PUBLIC POLICY OPPORTUNITIES
A Blueprint to Improve Kidney Health, Reduce Demand of Kidney Transplants and Dialysis, and Increase the Supply of Kidneys Available for Transplant

AGENCY: CMS/CMMI

1) Include a Kidney Health Assessment measure in the Merit-Based Incentive Payment System (MIPS) and Medicare Advantage Star Ratings.
The National Kidney Foundation is developing a kidney health assessment quality measure for use in the MIPS. We expect to complete development of the measure by the end of this year. We are also working with the National Committee for Quality Assurance (NCQA) to develop a companion Healthcare Effectiveness Data and Information Set (HEDIS) measure for commercial health plans.

SHORT TERM <2 YEARS

1) Test the National Kidney Foundation’s CKDintercept Payment Model through CMMI. The CKDintercept Payment Model is a collaborative CKD model that includes primary care practitioners and nephrologists working together to provide the right care to the right person at the right time in their CKD journey. We strongly believe this patient-focused care model will also increase the percentage of ESRD patients receiving a transplant and selecting home dialysis.

SHORT TERM <2 YEARS

1) Develop a measure of shared-decision making for renal replacement therapy (RRT) and implement it across value-based programs including the ESRD Quality Incentive Program (QIP). Selection of RRT, including transplant and home dialysis, should be in
alignment with opportunities to help patients achieve their lifestyle preferences, values and goals. However, significant gaps in providers discussing these topics with patients remain.

**MEDIUM TERM 2-5 YEARS**

**TRANSPLANT**

1) In public-private partnership, develop a learning action network (LAN) of OPOs, transplant programs, nephrologists and patients to identify best practices in maximizing the use of donated kidneys, including imperfect ones. The National Kidney Foundation has developed a concept paper for the LAN.

2) **Modify the Hospital Inpatient Prospective Payment System Diagnosis-Related Grouping (DRG) for organ transplants to allow for adjustments to payment for transplanting higher risk kidneys.** Often transplanting these kidneys requires more resources and time and thus are a disincentivized for transplantation and the fixed budget under the current DRG system does not account for these additional costs.

3) **Ensure transplant recipients have access to all immunosuppressive drugs under Part B and D to ensure patients receive the treatment best tailored to them to reduce their risk of organ rejection while minimizing side effects and fix delays caused in patients receiving their medications due to benefit category confusion.**

HHS/CMS has proposed as part of the drug pricing blue print to remove certain drug formulary requirements from Part D plans for immunosuppressive drugs used in organ transplants. Restrictions and delays in access increase the risk of organ rejection and also will stymie innovation in new immunosuppression opportunities – a critical need.

**SHORT TERM <2 YEARS**

**AGENCY: CDC**

**AWARENESS/PREVENTION**

1) Launch a multi-year CKD public awareness campaign as a public-private partnership

The National Kidney Foundation is in the process of developing a campaign, but it will take collaboration to launch it successfully

**MEDIUM TERM 2-5 YEARS**
1) To allow for more individualized, targeted treatment of CKD the National Center for Healthcare Statistics at the Centers for Disease Control and Prevention (CDC) and CMS should modify the ICD10-CM codes for CKD to differentiate between CKD 3a and 3b and include ranges of albumin to creatinine ratio (ACR) since both are key markers of risk of progression and mortality.

**AGENCY:** HHS

1) **Integrate CKD assessment and treatment into public health and education efforts in Cardiovascular Disease and Diabetes.** The National Kidney Foundation created a CKD change package based off the Million Hearts hypertension change package. Grants and cooperative agreements awarded to focus on diabetes and cardiovascular disease must also include a focus on chronic kidney disease as all three conditions are interlinked. The CKD Change Package is one resource that could be used to foster improvements in population health as it has recommendations and tools on how to integrate kidney health testing and treatment into existing efforts to address diabetes and cardiovascular disease.

1) **Continue to foster innovation in renal replacement therapy options by allocating funding now and in the future to KidneyX.** Given that there has been little innovation in dialysis technology we believe that further investing now to quicker drive development of new options for people with kidney failure and bring them to market is critical. New technologies should be designed in partnership with patients have the greatest potential of new options that truly make a difference in clinical outcomes and dramatically improve the quality of life for people with ESRD.
AGENCY: HRSA/OPTN

1) The Health Resources Services & Administration should allocate additional dollars through the Division of Transplantation (DoT) to NLDAC to raise the income limits to allow for more donors to be reimbursed and to include other categories of expenses. Currently the National Living Donor Assistance Center (NLDAC) provides some donors with reimbursement for travel expenses related to the organ donation including transportation, lodging and food. There are income requirements for the donor and the recipient that determine who is eligible for this assistance.

2) In addition, the National Kidney Foundation applauds HRSA DoT for its plans to launch a pilot on lost wages this summer. We think this a great start. We encourage HHS to allocate additional dollars to this pilot and also expand it to cover child care and medical care related to the donation when it is not otherwise covered by the donor or recipient’s health insurance.

3) Reduce Kidney Discards
   a. Change transplant program metrics used by OPTN. Remove “high-risk” kidneys from the 1 year graft survival metric and develop a patient quality of life metric 1-year post graft survival.

   The current metric of observed to expected survival of graft for 1 year has high performance, but the perception is that this metric has the unintended consequence of causing overly conservative behavior when evaluating high risk kidneys leading to the discard of organs that could give someone greater quality of life in the short and long-term.

   b. OPTN should require transplant programs to inform patients of high-risk kidney offers and afford them the opportunity to participate in shared decision-making regarding acceptance or decline of the offer. To help patients make informed decisions about high-risk kidney offers DoT, in conjunction with community partners, should develop, test and disseminate tools designed to assist kidney transplant candidates in making decisions about accepting offers of higher risk organs at the initial consent once waitlisted and when a high-risk organ offer has been made. HHS through HRSA or AHRQ could put out a request for proposals for grant funding to develop and test such tools.

   c. OPTN should identify transplant programs that never or very rarely accept high risk kidneys and make changes to the kidney allocation policy to allow OPOs to direct donations of high-risk kidneys to programs that are most likely to use them.

   Transplant
programs that do not use these organs should be able to voluntarily opt out of the allocation process for these kidneys. Disclosure of the transplant program’s decision to opt out, or a transplant program that is permitted to be bypassed due to the likelihood it will not accept a high-risk kidney, must be communicated to patients in order for patients to determine if alternate listing at another, less risk averse transplant program is necessary.

d. OPTN should also modify the kidney allocation policy to require each OPO to have at least three back-up transplant programs ready to accept the kidney if the first program declines. This will reduce the time the kidney is out of the body and in cold storage, which decreases the quality of the organ putting it at greater risk of wastage.

e. OPTN should develop a standardized process that all transplant programs and donor hospitals must follow to determine their genuine interest in viability of an organ offer to accelerate the time the kidney is out of the body and in cold storage. This includes standardization on how to conduct a biopsy when a transplant program requires one and how to obtain and review photos of the organ for the transplant program to determine usability prior to accepting allocation. This also includes the need for trained pathologists to interpret and report the results of deceased donor kidney biopsies at the time of organ retrieval.

AGENCY: NIH

TRANSPLANT

1) Perform a randomized trial of renal biopsy use in organ procurement and acceptance to understand the role of kidney biopsies in the evaluation of organ quality and impact on allocation/acceptance