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Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–3409-NC
P.O. Box 8010
Baltimore, MD 21244–8010

RE: CMS-3409-NC - Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities; published at Vol. 86, No. 230 Federal Register (68594-68608) on December 3, 2021.

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on the Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities – Request for Information (RFI). UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health Des Moines is home to the Iowa Methodist Transplant Center, one of three transplant centers in Iowa. For over 30 years, the Iowa Methodist Transplant Center has provided state-of-the-art kidney transplant services with over 1,000 transplants performed. In the state of Iowa, the Iowa Methodist Transplant Center is leading the way as the first center to utilize a humanitarian living donor as well as the first in robotic-assisted laparoscopic living donor nephrectomy.

UnityPoint Health respectfully offers the following input on select questions posed in this RFI:

TRANSPLANT PROGRAM CONDITIONS OF PARTICIPATION (CoPs)

CMS is soliciting comments on a number of questions pertaining to potential changes to the transplant programs CoPs, transplant recipient patient's rights, and quality metrics in organ transplantation in order to achieve program goals.

2. *Do transplant programs adequately protect the health and safety of living donors and transplant patients?*

Comment: All transplant centers including Iowa Methodist Transplant Center strive to keep recipients and living donors healthy, which means working with patients to achieve optimal outcomes. As a standard practice in patient safety and patient experience, our center actively monitors the biannual release of Scientific Registry of Transplant Recipients (SRTR) outcomes and utilizes predictive analytic tools to assess where the center will be in the next release. This standard practice has allowed us to apply a data-driven approach in patient selection as well as ensure improved patient outcomes and post-transplant care. For example, if our center experiences an increase in graft loss or adverse outcomes, it guides our selection committee to be more cautious. While being more selective may work against the center's main goal of performing more transplants in order to end dialysis and realize heightened quality of life and longer survival, it does allow for standard practice to achieve positive and consistent patient safety results and overall outcomes.

3. *How can the current transplant program CoPs be improved in order to incentivize and ensure performance quality in organ transplantation?*
   Comment: All transplant centers focus heavily on outcomes, not only for patient safety but also for their impact on regulators and payors. Specifically, outcomes heavily influence which transplant programs are included on payor preferred programs lists, and when transplant programs are reviewed by regulators for safety or performance improvement. This primary focus on outcomes, with particular emphasis on one-year and three-year outcomes, restricts transplants programs and disadvantages patients on transplant waiting lists. The impact to our center has been significant. Currently Iowa Methodist Transplant Center is a net importer of marginal organs and has seen a significant decline in offers following the removal of Donation Service Area (DSA) and Organ Procurement and Transplantation Network (OPTN) region from deceased donor kidney allocations. **UnityPoint Health would recommend incentivizing CoPs to create the possibility of combining high-quality care while allowing for more marginal kidneys to be accepted and transplanted and fewer kidneys discarded.** Shifting incentives would lead to a shorter waitlists and faster transplant rates.

4. *Do the initial approval requirements at § 482.80 create barriers to the establishment of new transplant programs? Do they require an excessive amount of hospital resources at program launch, resulting in hospitals retaining lower performing transplant programs? What alternatives for ensuring quality and oversight should be considered?*
   Comment: Transplant centers strive to grow and improve care. New programs, innovation in care, and growth all require hospital administration buy-in and approval. Hospitals must spend time and resources supporting each service line. **UnityPoint Health recommends standardizing policies from all governing bodies to allow transplant programs to redirect efforts to patient care.** This would help expand the transplant service line in a more efficient and effective manner.

5. *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?*
   Comment: Transplant centers work diligently to comply with program requirements and differing policies can make this challenging. For example, all centers understand the importance of organ verification, ensuring the right organ goes to the right patient. However, differing or conflicting policies create additional hurdles and undue confusion across the care team (operating room, anesthesia, transplant center, and staff). **UnityPoint Health recommends implementing one**

standardized policy for organ verification and check-in. This would result in less confusion with the care team and effectively increase patient safety.

6. *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?*
   Comment: All centers and OPOs utilize UNet, a centralized computer network that links transplant hospitals, OPOs, and histocompatibility labs on one platform. UNet has been able to integrate into their system HIPAA compliant mobile communication which many centers use today. **UnityPoint Health recommends utilizing an existing system, such as UNet, to enable communication by all centers and OPOs.** This will allow for more streamlined care and organ utilization as well as allow centers and OPOs to communicate in one system while maintaining compliance.

8. *Are there additional quality measures that CMS should consider in measuring a transplant program's performance?*
   Comment: Patient and graft survival has been the primary metric since 1987. A more holistic approach to evaluating transplant centers is being taken by SRTR. The SRTR 5-teir assessment[1] takes pre- and post-transplant measures into account which will allow for a complete picture of the center, organ acceptance rate, and transplant rate as well as outcomes. In addition, the waitlist mortality ratio and the offer acceptance ratio, paired with outcomes, will give a more accurate account of the risk that a center takes with different patient populations. Furthermore, the SRTR approach considers a center that accepts organs that would otherwise be discarded. **UnityPoint Health recommends the SRTR 5-teir assessment for pre- and post-transplant metrics as the standard in measuring quality, risk, and outcomes.**

9. *In the context of organ shortage and expanded use of marginal, suboptimal quality organs, and transplantation into standard and high-risk recipients, CMS is seeking public comments from the recipient perspective and expectations on meaningful measures including but not limited to graft survival benefit, shorter waiting list time, frailty improvement and quality of life after transplant, and other transplant benefits.*
   Comment: Reviewing and adopting best practices from centers that currently transplant higher-risk patients and marginal kidneys can benefit a larger patient pool. Iowa Methodist Transplant Center is a net importer of high KDPI kidneys in higher-risk patients. This patient population often takes more clinical resources until the patient has stabilized. However, in many cases these patients are successful and can lead better lives than if left on dialysis or without treatment. Our center has been using marginal kidneys for the last decade with a high success rate; this has led to a shorter waitlist and ultimately hundreds of lives saved.

TRANSPLANT RECIPIENT PATIENT RIGHTS

CMS is interested in understanding how the CoPs/CfCs, in particular the patient and transplant recipient rights requirements, could be revised to ensure that transplant programs, ESRD facilities, and OPOs are providing appropriate education and information to patients and their families on organ transplantation.

3. *Did the transplant program or transplant surgeon provide you with any information on organ offers*

[1] https://www.srtr.org/about-the-data/guide-to-using-the-srtr-website/txguidearticles/metrics-marked-as-most-important/#:~:text=Results%20%20%20%20%20%20Hazard%20ratio,%200.94%20%280.90-0.98%29%20%201%20more%20rows%20

that were made for you and were declined by the transplant program or surgeon?

Comment: There is merit in patients knowing about organs offered; however, this needs to be carefully evaluated. Often transplants happen in the middle of the night and off-hours and most centers have limited time to place organs after being notified of an offer. As a transplant center that utilizes marginal kidneys or high KDPI kidneys, not all offers are acceptable for all patients. For example, a 50-year-old patient who is not on dialysis with a GFR of 18, doing well and working full time - accepting a kidney with 16 hours of cold time, five hours from the transplant center, and a KDPI of 99 is not necessarily acceptable. However, this same offer would be a much better option for a patient who is 78 years old and on dialysis. **Reviewing organ offer parameters or filters with a patient at the time of annual listed reviews would be an acceptable and appropriate time to evaluate and change if necessary.**

EQUITY IN ORGAN TRANSPLANTATION AND ORGAN DONATION

CMS is soliciting comments on specific ideas to advance equity within the organ transplantation ecosystem, as they pertain to changes to the health and safety standards for transplant programs and 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?*

   Comment: Significantly lower donation rates exist among racial and ethnic minorities due to several issues including a distrust of the health care system and cultural and language barriers. It is up to the OPO to address gaps in real-time through education and support to potential donor families. Racial, ethnic, and psychosocial disparities exist in transplant just as they do in health care in general. This will look different for each transplant center, region, and patient population. Effects are felt in pre-transplant services through unconscious biases on listings, lack of resource support, and the challenges around fitting into the same "mold" as other candidates. In addition, disparities exist through assumptions around what quality of life might look like for individuals with mental health issues, advanced age, differing cultural norms, or available support systems. These same disparities can be seen in the patient's health history through lack of access to health care or inability to maintain adherence. **Time and resources are needed to study and implement best practices that aid in overcoming barriers in equitable access to transplantation.**

We are pleased to provide input on this RFI and its impact on our hospitals and health system, our patients and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at 319-361-2336 or cathy.simmons@unitypoint.org.

Sincerely,

Thomas P. Mulrooney, FACHE
Chief Operating Officer
UnityPoint Health - Des Moines
On behalf of the Iowa Methodist Transplant Center

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