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OFFICE OF
HEALTH POLICY

Advancing American Kidney Health: 2020 Progress Report

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U.S. Department of Health & Human Services

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Abbreviations

AAKH	Advancing American Kidney Health
AI/AN	American Indian and Alaska Native
AKI	Acute Kidney Injury
ASN	American Society of Nephrology
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPR	Office of the Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
CKD	Chronic Kidney Disease
CMS	Centers for Medicare & Medicaid Services
COIIN	Collaborative Innovation and Improvement Network
CY	Calendar Year
DPP	Diabetes Prevention Program
ESRD	End-stage Renal Disease
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
KHI	Kidney Health Initiative
MDPP	Medicare Diabetes Prevention Program
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
OCR	Office for Civil Rights
PROM	Patient-Reported Outcome Measures
PPS	Prospective Payment System
RFI	Request for Information
RRT	Renal Replacement Therapy
TPNIES	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies

Foreword from the Secretary

INTRODUCTION

In July 2019, President Trump announced the Advancing American Kidney Health (AAKH) initiative to transform the way we prevent and treat kidney disease in the U.S. Kidney disease affects 37 million Americans, and dialysis, needed to treat kidney failure, is one of the most burdensome, draining long-term treatments in health care. I noted my own personal experience supporting my father, who was on dialysis for years.

The AAKH initiative focuses on specific strategies to guide U.S. Department of Health and Human Services (HHS) actions to achieve three goals:

- **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

The launch of this initiative represented a bold step forward towards paying for kidney health and supporting the development and availability of alternatives to facility-based dialysis. The Department developed ambitious targets to drive improvement:

- Reduce the number of Americans developing end-stage renal disease (ESRD) by 25 percent by 2030.
- Have 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant.
- Double the number of kidneys available for transplant by 2030.

I am delighted to report that we have made tremendous progress in the intervening year since this initiative was announced. In the year since we rolled out our plan to transform kidney care, we have made great strides in addressing both the strategies that the Department laid out to address kidney health in its action plan and an accompanying Executive Order. HHS has continued to engage with stakeholders in our efforts to increase public awareness about kidney health, support and empower patients living with kidney disease, introduce new payment models for kidney care, and invest in innovative research and development.

COVID RESPONSE

In 2020, as we are confronting COVID-19, the pandemic underscores the importance of the Department's efforts to address kidney health as illustrated in this progress report. People with kidney disease and transplant recipients are at higher risk for developing serious complications from COVID-19. In addition, COVID-19 infection can cause acute kidney injury in some people, even in those who did not have kidney problems before they became infected with the virus. Based on analysis performed by the

Office of the Assistant Secretary for Planning and Evaluation (ASPE) using early Medicare claims data, the risk of COVID-19 infection among Medicare ESRD beneficiaries is 3.5 times greater compared to all Medicare fee-for-service beneficiaries. Moreover, the joint risk of COVID-19 infection and death is 5.2 times higher among Medicare ESRD beneficiaries compared to all Medicare fee-for-service beneficiaries.

The Administration's focus on patients with kidney disease during the pandemic has included convening experts from across the Administration to work with the kidney community to identify response challenges, integrate requirements, and address kidney community needs to better protect patients and staff, ensure continuity care, and save lives throughout the public health emergency.

CONCLUSION

This report focuses on HHS activities over the past year and reflects the Administration's ongoing commitment to making bold progress to Advance American Kidney Health, while strengthening collaborations with providers, patients, and caregivers to improve the health and well-being of people at risk for and living with kidney disease.

Alex M. Azar II
Secretary of Health and Human Services

Advancing American Kidney Health Initiative: Progress to Date

This report describes the progress the Department has made over the past year to implement the [Department's AAKH initiative](#) and the [Executive Order](#) that accompanied the initiative. This update is organized by the goals and objectives outlined in the AAKH initiative.

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

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

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

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

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

- The National Institutes of Health (NIH) has made investments in biomedical research to improve identification of populations at risk for chronic kidney disease (CKD), expanded research activities related to high-risk populations including racial and ethnic minorities, and increased opportunities for engaging with kidney health researchers. Publications from NIH-supported [Kidney Precision Medicine Project](#) studies have demonstrated the utility of kidney tissue in optimizing research tools and identifying specific types of cells associated with kidney disease. An October 2019 [article](#) highlighted findings related to NIH-supported research on apolipoprotein L1 (APOL1) testing among African American organ donors. The APOL1 gene explains why kidney disease progresses faster among African Americans compared to Caucasians. The "Identifying and Exploring Solutions to the Ethical Challenges of APOL1 Testing of Donors with Recent African Ancestry through Mixed Methods Research with Stakeholders" study focuses on understanding ethical and social issues associated with APOL1 testing and characterizing the participants' experiences with receiving APOL1 testing results. Findings from this study will help to inform the development of guidelines for APOL1 testing to identify African Americans at increased risk for CKD.
- In March 2020, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) hosted a [webinar](#) involving scientific staff and extramural investigators, "*Strategies for the Prevention or Treatment of Acute Kidney Injury in COVID-19 Infection,*" to assess needs in the field, especially in terms of drug development and clinical trials. Webinar attendees discussed the variability of COVID-19 presentation and outcomes in their patients, clinical issues related to COVID-19 patients with or without ESRD or acute kidney injury (AKI), and NIH resources and research funding opportunities.
- The Centers for Disease Control and Prevention (CDC) has increased information dissemination to raise public awareness regarding kidney health. Since July 2019, more than 50,000 subscribers have received five *Are you Aware: Quick Facts About Kidney Disease* emails from CDC that address the need for kidney disease screening, awareness of risk factors associated with kidney disease, and prevalence of food insecurity among people living with advanced CKD. Since September 2019, the CDC [Chronic Kidney Disease Surveillance Team](#) has published four articles on trends in CKD prevalence among racial/ethnic and socioeconomic status groups, CKD awareness by future risk of kidney failure, the relationship between dialysis-requiring AKI and recovery from ESRD, and reasons for state-level variation in new cases of dialysis-requiring AKI.

- In [National Trends in the Prevalence of Chronic Kidney Disease Among Racial/Ethnic and Socioeconomic Status Groups, 1988-2016](#), investigators found CKD prevalence in the United States has stabilized overall in recent years but has increased among Mexican American persons, and more importantly, gaps in CKD prevalence across racial/ethnic groups and levels of socioeconomic status have largely persisted for nearly 30 years.
 - Findings from [CKD Awareness Among US Adults by Future Risk of Kidney Failure](#) indicate that awareness of CKD, including among the highest risk individuals, remains consistently below that of hypertension and diabetes.
 - [The relation between dialysis-requiring acute kidney injury and recovery from end-stage renal disease: a national study](#) found that incidence of AKI requiring dialysis is an important driver of renal recovery rates among incident ESRD patients. Approximately 5 percent of incident ESRD patients in the U.S. recover enough kidney function to discontinue dialysis. In exploring reasons for state-level variation in incidence of dialysis-requiring acute kidney injury (AKI-D) in the United States, results suggest state-level variation in AKI-D incidence may be influenced by state-level variations in prevalence of and rates of hospitalization with several chronic health conditions.
- As part of its [CKD Initiative](#) 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, CDC has collaborated with other government agencies, universities, and national organizations to support a robust portfolio of epidemiological studies, including publications on declining incidence of diabetes-related ESRD in minority populations (in collaboration with the Indian Health Service), increasing hospitalizations for dialysis-requiring AKI in people with diabetes, and a stall in the decline in amputation rates in the high-risk population with both ESRD and diabetes. Please see: [Sustained Lower Incidence of Diabetes-Related End-Stage Kidney Disease Among American Indians and Alaska Natives, Blacks, and Hispanics in the U.S., 2000-2016](#); [US Trends in Hospitalizations for Dialysis-Requiring Acute Kidney Injury in People With Versus Without Diabetes](#); [Trends of Nontraumatic Lower-Extremity Amputation in End-Stage Renal Disease and Diabetes: United States, 2000-2015](#). In January 2020, CDC authors published findings from a study investigating kidney disease markers to diagnose early kidney function decline. Please see: [Do sodium-glucose cotransporter-2 inhibitors affect renal hemodynamics by different mechanisms in type 1 and type 2 diabetes?](#) Recent findings resulting from the CKD Initiative indicate hospitalizations for dialysis-requiring AKI are likely to continue to increase during the COVID-19 pandemic.
 - The CKD Epidemiology in the Military Health System is a collaborative effort between CDC and the Uniformed Services University of the Health Sciences, which 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. As part of this effort, CDC and other project staff presented on *Chronic Kidney Disease Prevalence in the US Military Health System by Laboratory vs. ICD-9 Coding* at the 2019 Kidney Week meeting of the American Society of Nephrology (ASN).

- In March 2020, HHS [launched a nationwide kidney risk awareness campaign](#) in collaboration with the National Kidney Foundation (NKF) and the ASN, in response to Section 3 of the President's Executive Order on Advancing American Kidney Health.

Objective 2: Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure

- IHS has strengthened its 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 IHS Special Diabetes Program for Indians and other related efforts continue to contribute to improvements in diabetes-related outcomes. A study published in June 2020 found that from 2000-2016, the incidence of diabetes-related ESRD incidence declined by 53 percent for AI/AN adults: [Sustained Lower Incidence of Diabetes-Related End Stage Kidney Disease Among American Indians and Alaska Natives, Blacks, and Hispanics in the U.S., 2000-2016](#).
- Since July 2019, participation in the CDC's [National Diabetes Prevention Program](#) (National DPP) has increased. The 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. As of June 2020, over 486,000 participants have enrolled in the evidence-based National DPP lifestyle change program. Between August 2019 and July 2020, there were 11,572 participants enrolled who were referred by a primary or non-primary health care provider.
- CDC's efforts to scale up the National DPP in underserved areas and to reach populations at highest risk include a focus on increasing participation among Medicare beneficiaries, men, African Americans, Asian Americans, Hispanics, American Indians, Alaska Natives, Pacific Islanders, and noninstitutionalized people with visual impairments or physical disabilities. From August 2019 to July 2020, CDC collaborated with the Innovation Center at the Centers for Medicare & Medicaid Services (CMS) to implement a community of practice for [Medicare Diabetes Prevention Program \(MDPP\)](#) supplier organizations that had successfully submitted MDPP claims. In FY 2021, CDC will work with CMS to build on this effort, helping organizations successfully apply to become MDPP suppliers. CDC is also testing models that will support community-based program delivery organizations with billing, legal, and other administrative functions necessary to sustain these services long term. As of July 2020, there are 248 MDPP suppliers with 396 administrative locations and 539 community settings.

- On June 9, 2020, CDC released an [update to the Hypertension Control Package](#) highlighting the interplay between kidney disease and hypertension and including a number of tools to address these connected conditions.
- NIH has increased support of research to develop evidence-based interventions to delay progression to kidney failure. NIH published multiple Notices of Special Interest and a [Funding Opportunity Announcement](#) to create a Consortium of Interlinked Community-engaged Research Projects to Understand COVID-19 Health Disparities across the United States, and to deploy implementation strategies to improve the reach, acceptance, uptake, and sustainability of COVID-19 testing, which in turn could lead to earlier interventions. COVID-19 has a disparate impact on ethnic and racial groups in the United States already disproportionately affected by diseases that lead to worse outcomes, including kidney disease and kidney failure.
- The Office of the Assistant Secretary for Preparedness and Response has expanded its network of partnerships to develop tools that can better predict and treat sepsis. Sepsis is defined as the body's overwhelming response to an infection that can lead to organ dysfunction, including kidney failure, and even death. The Biomedical Advanced Research and Development Authority created the [Solving Sepsis](#) program within the Division of Research, Innovation, and Ventures to reduce the incidence, morbidity, mortality and economic burden due to sepsis through a systems approach addressing education and awareness for patients and health care providers, host-based diagnostics that can predict, identify and prognosticate outcomes of sepsis, novel clinical management strategies and host-based therapeutics, and monitoring patients recovering from sepsis, all of which can prevent kidney injury.

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

- The CDC has increased outreach and education to encourage person-centered and safe treatment for patients with kidney failure. In collaboration with CDC's Division of Healthcare Quality Promotion, the CKD Initiative in CDC's Division of Diabetes Translation supports strategies to prevent bloodstream infections among patients in hemodialysis facilities, including educational tools and materials for providers and patients and support to the Making Dialysis Safer Coalition. In the last quarter of 2019, CDC posted two new coalition webinars as part of the "[Tune in to Safe Healthcare](#)" webinar series: September 25, 2019 webinar [Making Dialysis Safer for Patients: Innovative Approaches to Hand Hygiene](#) and December 10, 2019 webinar [Making Dialysis Safer for Patients: Bloodstream Infections, Wall Boxes, and Lessons Learned](#).

- The Office of the Assistant Secretary for Preparedness and Response has established an inventory of portable dialysis technologies to treat dialysis-dependent, at-risk populations during disasters and, as of July 2020, has deployed 50 Food and Drug Administration (FDA)-approved portable dialysis platforms in order to provide care to patients with AKI during the COVID-19 public health emergency. ASPR, in collaboration with the Centers for Medicare & Medicaid Services, has enhanced its dynamic datasets, mapping and artificial intelligence tools, online training programs, informational resources, and technical assistance to help public health authorities and their partners to anticipate, plan for, and address the needs of at-risk individuals that rely upon life-maintaining electricity-dependent medical equipment, including home dialysis machines, and healthcare services, such as in facility dialysis. Together, these tools are helping communities across the nation and U.S. territories to better protect health and save lives in the event of a public health emergency or disaster.
- Through the [National Healthcare Safety Network](#), CDC tracks bloodstream infections, including those caused by 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 related to care and treatment for people living with kidney failure.
- NIH has begun planning a workshop to be held in Spring 2021 on expanding opportunities for home-based dialysis treatment and increasing patient choice regarding dialysis for patients who progress from early stage kidney disease.
- The NIDDK’s Health Information Technology Working Group works to enable and support the widespread interoperability of data related to kidney health among healthcare software applications to optimize CKD detection and management, which can play a role in care coordination. A subgroup of the Working Group comprised of federal government and external experts has reported on development and validation of a CKD electronic phenotype that provides a pragmatic and accurate method for electronic health record-based identification of patients likely to have CKD: [Development and Validation of a Pragmatic Electronic Phenotype for CKD](#).
- The Office for Civil Rights (OCR) has been working to protect person-centric, safe care, free from discrimination for people living with kidney disease. In April 2020, OCR resolved a [compliance review](#) of the State of Alabama after the state removed ventilator rationing guidelines that allegedly discriminated on the basis of disability and age. The guidelines contained exclusion criteria that allegedly allowed for denying ventilator care to patients on the basis of disability and age, including patients with ESRD under certain circumstances. As a result of OCR’s intervention, the State of Alabama released new guidelines without such exclusions and clarified that it would not single out certain

disabilities for unfavorable treatment or use categorical age cutoffs in its current or future guidelines. In addition to Alabama, OCR has reached similar resolutions with the States of [Pennsylvania](#) (April 2020), [Connecticut](#) (June 2020), and [Tennessee](#) (June 2020) to remove potentially discriminatory provisions from their crisis standards of care plans. In June 2020, OCR participated in a podcast, [Protecting Civil Rights during COVID-19](#), sponsored by the ASN, discussing the actions taken by OCR to protect vulnerable patients from discrimination during the COVID-19 pandemic and OCR's enforcement activities to prevent discrimination in state crisis standards of care plans that could deprive life-saving care from patients with disabilities, including kidney patients, when resources are in short supply. In March 2020, OCR released a [bulletin](#) to remind entities that civil rights laws and protections, which are applicable to patients with kidney disease, remain in effect during COVID-19 and to offer best practices that ensure non-discrimination based on disability, age, race, color, national origin, sex, and requests for religious accommodation.

- To advance education and outreach and promote person-centered treatments for people with kidney failure, FDA's Office of Minority Health and Health Equity worked collaboratively with the American Kidney Fund to host a webinar, "Clinical Trials and Kidney Disease," in September 2019 in both [English](#) and [Spanish](#) to educate patients living with kidney disease on the importance of participating in clinical trials and also authored a blog titled, "[Minorities and Clinical Trials: Why it Matters.](#)"
- FDA is engaged with ASN's [Kidney Health Initiative \(KHI\)](#) to develop a methodology to collect Patient Perspective Information on wearable dialysis devices, which could be used as valid scientific evidence to determine the benefit-risk trade-offs patients with ESRD are willing to make to accept these novel therapies.
- In March 2020, HHS initiated a public-private working group comprised of HHS subject matter experts and external stakeholders to discuss current experiences and to develop strategies for protecting the health of individuals living with kidney disease during the COVID-19 public health emergency. Monthly working group discussions focus on identifying actions that HHS can take to address coordination of services for kidney patients and related topics including telehealth, patient education, and provider payment issues.

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

- In July 2019, the Innovation Center at CMS announced the [optional Kidney Care Choices \(KCC\) Model, which includes four payment options, to test](#) new incentives for preventing kidney disease and managing kidney patients' health in a more person-centered way. In the Kidney Care First (KCF) Option, participating nephrology practices will receive adjusted fixed payments on a per-beneficiary basis for managing the care of

Medicare beneficiaries with late-stage chronic kidney disease and beneficiaries with ESRD. The payments will be adjusted based on health outcomes and utilization compared to the participating practice’s own experience and national standards, as well as performance on quality measures. In addition, participating practices will receive a bonus payment for every beneficiary aligned to them that receives a kidney transplant based on the transplant remaining healthy for up to three years after the surgery. The Comprehensive Kidney Care Contracting (CKCC) Option, includes Graduated, Professional, and Global Options—in which capitated payments will be similar to the capitated payments under the KCF Option, but the Kidney Contracting Entities – which consist of nephrologists, transplant providers, and other health care providers including dialysis facilities – will take responsibility for the total cost and quality of care for their beneficiaries, and in exchange, can receive a portion of the Medicare savings they achieve or will be responsible for the losses they incur. The Innovation Center issued a Request for Applications to participate in the Kidney Care Choices Model in the fall of 2019, with applications due January 22, 2020. The first cohort of accepted applicants are scheduled to begin participating in the performance period of the Kidney Care Choices Model on April 1, 2021. The Innovation Center anticipates issuing a second Request for Applications in the spring of 2021. The Innovation Center also proposed a new payment model called [ESRD Treatment Choices](#) designed to provide new incentives to encourage use of dialysis in the home and transplantation. The proposed ESRD Treatment Choices Model is included in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Notice of Proposed Rule Making, and the public comment period for this Notice of Proposed Rule Making closed on September 16, 2019. These models are intended to address Sections 4 and 5 of the AAKH Executive Order.

- As a result of input from stakeholders and from a [December 2019 Technical Expert Panel](#) convened by a CMS contractor, CMS is taking steps to identify the unique costs related to home dialysis to meet the goal of aligning home dialysis resource use with payment.

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

- On March 26, 2020, Kidney Innovation Accelerator (KidneyX), an HHS partnership with ASN, announced 25 winners in the [KidneyX Patient Innovator Challenge](#), funded by the National Kidney Foundation, to highlight and advance patient-designed solutions to improve therapies and quality of life for people living with kidney diseases. On July 22, 2020, KidneyX, announced the six Phase 2 winners of the Redesign Dialysis Competition, which includes innovative approaches to design wearable dialysis machines and

implantable bio-artificial kidneys. In December 2019, HHS issued a Request for Information for the Artificial Kidney Prize, and included descriptions for how an artificial kidney would be considered for expedited FDA regulatory pathways, such as the Breakthrough Device Program, and CMS coverage options and payment pathways. These activities address Section 6 of the AAKH Executive Order.

- In October 2019, NIH released [NOT-DK-19-027, Notice of Special Interest \(NOSI\): Next-Generation Approaches to Renal Replacement Therapy Including Vascular Access](#), encouraging grant applications from small businesses. This NOSI aligns with major initiatives such as the [\(Re\)Building a Kidney Consortium](#) and KidneyX. Also, in alignment with AAKH, the NIDDK funded a grant in 2020 to support development of a drug for *Improving marginal allograft outcomes through cell junction stabilization in transplantation*. NIH is considering additional applications for funding in Fiscal Year 2020, and the NOSI remains active through January 7, 2023.
- FDA has been actively engaged with attempts to create an International Consortium to develop an Implantable Artificial Kidney. Two meetings were hosted with the International Federation of Artificial Organs: 1) the virtual [European Renal Association-European Dialysis and Transplantation Association](#) meeting June 9, 2020 and 2) [the American Association of Artificial Internal Organs](#) that presented advanced alternatives to current dialysis therapy using technologies that support wearable and implantable artificial kidney development.
- FDA is engaged in a public-private collaborative project with the [KHI](#) and [MDEpiNet](#) to develop a Coordinated Registry Network (CRN) to capture Real World Data and develop Real-World Evidence that FDA can use in regulatory decision-making for new breakthrough-designated medical devices on an ongoing basis. Further, this CRN will also support ongoing Patient Perspective Information as a longitudinal database to monitor changes in patient perspectives.
- FDA is engaged with [KHI](#) in an effort to identify the most appropriate clinical trial designs and endpoints for novel forms of renal replacement therapy (RRT). This project supports the KHI [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#) to ensure a clear pathway to commercialization or implementation for innovative RRT solutions. The goals of this project are to define terminology for future RRT products (i.e., wearable, portable, implantable, artificial kidney, regenerated kidney, bioartificial kidney, device, biologic) and to inform the most appropriate clinical trial designs and endpoints to support RRT product development, safety, approval, coverage, and reimbursement.
- FDA worked with KHI to publish [A Conceptual Framework for Patient-Reported Outcome Measures \(PROM\) for Transformative RRT Devices](#) in April 2020. Recognizing the significance of identifying patient priorities to be used in the regulatory context, this

project took the first step in identifying ways to capture the patient experience in clinical trials and regulatory submissions. This paper summarizes the proposed PROM conceptual framework, prioritizes PROMs based on their potential to be used in the regulatory environment, and identifies gaps and future needs to advance the development of PROMS that can be used in future clinical trials of novel RRT devices.

- Examples of FDA's programs that support efforts to stimulate innovation and reduce the time to market for devices for patients with kidney disease include the [Breakthrough Devices Program](#), the Medical Device Innovation Initiative, the [Payor Communication Task Force](#), and the Parallel Review Program.
- In the Calendar Year (CY) 2020 CMS ESRD Prospective Payment System (PPS) final rule, CMS established a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities. This includes items used for home peritoneal dialysis or home hemodialysis. CMS will pay this adjustment, which is called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), for equipment and supplies beginning CY 2021. In addition, in the [CY 2021 ESRD PPS proposed rule](#), CMS has proposed to pay TPNIES for new and innovative capital-related assets that are home dialysis machines used in the home for a single patient for a period of two years.

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

- [Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020](#), was published in the June 26, 2020 *Morbidity and Mortality Weekly Report*. The updated guideline aims to reduce the risk of unintended HIV, HBV, and HCV transmission, while preserving the availability of organs that can be used for transplantation.
- The goal of the three-year Organ Procurement and Transplant Network Collaborative Innovation and Improvement Network (COIIN), funded by the Health Resources and Services Administration (HRSA), was to increase kidney transplantation with a particular focus on utilization of kidneys with a higher likelihood of discard. The COIIN project supported collaboration among 58 participating transplant hospitals and organ procurement organizations. [Preliminary findings](#) show that the collaborative improvement approach combined with technical assistance for COIIN participants in the areas of waitlist management, organ-offer acceptance, and care coordination improved kidney transplant rates due to reduced discards and increased utilization of higher-risk

kidneys. In addition to the COIIN and policy related activities, HRSA issued a request for information (RFI) in November 2019 to seek information to make informed decisions about improving the operations of the national organ allocation system. As a part of its market research, HRSA sought to obtain information on the availability of modern information technology systems for facilitating complex resource allocation on a national scale or if there are entities capable of development such a system. HRSA, in collaboration with U.S. Digital, is reviewing responses received as a result of the RFI. These activities address Section 7 of the AAKH Executive order.

- On December 23, 2019, CMS published a proposed rule, “[Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage; Revisions to the Outcome Measures Requirements for Organ Procurement Organizations](#)” (84 F.R. 70628), which would revise the current Organ Procurement Organizations Conditions for Coverage to increase organ donation and transplantation rates by replacing the current measures with new transparent, reliable, and objective measures. CMS is currently reviewing, analyzing, and addressing comments received during the public comment period and intend to finalize by the end of the calendar year. This regulatory activity addresses Section 7 of the AAKH Executive Order.
- In 2019 and 2020, as part of its commitment to ensure that health care entities provide organ transplant services in a nondiscriminatory manner consistent with federal civil rights laws, OCR organized multiple listening sessions with advocacy organizations and other HHS components to discuss discriminatory practices in organ transplantation. In 2019, OCR favorably resolved a [complaint](#) against the University of North Carolina system (UNC Health Care) alleging that UNC Health Care unlawfully denied an individual with an intellectual disability the opportunity to be placed on the United Network for Organ Sharing (UNOS) transplant list on the basis of disability. UNC Health Care agreed to amend the medical records to clarify that the individual was eligible to be considered for placement on the UNOS list. Although this case was resolved prior to launching the Advancing American Kidney Health initiative, it serves as an important example that individuals with disabilities, including those with CKD, cannot be discriminated against in the organ transplant process.

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

- In December 2019, HRSA published a [proposed rule](#) that, if finalized as proposed, will expand the scope of reimbursable expenses for living organ donors to include lost wages, child care, and eldercare expenses to remove financial barriers to organ donation. In March 2020, HRSA published [proposed changes](#) to the Eligibility Guidelines for the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program that increase the household income eligibility threshold for living organ donors and organ recipients from 300 to 350 percent of the HHS Poverty

Guidelines. Together, these regulatory activities address Section 8 of the AAKH Executive Order.

- The NIH is planning a workshop to be held in 2021 on *Improving Access to Kidney Transplantation through Organ Optimization and Enhanced Evaluation of Deceased Donor Kidneys*. The goal of this workshop is to stimulate research and technology development that could lead to improved access to kidney transplantation for people with ESRD. The workshop will bring together experts from a wide range of disciplines to identify challenges and opportunities, stimulate multi-disciplinary collaboration, and accelerate research.