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Pittsfield, MA

February 1, 2022

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Kam Kalantar-Zadeh, MD, MPH, PhD  
Irvine, CA

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3409-NC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Secretary**

Chris Brown  
Cranbury, NJ

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Seattle, WA

**Past-President**

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Nashville, TN

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

**EDAC Chair**

Brandy Vinson  
Richmond, VA

Dear Ms. Brooks-LaSure,

**MAC Chair**

Kam Kalantar-Zadeh, MD, MPH, PhD  
Irvine, CA

The National Forum of ESRD Networks appreciates the opportunity to comment on the Request for Information CMS-3409-NC. Members of the Forum's Kidney Patient Advisory Council (KPAC) have reviewed the RFI and comments included in this correspondence reflect their experiences, observations and preferences.

**KPAC Co-Chair**

Derek Forfang  
San Pablo, CA

**EDAC Vice-Chair**

Vicky Cash  
Beachwood, OH

The KPAC is composed of at least one kidney patient representative from each of the 18 ESRD Networks in the United States; some Networks have 2 representatives serving on the KPAC. Members of the KPAC are actively involved in our local ESRD Network activities as well as the activities and initiatives of the Forum. As representatives for our Network and the Forum, we are in constant communication with other kidney patients in our regions to gather information and experiences which allow us to provide a broad perspective to projects such as this RFI.

**KPAC Co-Chair**

Dawn Edwards  
Jamaica, NY

**Members-At-Large**

Christine Logan, MD, FASN  
Seattle, WA

We have limited our comments to those sections of the RFI we feel are most pertinent to our membership. Below are our comments.

Kelly M. Mayo, MS

Tampa, FL

Keith Norris, MD, PhD

Los Angeles, CA

Thank you for your consideration.



Derek Forfang

Co-Chair, Forum Kidney Patient Advisory Council

Stephen Pastan, MD

Atlanta, GA

Katrina Russell, RN, CNN

Seattle, WA


Preethi Yerram, MD, MS, FASN

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Dawn Edwards

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**Forum Coordinator**

Dee LeDuc

Birchwood, WI

**Federal Register Page 68596:** 2. Transplant Program CoPs

***1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received?***

It is my observation that location of dialysis facilities/transplant centers inhibits the ability of marginalized individuals to access services relating to treatments for their CKD. Mobile Dialysis is a viable idea providing there are requirements in place that ensure underserved communities and their inhabitants be recipients of these services.

Establishment of brick-and-mortar facilities may seem to be a difficult task. These are facilities that can serve as neighborhood centers of health literacy education as well as service providers. The advantages to dialysis providers /owners locating more facilities in underserved areas would, of necessity, exist or be established. Tax incentives that are very conducive to the establishment of these new businesses are already available.

“Opportunity Zones”, often areas characterized by concentrated poverty, are designated by the Federal government. Investment in these areas is rewarded substantially with tax incentives and abatements. Major dialysis *providers can be educated to these opportunities*. Further, *incentives* could be sponsored by CMS that could, make it possible for these facilities to survive. One way of doing this would be *to track equitable* purveyance of services across all facilities. Due to served populations, these facilities might be incentivized by CMS for meeting or exceeding pre-established criteria.

**Federal Register Page 68597:** 3. Transplant Recipient Patient Rights

***4. What was the most helpful information about organ transplantation you received?***

During the Orientation Session, a transplant recipient spoke to the audience (me included) frankly about his experience. He did not sugar coat. That presentation has stuck with me for the last 10 years. Subsequently, after having my own transplant, I was requested to address prospective recipients and donors and did so many, many times. I have always realized the benefits of his address. He was a great role model!

***1. Did the transplant program provide you with information specific to your unique needs, medical situation, and potential transplant outcomes?***

I have been trying to get back on the transplant waitlist since last March and am very dissatisfied with the “care” and “service” I have received. I see why so many patients give up and never make it on the waitlist. The process is not designed to expedite the evaluation and get patients waitlisted. I received an orientation which was acceptable, and then met with the various disciplines in the transplant program. I felt quite hopeful about getting listed with this institution but was very disappointed when I was given a list and told to go get these tests done and have the results sent to us at this number. I believe the program should have been more helpful in assisting me in scheduling these tests with various doctors, more specifically, I expected to have the “evaluation” done at the transplant facility. After thinking about the way I

was treated, I called the facility to speak with someone about my dissatisfaction, and have not been able to speak to a live person or receive a call back yet. I will be transferring to another program as a result

- 2. Did the transplant program provide you with any information about waiting times specific to your type of organ transplant? If so, what was the waiting time estimate that the transplant program gave you?***

At the initial evaluation meeting, held with other hopeful wait listers, we were shown a presentation about the different types of transplants, the approximate wait times and educated about the benefits of accepting compromised organs. We were also encouraged to find a living donor and told how to start a campaign to find an altruistic donor. We were told it takes about 5-7 years for a deceased donor transplant and maybe sooner if we accept a compromised organ.

- 4. What is/was the most helpful information about organ transplantation you received? From which source did you receive this information? Did you receive other helpful information from other sources? If so, what were those sources?***

The most helpful information I received was through my own research on the topic of sensitized patients and the better chances of them getting transplants. I learned this from a transplant surgeon himself on a webinar. Most of my transplant education is learned from webinars by kidney stakeholders and articles from medical journals.

- 5. Are you satisfied with the communication and support you have received from your transplant program? What information from your transplant program did you find helpful in making your decision?***

Since attending the orientation and dropping off bloodwork, I have not had any follow-up from this transplant program. I was given a list of tests and medical clearances I needed to get done, with no direction or resources and support. I am so dissatisfied; I am planning to switch to a different transplant program.

- 6. For patients who are or were on dialysis, what information did you receive on organ transplantation from your dialysis center? Do you believe the dialysis center supported organ transplantation? Why or why not?***

My dialysis center is supportive of my decision and will provide any information or resources I ask for, but there is no liaison or encouragement given without asking. I am sure I will receive more support from my dialysis center when I transfer into their transplant program.

**Federal Register Page 68599:** 4. Equity in Organ Transplantation and Organ Donation

- 1. Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?***

I believe the transplant programs need to be held accountable for how many patients they successfully get active on waitlists. Far too many patients go to transplant programs and get stuck in the evaluation process because they are handed a list and told to go get these tests done

with no help in coordinating the tests. Patients often see several doctors, but some see no doctors besides those in the dialysis center and have no idea how to get referrals for the necessary tests and clearances. All tests and clearances need to be done at the transplant hospital in as few visits as possible. And transplants of the identified underserved should receive higher reimbursement. A requirement for transplant programs and OPOs to target disparate communities and provide education and resources may encourage more patients to initiate the transplant process. I firmly believe, if the process was easier, more patients would pursue transplants. A requirement for all testing to be done on premises, within a certain amount of time, unless the patient prefers to have their own doctors perform tests would incentivize the facilities to expedite testing and get patients waitlisted.

- 2. Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights? Social determinants of health are those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life-risks and outcomes. Obtaining consent for donation is vital to increasing the number of organs available for transplantation. However, studies have demonstrated that African Americans are half as likely as Whites to agree to donate a loved one's organs. In addition, studies have shown a "lower donation rate among racial/ethnic minorities, specifically including Blacks, Hispanics, and Asians". There are many factors that contribute to these differences, including medical mistrust and differing opinions on organ donation and transplantation. OPOs have a key role in educating the public on organ donation and reaching out to those in underserved populations to address concerns or misconceptions regarding organ donation. They must also obtain consent from families in underserved communities with cultural sensitivity, awareness, and empathy. In order to ensure that more organs are available for transplant to those in underserved populations that need them the most, we are therefore asking what role CMS can play to ensure that OPOs can better build trust and awareness in historically underserved populations and communities (including racial and ethnic minorities).***

CMS should require that OPOs be trained by community organizations on racial sensitivity and communication. We know that communities of color have higher mortality rates, therefore, could very well greatly influence the donor pool. The OPOs need to know when and how to effectively communicate to the families and provide information to them about how their potential donation can affect the lives of people of their own race. Not enough is known about organ donation in communities of color and many misconceptions exist. Because of these misconceptions and other causes mentioned in the question. Families of potential donors will not be receptive to OPOs when asking for donations of organs. Families are usually unprepared and grieving and the death may be traumatic and untimely. OPOs need to be trained to approach in a way that can achieve more positive responses and donations. Community education on organ donation and who needs those organs needs to be transparent, this should be a requirement of OPOs with measures to be sure this education is taking place in underserved communities. Outreach should also be extended to patients and families through education programs to encourage living donation as these same issues exist, encouraging family members of patients to donate can also be beneficial to increasing the donor pool. This should also be a measured and reported quality initiative for OPOs.

- 3. How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation? This would include ways that CMS can hold OPOs accountable for their outreach and communication to those underrepresented communities while maintaining cultural competency, such as awareness of various religious beliefs surrounding organ donation. Comments should include considerations of how to address issues pertaining to medical mistrust, disadvantageous social and economic factors, and the effects of systemic racism and discrimination on underserved populations.***

I believe CMS is responsible for setting the standard, and the OPOs are responsible for carrying out the standards. OPOs need measurable, outreach and education programs directed towards places people congregate, schools, community health centers, houses of worship, and other places people in underserved communities live and work. In an ideal society, television and radio airwaves would have public service announcements on the importance of organ donation in underserved communities, to make the conversations begin in the home and spread abroad. Schools should be targeted to educate the young and start them on the road to being informed about organ donation, the young may start those conversations at home and help to change some of the misconceptions and misinformation.

- 4. How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?***

A standardized, measurable, culturally sensitive and appropriate education curriculum should be taught to patients in underserved communities to ensure understanding of treatment options, transplant, and organ donation. Just handing a brochure or a website link has not shown to be productive methods of education from past history. The use of peer mentors and patient educators have shown positive results in patient education, empowerment and decision making. These peer mentors and educators should be paid, staff members and assigned to underserved communities and in OPOs should be present in dialysis centers as well as in the community holding workshops and collaborating with community health stakeholders to present information and educate.

- 5. What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?***

Currently, if a patient does not ask about transplant themselves, many do not receive information. Education is limited to a brochure and requirement to sign that they have been educated. This is unacceptable. Requirements of standardized, education for all patients, provided by a combination of health educators, specifically assigned to a facility as well as peer mentors should be responsible for providing education and support. Designated, staff should be part of the IDT to serve as transplant liaisons to help patients navigate the transplant process. These persons must be held accountable by submitting quantitative reports on the progress of each patient.

**6. *What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?***

More documentation and verification should be in place for decisions made that patients are not suitable candidates. A review board or some type of authority should be evaluating to ensure equity is in play including an interview or communication with the patient themselves. This will ensure accountability.

**Federal Register Page 68600: 2. Home Dialysis**

***The patient has the right to be informed***

I was not informed of the different dialysis modalities and peritoneal (which did not work out well) was selected for me. When I struggled with this modality, no other modalities were discussed. The dialysis Center where I received the peritoneal training was a joint venture with members of the nephrology practice in ownership. That is where I was sent for services – no choice.

**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?***

Kidney patients usually come to their "crash moment " at an Emergency room with Kidney failure it is far too late for doctors to either take the time to educate the patient with other options and are reacting so quickly that there is no time for any discussion. This is why there needs to be a mandate across U.S. that all kidney patients are given information about home therapy as an option. There is no universal level of standards for dialysis centers, therefore, patient-centered quality of care cannot be achieved. Implementation of a policy and procedure would ensure that all kidney patients prior to receiving treatments would at least be told and given resource materials on home therapies. Other realities / barriers the patient may have:

- Unable to find a dependable care partner.
- Lack of storage space for medical supplies.
- A physical inability / or disability to handle the inventory
- Water / and Pipe fitting for water purification.
- Financial means to be able to fill in the gaps.

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

All kidney patients need to register their ethnicity before treatments begin. If you cannot measure it, you cannot manage it. This is the only way CMS can be given accurate statistics information based on race. In order to have Health Equity / Racial Equity in kidney care you have to gather this information in order to achieve equality.

As a Native American, I can see that the 560 tribes, 2.2million Native Americans / Alaskan Indians are not even recognized with this report. Congress has consistently underfunded Indian

Health Services forcing hospital administrators to limit services offered. As a result, tribal members have a different kidney health care reality than many other U.S. citizens. Against this decades-long underfunding there are overarching challenges in healthcare that further exacerbate access to healthcare, kidney care for Native Americans is almost nonexistent, most do not have reliable transportation, and getting kidney care is difficult. The reality is that home therapy is an almost impossibility. Housing on the reservations are sub-standard, old pipes that are unable to sustain the clean water supply that is needed. (Some reservations water needs to be hauled in from the outlying areas of Indian Reservations). A problem that is more severe is a lack of medical personnel: A problem that is even more severe in tribal communities, especially those in remote reservation locations.

Statistics of the Navajo Nation:

1 out of 3 residents do not have access to electricity.

1 out of 3 residents do not have access to running water.

40 % unemployment rate

Solution or Health Equity in Rural areas / Indian Reservations:

- Invest in community health workers and centers.
- Build trust by working within the community.
- Increase Broadband Access.
- Improve transportation options to increase accessibility.
- Expand Tribal Public Health Services - offer kidney care and home therapies.
- Address social deterrents of health, food, housing security and health literacy.
- Address clean water and land. (toxic waste / dumping grounds are near reservations also known as Environmental Racism).

**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 of 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?***

Telehealth has had a very positive response during the Covid crisis. This technology has untapped a population that would not normally seek healthcare services - rural America. I know that living in Oregon for example, outside of the Portland Metropolitan area specialty services such as kidney care is very difficult. Central and Eastern Oregon is less populated and is vast with open land and wilderness, a very different landscape than most other states. Access to Broadband would allow physicians to leverage an increase of patients and Quality patient care no matter who you are or where you live would no longer be a barrier. Physicians would be able to see more patients, and patient choices can be made so custom-tailored treatments can start, hopefully before a kidney patient has their "crash moment."

**Federal Register Page 68600:** 3. Dialysis Alternative Settings a. Nursing Homes

**1. *Should dialysis facilities have geographical limitations for distance between the certified dialysis facility and nursing homes where they provide home dialysis services? Would health and safety issues be mitigated if there were some type of geographical limitation? Are there***

***areas where placing a geographical limitation could create access issues where there are no dialysis facilities near the nursing home? If so, why, and how could these issues be mitigated?***

As a patient who required care in a SNF, both with on-site dialysis and without, dialyzing off-site poses many safety issues. The infection control issues from Covid-19 taught us that it is impossible to maintain safety for patients in dialysis centers when nursing home patients are transported to off-site dialysis centers. A requirement for hospitals to send dialysis patients to SNFs that offer on-site dialysis would greatly protect patients in dialysis centers and make it safer for the patient requiring SNF care. In my experience, I was transported from the SNF to the dialysis center for treatment with a fractured hip, in the winter. The treatment schedule was inconvenient as I missed meals, important pain medication and visits from family because I was off-site. In addition, I traveled over half an hour from the SNF to the dialysis center, strapped to a stretcher, bouncing in the ambulance through traffic, which caused me terrible pain and discomfort. I was also recovering from ostomy surgery and I would have accidents during the time I was dialyzing and transporting, with no way to clean up and be made comfortable. This was both humiliating and dehumanizing having to dialyze and travel in my own filth. When I returned to the SNF, I often missed my meal and was in intolerable pain. If a SNF with on-site dialysis was provided for me, I would have been able to have meals, medication and attend to my ostomy needs at the facility.

It should be a shared decision what SNF a patient resides in with comprehensive discussion between the patient, family and care team as to the facility, their ability to meet the dialysis needs, and the ability of the family to visit the patient. These are all things that are very important to patients and impact morale and recovery. Some patients want to stay at their home facility because they feel comfortable with the staff they know, however in some cases, this is neither safe, nor feasible.

When I was in a SNF the second time, I demanded to be sent to a facility with dialysis on-site. The facility was far from home, but I was more comfortable and did not need to travel outside for treatments, it was my decision, with my family and we knew, because of the distance, they would not be able to visit in person. My needs were met and I was able to recover and receive my treatments and rehabilitation in one place.

**Federal Register Page 68600:** 3. Dialysis Alternative Settings d. Alternative Types of Dialysis Treatment Facilities Including Mobile Dialysis

***1. Should the use of mobile dialysis be limited to emergency circumstances and enrollment as a Special Purpose Renal Dialysis Facility?***

Mobile dialysis can fulfill some of the much-needed choices for patients for treatment and should not be excluded to emergency circumstances. Mobile dialysis can provide the use of home dialysis and self-care alternatives to patients who otherwise would not be able to access these modalities. Patients could access mobile units in rural areas and when traveling to take the stress off facilities in tourist locations. Mobile units would provide more access and increased patient choice, especially to underserved and rural areas.

***2. How can mobile dialysis be used? Should these units be independently certified or used as an extension to an existing facility if approved outside of emergency circumstances?***



Both independent as well as an extension to existing facilities would be beneficial to provide fairness, competitiveness, and patient choice. This can allow for new entities to enter the kidney care space and give patients choices on the provider they use.

**3. *What are the oversight considerations of these mobile dialysis units if units do not have a brick-and-mortar location and are moving among various locations? If used outside of an emergency circumstance, should there be geographical limitations?***

Mobile units should be held to high standards because they are not stationary. The priority should be given to rural and underserved areas, where patient treatment options are not available. Patients that desire home therapy but due to home structure or other factors are not able to do more frequent or home dialysis could benefit from treatment in these mobile settings. Transportation and access is a huge factor in underserved areas, home dialysis services are usually not available in underserved communities, requiring patients to travel long distances to participate in home programs and training. This makes patients feel like these modalities are not for them. Mobile units in tourist locations may also make services easier for traveling patients.

**5. *What health and safety standards are necessary to ensure a safe physical environment in mobile units?***

A mobile unit would need to operate on a tight schedule, adhering to appointment only requirements due to limited space, they must however have ample space for patients to wait, and offices for examinations if needed. IDT staff and supportive There must be sufficient space for necessary supplies and appropriate separation between patients receiving treatment.

**7. *How can CMS ensure appropriate staffing roles, responsibilities and oversight of patient's dialysis care and needs by interdisciplinary team members for mobile units? Would these units require different staffing mix or requirements than a stationary dialysis unit?***

A mobile unit should provide the same IDT staff and services as a brick-and-mortar facility. The patient/staff ratio should be comparable and support staff such as cleaning and maintenance staff should be appropriate to the unit size, hours of operation and patient census.

**8. *What other alternative types of dialysis treatment facilities should we consider?***

Facilities that offer home therapies only should be more available, particularly in underserved areas. These can be smaller facilities that offer training, respite care and home dialysis treatment education and training.

**12. *Given the importance of water quality for dialysis, how do we ensure safe water standards with facilities that do not have water treatment centers?***

With the current technology available and on the horizon, a variety of equipment can be utilized, particularly equipment that does not require water, instead pre-mixed dialysate would be highly reliable and convenient for many patients and tailoring to individual prescriptions can be offered.

**Federal Register Page 68605:**

***Information on organ acceptance practices***

CMS should track and evaluate this information. It should be disseminated to prospective recipients concurrently with information regarding success and survival rates of the Centers.

**Federal Register Page 68607:** D. Nephrology Joint Ventures

***“...to increase transparency....”***

1. YES. It would be helpful for CMS to collect information on joint venture arrangements.
2. YES. The dialysis facility or nephrologist be required to disclose information on joint venture arrangements especially its effect on patient care and choice
3. YES. Joint ventures (at least the one I encountered) have an impact on patient care and/or choice.

Thank you for your consideration.