



Agency Priority Goal Action Plan

Kidney Care

Goal Leader:

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Deputy Goal Leaders:

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Overview

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

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

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

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

- OCR's Civil Rights Division has received over 800 civil rights complaints related to COVID-19. Eighteen of the COVID-19 complaints are related in some way to dialysis facilities or someone who has kidney disease, diabetes, or is on dialysis, including an allegation that an individual was denied dialysis during treatment for COVID-19 due to limited resources. 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. Exclusion criteria in crisis standards of care plans could potentially exclude patients with kidney disease from receiving dialysis and other COVID-related treatment. OCR's compliance and enforcement 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.
- The number of kidney transplants performed (both living and deceased donors) during Quarter 2 of Calendar Year 2020 (April to June 2020) was a 16.4 percent decrease from the number of kidney transplants reported for January to March 2020, due in part to the impacts of the COVID-19 public health emergency. However, the number of kidney transplants performed during Quarter 3 of Calendar Year 2020 increased compared to Quarter 2. Performance on this measure could be affected 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.

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

- The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has funded several competitive revisions to expand existing research grant projects to study the effects of COVID-19 on the kidney. These research activities include three observational studies and one early phase clinical trial of the acute and longer term effects of COVID-19.
- American Indians and Alaska Natives have been affected 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.

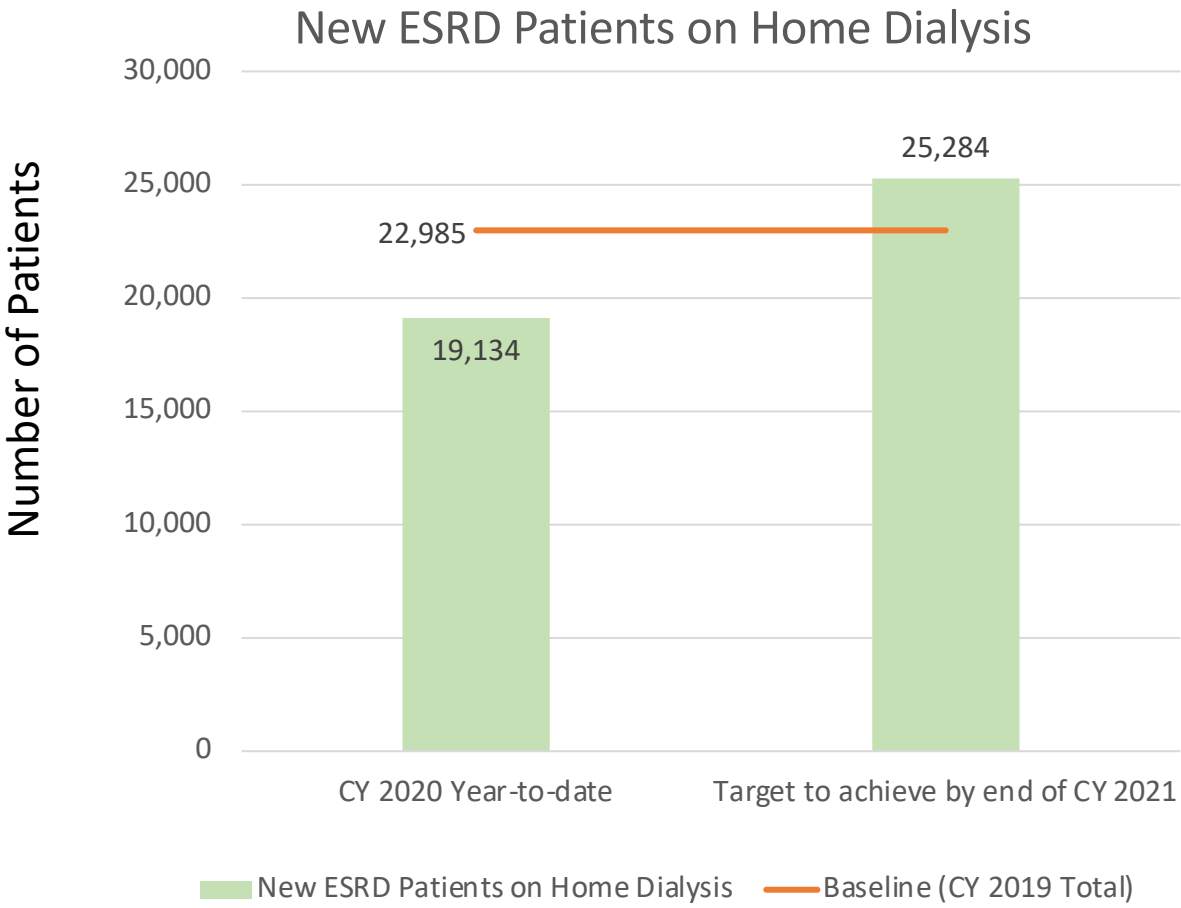
Key Indicators: Q3 Calendar Year 2020

Indicator Name	Target	Q3 CY 2020 Result*	Comments
<p>Increase by 10 percent the number of new end-stage renal disease (ESRD) patients on home dialysis.</p>	<p>25,284 Patients by the end of CY 2021</p>	<p>6,729 Patients</p>	<p>The 6,729 new ESRD patients on home dialysis in Q3 CY 2020 represented 20.1 percent of all Q3 CY 2020 incident ESRD patients.**</p>
<p>Increase by 10 percent the number of kidney transplants performed.</p>	<p>25,741 Transplants by the end of CY 2021</p>	<p>6,536 Transplants</p>	<p>This represents a 27.4 percent increase compared to the number of kidney transplants reported for Q2 CY 2020.</p>

**HHS is reporting progress for this APG on a Calendar Year (CY) cycle. This APG uses a CY 2019 baseline, and the Q3 CY 2020 Result represents progress for July-September 2020.*

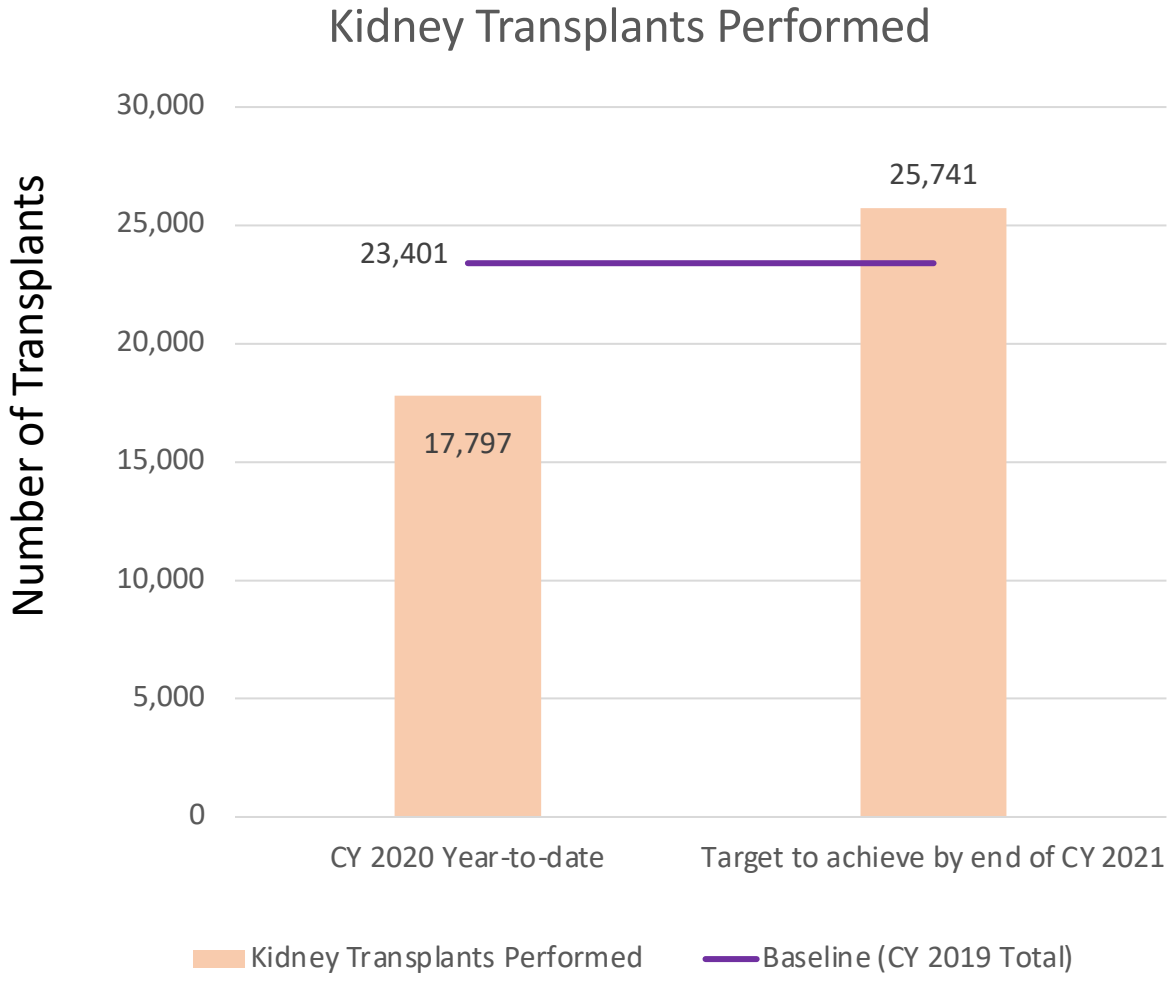
***Incident patients are new patients with ESRD in contrast to prevalent patients, which are all of the patients with the condition including those who developed ESRD in preceding years.*

Key Indicators: Q3 Calendar Year 2020



The Q3 CY 2020 results (6,729 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: Q3 Calendar Year 2020



The Q3 CY 2020 results (6,536 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 Q3 CY 2020 result because it includes all four quarters in the year.

Summary of Progress: Q3 Calendar Year 2020

- In September 2020, IHS completed its annual assessment of over 40 diabetes care process and outcome measures at IHS, Tribal, and urban Indian clinics across the country. This year's assessment was conducted on care provided in 2019 using over 130,000 charts of American Indian/Alaska Native people with diabetes at 325 facilities. Key outcomes included that about 70 percent of patients had a blood pressure less than 140/90, 62 percent of patients had both urine and blood tests for kidney disease done in 2019, and of the patients with chronic kidney disease (CKD), 72 percent of them were on an ACE inhibitor or ARB medication to help reduce the risk of CKD progression. These annual assessments help the IHS and its Tribal and Urban Indian Organization partners continue to improve the care provided to patients with diabetes and CKD, which are risk factors for kidney failure.
- In September 2020, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) funded a clinical trial to evaluate whether a multicomponent health system intervention decreases health disparities in living kidney transplantation. This type of intervention involves integrating both electronic health records surveillance to identify transplant candidates as well as an outreach and education component to assist candidates considering pursuing a kidney transplant.

Summary of Progress: Q3 Calendar Year 2020, continued

- In September 2020, the NIDDK resumed enrollment of people with acute and chronic kidney diseases in the [Kidney Precision Medicine Project](#) (KPMP) after temporarily suspending enrollment due to the COVID-19 public health emergency. The KPMP aims to ethically obtain and evaluate human kidney biopsies from participants with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) in order to identify critical cells, pathways, and targets for novel therapies to treat acute and chronic kidney diseases.
- ASPR has procured and deployed 50 portable dialysis platforms in order to provide care to patients experiencing acute kidney injury associated with complications from COVID-19. ASPR has developed a requirement for, and has received in its Strategic National Stockpile warehouses an additional 50 portable dialysis platforms. ASPR is currently surveying the impacted Regions and will be deploying these technologies in up to 10 additional healthcare systems. ASPR has also developed a requirement for, and is executing an award for up to 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	Complete	HRSA	This one-year pilot ended in July 2020
Center for Medicare and Medicaid Innovation Kidney Care Choices Model	Q1, CY 2021	On-Track	CMS	

Data Accuracy and Reliability

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. Results reported in prior quarters may be subsequently revised as part of the quality assurance process. Revisions will be reflected in current year to date totals.

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.