

**ADVANCING AMERICAN**

# Kidney Health



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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## INTRODUCTION

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One of the top healthcare priorities of the Trump Administration—and many other stakeholders in American healthcare—has been the shift from paying for sickness and procedures to paying for health and outcomes.

There is no better example of an area that needs this transformation than the way we prevent and treat kidney disease. Approximately 37 million Americans have kidney disease, and, in 2017 kidney disease was the ninth-leading cause of death in the United States. The primary form of treatment for kidney failure is dialysis, which is one of the most burdensome, draining long-term treatments modern medicine has to offer. I know this personally—as so many Americans do—because my father was on dialysis for years.

Dialysis is also far from sustainable: One hundred thousand Americans begin this treatment each year, and approximately one in five of them are likely to die within a year. Further, the best option we currently have to offer those with kidney failure is a kidney transplant, but there are almost 100,000 Americans currently on a waiting list for new kidneys. A kidney transplant saved my father's life; we want to make that same outcome possible for many more Americans, while also looking to the future to develop new, better options.

Today's status quo in kidney care also carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately \$114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program.

But there is hope. A system that pays for kidney health, rather than kidney sickness, would produce much better outcomes, often at a lower cost, for millions of Americans. The Trump Administration plans to effect this transformation through a new vision for treating kidney disease—*Advancing American Kidney Health*—laid out in this document.

We have set three particular goals for delivering on this vision, with tangible metrics to measure our success:

1. We need more efforts to prevent, detect, and slow the progression of kidney disease, in part by addressing upstream risk factors like diabetes and hypertension. **We aim to reduce the number of Americans developing end-stage renal disease by 25 percent by 2030.**
1. We need to provide patients who have kidney failure with more options for treatment, from both today's technologies and future technologies such as artificial kidneys, and make it easier for patients to receive care at home or in other flexible ways. **We aim to have 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant.**
2. We need to deliver more organs for transplants, so we can help more Americans escape the burdens of dialysis altogether. **We aim to double the number of kidneys available for transplant by 2030.**

With the help of many stakeholders, inside and outside of government, HHS has diagnosed the problems with our system, detailed what success looks like, and laid out how to get there. Over the next several years, we will execute on the strategies laid out in the following pages: pioneering new payment models, updating regulations, educating and empowering patients, and supporting new paths for research and development.

This effort will build on the work underway throughout many HHS agencies including ASPR, CDC, CMS, FDA, HRSA, IHS, and NIH, and will engage outside kidney-care stakeholders and innovators in other fields.

By executing on this bold, comprehensive vision, we can achieve our goals, bring kidney care for all Americans into the 21<sup>st</sup> century, and show that some of the most stubborn, costly problems in American healthcare can be solved.

*Alex M. Azar II*  
*Secretary of Health and Human Services*

# I. EXECUTIVE SUMMARY

## Goals for Advancing Kidney Health in America

As part of the Administration’s focus on improving person-centered care, the U.S. Department of Health and Human Services (HHS) is announcing its vision for advancing kidney health to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and most importantly, live. The initiatives discussed in this paper are designed to tackle the challenges people living with kidney disease face throughout the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members. The overall goals of these efforts are to:

- ▶ **GOAL 1:** Reduce the Risk of Kidney Failure
- ▶ **GOAL 2:** Improve Access to and Quality of Person-Centered Treatment Options
- ▶ **GOAL 3:** Increase Access to Kidney Transplants

## Brief Context on Kidney Disease

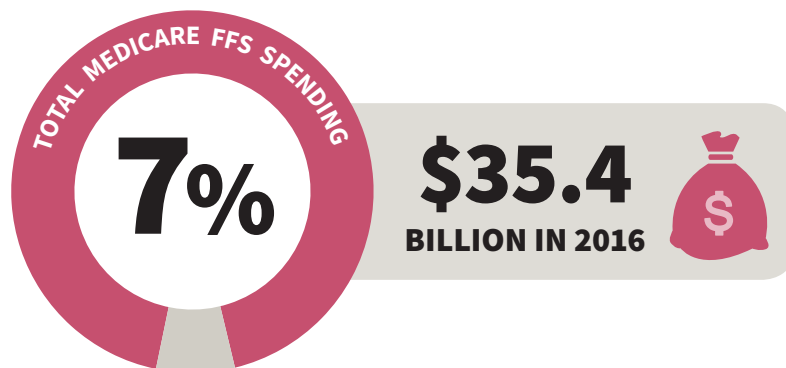
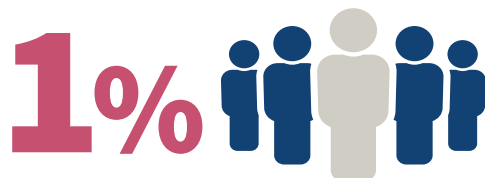
Approximately 37 million Americans, or 15 percent of the nation’s adults, have kidney disease.<sup>1</sup> Kidney disease reduces the ability of a person’s kidneys to filter blood, causing wastes to build up in the body. In 2017, the ninth leading cause of death in the United States was kidney disease.<sup>2</sup>

Major risk factors for kidney disease include uncontrolled diabetes, high blood pressure, and a family history of kidney failure. In some individuals, kidney disease progresses to kidney failure, often referred to as end-stage renal disease (ESRD), which requires dialysis or transplantation to survive.<sup>3</sup> ESRD is a life-threatening illness with a death rate (50 percent mortality in 5 years) worse than most cancers that significantly affects quality of life. Even ESRD that is well managed with dialysis can result in premature death or severe disability, heart disease, bone disease, arthritis, nerve damage, infertility, and malnutrition.<sup>4</sup> Infections, including those related to the dialysis procedure, are frequent causes of hospitalization and death among persons with ESRD. Dialysis treatments also pose a risk of non-infectious complications. Currently, the only treatment alternative that can restore some or most of normal kidney function is transplantation, which requires immunosuppressive therapy (to prevent rejection of the kidney by the recipient’s body) and therefore places recipients at risk for infection and malignancy due to immunosuppression.

**FIGURE 1**

### Medicare spending for ESRD beneficiaries

ESRD beneficiaries comprise less than



SOURCE: 2018 U.S. Renal Data System Annual Data Report.

Another indicator of the burden of kidney disease is the financial cost of treatment. Most individuals with kidney failure are eligible for Medicare coverage, regardless of age.<sup>5</sup> Many Medicare beneficiaries with kidney failure suffer from poor health status, often resulting from disease complications and multiple co-morbidities that can lead to high rates of hospital admissions and readmissions.<sup>6</sup> Total Medicare spending for beneficiaries with chronic kidney disease (CKD) and ESRD, including spending on comorbidities and other health care services that may be unrelated to ESRD, was over \$114 billion in 2016, representing 23 percent of total Medicare fee-for-service (FFS) spending, of which \$35.4 billion was spent on beneficiaries living with ESRD.<sup>7</sup> While less than 1 percent of the total Medicare population has ESRD, spending on ESRD beneficiaries accounts for approximately 7 percent of total Medicare FFS spending.<sup>8</sup> **Figure 1** (previous page) shows the proportion of Medicare FFS spending attributable to Medicare beneficiaries living with ESRD.

Over the past 70 years, there has not been the same level of innovation in treatments for people living with kidney failure compared to treatments for other health conditions.<sup>9</sup> To improve quality of life among people living with kidney failure, it is clear that new technological advances and alternatives to dialysis for renal replacement therapy are urgently needed.

Additional information about kidney disease and its risk factors can be found in the Appendix.

## Examples of Key Initiatives to Achieve Goals of the Kidney Care Vision

Efforts across HHS to advance kidney disease prevention and care in the United States include scaling programs nationwide to optimize screening for kidney diseases, educating patients on care options with coordinated care networks and other tools, supporting ground-breaking research to inform the next generation of targeted therapies, creating new payment models and financial incentives to encourage utilization of home dialysis and increase access to kidney transplants, encouraging accelerated development of innovative products such as an artificial kidney, and undertaking a variety of efforts to increase the number of kidneys available for transplant from both living and deceased donors.

### Goal 1: Reduce the Risk of Kidney Failure

Examples of how HHS is addressing **Goal 1** include the Indian Health Service's (IHS') efforts to adopt a person-centered approach to care to improve outcomes for American Indians and Alaska Natives (AI/ANs) at risk for diabetes complications such as kidney failure. The incidence of diabetes-related ESRD (ESRD-D) among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower levels of disease burden for patients and lower spending on ESRD care.<sup>10</sup> The Centers for Disease Control and Prevention (CDC) is updating its Hypertension Control Change Package for Clinicians to improve CKD detection and care quality among persons at high risk for CKD progression. CDC is also investing in state and local efforts to develop a public health response to CKD risk factors such as diabetes and heart disease.<sup>11</sup>

### Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

HHS' efforts to address **Goal 2** include the National Institutes of Health (NIH) Kidney Precision Medicine Project, which will use kidney biopsies to help redefine kidney disease into new molecular subgroups, paving the way for personalized treatments. The Office of the Assistant Secretary for Preparedness and Response's (ASPR's) programs are working to ensure individuals who need dialysis treatment have ready access to treatment in the aftermath of disaster situations, through the availability of portable dialysis technologies. The U.S. Food and Drug Administration (FDA) has cleared devices for home hemodialysis, and FDA actively supports innovative efforts to improve the quality of current dialysis treatment and to develop new alternatives to dialysis for renal replacement therapy through its Breakthrough programs and participation in KidneyX, the Kidney Innovation Accelerator. The Centers for Medicare & Medicaid Services (CMS) has reviewed potential refinements to the ESRD-Prospective Payment System to facilitate Medicare beneficiaries' access to certain innovative treatment options and, through the Center for Medicare and Medicaid Innovation (Innovation Center), is providing

financial incentives to help clinicians better manage care aligned with beneficiaries' preferences regarding home dialysis and kidney transplantation. CDC is working to translate evidence-based recommendations into practical strategies to improve the quality and safety of care for patients undergoing dialysis. CDC formed the Making Dialysis Safer for Patients Coalition, through which it collaborates with partner organizations and patient representatives to implement core interventions proven to reduce dialysis bloodstream infections.<sup>12</sup>

### **Goal 3: Increase Access to Kidney Transplants**

To advance **Goal 3**, The Office of the Assistant Secretary for Health (OASH) is considering recommendations from the Advisory Committee on Blood and Tissue Safety and Availability regarding updating the U.S. Public Health Service Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation, which may increase available options for individuals who need kidney transplants. The Health Resources and Services Administration (HRSA) is working to provide additional support for individuals who are considering living donation by reducing financial barriers. In addition, new Innovation Center models include financial incentives for health care providers to help Medicare beneficiaries move through the kidney transplantation process.

Given the substantial burden kidney disease places on patients and their caregivers, it is imperative that HHS continues to advance improvements and innovations in kidney disease prevention and care. This paper outlines HHS' goals for improving kidney care, finding alternatives to current dialysis treatment, and increasing access to kidney transplants, and it describes agency initiatives designed to address these goals.

## II. GOALS AND OBJECTIVES

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### Goal 1: Reduce the Risk of Kidney Failure

The number of people with kidney failure has been growing in recent years, afflicting more than 726,000 Americans in 2016.<sup>13</sup> Yet, 90 percent of adults with kidney disease and nearly half in advanced stages of CKD are unaware they have the condition.<sup>14</sup> Associations have been found between diabetes, hypertension, and CKD. For example, roughly 1 out of 5 adults with hypertension, and 1 out of 3 adults with diabetes, may have kidney disease.<sup>15</sup> Moreover, among U.S. adults aged 18 years or older, diabetes and high blood pressure are the primary reported causes of ESRD. Kidney disease usually progresses slowly in most individuals, and blood and urine tests can be used to monitor the progression of the disease. Depending on the person and the stage of the disease, interventions can sometimes slow this progression. Lifestyle and medication treatment for risk factors including diabetes and hypertension are also important factors to address the progression of CKD. Two objectives for HHS' efforts to reduce the risk of kidney failure are:

**OBJECTIVE 1.** Advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease

**OBJECTIVE 2.** Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure

### Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

More than 100,000 Americans begin dialysis each year.<sup>16</sup> Approximately one in five will die within one year, and half within five years.<sup>17</sup> Those with kidney failure typically must undergo dialysis (often at a dialysis center) at least three times per week for three to four hours per session, or through daily home peritoneal dialysis or home hemodialysis, and maintain an extremely restrictive diet. Infections are a serious adverse outcome related to dialysis. Each year, approximately 29,500 bloodstream infections occur in hemodialysis outpatients, and as many as one in two peritoneal dialysis patients develops peritonitis.<sup>18</sup> These types of infections can lead to sepsis and can compromise the patient's treatment options, including ability to receive a kidney transplant. Eighty-seven percent of Americans with kidney failure start treatment with hemodialysis. Of those on hemodialysis, the majority (98 percent) receive in-center hemodialysis and only 2 percent use home dialysis.<sup>19</sup> Up to 85 percent of patients are eligible for home dialysis,<sup>20</sup> and in one study, 25 to 40 percent of patients reported that they would select home dialysis if given the opportunity.<sup>21</sup> Higher survival has been reported among individuals in the U.S. receiving home dialysis when compared to individuals receiving in-center hemodialysis treatment.<sup>22,23,24,25</sup> Supporting person-centered treatment options means increasing the number of treatment modalities available for individuals living with kidney failure, including home modalities, transplantation, and other alternatives to in-center hemodialysis still under development.

Rapidly emerging technologies offer hope that new treatment options can improve patient outcomes and lower the cost of care. HHS therefore supports efforts to develop and bring to market novel treatments such as wearable, implantable, and/or biohybrid artificial kidneys as well as other biological and drug-based alternatives to current dialysis treatments.

HHS aims to reduce morbidity and mortality among people living with advanced kidney disease and increase the proportion of those with kidney failure receiving optimal treatment aligned with their individual needs and preferences, based on informed patient choice.

**OBJECTIVE 1.** Improve care coordination and patient education for people living with kidney disease

and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure

**OBJECTIVE 2.** Introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life

**OBJECTIVE 3.** Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment policies to incentivize innovative product development

### **Goal 3: Increase Access to Kidney Transplants**

Nearly 95,000 patients are on the waiting list to receive a kidney transplant.<sup>26</sup> Kidney transplantation is generally associated with better outcomes compared to dialysis,<sup>27</sup> but only 30 percent of individuals who have experienced kidney failure are living with a functioning kidney transplant.<sup>28</sup> Many Americans never have the chance to receive a kidney transplant due to shortages of available kidneys. Objectives to improve access to kidney transplants are:

**OBJECTIVE 1.** Increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate

**OBJECTIVE 2.** Increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support



## III. HHS INITIATIVES

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By coordinating across HHS and partnering with people living with kidney disease, their caregivers, organ donors, health care providers, and other stakeholders, HHS will enhance the ability of people with kidney disease to improve their day-to-day well-being and quality of life. The specific activities and initiatives HHS is undertaking to address the goals of this vision are described below.

### Goal 1: Reduce the Risk of Kidney Failure

#### **OBJECTIVE 1.** Advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease

In recent years, HHS has increasingly focused on developing better capabilities to identify kidney disease early among high-risk patient populations and to support new research to uncover clinically-useful biomarkers that allow better prediction of the course of CKD and identify patients who could be helped by particular therapies, or who should not be given specific drugs.

- ▶ CDC created and manages the national CKD Surveillance System, the only interactive and most comprehensive collection of CKD-related data in the United States, helpful for monitoring progress toward achieving national Healthy People<sup>29</sup> objectives. Through its investments in the CKD Surveillance System and innovative epidemiological research, CDC continues to strengthen understanding of kidney disease prevalence, risk factors, and health consequences.

*Find more information on the CKD Surveillance System at: <https://nccd.cdc.gov/ckd/default.aspx>*

- ▶ The NIH-funded Chronic Renal Insufficiency Cohort (CRIC) Study is examining risk factors for progression of CKD and cardiovascular disease among patients with established CKD. Additionally, the study is developing predictive models to identify high-risk subgroups, informing future treatment trials, and examining the effect of ongoing clinical management on outcomes. For example, CRIC researchers defined mortality risk subgroups in patients with CKD based on whether levels of the hormone FGF23 in the blood change over time. FGF23 levels in the blood were stable over time in most patients with CKD, but distinct subpopulations with rising FGF23 levels over time were linked to higher risk of death.

*Find more information about CRIC at: <https://www.niddk.nih.gov/about-niddk/research-areas/kidney-disease/effects-chronic-kidney-disease-adults-study-cric>*

- ▶ Hypertension is a leading cause of kidney disease and is the second leading cause of ESRD, accounting for 26 percent of ESRD cases.<sup>30</sup> Heart disease can lead to and exacerbate CKD. Hypertension can lead to kidney disease, which in turn can lead to worsened hypertension. It is a dangerous cycle that, if not stopped, can lead to a heart attack, stroke, heart failure, or kidney failure. The landmark NIH-funded Systolic Blood Pressure Intervention Trial (SPRINT) study showed that lower blood pressure targets decrease the risk of death in high-risk patients with cardiovascular disease (CVD) and CKD.<sup>31</sup>

*Find more information on the SPRINT trial at: <https://www.nhlbi.nih.gov/science/systolic-blood-pressure-intervention-trial-sprint-study>*

- ▶ Diabetes is another major risk factor for kidney disease. Although testing for kidney disease is recommended for people with diabetes, almost 60 percent of Medicare beneficiaries with a diabetes diagnosis are not screened for kidney-damage (albuminuria), and approximately 93

percent of those with hypertension only (a risk factor for kidney disease) are not being tested for this disease.<sup>32</sup> CDC is collaborating with NIH on the Longitudinal Study of Markers of Kidney Disease, and with the National Centers for Health Statistics to investigate and validate new markers for early kidney disease and identify new treatment options for diabetes-related kidney disease.

Find more information on the Longitudinal Study of Markers of Kidney Disease at: <https://www.cdc.gov/kidneydisease/about-the-ckd-initiative.html>

- ▶ The NIH-funded Kidney Precision Medicine Project seeks to uncover the biological root causes of kidney disease through high throughput molecular, genetic, and cellular techniques from research kidney biopsies. This will lead to new biomarkers, disease subgroups, molecular targets, and most importantly the development of new drugs to treat and possibly forestall kidney disease. Recruitment of patients for renal biopsy will start in Summer 2019.

Find more information on the NIH-funded Kidney Precision Medicine Project at: <https://www.niddk.nih.gov/research-funding/research-programs/kidney-precision-medicine-project-kpmp>

- ▶ The NIH-funded Preventing Early Renal Loss in Diabetes (PERL) Study is a randomized, double-blind trial to test whether the medication allopurinol can slow the progression of kidney disease in people with type 1 diabetes and early diabetic kidney disease. Results from this study are expected to be available at the end of 2019.

Find more information about PERL at: <http://www.perl-study.org/>

- ▶ Identification of patients with CKD for population health management, research and surveillance using data available in electronic health records (EHRs) is challenged by poor recognition and resulting under-diagnosis of the disease, particularly in its early stages. As a result, diagnosis codes cannot be used to accurately identify patients with CKD from the EHR. The NIH convened researchers, clinicians, and informaticists to develop and validate an electronic phenotype for CKD. An electronic phenotype is a defined set of data elements and rules that help identify groups of patients using a computerized query. The resulting NIH CKD phenotype uses laboratory measures commonly available in the EHR to identify patients likely to have CKD.

Find more information on the electronic phenotype at: <https://www.niddk.nih.gov/health-information/communication-programs/nkdep/working-groups/health-information-technology>

Looking forward, HHS will further intensify its efforts to make kidney disease detection more accessible, including:

- ▶ As part of its CKD Initiative, CDC will continue to collaborate with other government agencies, universities, and national organizations to support a robust portfolio of epidemiological studies, including cost-effectiveness studies of the long-term efficacy of public health interventions for CKD, and the Systematic Review on Barriers to CKD Screening Project, which identifies and synthesizes current evidence on kidney disease screening and screening rates in the United States. These activities support efforts to raise awareness of CKD and its complications, promote prevention and control of risk factors for CKD, and improve early diagnosis and treatment among people living with kidney disease.
- ▶ The CKD Epidemiology in the Military Health System (MHS), a collaborative effort between the CDC and the Uniformed Services University of the Health Sciences, aims to describe the epidemiology of kidney disease among the active duty and non-active duty populations and assess their risk factors for developing kidney disease. Specifically, this project examines 1)

the effects of maintaining good physical and psychological health on risk of CKD, and 2) the long-term effects of non-sedentary lifestyle on risk of chronic conditions, including CKD. Because the project includes non-active duty persons, i.e., family members of active duty individuals and retirees from active duty, the findings will have implications beyond military personnel.

Find more information on CKD Epidemiology in the MHS at: <https://www.cdc.gov/kidneydisease/about-the-ckd-initiative.html>

## **OBJECTIVE 2. Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure**

In the United States, 30 million individuals have diabetes, 84 million adults have prediabetes (are at high risk for type 2 diabetes), and 75 million adults have high blood pressure.<sup>33,34</sup> HHS has supported the development of several evidence-based national models for better managing kidney disease and risk factors for its progression. These models aim to reduce the national rate of kidney failure.

- ▶ American Indian/Alaska Native (AI/AN) populations have the highest prevalence of diabetes of any U.S. racial/ethnic group.<sup>35</sup> The Special Diabetes Program for Indians (SDPI) represents an important part of this broader approach to providing team-based care and care management. The program has included a number of different components over time such as community directed grants that focus on locally developed solutions to improve diabetes prevention and care, demonstrations and initiatives such as the SDPI Diabetes Prevention Initiative, which built on the findings of an earlier clinical trial at NIH, the diabetes audit which collects data on diabetic care provided by grantees to track outcomes, dissemination of diabetes treatment algorithms and standards of care, and ongoing educational programs such as webinars, periodic meetings and conferences, and consultations with health professionals that have expertise in diabetes. Since its implementation, the incidence of diabetes-related kidney failure among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower spending for programs that cover the costs of AI/AN ESRD care.<sup>36</sup> The SDPI and related efforts have also contributed to improvements in other diabetes-related outcomes, including childhood obesity trends,<sup>37</sup> hospitalizations for uncontrolled diabetes,<sup>38</sup> and diabetic retinopathy.<sup>39</sup>

Find more information on the SDPI at: <https://www.ihs.gov/sdpi>

- ▶ The CDC's National Diabetes Prevention Program (National DPP) is a partnership of public and private organizations working together to build a nationwide delivery system for a 12-month lifestyle change program proven to prevent or delay onset of diabetes.<sup>40</sup> Congress specifically authorized the National DPP in 2010 because of previous research—including the NIH-funded Diabetes Prevention Program (DPP) and the DPP Outcomes Study—that demonstrated the potential of the CDC-recognized lifestyle change program to prevent or delay the onset of type 2 diabetes. The National DPP is founded on four key pillars: 1) a trained workforce of lifestyle coaches; 2) national quality standards supported by the CDC Diabetes Prevention Recognition Program; 3) a network of program delivery organizations sustained through health benefit coverage; and 4) participant engagement and referral. CDC also supports states' efforts to make the NDPP and other diabetes management interventions available to high-burden populations and communities. These efforts include strengthening community-clinical linkages to screen, test, and refer people with prediabetes to CDC-recognized organizations offering the National DPP lifestyle change program; providing support to enroll and retain participants in the program; and supporting pharmacist-patient care processes that help people with diabetes better manage their medications.

Find more information on the CDC's National DPP at: <http://www.cdc.gov/diabetes/prevention>

- ▶ The NIH National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) promotes an integrated health system model of team-based clinical care based on the pragmatic experience of the IHS' Kidney Disease Program. NIDDK has developed new clinical tools and educational programs that improve the care of people with kidney disease in primary care settings. NIDDK works in collaboration with government, nonprofit, and health care organizations to raise awareness about screening for individuals at risk for kidney disease; educate individuals about how to manage their disease; provide information, training, and tools that help health care providers; and support important health systems changes.

*Find more information on the NIH NIDDK at: <http://www.niddk.nih.gov>*

- ▶ The Innovation Center's Medicare Diabetes Prevention Program (MDPP) expanded model is a structured behavior change intervention that aims to prevent the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes. This model is an expansion of the Diabetes Prevention Program model test under the authority of section 1115A of the Social Security Act.

*Find more information on the MDPP at: <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>*

Looking forward, HHS will continue to support these programs and look for known and innovative ways to scale their adoption, in partnership with communities.

- ▶ In late 2017, CDC announced a new five-year cooperative agreement to scale up the National DPP in underserved areas and populations including Medicare beneficiaries, men, African Americans, Asian Americans, Hispanics, American Indians, Alaska Natives, Pacific Islanders, and noninstitutionalized people with visual impairments or physical disabilities.
- ▶ In late 2019, CDC will update its Hypertension Control Change Package for Clinicians (HCCP) to include tools and resources to support CKD screening and early diagnosis among persons with hypertension. This effort, part of CDC's broader Million Hearts® initiative,<sup>41</sup> will better support clinician efforts to end the pernicious cycle between CKD and hypertension.

*Find more information on the Hypertension Control Change Package for Clinicians at: [https://millionhearts.hhs.gov/files/HTN\\_Change\\_Package.pdf](https://millionhearts.hhs.gov/files/HTN_Change_Package.pdf)*

*Find more information on the Million Hearts initiative at: <https://millionhearts.hhs.gov>*

- ▶ CDC has begun a collaboration with local health departments to develop innovative approaches to increase the reach and effectiveness of public health strategies for diabetes, heart disease, and stroke, including the use of clinical decision support tools within EHRs to promote early detection of kidney disease.
- ▶ HHS supports continued funding for the SDPI, as reflected in the President's Fiscal Year (FY) 2020 budget that proposes reauthorizing the SDPI at \$150 million per year through FY 2021.
- ▶ NIH has recently funded the Improving Chronic Disease Management with Pieces (ICD-Pieces) study, testing whether computer-generated reminders working in tandem with clinicians can reduce hospitalizations in patients with coexisting CKD, diabetes, and hypertension, and improve use of innovative and proven interventions.

*Find more information on the ICD-Pieces study at: <http://icd-pieces.com/>*

- ▶ ASPR is launching a new initiative called ExaHealth, to develop collaborative tools to accelerate discovery of new therapies. The ExaHealth initiative will be one of many partnerships with the Department of Energy to develop artificial intelligence tools and new methods for studying

complex biological functions in a concerted way, in order to develop new and more effective medical interventions. These interventions will focus on acute onset of disease during pandemics and man-made disasters, as well as and chronic diseases, whose onset can occur throughout a person's lifetime, including patients at risk for progression towards CKD and ESRD.

## Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

### **OBJECTIVE 1.** Improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure

HHS supports the data and knowledge infrastructure necessary to inform more person-centric transitions to safe and effective care for kidney failure.

- ▶ For example, the NIH supports production of the annual U.S. Renal Data System (USRDS) Atlas, which provides up-to-date statistics on incidence, morbidity, and mortality for patients transitioning through kidney failure. These data have been used to inform clinical practice for kidney disease patients and development of targeted interventions for specific populations. In 2018, USRDS published a special transitions section that describes the transition from CKD to ESRD in greater detail using linked data from the Veterans Health system. Key summary findings include the finding that heart failure and acute kidney injury (AKI) are the most common cause of hospitalizations in the six months before the start of hemodialysis, and infectious complications (vascular access infection, septicemia) are the most common causes of hospitalizations after the start of hemodialysis.<sup>42</sup> Future efforts of the USRDS include a detailed investigation of causes of early mortality among patients who start hemodialysis, as well as expanded exploration of data sets other than Medicare data to support additional analyses related to kidney disease and kidney care.

*Find more information on the USRDS at: <https://www.usrds.org/>*

- ▶ Through its Making Dialysis Safer for Patients Coalition, CDC coordinates a wide array of organizations and individuals to promote implementation of evidence-based interventions to prevent dialysis bloodstream infections. Best practices and strategies for implementation of these interventions include provider training and feedback, patient engagement and empowerment, and use of audit tools, checklists, and other resources. These interventions have been shown to significantly reduce dialysis-related bloodstream infections (by 30 to 50 percent) and associated outcomes.<sup>43</sup>

*Find more information on the Making Dialysis Safer for Patients Coalition at: <https://www.cdc.gov/dialysis/coalition/index.html>*

- ▶ Through the National Healthcare Safety Network (NHSN), CDC tracks bloodstream infections – including those caused by antibiotic resistant organisms, vascular access infections, and other outcomes among hemodialysis patients treated in clinics, and gives clinics immediate access to the data reported. CDC produces standardized infection ratios that are posted publicly on Medicare's Dialysis Facility Compare website. National aggregate rates of infection are used for benchmarking and in quality improvement initiatives.

*Find more information on NHSN at: <https://www.cdc.gov/nhsn/dialysis/index.html>*

- ▶ ASPR and CMS have formed a collaboration to improve access to dialysis care during every disaster and have launched the emPOWER program. emPOWER provides data and mapping tools

to help communities protect the health of more than 4.1 million Medicare beneficiaries who rely on electricity-dependent medical equipment and healthcare services, including nearly 400,000 dialysis patients. In the wakes of Hurricanes Irma and Maria, the emPOWER Program helped ASPR, CMS, and territorial public health officials identify healthcare and resource gaps for dialysis patients and immediately engage with End-Stage Renal Networks<sup>44</sup> and dialysis providers to ensure continuity of their life-maintaining healthcare services.

Find more information on the emPOWER Program at: [https://empowermap.hhs.gov/Fact Sheet\\_emPOWER\\_FINALv5\\_508.pdf](https://empowermap.hhs.gov/Fact Sheet_emPOWER_FINALv5_508.pdf)

Looking forward, HHS will continue to strengthen patient voices in policy development, address the needs of vulnerable populations with portable dialysis technologies, and use payment incentives to support patients making choices about their kidney care modalities.

- ▶ The Innovation Center has announced four new optional kidney care models: Kidney Care First (KCF) for nephrology practices and Comprehensive Kidney Care Contracting (CKCC) which offers three distinct payment options. These models will build on the existing Comprehensive ESRD Care (CEC) Model, which began in 2015 and will end in 2020, and incorporate design elements from the recently announced Direct Contracting and Primary Care First models. One of the key lessons learned from the CEC Model was the need to increase coordinated care for beneficiaries with late-stage chronic kidney disease and beneficiaries transitioning onto dialysis. These models will provide strong incentives to better manage and coordinate care for beneficiaries with kidney disease. Model participants will be incentivized through utilization measures and cost incentives to avoid unplanned dialysis starts in the hospital, in an effort to avoid the cost and high mortality that occurs when beneficiaries abruptly start dialysis. Additionally, CMS will also establish measures to demonstrate whether kidney disease is being delayed by the Model's interventions and develop a quality measure to incentivize better managing beneficiaries with late-stage CKD to avoid the more expensive and burdensome dialysis process.

Find more information on the CKC Model at: <https://innovation.cms.gov/initiatives/voluntary-kidney-models/>

- ▶ The FDA is developing a new survey to gain insight into patient preferences for new kidney failure treatments. Information collected will be used by FDA and its partners including device developers, patients, providers, payers, and other researchers to inform the development of new treatments, including alternatives to dialysis. The patient preferences survey will be an important example of how patient engagement can contribute to building infrastructure for expanded patient-centered outcomes research and how patient input can be used in FDA's review processes. Results and methods will also be shared with those involved in data collection efforts for other disease conditions to similarly inform the development of new treatments.
- ▶ NIH is developing and testing an interoperable open-source electronic care plan tool for people with multiple chronic conditions, including diabetes and kidney disease, to better coordinate their care. In the context of kidney care, this tool will enable patients, physicians, nurses, pharmacists, dieticians, and other health professionals, as well as community health workers, to transfer critical, person-centered kidney care information across multiple settings of care with diverse electronic health record systems using uniform data standards, supporting better coordination of kidney care and research.
- ▶ Dialysis facilities are currently required to inform patients of their care options. To strengthen patient education and support for patients' selection of treatment modalities, CMS is considering options for new ways to improve quality of life for dialysis patients while also reducing Medicare costs and minimizing regulatory burden.

- ▶ ASPR is working to ensure people living with kidney failure have access to readily available portable dialysis technologies and access to treatments in any situation. Currently, treatment options are limited following disaster events, and individuals on dialysis must be evacuated and provided temporary housing to continue treatments. Beginning in 2019, ASPR will procure and test portable dialysis units that can provide support to people living with kidney failure in low-resource settings or within their homes, so that they can have access to dialysis with minimal power and from publicly-available water sources, allowing them to return home sooner when a disaster occurs.
- ▶ CMS supports person-centered optimal starts for individuals living with ESRD. An “optimal start” reflects adequate patient preparation resulting in pre-emptive transplant, initiation of renal replacement with peritoneal dialysis or initiation of hemodialysis with a functioning permanent vascular access. The Innovation Center is announcing the ESRD Treatment Choices (ETC) Model, which will include financial incentives for ESRD facilities and Managing Clinicians selected to participate in the model to better align with beneficiary choice on modalities such as home dialysis or kidney transplants.

*Find more information on the ETC Model at: <https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/>*

## **OBJECTIVE 2. Introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life**

As part of HHS’ commitment to transition to payment and delivery models that focus on patient outcomes, preferences, and lowering costs, CMS is introducing a new payment model and has proposed another payment model to encourage more coordinated care to delay kidney failure and ensure that people living with kidney failure have access to the best available care options. Additionally, Medicare will continue to support payment rule changes for the ESRD PPS that focus on patient care, support innovation, reduce burdens, and lower costs.

- ▶ The Innovation Center’s ETC Model includes financial incentives for ESRD facilities and Managing Clinicians selected to participate in the model to better align with patient choice regarding home dialysis and kidney transplantation. The ETC Model will test the effectiveness of outcomes-based payment adjustments to health care providers to increase utilization of home dialysis and kidney/kidney-pancreas transplants. The Home Dialysis Payment Adjustment (HDPA) would be in effect for the first three years of the Model, and would increase payment for home dialysis and home dialysis-related services. The Performance Payment Adjustment (PPA) would decrease or increase payment for dialysis and dialysis-related services based on a participating ESRD facility or Managing Clinician’s rate of home dialysis and transplants. The goal of the Model is to increase the transplant and home dialysis rate across the country.
- ▶ The Innovation Center’s optional kidney care models (KCF and CKCC) include incentives for health care providers to better manage the care for beneficiaries with kidney disease including incentives for pre-emptive transplants, improving beneficiaries’ transition to dialysis, and ensuring dialysis initiation is appropriately timed. The Model also includes incentives to manage the total cost and quality of care for beneficiaries with kidney disease and kidney failure, and strong financial incentives to move beneficiaries through the transplant process. Together with the new ETC Model, the optional kidney care models demonstrate CMS’ commitment to supporting high quality, coordinated care for people living with ESRD.
- ▶ CMS is considering ways to encourage ESRD facilities to furnish new and innovative drugs and biological products for the treatment of ESRD. The Transitional Drug Add-on Payment Adjustment (TDAPA) is an add-on payment adjustment under the ESRD PPS intended to facilitate this goal for

Medicare beneficiaries. This is done by encouraging ESRD facilities to furnish certain qualifying new renal dialysis drugs and biological products by allowing additional payment for them while utilization data is collected.

- ▶ CMS recognizes that continual refinement of the ESRD PPS is necessary to benefit people living with ESRD, and is therefore working with an analytical contractor to perform payment analysis and develop potential refinements to the ESRD PPS. CMS plans to ask for stakeholder input on data collection.
- ▶ Based on comments received during and after the CY 2019 ESRD PPS rulemaking, CMS is considering issues related to payment for new and innovative supplies and equipment that are renal dialysis services furnished by ESRD facilities for ESRD beneficiaries.

**OBJECTIVE 3. Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment policies to incentivize innovative product development**

Ultimately, the best way to improve care for people living with kidney failure is to support the development of novel therapies extending beyond the choices available today. Investing in foundational research at the NIH, catalyzing rapid product development through public-private partnerships, and creating clear and forward-looking guidelines for marketing approval for emerging technologies like organ preservation may unleash innovation for years to come.

- ▶ KidneyX was officially launched in 2018 as a public-private partnership with the American Society of Nephrology to support the development of innovative therapies and diagnostics. KidneyX is designed to leverage rapidly emerging technologies in areas such as regenerative medicine, nanotechnology, and advanced materials to support early-stage development and lower the risk of commercialization. KidneyX's first prize, *Redesign Dialysis*, offers \$2.6M for kidney failure treatments beyond currently available options of dialysis and transplantation. Included among the 15 winning teams announced in April 2019, were companies developing advanced nanofiltration for toxin removal, miniaturized wearable dialyzers, real-time infection and clotting sensors, cell-based implantable dialyzers, and regenerative kidneys. The second phase currently underway will seek testable prototypes and announce winners in April 2020.

Find more information on KidneyX at: <https://www.kidneyx.org>

- ▶ In June 2019, the HHS Chief Technology Officer signed an agreement with the heads of CMS, NIH, FDA, and CDC to work closely together on KidneyX to ensure that unnecessary barriers to patient access for innovative technologies are addressed. In July 2019, KidneyX is also launching a patient innovator prize focused on identifying and scaling new products and practices that patients and caregivers have developed for their own care, recognizing that innovation often happens at the frontlines of health. In 2020, KidneyX plans to launch *Redesign Dialysis Phase III* to advance new products into human clinical trials, another prize focused on helping dialysis patients manage fluids, a leading cause of ESRD hospitalizations, and a prize focused on spur-ring development of therapies to slow progression of kidney disease.
- ▶ HHS and the Department of Veterans Affairs (VA) are exploring a partnership to streamline and expedite clinical trials for kidney care-related treatments using the VA health system, similar to the National Cancer Institute (NCI) and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE), a partnership between the VA and the NCI to facilitate enrollment of veterans with cancer into NCI-funded clinical trials.



- ▶ In May 2019, FDA issued final guidance that industry should consider when utilizing animal studies to evaluate organ preservation devices. This guidance will help support the development of next-generation organ preservation devices and systems, potentially capable of increasing the supply of transplantable kidneys by salvaging and maintaining more kidneys. In addition to recommendations that could be considered relevant for most animal studies such as developing animal study protocols with consideration of the applicability of anatomical, physiological, and immunological factors for humans, studies should include a control group as a comparator. Specifically, for kidney preservation devices, animal studies should consider three phases of the organ for transplantation: procurement, preservation, and reperfusion. Following these recommendations will speed the review of kidney preservation devices, as well as potentially improving the quality and functionality of these devices.

Find the FDA's final guidance at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/utilizing-animal-studies-evaluate-organ-preservation-devices>

## Goal 3: Increase Access to Kidney Transplants

**OBJECTIVE 1.** Increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate

From 2007 through 2017, the annual rate of kidneys procured but not transplanted has ranged between 18–20 percent. In 2017, the discard rate of 18.9 percent reflected 3,534 kidneys that were procured but not transplanted into waiting patients.<sup>45</sup> Some donor kidneys are not transplanted due to medically justifiable reasons; however, it is estimated that thousands of discarded kidneys could provide benefit to people on dialysis.<sup>46</sup> Education about the appropriate clinical use of kidneys would help maximize the limited supply of donated organs used.<sup>47,48</sup> Addressing the availability and utilization of kidneys is one of the ways HHS can help people living with ESRD through transplantation.

- ▶ HRSA supported a Collaborative Innovation and Improvement Network (COIIN) pilot project through the Organ Procurement and Transplantation Network (OPTN) with a limited number of participating kidney transplant programs. The goal was to increase transplantation and reduce the number of discarded kidneys, with a particular focus on increasing utilization of kidneys deemed to be moderate-to higher-risk due to their clinical characteristics. In addition to supporting education of transplant program staff, patients, and referring physicians on the effective use of these organs, the COIIN pilot also modified OPTN performance monitoring criteria to reduce the risk-avoidance behaviors associated with the current monitoring system. Initial results suggest that the COIIN pilot has resulted in increased utilization of kidneys among the first cohort of participating transplant programs. It is possible that a recent decline in the discard rate of moderate-risk kidneys may in part be related to the COIIN pilot.

Find more information on the HRSA COIIN at: <https://optn.transplant.hrsa.gov/resources/coiin/>

- ▶ The OPTN implemented a policy change in June 2018 to expedite the process of allocating organs and improve the efficiency of organ placement. This change reduces the amount of time a transplant program has to accept or refuse an organ offer, as well as reduces bottlenecks in the system by limiting the number of organ offers a program can accept for any candidate at the same time.
- ▶ CMS added a transplant waitlist measure to the ESRD Quality Incentive Program (QIP) for dialysis facilities via rulemaking in 2018 as a measure of dialysis center performance. The goal of the ESRD QIP is to promote high-quality services in ESRD facilities treating patients with ESRD. Under this value-based purchasing program, CMS pays for ESRD treatment by linking a portion of payment directly to dialysis facilities' performance on quality of care measures. A list of CMS quality measures for ESRD care is included in the Appendix.

Looking forward, HHS plans to take a number of actions directly aimed at increasing the utilization and availability of organs.

- ▶ HHS is updating the PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. The goal of the existing 2013 Guideline was to reduce risk of unintended HIV, HBV, and HCV transmission, while preserving availability of high quality organs: Since 2013, however, shifts in the composition of the donor pool, as well as advances in testing and treatment technologies, have created opportunities to revise the Guideline. The current initiative will re-evaluate and, where warranted, revise elements of the Guideline based on current risks to patients and improvements in technology. HHS is also considering the April 2019 recommendations of the Advisory Committee on Blood and Tissue Safety and Availability concerning revising the Guideline. The revised Guideline is intended to strengthen the overall process for assessing, communicating, and managing donor risk for HIV, HBV, and HCV.

Find the current PHS Guideline at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3675207/pdf/phr128000247.pdf>

- ▶ HRSA has funded the OPTN to expand the COIIN pilot project in 2020, allowing more kidney transplant programs to participate in this OPTN quality improvement activity focused on changing program waitlist management and organ acceptance practices.<sup>49</sup>
- ▶ The Innovation Center's ETC Model includes a learning collaborative operated by the Center for Clinical Standards and Quality (CCSQ), designed in collaboration with HRSA and informed by the HRSA OPTN COIIN, to reduce the disparity in performance among Organ Procurement Organizations (OPOs) and transplant centers with the goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers. This quality improvement learning component will bring HRSA, CMS, transplant centers, OPOs, and the nation's largest donor hospitals together to generate increased quality and cost-savings to Medicare through the use of systematic quality and process improvement. Additionally, this activity will directly engage patients and families to motivate, activate and empower them to drive the requirement/demand for utilization of viable kidneys.
- ▶ HHS is organizing a federal workshop to discuss considerations related to the use of Hepatitis C virus positive (HCV+) donor organs in recipients who do not have HCV. Due to the recent increase in the number of deaths from the opioid epidemic, more HCV+ potential organs are available. HCV is now considered to be largely curable with the advent of direct acting anti-viral (DAA) therapy. Ten clinical trials are in process or have been completed to study whether intentional use of HCV+ donor organs in HCV uninfected recipients is safe and effective when recipients are proactively treated with DAA agents. The planned federal workshop is intended to help facilitate a proactive and coordinated approach to developments in this area of study, specifically with regards to potential changes in the standard of clinical care in transplantation.
- ▶ NIH research led to the seminal discovery of the APOL1 gene, which explains why kidney disease progresses faster among African Americans compared to Caucasians. Building on the discovery of the APOL1 gene in African Americans, NIH founded the APOLLO initiative, which will produce information about the best use of donor kidneys with APOL1 gene variants and also improve donor-recipient matching to decrease the rate of organ discard. OPOs nationwide are participating in this study. Recruitment began in 2019 and will continue at least through 2021. More precise quantification of risks of poor outcomes related to donor/recipient genetic architecture will enhance the efficacy of the allocation of precious donor kidneys. Study results are anticipated in 2023.

Find out more information on the APOLLO initiative at: <https://theapollonetwork.org/info.cfm>

- ▶ HRSA, through the OPTN, is developing a new model to test accelerated placement of certain kidneys that are at high risk for discard. Following recommendations from the National Kidney Foundation Consensus Conference,<sup>50</sup> the OPTN Organ Center will develop and test a proof of concept for expediting allocation of these organs with safety monitoring. The OPTN will evaluate the concept for safety and improvements in allocation efficiency.
- ▶ HHS is analyzing and improving transplantation metrics with a focus on increasing organ utilization while maintaining good outcomes.
- ▶ HRSA, through the OPTN, convened an Ad Hoc System Performance Committee, which among other issues, has discussed new potential performance metrics that monitor patient safety while encouraging innovative practice.
- ▶ Per the 2019 OMB regulatory agenda, CMS is reviewing the OPO conditions for coverage and will be proposing changes to the standards used to evaluate OPOs to ensure proper data collection on the availability of transplantable organs and transplants.
- ▶ CMS has begun to develop and test new dialysis facility transplant referral measures, which, if approved, could be added to Quality Incentive Program (QIP) through rulemaking in the future and then via the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system and ultimately, Dialysis Facility Compare.<sup>51</sup>

**OBJECTIVE 2. Increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support**

Living donors account for 30 percent of all kidney transplants in the U.S. However, many financial and risk-based disincentives to donation persist, which may serve as barriers for individuals who would otherwise be willing to donate a kidney.

- ▶ To further support living donors, HRSA is planning to expand the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program by increasing the eligibility income threshold. HRSA is implementing a pilot to expand the qualifying expenses to include coverage for lost wages and family expenses. The expansion of the current reimbursement program will reduce financial barriers to organ donation and support the goal of increasing living donor transplants.

*Find more information on the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program at: [https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm\\_rtc=16&dm\\_attid=49472bf1-7438-42ff-b406-d597fcf3b498](https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm_rtc=16&dm_attid=49472bf1-7438-42ff-b406-d597fcf3b498)*

- ▶ In FY 2019, HRSA awarded a demonstration cooperative agreement to provide for reimbursement of up to \$5,000 in lost wages related to donor evaluation and surgical procedures regardless of the donor's income. Findings from this three-year demonstration project will inform whether expansion of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program has a positive effect on kidney donation.

# TECHNICAL APPENDIX

## Background Information on Kidney Disease

### Prevalence of Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD)

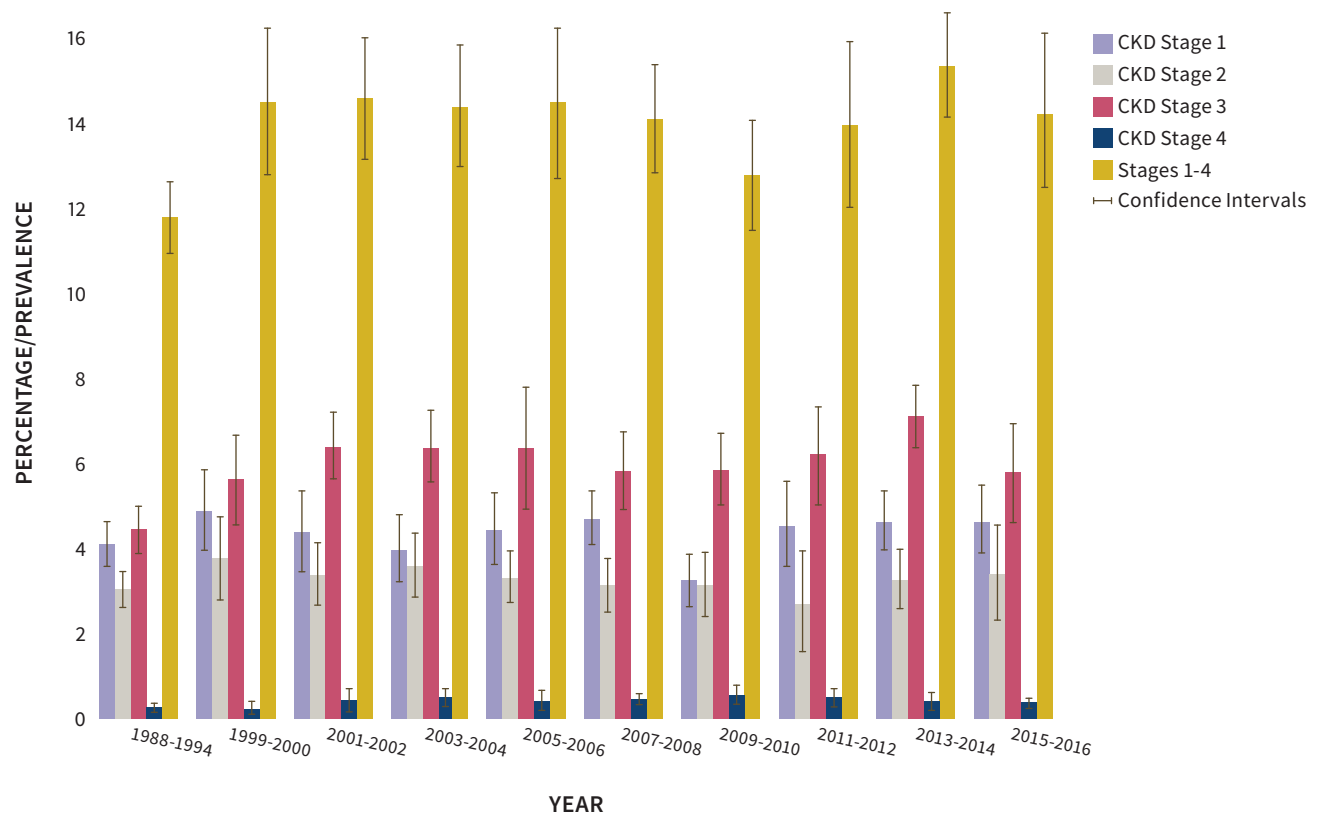
Kidney disease occurs when kidneys are damaged and become unable to filter blood optimally, causing wastes to build up in the body. The condition is clinically categorized into five stages as the disease progresses. The last stage of the disease occurs when the kidneys stop working altogether, which is often referred to as ESRD. Individuals in this stage of the disease require ongoing dialysis, if a transplant is not available, in order to filter wastes out of the body.

**Figure 2** shows the prevalence of CKD in the U.S. population for stages 1 through 4 of the disease.<sup>52</sup>

**Figure 3** shows the disproportionate prevalence of the disease among older and minority individuals.

**FIGURE 2**

Prevalence of CKD by Stage, 1988-2016



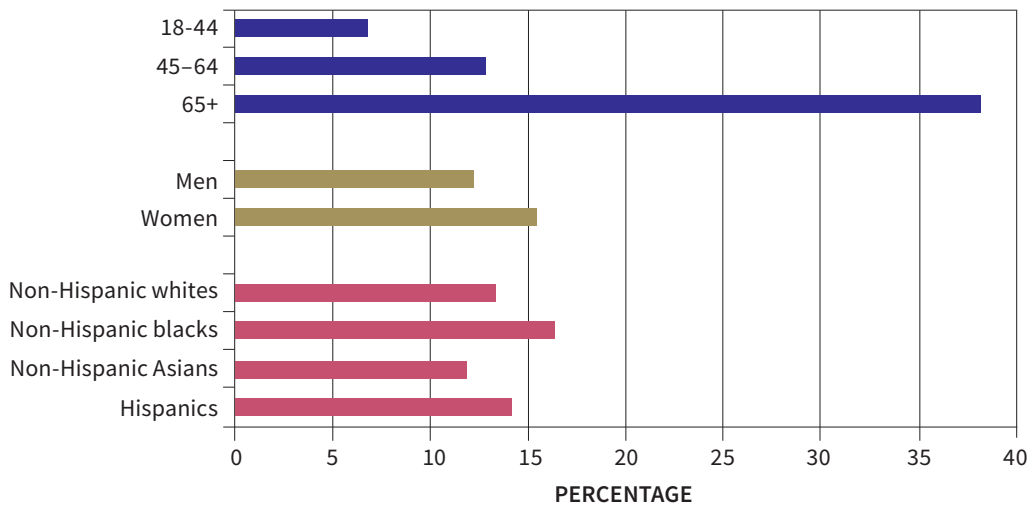
SOURCE: Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. Website. <https://nccd.cdc.gov/CKD>.

NIH research led to the seminal discovery of the APOL1 gene, which explains why CKD progresses faster among African Americans compared to Caucasians.<sup>53</sup>

As of December 31, 2015, the prevalence of dialysis treatment was 1,470 per million U.S. population. **Figure 4** shows that the prevalence of ESRD has been increasing over time. The prevalence of ESRD more than doubled between 1990 and 2015, and the number of prevalent ESRD cases has continued to rise by approximately 20,000 cases per year, reaching 726,331 prevalent cases by 2016.<sup>54,55</sup>

**FIGURE 3**

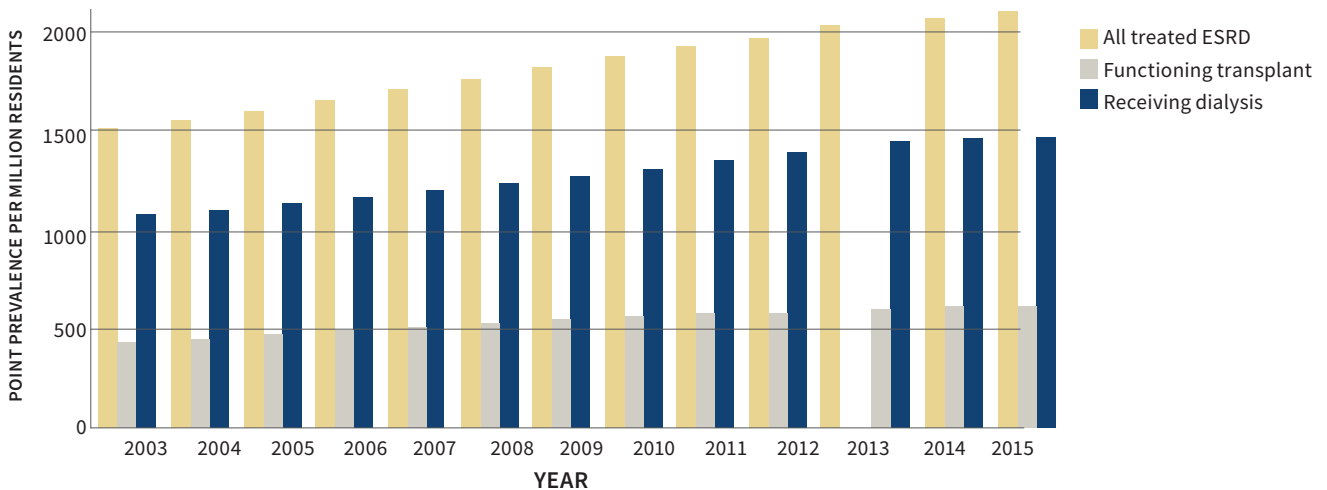
**Percentage of CKD Among U.S. Adults Aged 18 Years and Older, by Sex and Race/Ethnicity**



**SOURCE:** Centers for Disease Control and Prevention. Percentage of CKD stages 1–4 among US adults aged 18 years or older using data from the 2013–2016 National Health and Nutrition Examination Survey and the CKD Epidemiology Collaboration (CKD-EPI) equation.

**FIGURE 4**

**Prevalence of Treated ESRD, 2003-2015**



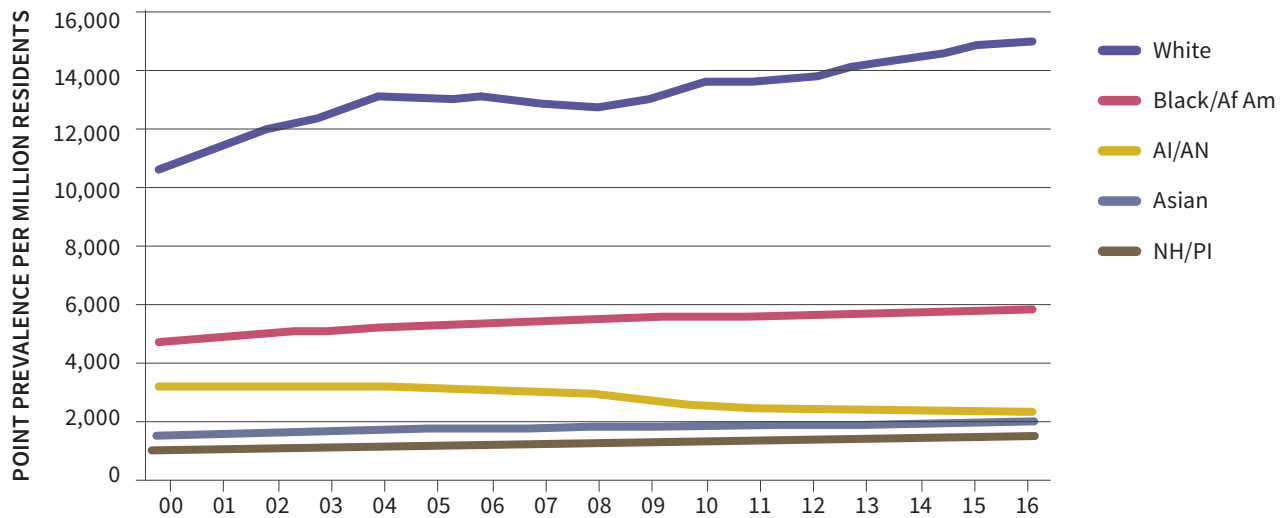
**SOURCE:** Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. Website: <https://nccd.cdc.gov/CKD>.

Similar to trends for CKD, **Figure 5** shows that the prevalence of ESRD is higher among racial minorities.<sup>56</sup> Compared to Whites, ESRD prevalence in 2016 was approximately 9.5 times greater in Native Hawaiians and Pacific Islanders (NH/PI), 3.7 times greater in African Americans (Black Af/Am), 1.5 times greater in American Indians and Alaska Natives (AI/AN), and 1.3 times greater in Asians.<sup>57</sup>

**Figure 6** shows that the burden of ESRD varied significantly by state in 2015, ranging from highs of 2,428.8 per million residents in the District of Columbia, 2,212.6 in Illinois, and 2,203.6 in South Dakota to lows of 1,185.8 per million residents in Vermont, 1,175.6 in Maine, and 1,155.7 in New Hampshire.<sup>58</sup>

**FIGURE 5**

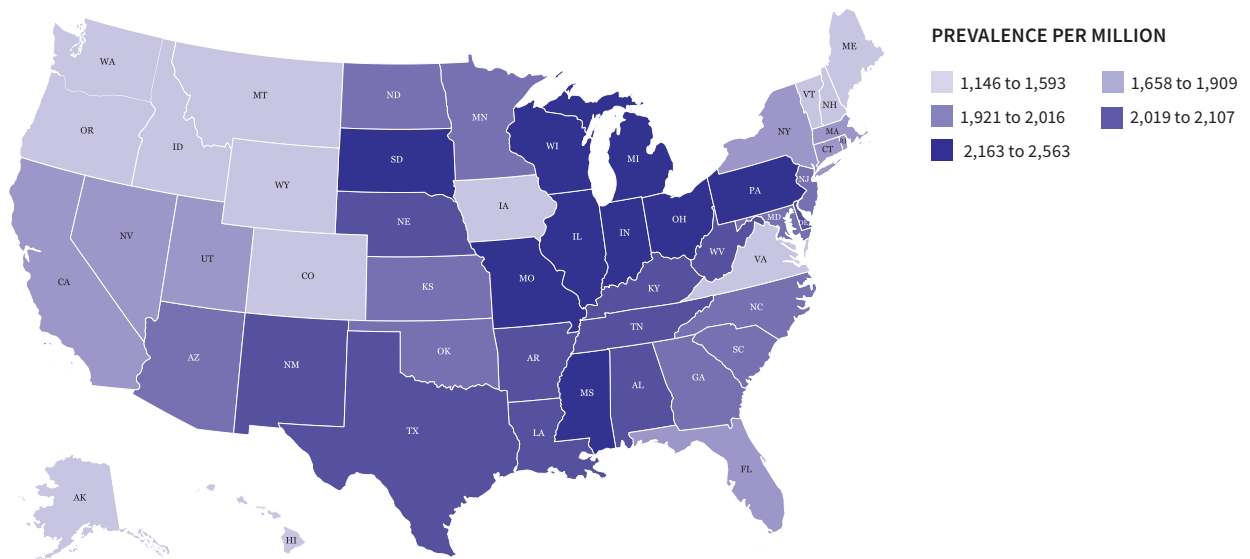
Trends in the Standardized Prevalence of ESRD, by Race, 2000-2016



SOURCE: USRDS Annual Data Report. Special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the age-sex distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviations NH/PI: Native Hawaiian/Pacific Islander; AI/AN: American Indian/Alaska Native.

**FIGURE 6**

Prevalence of ESRD by U.S. State for 2016



## Risk Factors

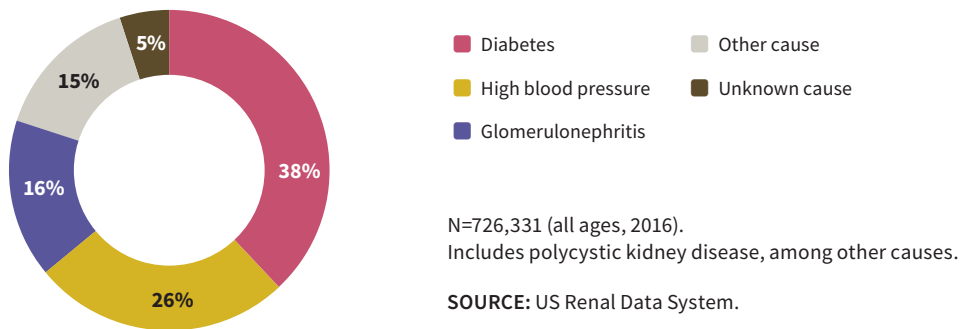
Major risk factors for ESRD include diabetes and high blood pressure (see **Figure 7**), in addition to having a family history of kidney failure. Approximately 48 percent of individuals with severely reduced kidney function who are not on dialysis, are not even aware they have CKD.<sup>59</sup>

One positive trend is the decreasing rate of ESRD among American Indians and Alaska Natives (AI/ANs). The incidence of diabetes-related ESRD (ESRD-D) among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower levels of disease burden for patients and reduced spending for programs that cover the costs of AI/AN health care.<sup>60</sup> Measures related to the assessment and treatment of ESRD-D risk factors showed more improvement during this period in AI/ANs than in the general U.S. population.<sup>61</sup> This reduction in ESRD rates occurred after the Indian Health Service (IHS) began implementing public health and population management approaches to diabetes and improvements in clinical care in the mid-1980s. The approach taken by IHS to reduce diabetes may be a model for reducing ESRD risk factors in other health care systems.

**Figure 8** shows the significant decline in ESRD-D incidence in AI/ANs compared to Whites between 2001 and 2015.

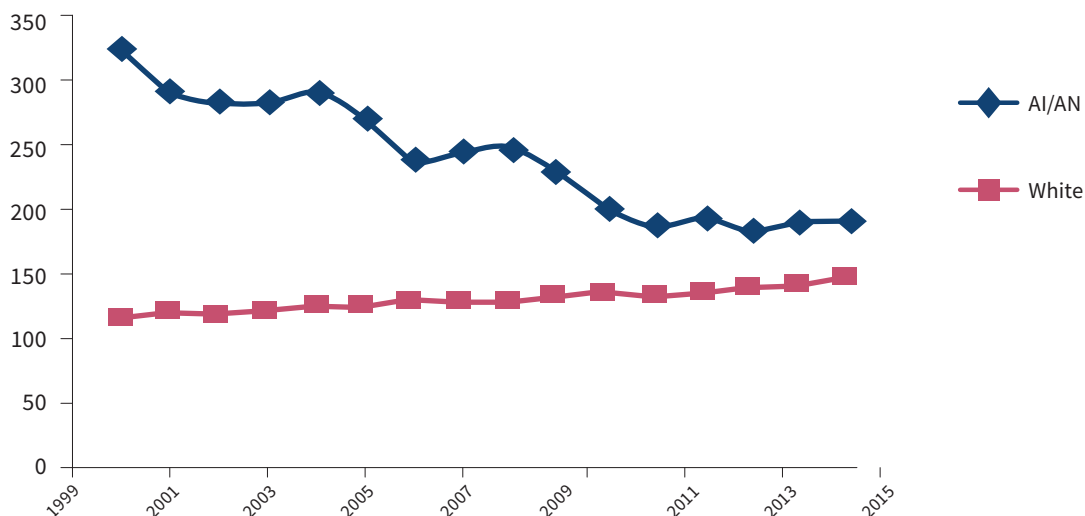
**FIGURE 7**

### Reported Causes of ESRD in the United States



**FIGURE 8**

### Incidence per Million of Diabetes-Related ESRD in AI/AN and White Populations



SOURCE: ASPE Analysis of USRDS 2017 Annual Data Report Reference Tables.

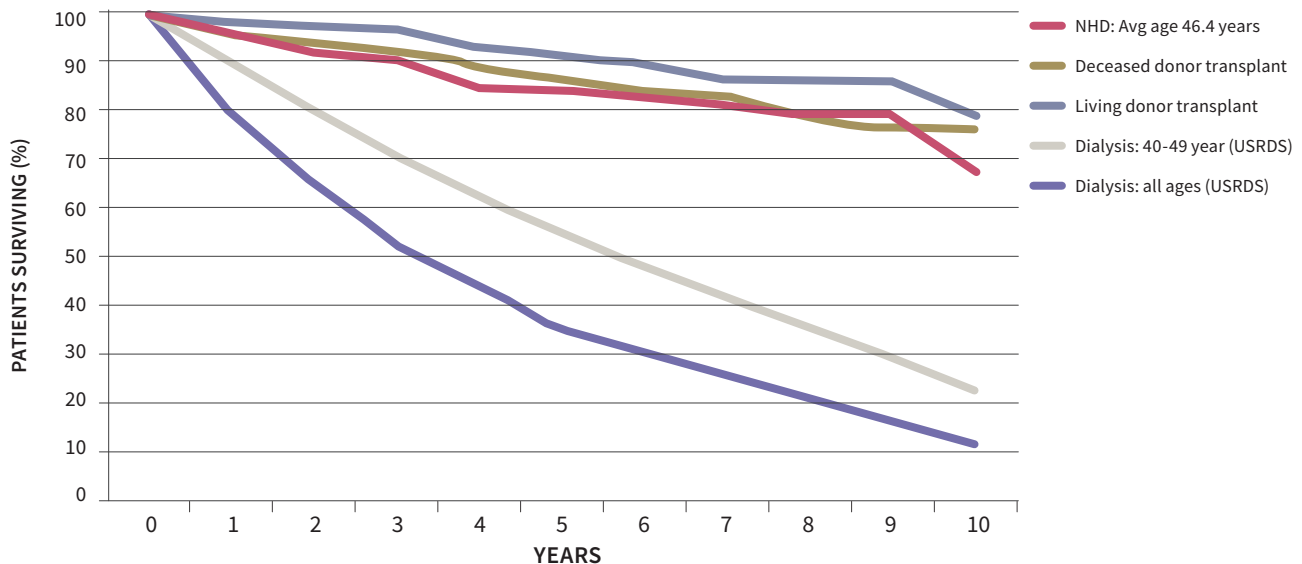
## Treatment Options for ESRD

USRDS data indicate that at the end of 2016, approximately 63.1 percent of all prevalent ESRD patients were receiving hemodialysis (HD) therapy, 7.0 percent were treated with peritoneal dialysis, and 29.6 percent had a functioning kidney transplant. Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home HD.<sup>62</sup> While home-based dialysis may not meet the needs of every patient, home dialysis has clear benefits for those who are suitable candidates. In addition to being more convenient for many people living with ESRD, **Figures 9** (below) and **10** (following page) show that survivability rates for home dialysis are comparable to those of transplant recipients and hemodialysis.<sup>63,64</sup>

A 2015 Government Accountability Office (GAO) report found that facilities have financial incentives in the short term to increase provision of hemodialysis in facilities rather than increasing home dialysis.<sup>65</sup> For example, hemodialysis facilities may be able to increase the number of in-center patients without adding a dialysis machine because each machine can be used by six to eight in-center patients. However, for each new home patient, facilities may need to pay for the cost of an additional dialysis machine. GAO also reported that facilities might be less inclined to provide home dialysis depending on the adequacy of Medicare’s payments for home dialysis training and because Medicare’s monthly payments to physicians for managing the care of home dialysis patients are often lower than for managing in-center patients.<sup>66</sup>

The CMS Innovation Center is announcing five new payment models, which include incentives to optimize care for Medicare beneficiaries with kidney disease. These models represent important efforts by HHS to improve care for patients with chronic kidney disease in the near future. Looking further into the future, investments in research and new technology may be able to increase access to even better treatment options. Innovations in kidney disease treatments include technology such as wearable, implantable, and biohybrid dialysis units, which could substantially improve quality of life for people living with ESRD. NIH funding for biomedical research related to kidney disease totaled approximately \$600 million in fiscal year 2018.<sup>67</sup> The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**FIGURE 9**  
Survivability Rates for Nocturnal Home Hemodialysis (NHD)  
vs. Other Treatment Modalities

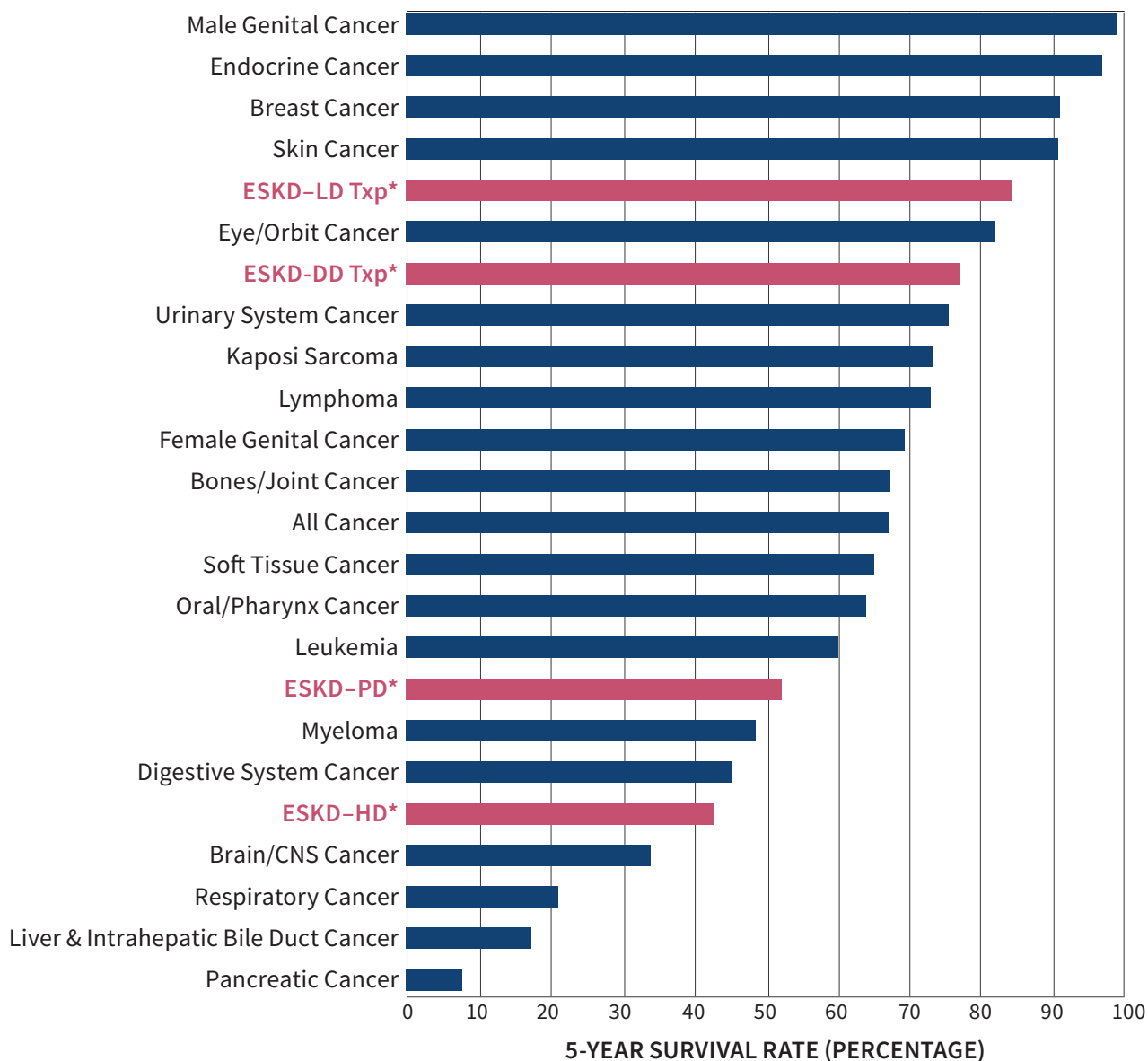


SOURCE: USRDS 2018 Annual Data Report.



**FIGURE 10**

**5-Year Survival of Cancers and ESRD by Treatment Type**



\*Reference population: incident ESKD patients, 2011. Adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis

**LEGEND**

- ESKD-LD Txp: end-stage kidney disease, received living donor transplant
- ESKD-DD Txp: end-stage kidney disease, received deceased donor transplant
- ESKD-PD: end-stage kidney disease, receiving peritoneal dialysis
- ESKD-HD: end-stage kidney disease, receiving hemodialysis

SOURCES: United States Renal Data System, 2018 USRDS annual data report; SEER Cancer Statistics Review, 1975-2015.

provides the majority of NIH's funding for biomedical research on kidney disease, ESRD treatment, and kidney donation.<sup>68</sup> HHS, in partnership with the American Society of Nephrology, also supports KidneyX, which is designed to improve kidney care by investing in the development of new products and technologies like wearable and implantable dialyzers and regenerative kidneys.

## Health Care Spending on CKD and ESRD

When Medicare entitlement was first extended to individuals with ESRD in 1972, approximately 10,000 individuals were receiving dialysis. By 2016, excluding transplant patients, there were 511,270 beneficiaries being treated for ESRD. While ESRD patients comprise less than 1 percent of the total Medicare population, they accounted for approximately 7 percent of Medicare FFS spending, totaling over \$35.4 billion in 2016.<sup>69</sup> Medicare spending on CKD and ESRD was over \$114 billion in 2018, representing 23 percent of total Medicare FFS spending.<sup>70</sup> Growth in total CKD spending has primarily been driven by an increase in the number of identified cases, particularly those in the earlier disease stages (CKD Stages 1-3).<sup>71</sup> In 2016, Medicare patient obligations – which may be paid by the patient, by a secondary insurer, or may be uncollected – represented 9.6 percent, or approximately \$4 billion, of total FFS Medicare Allowable Payments.<sup>72</sup>

Between 2015 and 2016, average per person per year spending for hemodialysis (HD) care increased from \$88,782 to \$90,971, or 2.5 percent, while total spending on HD care rose from \$26.8 billion to \$28.0 billion, or 4.5 percent (similar to the total growth in ESRD spending of 4.6 percent).<sup>73</sup> Total spending for patients who have received kidney transplants increased from \$3.3 billion to \$3.4 billion, or 3 percent, and per capita spending increased from \$34,080 to \$34,780, or 2.1 percent.<sup>74</sup>

## Kidney Transplantation

For some people living with ESRD, a transplant using a healthy kidney from a donor may be an option. The Innovation Center's ETC Model will support the goal of increasing access to kidney transplants through financial incentives for ESRD facilities and Managing Clinicians. A functioning transplanted kidney does a better job of filtering wastes than dialysis,<sup>75</sup> and transplant recipients have improved life expectancy compared to individuals on dialysis.<sup>76</sup> Of the 36,529 organ transplants performed in the U.S. in 2018, approximately 21,000 were kidney transplants.<sup>77</sup> Of these, approximately 30.4 percent were from living donors and 69.6 percent from deceased donors.<sup>78</sup> One-year patient survival rates are similar for individuals who received transplants from living kidney donors and from deceased donors: 98.8 percent and 96.3 percent, respectively. Five years after transplantation, the patient survival rate among those who received a kidney transplant from a living donor is 92.1 percent, compared to 83.2 percent for those who received a kidney transplant from a deceased donor.<sup>79</sup>

The OPTN reports there are nearly 95,000 candidates on the waiting list to receive a kidney transplant. On average, twenty candidates die each day while waiting for an organ transplant.<sup>80</sup> One important factor contributing to the size of the waiting list is the number of discarded kidneys from deceased donors.

**Figure 11** (see following page) is a chart displaying the demand for kidney transplants and the policy options that can optimize the availability of donor kidneys for transplantation.

## Organ Donation and Procurement

More than 145 million Americans are registered to become organ donors.<sup>81</sup> However, signing up to be a donor does not guarantee that the donor's organs or tissues will be suitable for transplantation, and registering as a donor usually takes place many years before donation becomes possible. In the case of living donation, transplant centers evaluate potential living donors to determine whether they are suitable to be a donor and to avoid the occurrence of any adverse physical, psychological, or emotional outcome before, during, or after the donation.

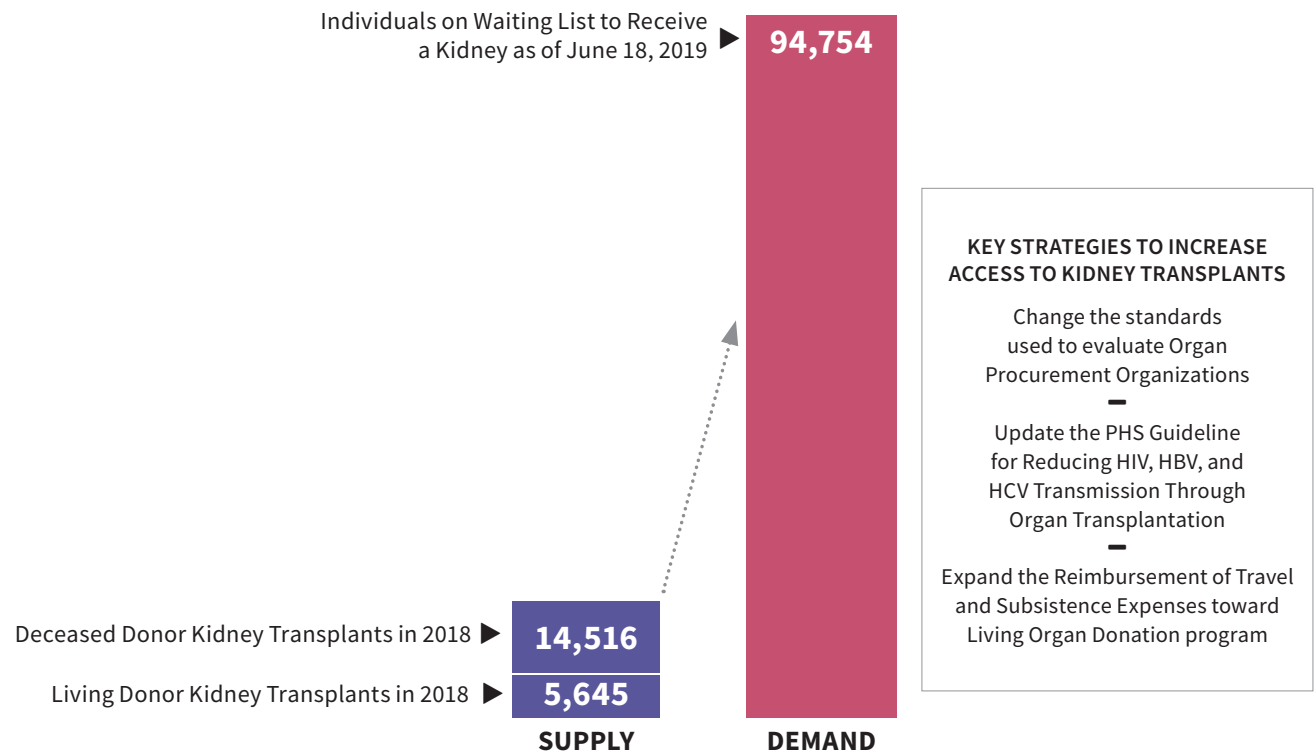
To become a deceased donor, an individual has to die under specific circumstances, such as after an accident involving severe head trauma, or a brain aneurysm or stroke. In such cases where an individual is severely injured and unresponsive, physicians attempt to save the individual’s life and then perform tests to determine whether the individual is brain dead and cannot breathe on his or her own. Organ donation occurs only after the donor is legally declared dead. In accordance with federal regulations, hospitals notify the local Organ Procurement Organization (OPO) of every patient who has died or is nearing death and provide information to the OPO to determine whether deceased patients have the potential to be an organ donor.<sup>82</sup>

The OPO transplant coordinator searches the organ donor registries to see if the deceased person is registered as a donor. If so, that registration serves as legal consent for organ donation. If the deceased person has not registered as a donor and there was no other legal consent for donation such as a notation on the driver’s license, the OPO asks the deceased individual’s spouse or next of kin for authorization. After authorization, a medical evaluation takes place, including obtaining information about the deceased person’s medical history from his or her family. If the deceased person is determined to be an eligible donor based on the medical evaluation, the OPO contacts the Organ Procurement and Transplantation Network (OPTN).<sup>83,84</sup>

The OPTN operates the national database of all patients in the U.S. waiting for a transplant. OPTN’s computer system matches the donor’s organs to potential recipients. The network has policies that define how donor organs are matched and allocated to patients on the waiting list. The OPTN policies take into consideration the unique medical needs of children and provide priority to children for some organs. OPTN policy also addresses the needs of patients with a highly sensitized immune system and therefore at higher risk of rejecting a donor organ.

**FIGURE 11**

**Gap between Supply and Demand for Kidney Transplantation**



SOURCE: Organ Procurement and Transplantation Network data

When matching organs from deceased donors to patients on the waiting list, many of the factors taken into consideration are the same for all organs. These usually include:

- Blood type
- Body size
- Severity of patient's medical condition
- Distance between the donor's hospital and the patient's hospital
- The patient's waiting time
- Whether the patient is available (for example, whether the patient can be contacted and has no current infection or other temporary reason that transplant cannot take place)

However, depending on the organ, some factors become more important, so there is a different policy for each organ. For example, some organs can survive outside the body longer than others, so the distance between the donor's hospital and the potential recipient's hospital may be given greater weight than other factors in certain situations.

After the OPO enters information about a deceased donor into the database, the computer system generates a list of patients who match the donor, by organ. Each available organ is then offered to the best-matched patient for evaluation by the patient's transplant team.

After a match is identified, the transplant team determines whether the available organ is medically suitable for the matched patient. Even if an organ is suitable, the transplant team may decline the organ offer for example, if the patient is too sick to undergo a transplant, has an untreated infection, or is unavailable for transplant. In these situations, the organ is then offered to the next patient on the waiting list. During the organ matching process, organs are maintained on artificial support, and the hospital medical staff and the OPO procurement coordinator closely monitor the condition of the donated organs. After removal from the donor, organs remain viable for transplantation for only a limited period of time, which varies by organ type, so the OPO must arrange timely transportation of the organs to the hospitals of the intended recipients. **Figure 12** is a list of the reasons recovered kidneys are not used.

#### FIGURE 12

##### Reported reasons why recovered kidneys are not used for transplantation:

- infection
- organ trauma
- too old on pump
- too old on ice
- ureteral damage
- deceased organ
- vascular damage
- biopsy findings
- positive hepatitis
- donor social history
- poor organ function
- donor medical history
- organ not as described
- anatomical abnormalities
- warm ischemic time too long
- no recipient located – list exhausted
- recipient determined to be unsuitable for transplant in the operating room

SOURCE: OPTN/SRTR 2016 Annual Data Report: Deceased Organ Donation

## Current Quality Measures Relevant to Kidney Care

### Calendar Year 2019 Quality Payment Program (QPP) Measures for Clinicians by Reporting Method

QPP #	Measure Name	Claims	Registry	QCDR	Web Interface	EHR
1	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	✓	✓		✓	✓
46	Medication Reconciliation Post-Discharge	✓	✓			
47	Advance Care Plan	✓	✓			
119	Diabetes: Medical Attention for Nephropathy		✓			✓
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure		✓			
325	Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions		✓			
327	Pediatric Kidney Disease: Adequacy of Volume Management		✓			
328	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL		✓			
329	Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis		✓			
330	Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days		✓			
403	Adult Kidney Disease: Referral to Hospice		✓			
405	Appropriate Follow-up Imaging for Incidental Abdominal Lesions	✓	✓			

## Qualified Clinical Data Registry (QCDR) Measures

QCDR Measure ID	Measure Name
MUSIC15	Kidney Stones: SWL in patients with total renal stone burden > 2 cm or > 1 cm lower pole stones
ACRad26	Appropriate venous access for hemodialysis
RPAQIR9	Advance Care Planning (Pediatric Kidney Disease)
RPAQIR4	Arteriovenous Fistula Rate
RCOIR7	Improved Access Site Bleeding
RCOIR5	End Stage Renal Disease (ESRD) Initiation of Home Dialysis or Self-Care
RPAQIR13	Rate of Timely Documentation Transmission to Dialysis Unit/Referring Physician
RPAQIR5	Transplant Referral
RPAQIR16	Peritoneal Dialysis Catheter Success Rate
RPAQIR17	Peritoneal Dialysis Catheter Exit Site Infection Rate
RPAQIR18	Advance Directives Completed
RCOIR10	Upper Extremity Edema Improvement
RCOIR1	CKD 3-5 Patients Seen at the Recommended Frequency Levels
CLLC5	Monitoring for albuminuria in patients with CKD
RCOIR3	CKD 3-5 Patients with a Urine ACR or Urine PCR Lab Test
PPRNET13	Chronic Kidney Disease (CKD): eGFR Monitoring
PPRNET14	Chronic Kidney Disease (CKD): Hemoglobin Monitoring
RPAQIR1	Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy
RCOIR4	CKD 4-5 Patients with Transplant Referral
CLLC7	Renal Dysfunction: New Oral Anticoagulants (NOACs) Management
AQUA15	Stones: Urinalysis documented 30 days before surgical stone procedures
AQUA14	Stones: Repeat Shock Wave Lithotripsy (SWL) within 6 months of treatment

## Quality Incentive Program (QIP) Measures for Dialysis Facilities by Data Source

SHORT NAME	MEASURE NAME	PY 2021	PY 2022	PY 2023	DATA COLLECTION PERIOD CY 2021 /CY 2022 /CY 2023
<b>CLAIMS-BASED MEASURES</b>					
SRR	Standardized Readmission Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
STrR	Standardized Transfusion Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
SHR	Standardized Hospitalization Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Fistula	Standardized Fistula Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Catheter	Long-Term Catheter Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
<b>CROWNWEB BASED MEASURES</b>					
Depression	Clinical Depression Screening and Follow-up	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Fistula	Standardized Fistula Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Catheter	Long-Term Catheter Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
UFR	Ultrafiltration Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
Kt/V	Comprehensive Dialysis Adequacy	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
Hyp	Hypercalcemia	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
PPPW	Percentage of Prevalent Patients Waitlisted	x	✓	✓	January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
MedRec	Medication Reconciliation	x	✓	✓	January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
<b>NHSN BASED MEASURES</b>					
NHSN BSI Reporting	NHSN Dialysis Event Reporting	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
NHSN BSI Clinical	NHSN Bloodstream Infection in Hemodialysis Patients	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
<b>ICH_CAHPs BASED MEASURES</b>					
ICH_CAHPs	In-center Hemodialysis Consumer Assessment of Healthcare Provider and Systems	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021

## List of Acronyms

AI/AN	American Indian/Alaska Native
APOL1	Apolipoprotein L1
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
CEC	Comprehensive ESRD Care
KCF	Kidney Care First
CKCC	Comprehensive Kidney Care Contracting
CKD	Chronic Kidney Disease
CMS	Centers for Medicare and Medicaid Services
COIIN	Collaborative Improvement and Innovation Networks
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CTO	Chief Technology Officer
DAA	Direct-acting Anti-viral
DPP	Diabetes Prevention Program
EMP	ESA Monitoring Policy
ESA	Erythropoietin Stimulating Agent
ESRD	End Stage Renal Disease
ESRD-D	Diabetes-related ESRD
ETC	ESRD Treatment Choices
FDA	Food and Drug Administration
FFS	Fee-for-Service
FY	Fiscal Year
GAO	Government Accountability Office
HD	Hemodialysis
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MHS	Military Health System
NIH	National Institutes of Health
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NKF	National Kidney Foundation
OASH	Office of the Assistant Secretary for Health
ONC	Office of the National Coordinator for Health Information Technology
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
PHS	Public Health Service
PPS	Prospective Payment System
QCDR	Qualified Clinical Data Registry
QIP	Quality Incentive Program
QPP	Quality Payment Program
SDPI	Special Diabetes Program for Indians
USRDS	U.S. Renal Data System



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80. Health Resources and Services Administration (2019). Organ Donation Statistics. Available online at <https://www.organdonor.gov/statistics-stories/statistics.html#glance>

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82. OPOs evaluate potential donors, discuss donation with surviving family members, and arrange for the surgical removal and transport of donated organs. There are 58 OPOs in the U.S., each with its own designated service area. OPOs must be certified by the Centers for Medicare and Medicaid Services (CMS) and abide by CMS regulations.

83. An eligible death is defined as per OPTN Policy 1.2 as death of a person aged 70 years or younger who is legally declared brain dead according to hospital policy and does not exhibit any of the following indications: tuberculosis, human immunodeficiency virus (HIV) infection with specified conditions, Creutzfeldt–Jacob Disease, herpetic septicemia, rabies, reactive hepatitis B surface antigen, any retrovirus infection, active malignant neoplasms (except primary central nervous system tumors and skin cancers), Hodgkin disease, multiple myeloma, leukemia, miscellaneous carcinomas, aplastic anemia, agranulocytosis, fungal and viral encephalitis, gangrene of bowel, extreme immaturity, or positive serological or viral culture findings for HIV.

84. The purpose of the OPTN is to improve the effectiveness of the nation’s organ procurement, donation, and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure. The OPTN is administered by United Network for Organ Sharing (UNOS) under contract to the U.S. Department of Health and Human Services.

