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January 31, 2022

Hon. Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: CMS-3409-NC - Request for Information; Health and Safety Requirements for  
Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease  
Facilities

Dear Administrator Brooks-LaSure:

Dialysis Patient Citizens (DPC) writes to offer comments on selected queries in the above  
referenced Request for Information (RFI).

DPC's membership, currently 30,000, is restricted to kidney disease patients and their family  
members. DPC is a patient-led organization. Our by-laws require that the President, Vice  
President and at least 51% of the Board be current dialysis patients. The non-dialysis patients  
serving on our Board are former dialysis patients with kidney transplants. Nearly all our  
volunteer board members have represented their peers on CMS technical expert panels and/or  
advisory committees of other health care organizations such as the National Quality Forum and  
Patient-Centered Outcomes Research Institute. DPC also conducts an Annual Membership  
Survey to ascertain patients' experiences with their care and views on health policy issues. DPC  
is committed to promoting access to high-quality dialysis care for individuals with ESRD; to  
prevention of, delayed onset of, and safe transition to ESRD among individuals with chronic  
kidney disease; and access to kidney transplantation as well as to other alternatives to dialysis  
that may emerge.

#### Equity in Organ Transplantation

The RFI notes that "Organ transplantation and donation in the United States remains highly  
inequitable amongst racial and ethnic minorities as compared to White Americans." As one study  
notes regarding kidney transplants, "racial disparities were observed in access to referral,  
transplant evaluation, waitlisting and organ receipt."

We are pleased that the Agency acknowledges that "critical improvements cannot, and will not,  
be achieved only through revisions to the transplant CoPs, OPO CfCs alone, or the ESRD facility  
CfCs." To the extent that a poor record of referrals to kidney transplantation results from

“clinicians' implicit or explicit biases, including physician misperceptions about the benefits of transplants for Black individuals or discordant and inaccurate beliefs regarding causes or prevalence of these disparities,” the Agency should explore remedial regulatory measures. But when disparities result from lack of resources on the part of disadvantaged patients, we believe the only effective strategy is to compensate for the disadvantage.

That is the rationale for federal “compensatory education” funding under Title I of the Elementary and Secondary Education Act (ESEA). Title I provides financial assistance to disadvantaged school districts to level the playing field among children. It is time to develop analogous funding mechanisms to address to health disparities.

More money for the care of kidney patients has been proven to reduce racial disparities in transplantation. Harhay et al. conducted an observational study of adults preemptively listed for kidney transplantation three years before and three years after Medicaid expansion. Comparing the proportion of preemptive listings with Medicaid coverage in the 24 states that had fully expanded Medicaid with the 19 that had not, they found larger increases in Medicaid coverage among racial and ethnic minority listings compared to white listings (whites, from 4.3% to 5.7%; blacks, 11.1% to 15.1%; Hispanics, 14.5% to 20.4%; and other race/ethnicities, 7.2% to 12.5%).<sup>1</sup>

DPC has, in a previous comment letter, proposed that CMS add a Social-Needs Payment Supplement to augment the ESRD bundled payment and assist disadvantaged patients. Such a payment could fund, among other things, additional services to patients who need extra help to navigate the transplant process. Initially this could be funded by ESRD dollars budgeted for adjusters or outlier pools that have gone unspent.

We have also endorsed two other measures that would expedite transplantation for disadvantaged patients. First, Medicare coverage for medically necessary dental care for transplant candidates, which we believe can be implemented under current law.<sup>2</sup> Second, reimbursement to living donors of all their costs, which the Arnold Foundation estimates could shave a half-percent off Medicare costs.<sup>3</sup>

We believe that Agency leadership is sincere in its pronouncement that CMS wants to reduce racial disparities during this Administration. But a true commitment will be accompanied by investments in patient care. The legacy of 250 years of slavery and another century of segregation is unlikely to be reversed by regulation, or asking providers to find loose change under the couch cushions. We urge that when this exercise is completed, CMS staff prepare bold policy options for leadership that involve tangible investments.

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<sup>1</sup> Harhay MN, McKenna RM, Boyle SM, et al. Association between Medicaid Expansion under the Affordable Care Act and Preemptive Listings for Kidney Transplantation. *Clin J Am Soc Nephrol*. 2018;13(7):1069-1078. doi:10.2215/CJN.00100118

<sup>2</sup> See <https://medicareadvocacy.org/medically-necessary-oral-health-care-is-coverable-under-current-medicare-law/>

<sup>3</sup> See <https://onepercentsteps.com/policy-briefs/removing-all-financial-disincentives-to-living-kidney-donation/>

## Discarded Organs

A recent study used simulations to test the impact of different report card formats on readers.<sup>4</sup> The investigators found that “when report cards displayed a transplant survival metric stratified by donor risk status, both lay participants and medical trainees favored the transplant center with high organ acceptance rates more strongly than they did when the report card displayed only the standard 1-year posttransplant survival metric.” We urge the Agency to review the study and consider alternative formats for transplant center report cards.

We also urge the Agency to heed the findings and recommendations of a 2019 paper by Husain et al.<sup>5</sup> The investigators note that a transplant center has the ability to decline an organ offer on behalf of a dialysis patient “without informing the candidate of the offer or the reason it was declined. Despite the advantages of earlier transplant for patients with ESRD, deceased donor kidneys are offered to a median of 7 different candidates before being accepted for transplant, with one-quarter of transplanted deceased donor kidneys offered first to at least 73 candidates. Organ offers are often declined on the basis of center-level organ selection practices rather than a detailed assessment of the advantages to each individual candidate of receiving that kidney allograft, including a shorter time receiving dialysis.” They further note that a large number of dialysis patients die waiting for an organ after an organ was rejected by their surgeon and later transplanted to someone else, most likely successfully.

The authors urge regulatory reform:

Patient centered decision-making processes should prioritize the survival and quality-of-life advantages associated with transplants and should favor an early transplant. In contrast, the current regulatory framework for a transplant in the United States is focused on short-term patient and graft survival for the subset of patients with ESRD who are fortunate enough to be wait-listed and subsequently receive an allograft. This focus may be associated with the risk aversion at many centers and their reluctance to use anything but ideal deceased donor kidneys to ensure excellent short-term outcomes, although this practice is inconsistent with optimizing overall candidate survival or with patient preferences for minimizing wait time

The authors offer three specific policy recommendations, which we endorse:

- Transplant candidates should be made aware of all offers declined on their behalf. “Although the time constraints of organ allocation are not conducive to real-time shared decision-making... post hoc reporting to patients and their nephrologists about declined

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<sup>4</sup> Alison E Butler, Gretchen B Chapman Don't Throw Your Heart Away: Increased Transparency of Donor Utilization Practices in Transplant Center Report Cards Alters How Center Performance Is Evaluated. [Medical Decision Making](#). 272989x211038941 - October 2021.

<sup>5</sup> Husain SA, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, Mohan S. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open*. 2019 Aug 2;2(8):e1910312. doi: 10.1001/jamanetworkopen.2019.10312

offers might improve communication and patient engagement while prompting centers to reconsider how or when to decline offers.

- Center-level data regarding offer-acceptance trends and minimum acceptance criteria should be made publicly available along with currently reported transplant center metrics. “Such a policy may allow candidates to identify centers whose offer-acceptance patterns align with their own values and would compel centers to prioritize candidate preferences.”
- Reduce the emphasis on marginal differences in early post-transplant outcomes in favor of metrics that examine outcomes for all patients with ESRD. “Such an approach might help shift the current focus from short-term outcomes to patient priorities.”

### Waitlist Concerns

The Agency asks several questions about communication and information patients receive from transplant centers. We understand that, frequently, information sharing among transplant programs, dialysis patients, and kidney clinicians is poor, with patients and clinicians unsure of the patient’s status on the waitlist, and transplant centers sometimes unaware that patients have died while waiting for a kidney.

Quality Insights Renal Network 3 implemented a pilot project to collect and share information among transplant programs, dialysis patients, and kidney providers so that patients’ waitlist status would be clear to all. We recommend that this program be scaled up across the country, and that CoPs and CfCs for transplant programs and dialysis facilities respectively be amended to require their cooperation with the program. We believe that making it easier to monitor status will help disadvantaged patients navigate a system that generally favors those with more resources.

### Home Dialysis

DPC uses its member surveys to gauge patient priorities and preferences, and gather information to guide our advocacy. We frequently ask the same questions over time to ascertain trends.

The Appendix to this letter reports responses from the 2021 DPC Member Survey relevant to modality consideration. Our surveys continue to find that a large proportion of patients do not recall being meaningfully informed of transplant and home modality options. We understand that often, the exigent and overwhelming circumstances of “crashing” into kidney failure can make it difficult for patients to process such information, or leave them fatalistic about preparing for the future.

Our surveys also continue to find a large proportion of patients who have been informed of home modalities did not and would not seriously consider them. While some patients cite logistical concerns relating to space at home, more cite personal preferences for in-center care.

A surprising finding in our 2021 survey was that there has been no change since 2013 in the proportion of patients who say they were informed of modalities other than in-center dialysis,

nor in the proportion seriously considering alternate modalities such as home or transplant. In both 2013 and 2021 about 70% reported being informed about PD, and only 40% seriously considered it. In both years, about 87% said they would not consider it further. We would have expected, given Agency efforts beginning during the Trump Administration, and also contemporaneous efforts by kidney care providers, ESRD Seamless Care Organizations, and ESRD Networks to promote home dialysis, for these numbers to have edged higher. We are particularly perplexed by the change in one number in the middle of a pandemic: In 2013, 30% gave as a reason for not considering PD “I am worried about infections.” In 2021 that percentage doubled to 63%. The number saying they felt safer in the clinic remained stable (51% to 49%).

While conventional wisdom holds that vulnerable people would feel safer at home during a pandemic, our data does not bear that out. We urge the Agency to further explore this dynamic and address it if the Agency’s findings mirror our own. We suspect that the type of paradigmatic changes the Agency hopes to spur may not be possible on the short timeline over which the Agency expects results. We also wonder if the patient-preference “ceiling” for home care in the U.S. may be more static, and lower, than the Agency assumed.

#### Care at Home Provision of Conditions for Coverage

The Agency has solicited comments on how it can “increase availability and use of home support resources with regard to home dialysis,” asking specifically if there is “a need to revise the current standards in § 494.100, including but not limited to updating and revising training and care delivery requirements?” It further asks whether “allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients [would] increase the selection of and uptake of home dialysis as a modality?”

We presume that these questions are inspired by the Innovate Kidney Care coalition. We are aware that that this group seeks regulatory relief, but the exact revisions they seek have not been communicated to stakeholders. We know only that they have asked the Agency to “remove barriers that make it challenging for self-dialysis, home training, and support to be provided in existing health care settings” and “expand options to provide accessible, safe virtual care and training to patients electing self-dialysis modalities.”

DPC urges the Agency to be guided by these principles in considering requests to revise the Conditions for Coverage:

- Patients should be able to exercise informed choice as to their preferred modality.
- Revisions to promote “transitional care via in-center self-dialysis” should be limited to circumstances where self-care already has an evidentiary basis for being implemented safely.
- Self-dialysis must not become a default for patients to start on but limited to instances where the patient has been fully informed of all modalities in an objective manner and consents to an innovative treatment pattern.

- To maintain patient safety, protections analogous to and equivalent to existing protections must be enforced for the new treatment patterns.
- Patients should retain the right to onsite clinical support while dialyzing.
- Any facility or specialized transitional unit eligible for regulatory relief should be affiliated with a broader facility or program that can offer all modalities, and educate on and perform tasks necessary for transplant workup and referral.

### Promoting Upstream Chronic Kidney Disease (CKD) Treatment

The RFI asks “What can be done to increase screening of at-risk individuals and how can we ensure that PCPs provide timely referrals to nephrologists for individuals with poor or declining kidney function?”

We continue to be concerned about the role that illness-triggered insurance coverage changes play in disincentivizing optimal CKD detection and treatment. We refer to the fact that CKD patients become eligible for Medicare upon kidney failure. To the extent that CKD patients have comorbidities that make them expensive, kidney failure becomes an opportunity for an employer, commercial insurer, or Medicaid managed care plan to drop them and shift costs to the federal government. The 30-month coordination period mandated by the Medicare Secondary Payer statute was designed to penalize employers for poor CKD care, but it is threatened by a pending U.S. Supreme Court case. Meanwhile, this mechanism has no analog in the Medicaid sphere.

With new kidney-preserving drugs coming to market and the rise of the renal care management industry, there is plenty of opportunity for insurers to make an impact on CKD. The question is whether incentives are properly aligned to exploit these developments. The Agency needs to monitor this situation as it relates to the working-age population. With regard to kidney patients covered by Medicaid, the Agency should scrutinize the cases of new Medicare ESRD beneficiaries transitioning from Medicaid to ascertain whether deficiencies in chronic disease care led to kidney failure that could have been delayed with proactive interventions. If, as we suspect, Medicaid managed care organizations are not prioritizing CKD care, the Agency should develop creative financial structures to align incentives.

### Disclosure of Joint Venture Arrangements

The Agency asks whether a dialysis facility or nephrologist should be required to disclose information on joint venture arrangements to patients for improved transparency. We believe it would be appropriate to report such information on the Dialysis Facility Compare website.

Disclosure of physician financial interests has become a norm, with enactment in the Affordable Care Act of mandatory disclosure of physician ownership of imaging equipment and payments from drug and device manufacturers. While we are realistic about the likelihood of patients seeking out such information, we think the information should be available to patients who want to make such inquiries.

Thank you for your consideration of our comments and concerns. If you have any questions or would like additional information, please do not hesitate to contact me or our Vice President of Public Policy Jackson Williams (at 202-768-4506 or [jwilliams@dialysispatients.org](mailto:jwilliams@dialysispatients.org)).

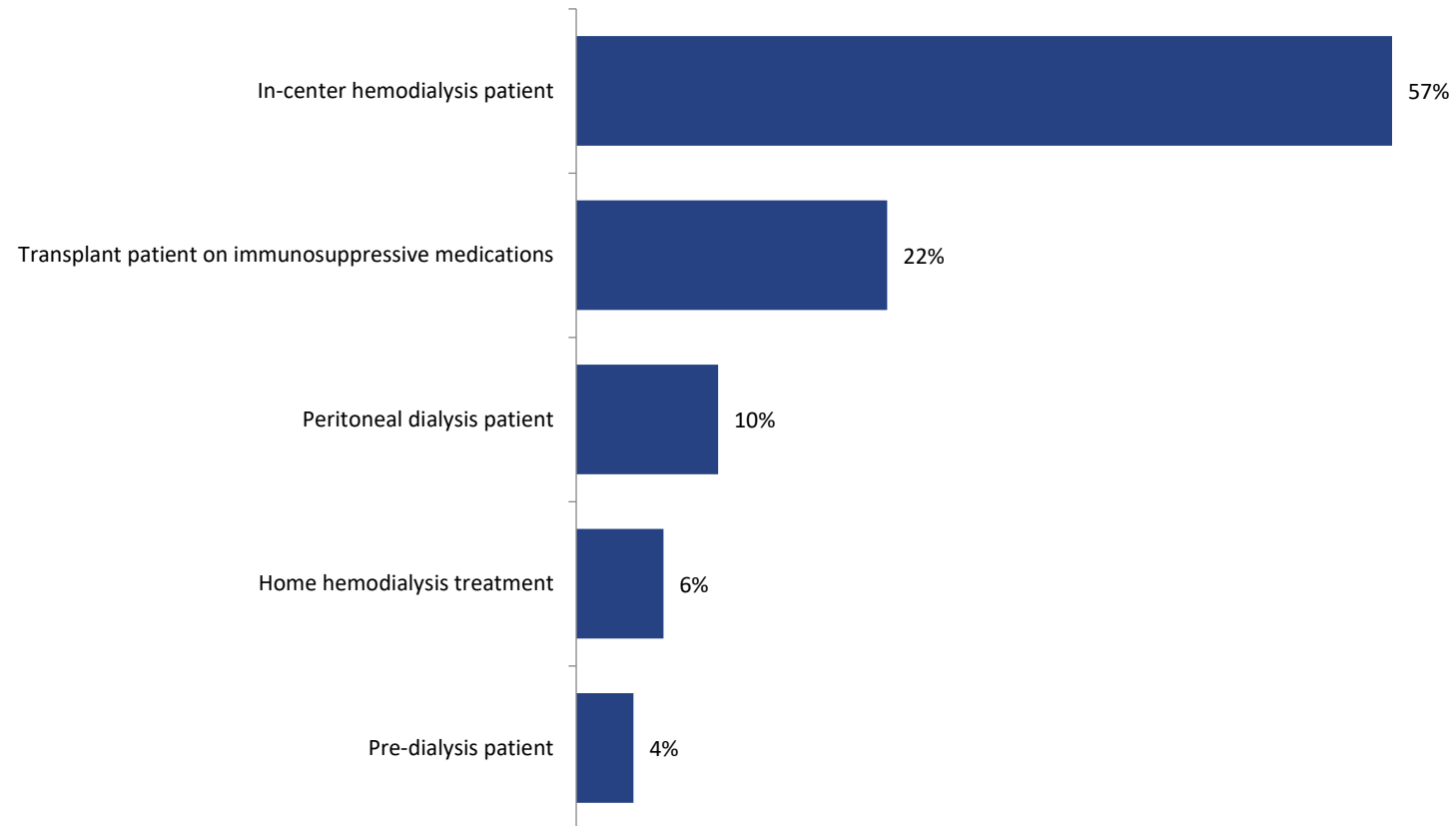
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Hrant Jamgochian". The signature is fluid and cursive, with a long horizontal stroke at the end.

Hrant Jamgochian, J.D., LL.M.  
Chief Executive Officer

# Treatment Modality

In-center hemodialysis is the most common treatment type among individuals with CKD, followed by transplant and peritoneal dialysis.



Base: Patients with CKD (n=526)

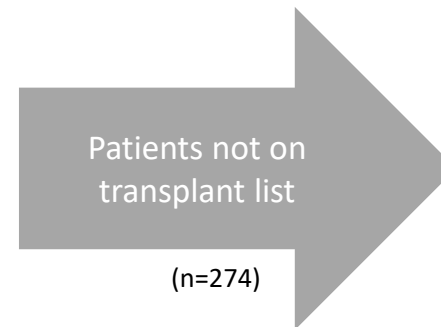
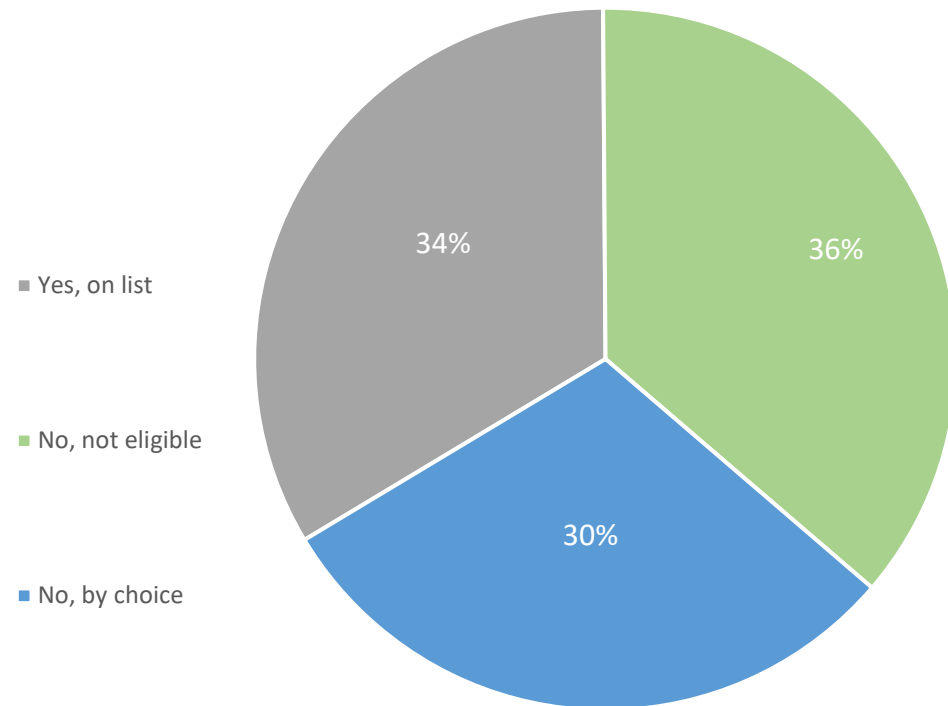
B1. What treatment do you receive for your chronic kidney disease (CKD)? *Select one.*



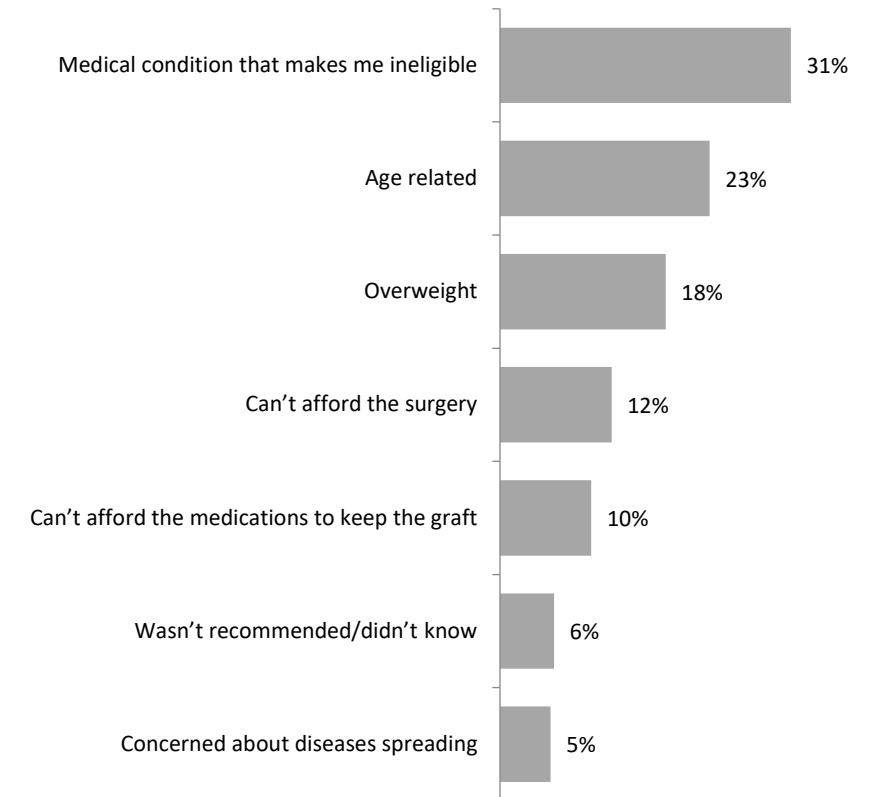
# Transplants

When asked about kidney transplants, two-thirds of patients declare they are not on the transplant list, whether it be by choice or being ineligible. The top reason cited among non-transplant patients for not being included on the transplant list is due to medical conditions that make them ineligible.

## Transplant list



## Reasons NOT on transplant list



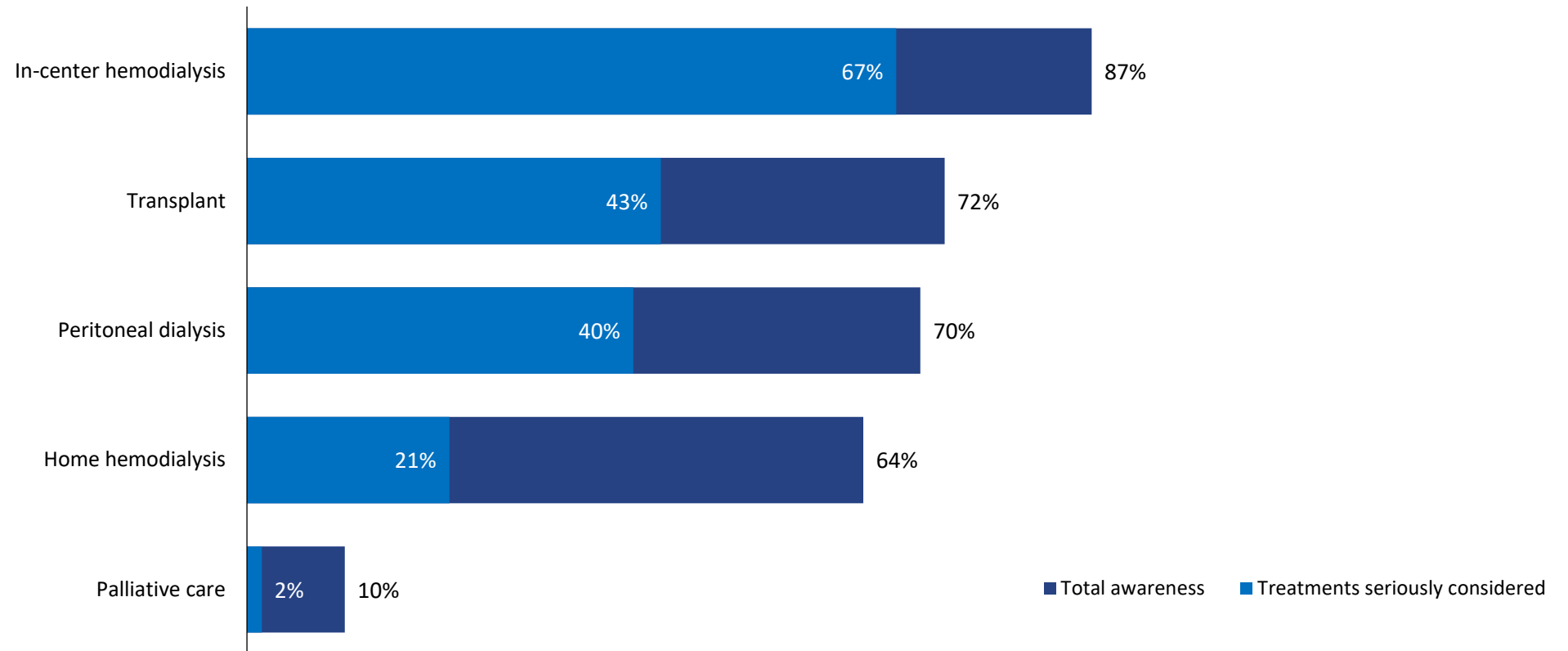
Base: Patients without transplants (n=412)

B1a. Are you on the transplant list?

B2. [ASK IF B1A=NO] What are the reasons you are NOT on the transplant list? Please select all that apply.

# Treatment Option Awareness & Consideration

7 in 10 patients with CKD say they have been informed about peritoneal dialysis by their healthcare team. Furthermore, nearly 2 in 5 patients say they have seriously considered peritoneal dialysis as a primary treatment option.



Base: Patients with CKD (n=526)

B3. What treatment options were you informed of by your healthcare team? Please select all that apply.

B3a. Of the dialysis options that you were informed of, which did you seriously consider? Please select all that apply.

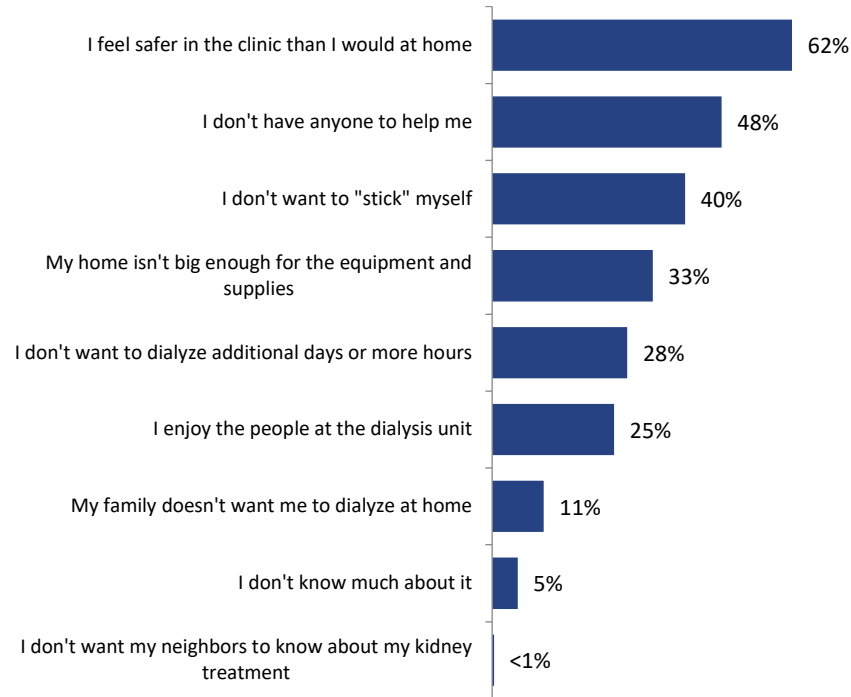
# Reasons to Consider / Not Consider Home Hemodialysis Among Those Informed But Not Considering

Among those who did not consider home hemodialysis, nearly two-thirds say the primary reason for not considering this treatment option is that they feel safer in a dialysis clinic than they would at home. Though two-thirds of patients would not reconsider home hemodialysis, more than 2 in 5 patients not considering mention they would be inclined to try home hemodialysis if new technology made home dialysis easier.

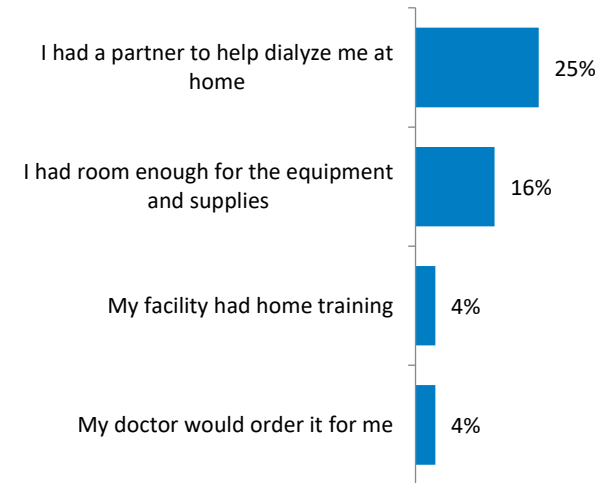
**67%**  
of patients who have been informed about home hemodialysis say they did not seriously consider this form of treatment for themselves



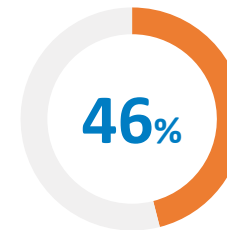
## Reasons to not consider home hemodialysis



## Reasons to rethink using home hemodialysis



**66%**  
of patients say they would still prefer not to do home dialysis



of patients would reconsider their decision if new technology made home dialysis easier

Base: Patients with CKD who were informed of but did not consider home hemodialysis (n=225)

B4. [ASK IF B3=2 BUT B3a NOT=2] Why did you not seriously consider home hemodialysis?

B5. [ASK IF B3=2 BUT B3a NOT=2] Which of the following, if any, would make you consider home hemodialysis?

4 B6. [ASK IF B3=2 BUT B3a NOT=2] If new technology made dialysis easier to do at home would you reconsider your decision?

# Reasons to Consider / Not Consider Peritoneal Dialysis

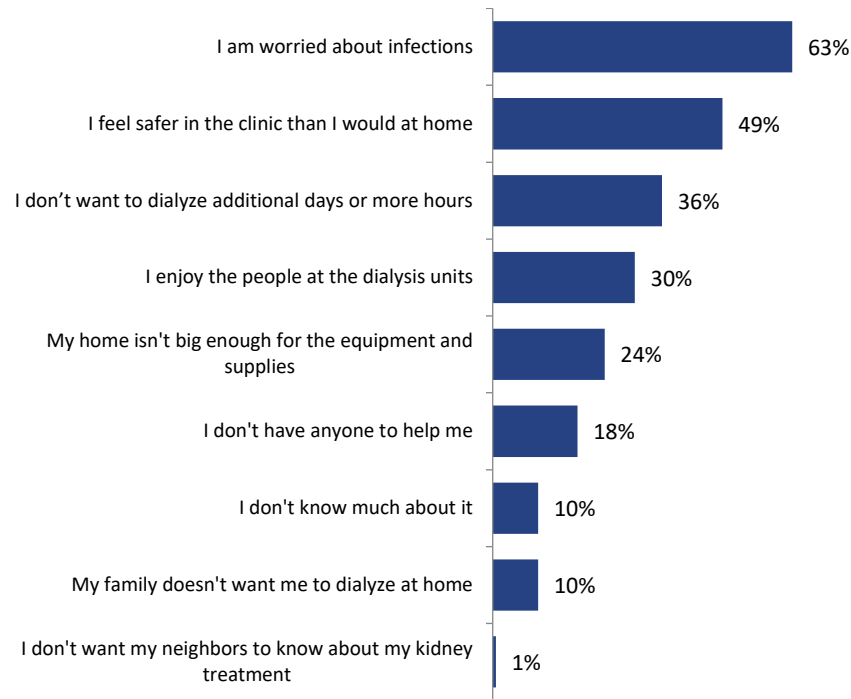
## *Among Those Informed But Not Considering*

Among those who did not consider peritoneal dialysis, more than 3 in 5 say the primary reason for not considering this treatment option is due to risk of infection. Over 4 in 5 patients not considering also mention that they would still prefer not to do peritoneal dialysis no matter the circumstance.

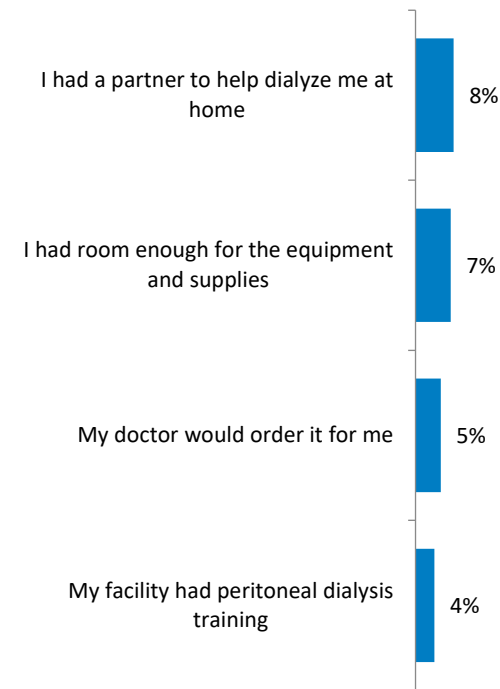
**43%**  
of patients who have been informed about peritoneal dialysis say they did not seriously consider this form of treatment for themselves



### Reasons to not consider peritoneal dialysis



### Reasons to rethink using peritoneal dialysis



**86%**  
of patients say they would still prefer not to do peritoneal dialysis

Base: Patients with CKD who were informed of but did not consider peritoneal dialysis (n=156)

B7. [ASK IF B3=3 BUT B3a NOT=3] Why did you not seriously consider peritoneal dialysis?

B8. [ASK IF B3=3 BUT B3a NOT=3] Which of the following, if any, would make you consider peritoneal dialysis?