



February 1, 2022

Via Electronic Submission

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3409-NC
Mail Stop C4-26-05
7500 Security Boulevard, Baltimore, Maryland 21244

RE: Request for Information, Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations and an End-Stage Renal Disease Facilities, Docket No. CMS-3409-NC

Dear Administrator Brooks-LaSure,

The Kidney Transplant Collaborative, Inc. (KTC) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) request for information (RFI) on the Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations and an End-Stage Renal Disease Facilities (Docket No. CMS-3409-NC, RIN-0938-AU55), published in the Federal Register on December 3, 2021.¹ KTC is grateful that CMS has issued the RFI highlighting several crucial areas of concern for the transplant community, and has sought information on a wide range of questions spanning the numerous stakeholders and participants in the transplant process.

CMS has a critical role to play in both monitoring and regulating the existing entities involved in transplantation, as well as in developing new and innovative regulations and guidance that will allow all stakeholders in the process to collaborate more effectively in the future to both address health equity in the transplant space, improve outcomes and save costs. We hope our comments below will assist the Agency in formulating new and improved policies that will increase kidney transplant in both the short-term and long-term.

About KTC: The Kidney Transplant Collaborative (KTC) is a national non-profit advocacy organization that is dedicated to increasing kidney transplants while decreasing the financial obstacles and other challenges kidney recipients, donors, and families often experience during the kidney transplantation process. KTC is a relatively new organization, founded in February 2021, with the sole and specific mission of supporting programs and policy solutions to

¹ 86 Fed. Reg. 68594 (Dec. 3, 2021).



increase kidney transplants and reduce transplant barriers. KTC has engaged experts with technical, clinical, and quality expertise from the renal and transplant community to serve on the Board of Directors and Expert Advisory Panel (EAP), who assess the organization's grant and policy priorities.

In the past month, KTC has authorized approximately \$3.2 million to fund five grant proposals directed towards increasing kidney transplants. The grants will address pulsatile perfusion of kidneys from procurement to delivery, using machine learning to improve utilization and reduce discards, using shared decision making in the kidney transplant process, rapid organ recovery from donation after uncontrolled circulatory death, and exploring deceased kidney donor chains. Notably, following the kickoff of its grant program in mid-2021, KTC received nearly four times the anticipated number of grant proposals from nationally recognized institutions across the country, with 70 different proposals seeking over \$43 million in funding. Several common themes and issues emerged from the proposals, including improving living donor compensation, expansion of paired and chain kidney donation programs, patient engagement regarding organ acceptance and discard rates, and transplant waitlist management. Projects proposed various strategies to address these issues, including educational, medical, and technological interventions, engaging in strategic partnerships, and implementing creative models to address staffing, processes and organizational infrastructure.

We highlight our recent experience because the grant proposal response, as well as the information contained in the proposals, underscore that significant gaps continue to be prevalent in the kidney transplant system today. In addition to its anticipated future regulatory agenda, we urge CMS to consider funding further research studies, as the KTC experience has demonstrated that significant meritorious research projects remain to be pursued in the coming years.

Summary of Comments and Key Recommendations:

In response to the questions below, KTC has the following recommendations for CMS:

- Eliminate from existing regulation the two hard outcome measurement requirements, 42 C.F.R. 482.80(c) and 482.82(b)(2). Requiring transplant programs to meet hard outcome measurements is no longer warranted, and results in programs declining all but the healthiest patients in need as well as otherwise viable and appropriate organs for transplant. It is time to eliminate these historic regulations;
- Explore the propriety of implementing Shared Decision Making between patients and their families, nephrologists, other physicians, OPOs and transplant programs, to improve patient care;
- Update the living donor regulations and build a living donor program within the Agency to comprehensively manage living donors through each step of the donation process. Within the proposed new living donor program, create an office of living donor advocacy



to ensure that living donors are represented in each stage of the donation process, and have an advocate to ease the process for them, The proposed program should also create national standards for living donor programs, educate the public, and particularly minorities and the under-served, about living donation opportunities, among other objectives, while promoting the opportunity and need for living donation to all sectors of society;

- Harmonize existing regulation and consolidate current regulatory bodies involved in transplantation into a single Office of Transplantation within the Office of the Secretary or the Office of the Assistant Secretary for Health;
- Require enhanced communication between OPOs, transplant programs, patients and their nephrology providers involved in organ offers to reduce declines of offers and discard rates;
- Promote health equity by purposefully identifying opportunities for minority and rural engagement, and intentionally increasing education and communication with those underserved by current transplant programs (including the ESRD Treatment Choices (ETC) Model and Kidney Care Choices model), and closely examine the current discussions about the use of eGFR equations; and
- Expand opportunities for preemptive transplant by facilitating the living donor process and encouraging nephrologists and treating physicians to regularly advise patients on the availability of preemptive transplant as a treatment option, as well as the importance of living donation.

Select CMS Questions and KTC Responses:

1. Improving Existing Condition of Participation Regulations

CMS Question: “We are requesting the public’s input on issues pertaining to potential changes to the transplant program CoPs, transplant recipient patient’s rights, and equity in organ transplantation, in order to achieve these goals.” (Question II.A.1, 86 Fed. Reg. at 68596 col. 2).

KTC Comment: We appreciate CMS asking this broad-based question, and while we will answer the question in more detail in response to the more specific questions that follow, we highlight three regulatory changes that we urge the Agency to consider proposing for comment and adoption:

1. **Measurement of transplant outcomes as a basis for certification and recertification of transplant programs -- 42 C.F.R. 482.80(c) and 482.82(b)(2):** CMS correctly notes in its RFI that “the number of organs discarded continues to be high” and “this number could be significantly reduced.” It is deeply troubling that 5,085 organs (including 3,755 kidneys) were discarded in 2018, and the numbers have likely grown since that time. CMS is correct that more needs to be done to ensure transplant programs and physicians are “accepting and utilizing more organs that



are deemed “marginal”, thus ensuring that more patients on the waitlist receive lifesaving transplants.”

A challenge for transplant centers to accept so-called “marginal” kidney is that the center risks upsetting its outcome measurements using 1-year post-transplant graft failures. Simply put, organ transplant, and kidney transplant specifically, has matured as a medical procedure to the point that it is no longer appropriate to be measuring transplant centers on their expected vs. actual 1-year graft survival rates. We note that of the numerous CMS regulatory requirements for general hospitals, specialty hospitals, rehabilitation hospitals, and all other types of hospitals, transplant programs are the sole hospital function that has hardwired “outcome measurements” in regulation. “[Kidney Transplant] surgery involves the same level of risk for the donor as any other major surgery.”² While it is difficult to compare outcomes for recipients against the outcomes in other surgical procedures, we believe that transplant surgery today does not bear unusual risks and surely is no longer “experimental.” We urge CMS to align transplant hospital regulations with all other hospital regulations and eliminate the hard outcome measurements in the cited regulations

2. **Shared Decision-Making:** In eliminating the hard-wired outcome measures, we also urge the Agency to explore how to best incorporate the process of “shared decision making” (SDM) into the organ transplant regulations. CMS is well familiar with the SDM process, “a patient-centered approach in which clinicians and patients work together to find and choose the best course of action for each patient’s particular situation,”³ and has incorporated SDM principles into a number of other regulatory schemes across the Medicare program.⁴ KTC believes that SDM principles and practices are particularly relevant to the transplant program generally, and to the reduction of kidney discards specifically. To the extent that OPOs, Transplant programs, patients and their families, and other stakeholders are able to communicate and share in the decision-making regarding transplantation generally, and the availability of offered organs specifically, discards may be reduced as patients and their physicians are able to communicate more effectively about the utilization of so-called “marginal” organs.

There are numerous models of shared decision making which CMS can consider in implementing a SDM framework for organ transplant, including the National Quality Forum’s

² <https://www.kidney.org/transplantation/livingdonors/risks-of-surgery>

³ Wieringa, et al. Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. *Syst Rev* 8, 121 (2019). <https://doi.org/10.1186/s13643-019-1034-4>, available at <https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-019-1034-4>

⁴ See, e.g., 42 C.F.R. 425.112(b)(v) (ACO regulations); 42 C.F.R. 414.1305 (definition of “Aligned Other Payer Medical Home Model” which includes SDM principles); Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT). (CAG-00439N). Centers for Medicare and Medicaid Services; <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=274> (last accessed December 27, 2021); CMMI, Beneficiary Engagement and Incentives Model, May 2021: <https://innovation.cms.gov/webinars-and-forums/bene-sdmloi> (last accessed December 27, 2021).



NQP Playbook: Shared Decision Making in Healthcare,⁵ and the Renal Physician's Association's "Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis."⁶ The American Society for Transplantation and the American Society of Transplant Surgeons have also found SDM to be feasible in kidney transplantation.⁷ Using these models, or other models already implemented by CMS in other therapeutic arenas, CMS should consider the best use of SDM by the nephrologist (with or without a Chronic Kidney Disease ("CKD") team), in a CKD clinic; or by a team of qualified independent health professionals. SDM practices should also be explored (in a manner that ensures they are more than a "check the box" activity) at several stages of the transplantation journey, including at the initiation of ESRD care to the CKD patient, when the patient reaches the stage of becoming seriously ill, and during the course of ESRD care (including, but not limited to, dialysis). These practices include situation diagnosis, choice awareness, option clarification, discussion of harms and benefits, deliberation of patient preferences, and making the decision.⁸ The International Patient Decision Aid Standards (IPDAS) require that a decision aid support these key elements.⁹ We urge CMS to develop the appropriate Decision Aids that could assist the SDM process around kidney transplantation, in order to explore a meaningful way to incorporate SDM into the transplant process.

3. Update National Living Donor Regulations: The current transplant regulation is quite detailed as to virtually every aspect of the transplantation process, and includes specific metrics used to monitor and evaluate OPOs and transplant centers, the specific staff that each should have and the qualifications for such staff, and numerous other details regarding the transplant process. When it comes to living donors, however, existing regulation (other than the donor's "bill of rights") fall short, simply requiring transplant hospitals to have a "living donor advocate" or "living donor advocate team." 42 C.F.R. 482.98(d)). The regulations only speak to the qualifications of the team, but do not address specifics regarding the living donor experience or standards that living donor programs must meet. We urge CMS to overhaul the living donor regulations, to both provide details that directly speak to multiple steps that living donors must undertake when participating in the donation process, as well as reform the living donor cost reimbursement process within the limits of NOTA. We address these issues in more detail below.

⁵ https://www.qualityforum.org/Guidance_to_Improve_Shared_Decision_Making.aspx

⁶ <https://connect.aahpm.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=6ec5a73d-ecab-44f9-b3ee-7e99702e67b5>

⁷ Gordon, et al., Opportunities for shared decision making in kidney transplantation, PMID: 23489435 DOI: 10.1111/ajt.12195; Am. J. Transplant (May 2013)

⁸ Weiringa, *supra*, footnote 5.

⁹ See <http://www.ipdas.ohri.ca/resources.html>



2. Living Donor Program Regulation

CMS Question: “Do transplant programs adequately protect the health and safety of living donors and transplant patients? Please provide data, research, studies, or firsthand accounts that would be illustrative of how transplant programs are performing with regards to adequately protecting patient health and safety.” (Question II.A.2.2, 86 Fed. Reg. at 68596 col. 2).

KTC Comment: As referenced above, KTC does not believe that transplant programs are as effective as possible in managing the living donor experience, and we advocate that that CMS create standards and program protocols that all living donor programs must meet. As of 2021, there are approximately 93,000 Americans waiting for a kidney transplant. The average wait for a kidney is 3-5 years; 12-17 persons die each day waiting for a kidney transplant. The waiting list is growing faster than organs from deceased donors are becoming available. While more needs to be done to improve kidney recovery from deceased donors, the gap can be closed even faster if living donations increase. In 2020 31% of all kidney donations come from living donors (12,587 deceased donors and 5,725 living donors). And increasing donations has been documented to save the federal government significant funds.

Living “paired,” “chain” and “directed” donations are safe, ethical, and have been effectively transplanted for decades. Unfortunately, however, the living donation system is not centrally organized, is not donor-centric and lacks meaningful federal support, resulting in several non-profits and dozens of transplant centers operating a balkanized living donor system. Minimal resources are available to serve as patient navigators for the true heroes of the system – those altruistic individuals who volunteer to donate a kidney and save a life.

The federal government has provided extensive support for many aspects of the transplant process, funding the Organ Procurement Transplant Network to maintain the national transplant waitlist, paying for dozens of Organ Procurement Organizations to work across the country to recover organs from deceased donors, and reimbursing transplant hospitals to cover the cost of transplants for Medicare and Medicaid beneficiaries. Yet, there is no federal program to support and coordinate living donations, which are a promising source of new organs to save lives. Nor is there a program to provide the needed donor care necessary to ensure that these American heroes are properly cared for during the transplant process, or after kidney donation.

CMS could implement a comprehensive regulatory regime that creates the national living kidney donation program (the "Program") to increase the number of transplants for recipients suitably matched to related and unrelated donors of kidneys, to provide patient navigators and other assistance to living kidney donors. The Program could match donors with transplant candidates (which only occurs at the local level today within transplant hospital networks), recruit and screen donors through a network of federal resources, undertake necessary public information campaigns, and pursue data collection and reporting. This program could be implemented in a



way that respects and honors the physician-donor relationship, and that learns from the best practices of the non-profit sector that is already innovating in this area. CMS could also establish its own office of donor advocacy (the “Office”), to ensure that donors are guided and cared for at each step of the donation process. The Office is intended to supplement, and not replace, existing donor navigation programs operated by transplant centers, and to allow transplant centers to partner with the Office for donor navigation services.

The proposed living donor Program should also work to recruit donors, focusing on minorities and other populations to advance health equity, and undertake an information and education campaign to recruit potential donors, all of which are integral to creating the cultural awareness and attitude needed to expand living donation in this country. Further, we believe CMS should create a baseline of uniform donor criteria that can be used by transplant centers as default criteria for their own standards (even while recognizing that physicians and transplant centers may require additional medical information beyond the minimum data set established in regulation). CMS could also provide information to the public about the Program and to collect comments from the public to improve Program operations. The Agency should also consider post-transplant care for living donors experiencing transplant-related health conditions as a requirement for transplant programs.

Finally, a CMS-based program could consult directly with relevant stakeholders, including the National Marrow Donation Program, the Departments of Defense and Veterans Affairs, the existing not-for-profits engaged in living kidney donation, and others, to improve living donor programs, both centrally and across the country. A national CMS living donor program could explore ways to coordinate living donation across international borders, particularly for hard-to-match individuals, to improve their chance of securing a transplant.

We note that the RFI does not seek information regarding living donor cost reimbursement,¹⁰ which is an important element of the living donor experience. While the National Living Donor Assistance Center (NLDAC) is doing what it can to address this issue within the guidelines provided by the Health Resources and Services Administration (HRSA), that Agency needs to be far more aggressive in meeting the financial and other health and wellness needs of living donors in order to create the landscape necessary to allow willing volunteers to become living donors.

We would welcome further discussion with CMS as to ways in which the Agency could establish a national living donor program that would elevate living donors to their true status as health

¹⁰ We appreciate that HRSA recently completed a rulemaking on this issue, 85 Fed. Reg. 59438 (Sept. 22, 2020). In KTC’s view, however, the rulemaking did not adequately address the need to provide comprehensive cost and expense reimbursement to living donors. We also appreciate that CMS may not have included information about the NLDAC in its RFI given that NLDAC falls under the jurisdiction of the Health Resources and Services Administration (HRSA). To the extent that is true, it highlights the need for HHS to consolidate the transplant program in one single office within the Department. We address that issue below.



heroes, improve the living donor experience and reduce the logistical difficulties associated with living donation, coordinate and expand cost reimbursement, and increase this important pool of organs to reduce transplant wait times.

3. Harmonizing Policies Across Agencies

CMS Question: “We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies? Question II.A.2.5, 86 Fed. Reg. at 68596 col. 3).

KTC Comment: KTC strongly encourages the Secretary to consolidate and harmonize all transplant functions across CMS and HRSA¹¹ into a single Agency (or group within the Office of the Secretary). While KTC appreciates the Agencies’ need to separate treatment of Medicare beneficiaries from others in the transplant system, the result is a suboptimal set of policies that are not appropriately coordinated across the relevant Agencies. As noted above, the fact that CMS regulates transplant programs and hospitals, yet HRSA regulates the NLDAC and Organ Procurement Organizations (OPOs) inevitably creates disconnects for transplant donors and recipients, duplicative and uncoordinated regulatory and sub-regulatory policies, and a lack of responsibility across the federal agencies. In the same way that the transplant program uniquely touches both Medicare beneficiaries and non-beneficiaries, a new Transplant Office could be created in the Office of the Assistance Secretary for Health that addresses both sets of stakeholders, and manages reimbursement issues through inter-agency transfers, rather than through separate programs. We urge the Secretary to restructure the program within the Department to bring accountability and avoid duplication and missed opportunity, to the federal transplant program.

4. Improving Communications Between OPOs, Transplant Centers and Patients; Reducing Discards

CMS Questions: Are there additional requirements that CMS could implement that would improve the manner, effectiveness and timeliness of communication between OPOs, donor hospitals, and transplant programs? Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS’ decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval? (Question II.A.2.6 and 7, 86 Fed. Reg. at 68596 col. 3). “How can transplant

¹¹ Because the Food and Drug Administration’s role is so fundamentally different, we do not address FDA here.



programs facilitate greater communication and transparency with patients on their waiting list regarding organ selection while limiting undue delays or undue anxiety to their patients?"
Question II.A.3.1, 86 Fed. Reg. at 68597, col. 1).

KTC Comment: The RFI highlights the current kidney discard “crisis,” and the difficult loss of kidneys from the transplant system due to unnecessary discards. As documented in the literature cited by CMS,¹² there are numerous reasons for discards, including social determinants of health, race, and even transplant surgery scheduling. KTC suggests there are two other issues that also need to be addressed in evaluating the unnecessary discard issue: possible communication issues at the time an offer is made, as well as the absence of clear statistics about the frequency and causes of organ discards. In our view, improved communications between transplant centers and patients awaiting a transplant could reduce the discard rate.

Solving these communication and reporting issues is both controversial and complex. For example, it may be the case that the hard outcome measures found in 42 C.F.R. 482.80(c) and 482.82(b)(2) motivate transplant centers and physicians to be more cautious than needed in accepting kidneys with a relatively high Kidney Donor Profile Index (“KDPI”) score.¹³ See pages 3-4, above. Further, transplant centers (and treating physicians) will often solicit the recipient’s preference for so-called “marginal” kidneys at the time the recipient is added to the center’s waitlist, but the recipient’s preference may change – particularly if the recipient has had to endure months of dialysis. At the same time, KTC recognizes there often are medical reasons or practical and logistical considerations that require a transplant program or physician to reject an otherwise viable kidney for transplant, and there is no reason to burden either the provider or the potential recipient with a mandatory communication that will result in an inevitable outcome.

In addition to shared decision-making which we strongly support, better communication is needed among all providers responsible for the health of the patient. Specifically, greater communication with the nephrologist could improve the rate of discarded organs but also

¹² See 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. Erratum in: *JAMA Network Open*. 2019 Oct 2;2(10):e1914599. PMID: 31469394; PMCID:PMC6724162, cited at 86 Fed. Reg. 68596 n.6; Mohan S, Foley K, Chiles MC, Dube GK, Patzer RE, Pastan SO, Crew RJ, Cohen DJ, Ratner LE. The weekend effect alters the procurement and discard rates of deceased donor kidneys in the United States. *Kidney Int*. 2016 Jul; 90(1):157–63. doi: 10.1016/j.kint.2016.03.007. Epub 2016 May 12. PMID: 27182001; PMCID: PMC4912390, cited at 86 Fed. Reg. at 68604 n.35; Mohan S, Chiles MC, Patzer RE, Pastan SO, Husain SA, Carpenter DJ, Dube GK, Crew RJ, Ratner LE, Cohen DJ. Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int*. 2018 Jul;94(1):187–198. doi: 10.1016/j.kint.2018.02.016. Epub 2018 May 5. PMID:29735310; PMCID: PMC6015528, cited at 86 Fed. Reg. at 68604 n. 37..

¹³ See Peters, T., Editorial: Good News Regarding Race and Kidney Transplant Access in America, *American Journal of Transplantation* 2012; 12: 810–811, doi: 10.1111/j.1600-6143.2011.03902.x (2012) (noting “analysis of regulatory effects may be fertile ground” for further investigation in addressing transplant issues).



increase patient outcomes and satisfaction. The treating nephrologist is responsible for the day-to-day diagnoses, treatment, and management of the acute and chronic kidney patient that will be receiving the organ. Given this proximity to the patient, the nephrologist has useful insight into the patient's condition that could be better incorporated into the transplant decision making process.

Given that more work is needed on these issues, we call on CMS to convene an expert advisory panel to offer recommendations on how to improve communications without interfering with medical decision-making and the physician-patient relationship. The expert advisory panel should also consider and recommend how CMS could develop a standardized reporting metric addressing organ refusal rates in a manner that would not skew care. Finally, we also urge CMS to consider mechanisms that ensure providers are properly "coding" the reason for organ refusal so that the information currently captured by the SRTR is as accurate as possible.

5. Health Equity

CMS Question: 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?" Question II.A.4.3 (56 Fed. Reg. at 68599, col. 2)

KTC Comment: We commend CMS for posing the appropriate questions regarding health equity in the transplant system. As CMS notes, health disparities have persisted for decades across a range of issues in transplant programs, including a vast underrepresentation of racial minorities, lack of access to those living in rural communities, and a disregard of people with disabilities. Both explicit and implicit bias have played a role, and unfortunately it will take years and a dedicated effort to eradicate this discrimination across all stakeholders.

KTC acknowledges the OPTN's commitment to health equity through "increased equity in access to transplant as measured by UNOS-published equity in access methodology[; r]eduction in time from policy project origination to implementation[; the volunteer workforce will reflect the patients and professionals served by the OPTN[; and an i]ncrease [in] the average number of individuals per cycle participating in the OPTN public comment period."¹⁴ Yet, KTC believes more needs to be done. Studies of health equity shortfalls in kidney transplant have been available for a decade or more.¹⁵ As KTC itself takes steps to address and help eliminate racial and gender disparities in kidney transplantation, we urge CMS to do the same by requiring all transplant stakeholders to identify the issue, measure equity outcomes, evaluate social determinants of health, promote examples and models of successful (living and deceased donor)

¹⁴ <https://optn.transplant.hrsa.gov/about/strategic-plan/goal-2/>

¹⁵ See Gordon, et al, Disparities in Kidney Transplant Outcomes: A Review, *Semin Nephrol.* 2010 Jan; 30(1): 81. doi: 10.1016/j.semnephrol.2009.10.009 (Jan. 2010), citing articles.



transplantation in minority communities, and ensuring affordable access across minority and rural communities to transplantation.

African American patients have lower rates of completing the transplant evaluation process and of being placed on the kidney transplant waiting list. However, there are few studies that explore the disparities that exist in completing the early steps in the kidney transplant process, such as receiving a transplant referral, initiating the transplant evaluation, and finishing the transplant evaluation. We recommend that CMS requires the collection of national data on these pre-waitlisting steps so that reasons for disparities can be identified and used to target quality initiatives to improve equity in access to renal transplantation.

Program transparency, deliberate data collection and response to findings, and persistent leadership by CMS in continuously raising the health equity issue and development of educational and other materials to battle the bias across the transplant landscape remains needed. KTC welcomes joining with CMS to address these issues. Related, KTC highlights the proposal above to establish a dedicated living donor Program within HHS that would educate potential living donors in a culturally and ethnically appropriate manner on the opportunities to participate in the transplant program as one step in addressing the equity challenge in transplantation.

KTC also acknowledges the current debate over the use of patient's estimated glomerular filtration rate (eGFR) and the adjustment in that estimate based upon race. Although we understand that development of eGFR was never intended to create racial inequity, we urge CMS to evaluate the 2021 recommendations of the National Kidney Foundation and the American Society of Nephrology task force concerning the CKD-EPI equation refit without race.¹⁶ We also urge CMS to consider the very recent data suggesting that improved prediction of ESKD progression can be obtained using the Kidney Failure Risk Equation (KFRE) score.¹⁷ While this important issue needs to be addressed, KTC notes that the use of eGFR rates is but one of numerous issues that needs to be revisited to restore health equity in the transplant process, and that achieving equity in kidney health will require a broader focus by CMS in the months and years to come.

6. Preemptive Transplantation

CMS Question: To improve long-term outcomes and quality of life, how can we support and

¹⁶ Delgado C, Baweja M, Crews DC, et al. A unifying approach for GFR estimation: recommendations of the NKF-ASN task force on reassessing the inclusion of race in diagnosing kidney disease. *Am J Kidney Dis.* 2021. [PMID: 34563581] doi:10.1053/j.ajkd.2021.08.003.

¹⁷ Bundy JD, Mills KT, Anderson AH, et al; CRIC Study Investigators. Prediction of end-stage kidney disease using estimated glomerular filtration rate with and without race. A prospective cohort study. *Ann Intern Med.* 11 January 2022. [Epub ahead of print]. doi:10.7326/M21-2928.



promote transplantation prior to the need for dialysis (preemptive transplantation)? Question II.B.1.7.1 (56 Fed. Reg. at 68600, col. 1)

KTC Comment: KTC strongly supports taking measures to encourage those suffering from ESRD to consider pre-emptive transplant as an alternative to dialysis. Whether measured from a health outcomes, cost, or other perspective, preemptive transplant is almost always preferable to dialysis care. KTC appreciates that the CMS ESRD facility conditions or participation require each ESRD facility's interdisciplinary team to evaluate each patient for "suitability for transplantation referral," 42 C.F.R. 494.80(a)(1), 494.90(a)(7)(A-C), but KTC respectfully suggests that these measures are not enough. More specifically, we recommend that CMS consider requiring ongoing and continuous patient education in both the nephrology and other medical provider settings about the benefits of pre-emptive transplant, emphasizing the benefits to patients of exploring preemptive transplant as a treatment option. Through a comprehensive education effort that includes the issues of living donation, more ESRD patients and their families can learn of and seriously evaluate transplantation as a treatment option

Conclusion

We again thank CMS for its thoughtful and wide-ranging RFI and hope the above comments will assist CMS in further formulating new policies to address and improve kidney transplantation in the United States. As the Agency itself points out, the current waiting list is too long and growing, and more needs to be done to increase kidney transplants across our country. We welcome further partnership with CMS on these important issues. To that end, we thank you for consideration of these comments and welcome any questions or follow up that you may have. Please feel free to contact me at 301.832.2734 or ldiamond@kidneytransplantcollaborative.com if we can provide any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Louis Diamond", with a long horizontal flourish extending to the right.

Dr. Louis Diamond
President & CEO
Kidney Transplant Collaborative