



Service to those affected by chronic kidney disease

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February 21, 2020

The Honorable Alex M. Azar, II  
Secretary  
Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C4-26-05  
Baltimore, MD 21244-1850

**RE: CMS–3380–P: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization**

Dear Secretary Azar and Administrator Verma,

I am writing as the Founder and President of the Renal Support Network (RSN), a nonprofit organization founded in 1993 to empower people who have kidney disease to become knowledgeable about their illness and proactive in their care. I have had kidney disease since 1968, survived 50 plus surgeries and 13 years of dialysis, and am now living with my fourth kidney transplant. The Executive Order released on July 10, 2019 aims to establish more transparent and reliable metrics for kidney procurement in order to lower the discard rate and expedite kidney matching, and we agree that it will help immeasurably if done correctly.

This proposed rule will increase accountability and availability of the organ supply and update the conditions for coverage that OPOs (Organ Procurement Organizations) must meet to receive Medicare and Medicaid payment and remove financial barriers to living organ donation, but it is important these changes be made incrementally.

There are millions of people in the US living with some form of kidney disease and that number is growing. It is imperative to update, improve and successfully manage the organ recovery and transplantation process. We hope these new policies allow more people living with kidney disease to get on the transplant list and to receive transplants. The kidney community agrees that efforts need to be made to effectively regulate OPOs, living donor procurement and transplant center criteria and policies without the intention to penalize them and put patient care in jeopardy, but with the intention to improve processes for all involved parties. And we also see the need to value living donors, both through a streamlined process, compensation and care.

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An illness is too demanding when you don't have hope!

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We've been hopeful about proposed changes to legislation before and been disappointed because when put into action, there are often unforeseen consequences. An important question to ask is what is the measure of failure for any proposed changes? Sometimes when determining a uniform structure to which multiple organizations must comply, information is not considered that impacts the outcome. Here is an example:

In 2004, the Centers for Medicare & Medicaid Services (CMS) created the Fistula First initiative. In this press release they said, *"This new initiative aims to improve the quality of care and quality of life for Americans living with kidney failure,"* said Health and Human Services' Tommy G. Thompson. *"It is one of the many ways we're working to help people receiving Medicare to get the best possible treatment."*

A fistula is a "connection" surgically created by joining a vein and an artery in the forearm that allows blood from the artery to flow into the vein and provide access for dialysis.

*"Fistulas are the 'gold standard' for establishing access to a patient's circulatory system in order to provide life-sustaining dialysis,"* said CMS Administrator Mark B. McClellan, M.D., PhD. *"They last longer, need less rework, and are associated with lower rates of infections, hospitalization and death for Medicare beneficiaries than other types of access."* (1)

The above statements are all true. Fistulas take longer to mature than a synthetic graft which they were trying to avoid. Fistulas take a bit more skill by a surgeon and cannot be used right away. This policy resulted in patients needing more catheters while they waited for the fistula to mature and sometimes it never worked due to the patient's vascular anatomy. A graft can be the best choice for a patient given all their circumstances. On many occasions we heard fistulas were being placed in inappropriate candidates. Catheters yield a higher rate of mortality for people on dialysis, but the kidney community did not realize that situation would happen at the time of the policy. So now the dialysis community agrees that catheters should be the last option and the first is a choice between a graft or fistula.

It takes time to determine the effectiveness of new rules and policies and in the interim, patients often suffer despite it being a move to better patients' quality of life.

### **Organ Procurement Organizations (OPO) Conditions for Proposed Rule**

The average wait time for a kidney here in Los Angeles is up to ten years. It is disheartening that one-third of potential donor organs are not used and that all OPOs receive the same contracts regardless of how many organs they recover. The goal is to use as many organs as possible, but it is critical that they can be used successfully. Not all facilities have surgeons with the necessary expertise to ensure organ safety and survival.

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OPOs need to have a set of best practices to ensure that the transplant centers are given the full scope on the kidney by performing the necessary tests such as a kidney biopsy or placing the organ on a machine pump and not cutting corners to save costs. Some kidneys are used for research and some are used for transplantation, and this should be differentiated when reporting. Also, the liver transplant community changed their geographic allocation region to encompass a larger area. Their goal is to help equalize the waittimes and help patients have a fairer shot in their area to receive the life saving gift. People who have the resources and need a kidney often multi-list. People in my area list in Los Angeles, San Diego and Las Vegas, Northern California and Arizona if they have the means to do so. They are all within a 2- 6 hour drive. Additionally, there is a need to educate older and at-risk patients about kidneys with a higher Kidney Donor Profile Index (KPDI) score (lower scores mean longer kidney life) which though not ideal, may statistically be a better life-prolonging option than staying on dialysis.

Current and realistic performance measures are critical to propel accountability, provided care is not hindered. Strengthening OPOs transparency and giving the transplant center the necessary information to make a decision on the organ will allow more potentially discarded kidneys to be used and more people who want kidneys can have access to resources and education. Payment always drives practice and it's important to use successful OPOs as a guide so the best practices can be utilized. In 2019, US OPOs recovered 11% more donors than ever before, marking nine consecutive years of record-setting organ recovery (11,870 Organ Donors from an estimated 18-20,000 potential donors). We want to remember that these increased numbers are from the generosity of donors and donor families who choose to give the gift of life. It would be wise to learn what the OPOs who are having the best success do to achieve these outcomes.

We are deeply concerned about the proposed rule which relies upon a state-provided death certificate as the deceased donor's cause of death information. Death certificates are broadly reported as inaccurate. Death Certificates exclude secondary diagnoses, like cancers, that did not cause the death, but regularly rule out deceased organ donation. Death certificates include no information on the most critical factor required for organ donation: neurological injury that leads to brain death.

### **OPOs, Transplant Centers and Dialysis Clinics Need to Work Together**

The road to transplant is a long one and many factors determine who is viable and who isn't There are barriers in place at many stages of the transplant process. As mentioned, along with OPOs, transplant centers and dialysis clinics must also be held accountable for their role in increasing transplantation, but it's a trickier prospect Currently, dialysis facilities are measured for percentage of people they serve who are on the waitlist and transplant facilities do not have any measures, yet they are ultimately responsible for the transplant. Each dialysis facility and transplant center has its own individual criteria as no two are equal, but unfortunately, a dialysis center will get penalized for not getting

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enough people transplanted or put on the waitlist, but nothing happens to transplant centers or the physician who is treating the patient.

Best practice guidelines may offer a solution so all parties involved can be on the same page. There are always outliers as people who live with organ failure don't want a one-size-fits-all health care system. Transplant centers need basic standardized criteria they *all* agree on which will prevent dialysis facilities from referring poor transplant candidates to an already overburdened transplant center. These criteria will help evaluate if a patient is a good candidate for a successful kidney transplant.

There are legitimate reasons certain people cannot be transplanted. Often already overburdened transplant centers cannot take everyone and accept even less people though some are viable candidates. They work as “silos”, so in order for less patients to fall through the cracks, centers need to be improved, not penalized or standardized. When you penalize with payment, they make financial choices that aren't always in the interest of the patient, again an example of payment driving practice. The Department of Health and Human Services (HHS) and CMS should work with kidney and transplant community experts to develop appropriate ways to address inconsistent transplant center waitlist criteria and make the transplant process more transparent and patient-friendly.

Here is a local kidney transplant center's evaluation list:

### **Absolute Recipient Contraindication**

- Body Mass Index (BMI) > 40
- Presence of active infection
- Active/recent substance abuse
- Advanced cardiovascular disease
- Presence of malignancy other than skin cancer (except melanoma of skin)
- Active infected wound based on clinical observation
- Advanced pulmonary disease
- Advanced liver disease (when not eligible for liver transplant)
- Severe peripheral vascular disease
- No social support system
- Active systemic disease (i.e. systemic lupus, Wegener's, sickle cell)
- Conditions that affect adherence that would significantly impair the patient's ability to comply with the complex pre- and post-transplant medical regimen

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## Relative Recipient Contraindications

- Body Mass Index (BMI) > or equal to 35-40 kg/square meter will be considered on an individual basis
- Active tobacco use, especially with co-existence of cardiac or peripheral vascular disease
- History of malignancy
- Inadequate social support system

Patients live in extremely varied geographic and socioeconomic regions and communities. Barriers to transplant vary from place to place. Many centers have financial criteria that patients must meet, which generally excludes transplant list access to patients with lower socio-economic status, and often this involves race as well. Kidney disease rises every year in communities of color, so this is significant. Patients must be available for blood work and follow up care (as well as other appointments), and usually must have a caregiver to even be considered for the transplant list. Additionally, a viable candidate must have the resources to pay for time off, usually for themselves or a family member, parking, food, travel and additional costs. The whole kidney community suffers from a shortage of nephrologists, but dialysis clinics and transplant centers are particularly impacted by a shortage of nephrologists as well as other staff, especially in rural areas. This makes care even more difficult for all patients, but especially patients with additional health issues. As a result of these barriers that give an advantage to the healthiest most financially-secure patients, patients are needlessly being denied access to life-saving transplants. Sadly, the US Healthcare system is set up so people with lower economic status can't afford the healthcare and medicine they need that would keep them from getting kidney failure in the first place, like insulin that helps manage diabetes.

All these factors must be considered when determining how to effectively analyze performance. While it's important that organizations like OPOs be held accountable, the standards need to be realistic and not lead to cherry picking so the kidney community is incentivized to make the right choice for their patients and more patients get in the door. And they deserve access to healthcare and medicine once they're in the door. It is also important that patients and their physicians work together to determine whether a transplant is the right option for that individual patient. Transplant criteria should not interfere with that ultimate patient decision-making process.

The decision to accept a patient as a candidate for transplant is complex and multifactorial, but we must ensure that waitlist and living donor candidacy criteria are as inclusive and patient-centered as possible, giving all patients a chance to pursue a transplant if they so choose.

## Annual Review

CMS is proposing four new parts to the proposed rule to make the current measure more "objective and reliable" including Donation Rate Measure, Transplantation Rate Measure, Top 25 Percent Benchmark and 12-month reviews.

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As it stands, OPOs are only reviewed every 4 years. Between the fact they now self-report and that the rate of people waiting for transplants/acquiring kidney disease increases at an unprecedented rate each year, it makes sense that after encouraging incremental change, they be evaluated every 12-months as proposed to keep information current and accurate, therefore useful. The information and data also need to be public and easy to find, so people seeking a transplant can make more informed decisions. If after a sufficient number of annual reviews and the OPO is still not producing adequate numbers, decertification may be the best course of action.

We support holding OPOs accountable who are not meeting a reasonable standard, provided there's no interruption of donations or care already in progress. But in order to decertify an OPO there must be an alternative in place.

Allowing better-performing OPOs access to the service area of the decertified OPO is one option. And it is critical that throughout this process, CMS not allow any lapse in a service area that would lead to a gap in organ collection and distribution. Federal law requires OPOs to ship 6 antigen match kidneys to the recipient if in a different OPO, so we don't want to create an environment where OPOs are bidding on each other's contracts and can potentially benefit if they fail. Again, payment drives practice.

### **Removing Financial Disincentives to Living Organ Donation**

More support needs to be given to both acquiring and caring for living donors. Things will improve if we incentivize living donation and donors through financial compensation and care. Financial barriers to living organ donation need to be lessened by expanding the definition of "allowable costs" – this includes increasing the income allowed for eligibility under the Living Organ Donation Program and allowing for reimbursement for expenses ranging from childcare to elder care. This is crucial because fear of lost wages is one of the biggest deterrents to donating, but there are other financial burdens. In 2018 Living Donors became covered by FMLA (Family Medical Leave Act) so fear of losing jobs entirely is gone but losing health insurance and unforeseen expenses (donor expenses generally range from \$900-\$3000) still exist and aren't specifically addressed. Also, the fact that after a living kidney donor is proven to be in excellent physical condition (a criteria for donating), and it's understood in the medical community you can live with one kidney without issue, a living donor is considered to have a "pre-existing condition" after donating. This means his/her medical care is at risk. This medical terminology and label need to be changed and be part of living donor protection as well.

Also, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019 (HR 5534) was introduced in the US Senate by Sens Bill Cassidy (R-LA) and Dick Durbin (D-IL); and in the House of Representatives by Reps Ron Kind (D-WI) and Michael Burgess (R-TX) and will extend immunosuppressive coverage past the 36-month Medicare cut-off currently in place to cover the medications for the life of the transplant. Immunosuppressants are the daily medications people who have been transplanted must take to lower the body's

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ability to have an immune response, so they do not reject the donated organ. It seems prudent to help people who have received the “gift of life” to keep it. Every effort should be made to pass this bill into a law.

### Summary

Good policy improves the lives of those living with kidney disease and protects them. Meaning patients receive *optimal*, as opposed to adequate, care. Bad policy promises people living with kidney disease things it cannot deliver. **CMS-3380-P** sounds like what could be a meaningful step towards improving kidney care as long as the suggestions we’ve made are considered. Implementing gradual change and minor restructuring in the proposed rule will stimulate those efforts.

I appreciate your attention of our input. I know this issue affects you very personally, Mr. Secretary. As you know, for people living with kidney disease, this is literally a matter of life and death and we welcome a continued dialogue about issues affecting the kidney community. I constantly tell people, “An illness is too demanding when you don’t have Hope” and in addition to practical advantages, this proposed rule would also increase the amount of hope among those living with kidney disease if more kidneys are available so they can receive a successful kidney transplant.

Sincerely,



Lori Hartwell  
President/Founder

#### 1. CMS LAUNCHES “FISTULA FIRST” INITIATIVE TO IMPROVE CARE AND QUALITY OF LIFE FOR HEMODIALYSIS PATIENTS

<https://www.cms.gov/newsroom/press-releases/cms-launches-fistula-first-initiative-improve-care-and-quality-life-hemodialysis-patients>