy.

We appreciate OMB's openness to engage with stakeholders like the Alliance for Home Dialysis on these important issues. We are eager to serve as a resource as the Administration considers policy solutions to increase equity in healthcare, particularly as it relates to kidney disease.

I. Background

Although the burden of kidney disease is felt in all communities across the country, the degree of burden differs significantly depending on socioeconomic, racial, cultural, political, and

geographic factors. Research shows that communities of color are disproportionately affected by chronic kidney disease (CKD) and possess a much higher risk of developing kidney failure due in part to this population's increased propensity to experience dialysis risk factors, such as hypertension and diabetes.¹ In 2018, approximately 0.59% of all Black Americans, 0.33% of all Hispanic Americans, and 0.32% of all American Indians/Alaska Natives experienced end-stage renal disease (ESRD).² Compared to white people, the prevalence of ESRD was about 3.4 times greater in Black Americans, 1.9 times greater in American Indians/Alaska Natives, and 1.3 times greater in Asian Americans.³

There are two types of home dialysis: peritoneal dialysis (PD) and home hemodialysis (HHD). PD treatment uses a special solution injected into the individual's abdominal cavity to filter blood and remove waste. This process occurs several times during a 24-hour period and can be done at home, in the workplace, or in other non-medical settings. Individuals treated with PD can also use a machine, known as a cycler, to perform these exchanges while they are sleeping.⁴ Hemodialysis (HD) is a treatment in which an artificial membrane, known as a hemodialyzer, filters the blood. This is the most common type of treatment used in dialysis facilities, but it can also be done at home.⁵ At the end of 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients. Nearly 85% of patients on home dialysis performed peritoneal dialysis.⁶ While the portion of dialysis patients performing home dialysis in the United States is slowly increasing, the U.S. lags behind many other industrialized countries.⁷

Home dialysis offers significant clinical, socioeconomic, and quality of life advantages. When compared to traditional in-center dialysis, home patients experience increased survival rates, better preservation of residual renal function, and fewer low blood pressure episodes.⁸ In addition, home dialysis provides patients greater autonomy and flexibility over when they dialyze, reduces the need for dependence on transportation, and is more conducive to financial stability because it allows many patients to continue to work.^{9,10} In fact, one study found that home dialysis patients are 5 times more likely to hold employment than patients who dialyze in-center.¹¹

¹ <https://www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity>

² <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

³ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

⁴ <https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725>

⁵ <https://www.healthline.com/health/dialysis#types-of-dialysis>

⁶ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

⁷ <https://adr.usrds.org/2020/end-stage-renal-disease/11-international-comparisons>

⁸ <https://www.nxstage.com/patients/benefits-of-home-hemodialysis/>

⁹ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2749760>

¹⁰ <https://www.nxstage.com/patients/benefits-of-home-hemodialysis/>

¹¹ <https://onlinelibrary.wiley.com/doi/10.1111/nep.12482>

Relatively low utilization of home dialysis in the U.S. is partially attributable to the disproportionate lack of home dialysis access for low-income communities and communities of color, which make up a significant portion of dialysis patients. Data make clear that, in the United States, people of color have less access to home dialysis therapy.¹² Nationally, Black patients are 30.1% less likely, and Hispanic patients 7.6% less likely, than white patients to start on peritoneal dialysis (PD). Similarly, for home hemodialysis (HHD), Hispanic patients are on average 42.1% less likely, and Black patients are 9.8% less likely, to receive HHD (see Appendix I for more details).¹³ Further, access to pre-dialysis nephrology care – and, indeed, access to insurance – are less prevalent among minority patients.¹⁴ These patients often do not receive adequate education about their treatment options in stages of their kidney disease during which they can make plans for the type of dialysis modality that best suits them; as a result, too many “crash” into dialysis in the emergency room, where traditional hemodialysis is the most seamless option.¹⁵

While these disparities have long existed, the COVID-19 pandemic has exacerbated them, along with so many other health inequities that have been made worse during this emergency. According to the Centers for Disease Control and Prevention (CDC), people of color are more likely to experience serious COVID-19 complications and even death once infected.¹⁶ Similar risk applies for patients with preexisting kidney disease.¹⁷ These risks make it all the more important that ESRD patients, especially patients of color, dialyze at home. Home modalities give those patients the chance to avoid potentially dangerous contact with individuals that are infected with COVID-19, including those in a dialysis clinic or doctor’s office. According to a study conducted in New York during the initial months of the pandemic, home patients were less likely to test positive or be hospitalized for COVID-19 than in-center patients.¹⁸ Even as COVID-19 vaccines have become widely available, vaccination rates in Black and Brown populations continue to lag in many states and data suggests that dialysis patients will continue to be at risk from COVID-19 infection and need to socially distance.^{19,20}

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4926974/>

¹³ Distribution of Dialysis Patients Utilizing Home Modalities in 2018 by State, the Moran Company

¹⁴ <https://www.healio.com/news/nephrology/20200219/home-dialysis-use-varies-by-race-largely-due-to-socioeconomic-factors#>

¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950106/#:~:text=There%20are%20varying%20definitions%2C%20but,catheter%20or%20during%20a%20hospitalization>

¹⁶ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>

¹⁷ <https://pubmed.ncbi.nlm.nih.gov/32247631/>

¹⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685041/>

¹⁹ <https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-race-ethnicity/>,

Figure 2

²⁰ <https://www.healio.com/news/nephrology/20210413/study-reveals-how-patients-on-hemodialysis-respond-to-pfizers-covid19-vaccine>

II. A Culture of Support for Home Dialysis

As we explored in our recent 2021 Home Dialysis National Policy Roundtable, advancing health equity for ESRD patients calls for policy changes to help underserved patients surmount common and oftentimes prohibitive barriers to home therapy. Many of these barriers stem from the prevalence of unplanned, or “crash” dialysis starts. Nearly half of all new dialysis patients begin treatment without previous access to a nephrologist; these unplanned starts are associated with increased patient morbidity and mortality, as well as lower quality of life scores.^{21,22} Moreover, too many clinicians, hospitals, and payors are unfamiliar with the benefits that can be achieved for appropriate patients on home dialysis, and thus they may be less likely to prescribe it to crash patients, causing them to miss out on a potentially life-changing modality.

In a familiar theme, minority patients bear the brunt of crash starts, in no small part because of lack of access to primary care. This lack of access is partially caused by a relative lack of health insurance, compared to whites.²³ For example, 2018 data shows that Blacks are 1.5 times more likely to be uninsured than whites, while the Hispanic uninsured rate was almost 2.5 higher than the rate of whites.²⁴ Further, a report by the Agency for Healthcare Research and Quality found that Blacks and Hispanics had worse access to care for all the measures related to timely access to care when compared with whites.²⁵ A recent survey of patients with ESRD showed that a greater proportion of Black patients (57%) than white patients (44%) had an emergent start or “crash” dialysis start.²⁶ Unfortunately, the crash setting is not conducive to informed decision-making. For example, at the 2021 Home Dialysis National Policy Roundtable earlier this year, a New York nephrologist shared the story of a patient who crashed, and was unaware that she could dialyze at home, which he understood was because her emergency room physician decided she was a poor candidate for therapy without discussing it with her.²⁷

Patients who do choose home dialysis need, and often lack, assistance and moral support when beginning dialysis, for themselves and potential care partners. Care partners are critical to assist patients with important tasks, such as setting up the home dialysis equipment, cooking meals, and running errands – as well as providing support and encouragement. All too many patients lack care partners entirely, and already underserved patients are less likely to have someone in their support network who can manage the economic burden of this unpaid work.

²¹<https://www.beckershospitalreview.com/quality/earlier-diagnosis-patient-education-and-integrated-care-can-help-reduce-the-prevalence-of-dialysis-crash-starts.html>

²² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950106/>

²³ <https://www.kff.org/racial-equity-and-health-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/>

²⁴ Ibid.

²⁵ <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrd/2019qdr.pdf>

²⁶ <https://www.renalandurologynews.com/home/news/black-white-race-health-disparities-kidney-dialysis-care-survey-results/>

²⁷ *Empowering Patients in Both Planned and Unplanned Starts* (Roundtable Panel). 2021 Home Dialysis National Policy Roundtable: A Dialogue on Disparities, Systemic Inequities, and Access. February 25, 2021.

Furthermore, those who do serve as care partners are highly vulnerable to burnout. When adequate support is lacking, especially in the beginning of a home dialysis journey, patients may be forced to revert to in-center treatment. One study found that around 9% of patients discontinued HHD within 3 months, while nearly 25% of the patients discontinued by one year mark. Compared with white patients, the risk of transferring from the home dialysis modality to in-center hemodialysis was higher in Black ESRD patients.²⁸ This study concluded that this was partially due to the complexity of performing hemodialysis and that increasing support for these patients is a potential strategy for reducing HHD discontinuation.²⁹

We encourage policymakers to focus their efforts on shifting this paradigm for all patients – but particularly patients of color – who face a “crash” start to dialysis. Policy action can help to provide needed support both before and after kidney failure and empower patients to participate in their own healthcare decision-making.

III. Education and Information

Access to education about ESRD and available dialysis treatment options is crucial to any patient with kidney disease; however, Black patients are shown to be less likely to receive pre-ESRD nephrology care than their white counterparts and often are not exposed to the same opportunities for early education.³⁰ Socioeconomic factors have been found to impact the awareness and utilization of treatment options, such as home dialysis or kidney transplant.³¹

At the 2021 Home Dialysis National Policy Roundtable, a Black patient shared that when she crashed into dialysis, her physician provided only perfunctory education, and ultimately steered her away from a home modality. She said she was immediately put onto in-center hemodialysis with little explanation and that not being able to dialyze at home significantly lowered this patient’s quality of life, motivating her to seek out information on alternative dialysis options. The patient learned about PD through her own research, and after switching to PD, her quality of life significantly improved.³² Patient stories like this are common, suggesting that conventional sources of education are not enough to reach underserved communities and that more creative, patient-centered approaches may be needed.

Stakeholders in the kidney community are learning that impactful patient education requires meeting patients where they are. For example, a kidney technology company recently paired with the National Kidney Foundation to survey dialysis patients and found that a lack of education and socioeconomic factors, rather than an inherent racial difference, contribute to the lower rate of home dialysis uptake in communities of color. These results led the two

²⁸ <https://www.newswise.com/articles/study-examines-differences-over-time-in-home-dialysis-initiation-by-race-and-ethnicity>

²⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4808342/>

³⁰ <https://www.outsetmedical.com/perspective/nkf-survey-eskd-patients-racial-health-disparities-home-dialysis/>

³¹ IBID

³² *Empowering Patients in Both Planned and Unplanned Starts* (Roundtable Panel). 2021 Home Dialysis National Policy Roundtable: A Dialogue on Disparities, Systemic Inequities, and Access. February 25, 2021.

organizations to develop a pilot treatment-focused curriculum to be delivered to patients at risk for kidney failure in their own communities. Approaches like these should be studied and potentially emulated, with policies to support and expand those that work.

The Medicare program does offer a Kidney Disease Education (KDE) benefit, which covers up to six sessions of kidney disease education services for pre-dialysis patients. Doctors, physician assistants, nurse practitioners, and clinical nurse specialists can offer these services. Beneficiaries can use this benefit to learn about various CKD-related topics, such as managing health conditions and potential treatment options.³³ However, the Government Accountability Office (GAO) found that few Medicare beneficiaries have used the KDE benefit, and that the low utilization may result from statutory payment limitations on the types of providers permitted to furnish the benefit and on the Medicare patients eligible to receive it.³⁴

The Alliance has long advocated for policies that will reduce barriers to this important education, including elimination of patient cost-sharing and expanding eligibility for the KDE benefit. Specifically, the Alliance has recommended that the Centers for Medicare and Medicaid services (CMS) consider waiving the coinsurance requirement associated with KDE and designate KDE as a preventive service.³⁵ Beyond these changes to increase access, the Medicare program should consider a uniform curriculum for the provision of KDE to address disparities in the quality of KDE programs from one community to another.

As emerging research demonstrates the critical role that pre-dialysis education plays in making an informed dialysis modality choice, policymakers have important opportunities both to standardize kidney disease education through creative initiatives and partnerships that help deliver needed information and resources to underserved communities.

IV. Technology and Innovation

As new technologies – like telehealth and remote patient monitoring – have emerged to help improve a patient’s quality of, and access to, a wider array of kidney care modalities, the Alliance has advocated for broader access to these innovations. Recently, CMS provided waivers for the public health emergency to expand reimbursement to dialysis-related services through telehealth.³⁶ We were also encouraged to see Congress appropriate \$200 million in the CARES Act for the Federal Communications Commission (FCC) to support the efforts of health care providers to provide telehealth.

Still, some patients continue to experience poor access to necessary technologies and are not able to fully benefit from new digital tools or expanded access to telehealth. This “digital

³³ <https://www.medicare.gov/coverage/kidney-disease-education>

³⁴ <https://www.gao.gov/assets/gao-16-125.pdf>

³⁵ <http://homedialysisalliance.org/wp-content/uploads/2018/09/Alliance-ESRD-PPS-CY19-FINAL.pdf>

³⁶ <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

divide” has only been accentuated during the pandemic.³⁷ Low-income patients may encounter connectivity and broadband issues, or not have appropriate access to communication devices. In addition, most home devices will require access to a dedicated electrical outlet or may need small plumbing modifications. This is often a challenge in low-income housing, as landlords may not allow the modifications, and if they do, patients cannot afford to make them. Manufacturers and providers would be willing to pay for these small home modifications but are concerned they would run afoul of anti-kickback laws. Multiple patients present at the 2021 Home Dialysis National Policy Roundtable shared first-hand experiences with these barriers, including having to use public broadband sources to connect with their doctors via telehealth or having to choose between paying their internet bill to access their doctor visits or paying for groceries.³⁸

V. Data Collection³⁹

Existing data and ongoing research paint a picture of troubling disparity in ESRD care and ensuing outcomes. We encourage federal policymakers to leverage their unique access to large and comprehensive databases (e.g., Medicare claims data, Hospital Consumer Assessment of Healthcare Providers and Systems survey) to learn lessons about patient experience and outcomes in the present, as well as conduct real-time evaluation of new models such as the ESRD Treatment Choices Model, to ensure that communities of color reap the benefits. Following are some suggestions on how further data collection and research might be operationalized.

- Some data is available on home dialysis retention by modality, but more information about what leads patients struggling with home dialysis to give it up entirely would help policymakers effectively target sources of inequity.
- CMS should consider a survey of in-center patients, organized demographically, to determine patient’s understanding of the perceived barriers to dialyzing at home. One pathway to conducting this survey would be through the ESRD Networks.⁴⁰ Another approach would be to focus on specific geographic regions using existing classifications like the Hospital Referral Region (HRR).
- Dialysis claims are an opportunity to gather more information about individual patients, their circumstances, and social determinants of health that may inform future policy targets. For example, reporting “Z” codes on dialysis claims would enable CMS to better

³⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7648180/>

³⁸ *How Advancements in Technology can Increase Access to Home Dialysis and Quality of Care* (Roundtable Panel). 2021 Home Dialysis National Policy Roundtable: A Dialogue on Disparities, Systemic Inequities, and Access. February 25, 2021.

³⁹ Area 1 of the RFI includes the following question: *How might agencies collect data and build evidence in appropriate and protected ways to reflect underserved individuals and communities and support greater attention to equity in future policymaking?* In response, we propose the following policy solutions

⁴⁰ <https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations>

understand what non-clinical barriers patients are facing that might be dissuading otherwise-qualified candidates from home dialysis.

- While in-center hemodialysis patients can report their experience using the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey, there is no patient-reported experience measure for assessment of patient experience of care for peritoneal dialysis or home hemodialysis. We encourage CMS to consider development of such a measure, informed by ongoing work in the academic community.⁴¹
- According to a clinical expert in the field of kidney care, measuring the impact of innovative care models in real time will be instrumental in understanding their impact on disadvantaged communities and will help ensure that these models promote health care delivery in an equitable manner.⁴²

VI. Conclusion

We applaud President Biden's commitment to improving data and measurements to advance equity in his *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. For these commitments to become reality for the patients we serve, policymakers must focus on increasing awareness of dialysis options, and on constructing a better support system for patients who choose to dialyze at home. Federal programs that seek to drive and incentivize access to home dialysis should be recognized as important ways to address inequitable outcomes for vulnerable patients.

The Alliance appreciates your consideration of this response and looks forward to continuing our work with OMB to advance policies that equitably serve all individuals and communities, including those who utilize home dialysis. Please feel free to contact me at michelle@homedialysisalliance.org or 202-733-7326 if we can provide additional information to support this response.

Respectfully,



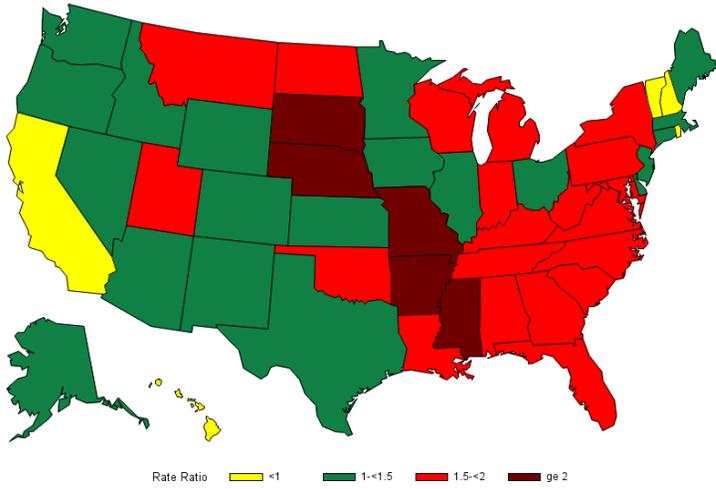
Michelle Seger
Managing Director

⁴¹ [Researchers develop tool to assess satisfaction with home dialysis \(healio.com\)](#)

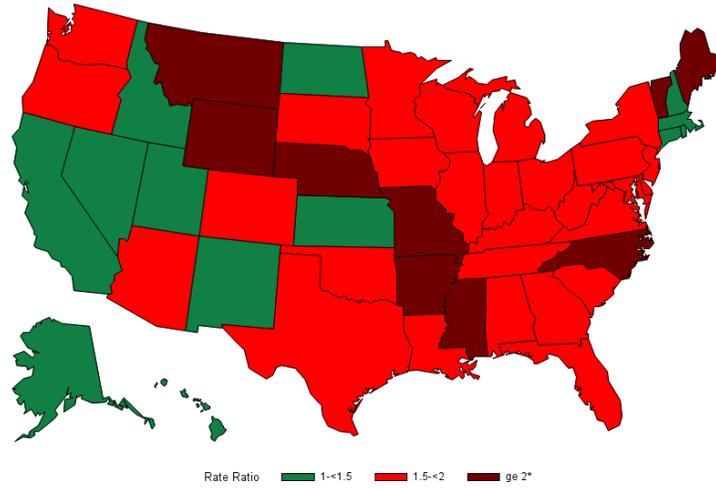
⁴² *Overview of Health Disparities and Inequity in Dialysis: Framing the Discussion* (Roundtable Panel). 2021 Home Dialysis National Policy Roundtable: A Dialogue on Disparities, Systemic Inequities, and Access. February 25, 2021.

Appendix I:

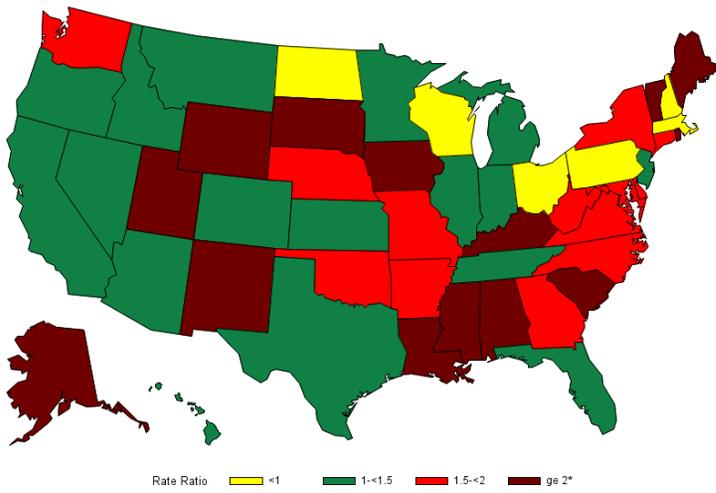
Peritoneal Dialysis - Difference In Uptake Between White Patients And All Other Patients



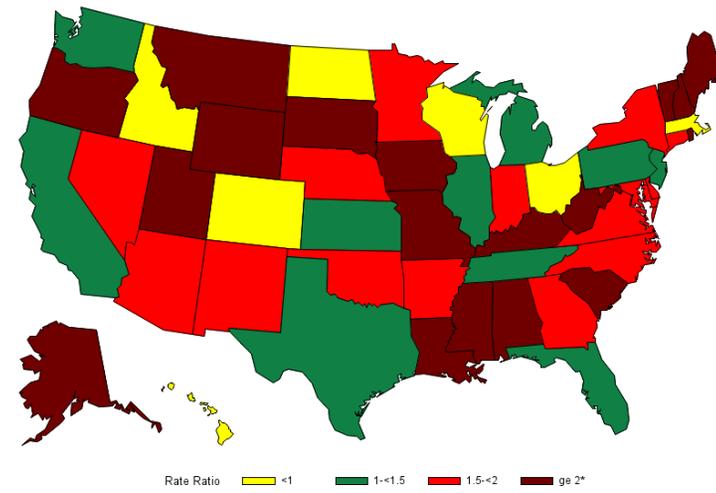
Peritoneal Dialysis - Difference In Uptake Between White Patients And Black Patients



Home Hemodialysis - Difference In Uptake Between White Patients And All Other Patients



Home Hemodialysis - Difference In Uptake Between White Patients And Black Patients





American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association*
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Cleveland Clinic
DEKA*
DaVita*
Dialysis Clinic, Inc.*
Dialysis Patient Citizens*
Fresenius Medical Care*
Home Dialyzors United
ISPD North America
Medical Education Institute
National Kidney Foundation*
National Renal Administrators Association
Northwest Kidney Centers*
Outset Medical*
Renal Physicians Association*
Satellite Healthcare*
The Rogosin Institute*
TNT Moborg International Ltd.

**Denotes Steering Committee member*