



# Agency Priority Goal Action Plan

## Kidney Care

### Goal Leader:

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### Deputy Goal Leaders:

Janai Hollinger and Lea Carroll, Health Resources and Services Administration

# Overview

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Goal Statement: Reduce morbidity and mortality associated with end-stage renal disease and increase patient choice by improving access to alternatives to center-based dialysis. Starting from the baseline for the calendar year ending December 31, 2019, by December 31, 2021:

- Increase by 10 percent the number of new end-stage renal disease patients on home dialysis.
- Increase by 10 percent the number of kidney transplants performed.

# Overview

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## Challenge

- There is no better example of an area that needs 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.

## Opportunity

- 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.

# Leadership

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## Goal and Deputy Goal Leaders:

- Immediate Office of the Secretary (IOS)

## Goal Team:

- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office for Civil Rights (OCR)

# Goal Structure & Strategies

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More information on HHS's strategies for this APG can be found in the Department's plan for [Advancing American Kidney Health](#):

- Reduce the risk of kidney failure
- Improve access to and quality of person-centered treatment options
- Increase access to kidney transplants

# Impact of COVID-19 on Kidney Care: Calendar Year 2020

- The number of kidney transplants performed (both living and deceased donors) during Quarter 2 of Calendar Year 2020 (April to June 2020) represents a 16.4 percent decrease from the number of kidney transplants reported for January to March 2020. The volume of kidney transplants decreased dramatically during this period in large part due to the impacts of the COVID-19 public health emergency. HRSA anticipates performance on this measure may be impacted for the duration of the public health emergency as hospitals prioritize resources to COVID-related activities and reassess the potential transmission risk to transplant recipients.
- OCR's enforcement and policy work has increased in response to the COVID-19 pandemic. OCR's Civil Rights Division has received over 600 civil rights complaints related to COVID-19, and OCR has initiated multiple detailed compliance reviews of states with crisis standards of care plans that could discriminate against patients based on disability and age in rationing health care, including dialysis. Fifteen of the COVID-19 complaints are related in some way to dialysis facilities or someone who has kidney disease, diabetes, or is on dialysis. OCR also released several [bulletins](#) intended to assist covered entities in complying with civil rights laws during the pandemic to ensure individuals receive necessary care. This work is relevant to the Kidney Care APG because it ensures that older patients and patients with disabilities, including kidney patients, are not subjected to discrimination in the delivery of health and human services, including dialysis care and kidney transplantation.

# Impact of COVID-19 on Kidney Care: Calendar Year 2020, continued

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- American Indians and Alaska Natives have been impacted by the COVID-19 pandemic, and IHS facilities have been focused on providing COVID-related services and other emergency care during this pandemic response. To avoid potential coronavirus exposure risk, there have been fewer in-person diabetes visits, though increased utilization of telehealth has helped address some of the needs for chronic disease management. For people with diabetes, control of blood sugar and blood pressure, along with regular monitoring of kidney function are important to help prevent kidney failure.

# Key Indicators: Q2 Calendar Year 2020

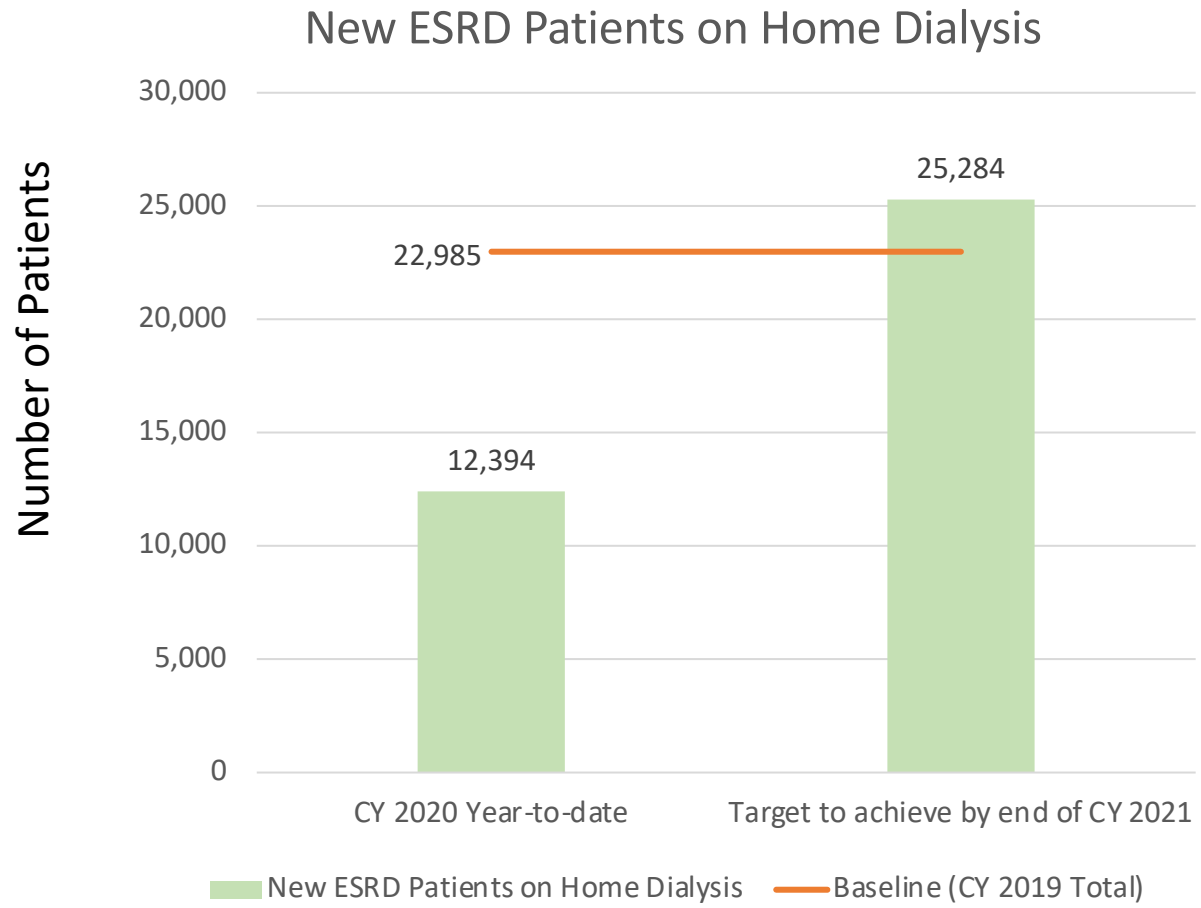
Indicator Name	Target	Q2 CY 2020 Result*	Comments
<p>Increase by 10 percent the number of <b>new end-stage renal disease (ESRD) patients on home dialysis.</b></p>	<p>25,284 Patients by the end of CY 2021</p>	<p>6,068 Patients</p>	<p>The 6,068 new ESRD patients on home dialysis in Q2 CY 2020 represented 19.6 percent of all Q2 CY 2020 incident ESRD patients.**</p>
<p>Increase by 10 percent the number of <b>kidney transplants performed.</b></p>	<p>25,741 Transplants by the end of CY 2021</p>	<p>5,126 Transplants</p>	<p>The number of transplants performed in Q2 decreased compared to Q1.</p>

*\*HHS is reporting progress for this APG on a Calendar Year (CY) cycle. This APG uses a CY 2019 baseline, and the Q2 CY 2020 Result represents progress for April-June 2020.*

*\*\*Incident patients are new patients with ESRD in contrast to prevalent patients, which are all of the patients with the condition including those who developed ESRD in preceding years.*

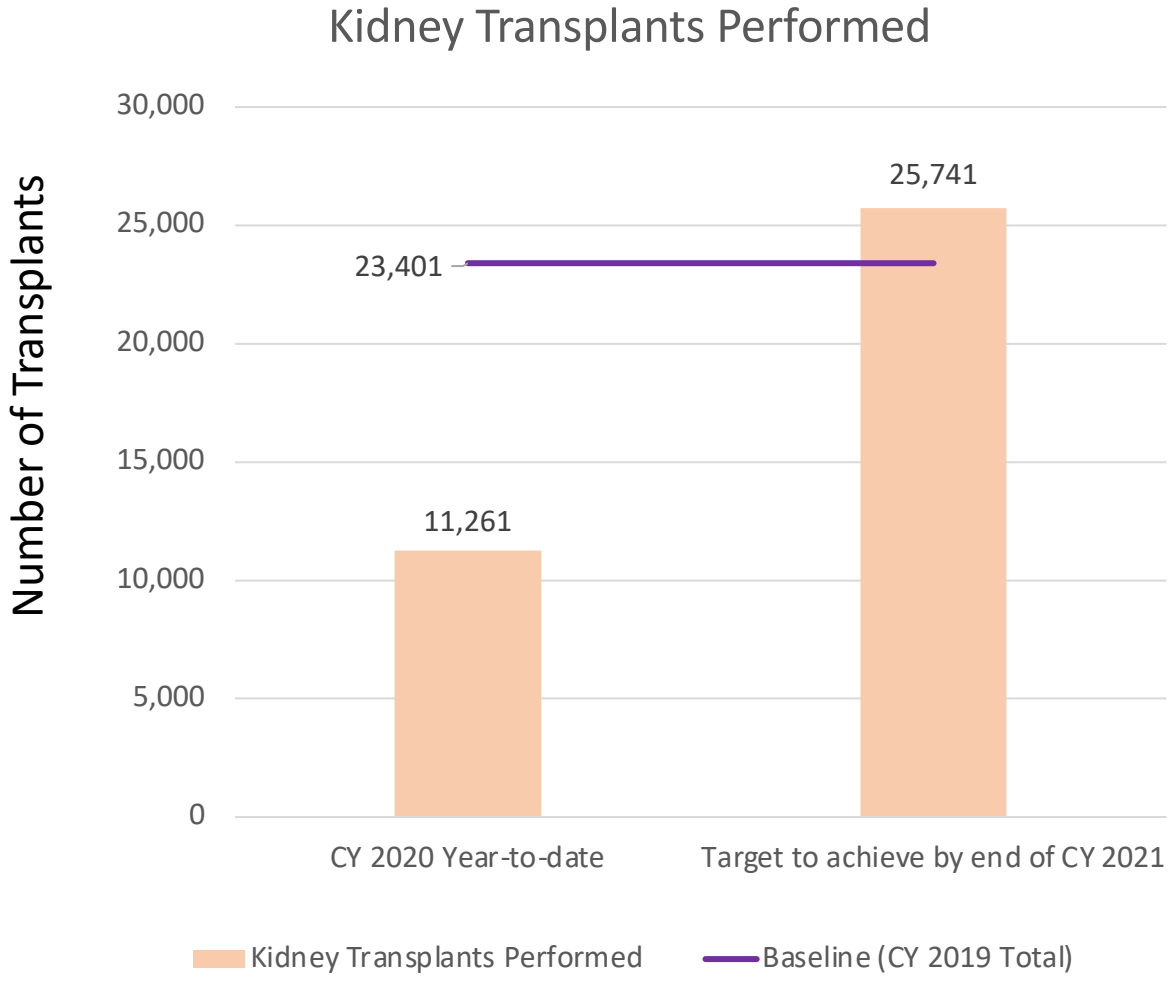


# Key Indicators: Q2 Calendar Year 2020



The Q2 CY 2020 results (6,068 new end-stage renal disease patients on home dialysis) are included in the CY 2020 Year-to-date amount, displayed relative to the Baseline (CY 2019) and the Target to achieve by end of CY 2021. The CY 2019 baseline reflects all new ESRD patients for that year.

# Key Indicators: Q2 Calendar Year 2020



The Q2 CY 2020 results (5,126 kidney transplants performed) are included in the CY 2020 Year-to-date amount, which is displayed relative to the Baseline (CY 2019) and the Target to achieve by end of CY 2021. The baseline is larger than the Q2 CY 2020 result because it includes all four quarters in the year.

# Summary of Progress: Q2 Calendar Year 2020

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- CMS announced the Kidney Care Choices (KCC) model will provide incentives for kidney care providers to improve management of care for patients with late-stage chronic kidney disease (CKD) and ESRD to delay the onset of dialysis and encourage kidney transplant.
- CMS has proposed a rule for Organ Procurement Organizations (OPO) that revises key outcome metrics to encourage OPOs to increase the organ donor pool and the rate of actual transplant of acquired organs.
- CMS proposed to allow transitional add-on payments to ESRD facilities for purchasing new and innovative home dialysis machines. If finalized, this proposal will allow ESRD facilities that purchase new and innovative home dialysis machines for use by an individual patient in their home to receive an additional payment for two years to offset the cost of acquiring and integrating into their operations innovative equipment to support home dialysis.
- CMS finalized in the ESRD Quality Incentive Program, a quality measure to encourage ESRD facilities to facilitate getting eligible dialysis patients on the kidney transplant waitlist beginning in performance year 2021.

# Summary of Progress: Q2 Calendar Year 2020, continued

- CMS proposed the ESRD Treatment Choices (ETC) Model to encourage increased use of home dialysis and kidney transplantation for Medicare ESRD beneficiaries. The model will provide resources to ESRD facilities and clinicians managing ESRD patients to support provision of home dialysis and transplant services.
- OASH and CDC published [“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”](#) in the June 26, 2020 *Morbidity and Mortality Weekly Report (MMWR)*. CDC is developing education and communication materials including patient and provider fact sheets related to the revised PHS Guideline.
- CDC and IHS published an article on kidney care data among American Indians and Alaska Natives, titled “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” by Nilka Ríos Burrows, Yan Zhang, Israel Hora, Meda E. Pavkov, Karen Sheff, Giuseppina Imperatore, Ann K. Bullock, and Ann L. Albright in *Diabetes Care*.

# Summary of Progress: Q2 Calendar Year 2020, continued

- IHS continues to monitor diabetes-care measures among IHS patients. For people with diabetes, control of blood sugar and blood pressure, along with regular monitoring of kidney function are important to help prevent kidney failure.
- 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 end-stage renal disease 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.

# Summary of Progress: Q2 Calendar Year 2020, continued

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- ASPR has procured and deployed 50 portable dialysis platforms in order to provide care to patients succumbing to acute kidney injury associated with complications from COVID-19. ASPR has developed, and is executing towards, a requirement for 50 more portable dialysis platforms and 500 continuous renal replacement therapy devices in order to address the kidney care needs associated with COVID-19. These platforms are FDA-approved and will continue to be deployed to COVID-19 hotspots, as requested by State and Local authorities during disaster responses.

# Key Milestones

Information about the Key Milestones for this APG can be found in HHS's plan for [Advancing American Kidney Health](#).

## Milestone Summary

Key Milestone	Milestone Due Date	Status	Owner	Comments
Publish Notice of Special Interest (NOSI): Next-Generation Approaches to Renal Replacement Therapy Including Vascular Access	Q4, CY 2019	Complete	NIH	This NOSI invites small business grant applications in these areas.
Submit revised 2020 Office of Health and Safety Guideline for HHS clearance	Q1, CY 2020	Complete	OASH	The Public Health Service Guideline was cleared by HHS and released to MMWR for publication.
Publish 2020 Public Health Service Guideline	Q2, CY 2020	Complete	OASH	
Establish an inventory of portable dialysis technologies to treat frail populations during disasters	Q2, CY 2020	Complete	ASPR	Portable dialysis technology on contract and deployed to COVID-19 hotspots by the Strategic National Stockpile
Establish a training capability for disaster response personnel to provide care in disaster settings	Q2, CY 2020	Complete	ASPR	Initial training with NDMS occurred in December 2019
Kidney Accelerated Placement Project	Q3, CY 2020	On-Track	HRSA	A one-year pilot
Center for Medicare and Medicaid Innovation Kidney Care Choices Model	Q1, CY 2021	On-Track	CMS	

# Data Accuracy and Reliability

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To report this APG, HHS is tracking several data sets. HHS uses the ESRD National Coordinating Center's (NCC) mortality data from CROWNWeb. These data include mortality for patients in the first 90 days and in first year after dialysis initiation. For this APG, the NCC will conduct internal quality assurance on these data before providing them to HHS on a quarterly basis.

HHS uses incident dialysis modality utilization rates for dialysis on home therapy collected through CROWNWeb. This data includes dialysis modality as well as patient characteristics including time of dialysis initiation.

“New ESRD Patients” starting on a home modality is defined as patients that are dialyzing via Peritoneal Dialysis or Home Hemodialysis within 180 days of dialysis initiation.

NCC collects these data and Numerator/denominator flags are calculated using SQL code that has been independently coded by two analysts. Raw data are imported into SAS by a third analyst to create summary tables for delivery to CMS. Final results tables undergo a final round of review by a fourth team member before delivery.

For information on kidney transplants, HHS reports data from the Organ Procurement and Transplantation Network (OPTN). Transplant hospitals and organ procurement organizations are required to submit transplant-related data to the OPTN according to the OPTN Final Rule (FR 121.11(b)(2)) and OPTN data submission policies. The OPTN database includes all records of candidates ever added to the waiting list for transplant as well as all deceased and living donor transplants that have occurred since October 1, 1987. The OPTN database represents the single source of this information. Authorized users at OPTN member institutions attest that the data they enter are accurate, timely, and complete to the best of their knowledge, information and belief; and that the data are based upon information contained in corresponding medical records and other source documents, or where appropriate, are based upon clinical observation. HHS receives final reports of OPTN data three months after the close of the quarter. In the interim, HHS will report the preliminary OPTN data it has received and provide an update once the OPTN data become final.



## Stakeholder / Congressional Consultations

HHS's activities for this APG are part of the Department's approach for implementing the Advancing American Kidney Health Initiative. Coordination with Congress has been continual over the course of the initiative.

- In June 2020, OCR participated in a podcast, [Protecting Civil Rights during COVID-19](#), sponsored by the American Society of Nephrology (ASN). OCR Director, Roger Severino, discussed the actions taken by OCR to protect vulnerable patients from discrimination during the COVID-19 pandemic. OCR released a [bulletin](#) on March 28, 2020 to remind entities that civil rights laws and protections 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. Director Severino also discussed 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.