

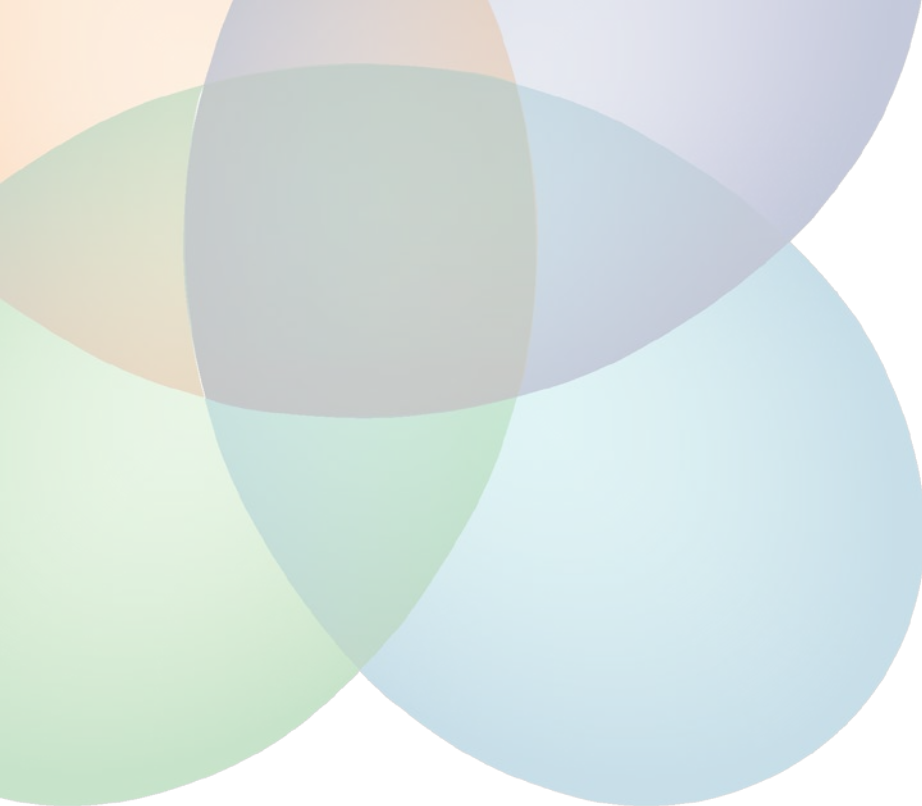


# Advancing American Kidney Health Initiative

*ASN Webinar*

*Wednesday, July 24, 2019*

*2:00 p.m. – 2:45 p.m. EDT*



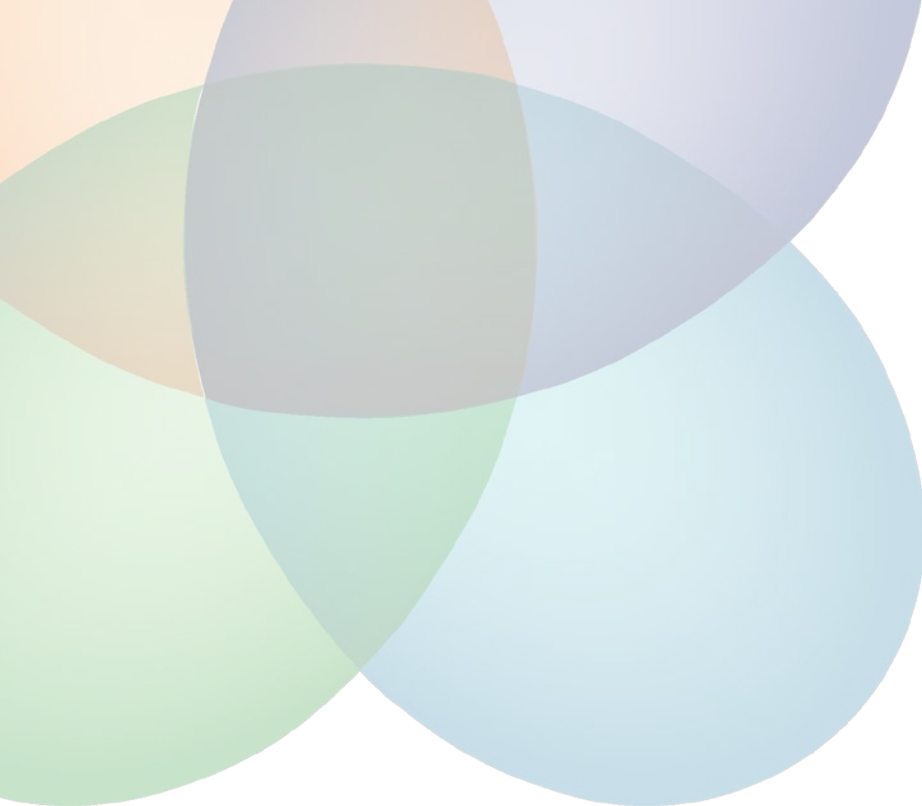
# STATE OF KIDNEY HEALTH

# Kidney Care in the United States

- Kidney diseases were the 9<sup>th</sup> leading cause of death in 2017
- Approximately 37,000,000 Americans have kidney diseases
- More than 726,000 Americans have kidney failure
- More than 100,000 Americans begin dialysis each year and nearly 60% of those will die within the first 5 years of treatment
- Nearly 100,000 Americans are on the kidney transplant waiting list

# STATE OF KIDNEY HEALTH





# EXECUTIVE ACTION

# Executive Order on Advancing American Kidney Health

- Signed on Wednesday, July 10 by President Donald J. Trump
- Three major goals:
  - Reduce the risk of kidney failure
  - Improve access to and quality of person-centered treatment options
  - Increase access to kidney transplants







# Executive Order on Advancing American Kidney Health



10 July 2019

[whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health](http://whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health)

Designed by: Tejas Desai, MD | @nephondemand

## Goals



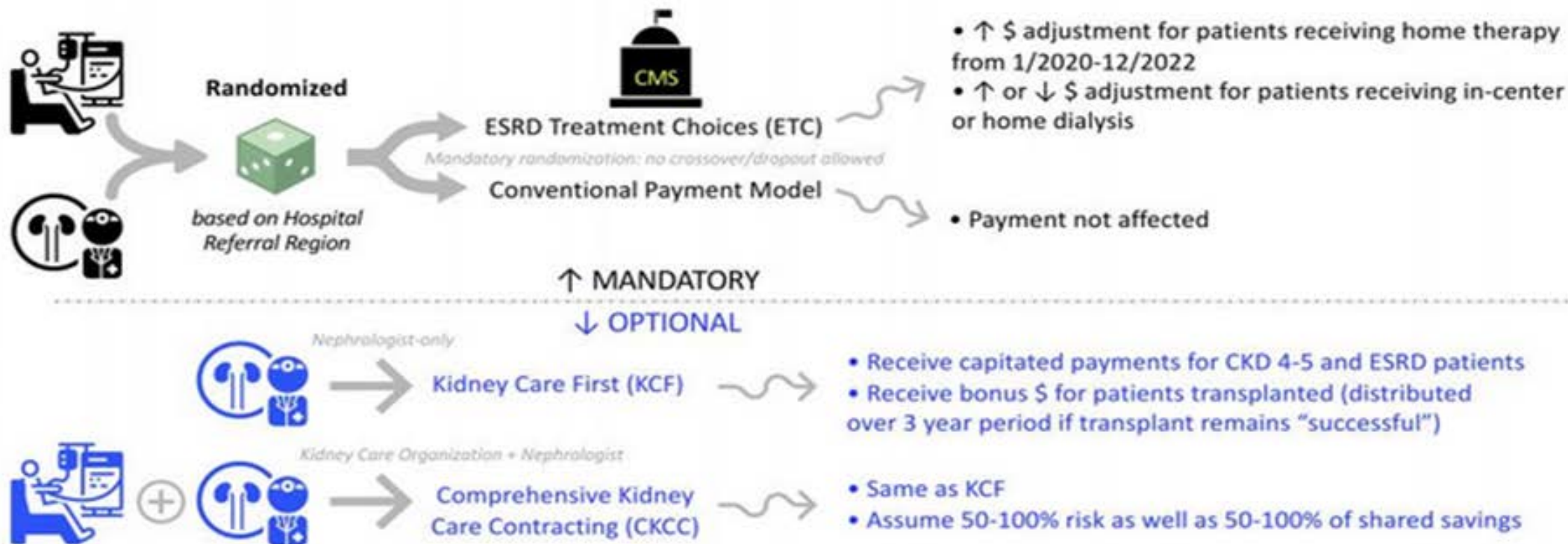
- 80% of incident ESRD patients receive either home dialysis therapy or transplantation by CY 2025
- Standardize organ procurement reduce percentage of discarded organs
- Remove financial barriers for living kidney donors
- Encourage development of the artificial kidney
- Restructure payment models to incentivize prevention, home therapy/transplantation

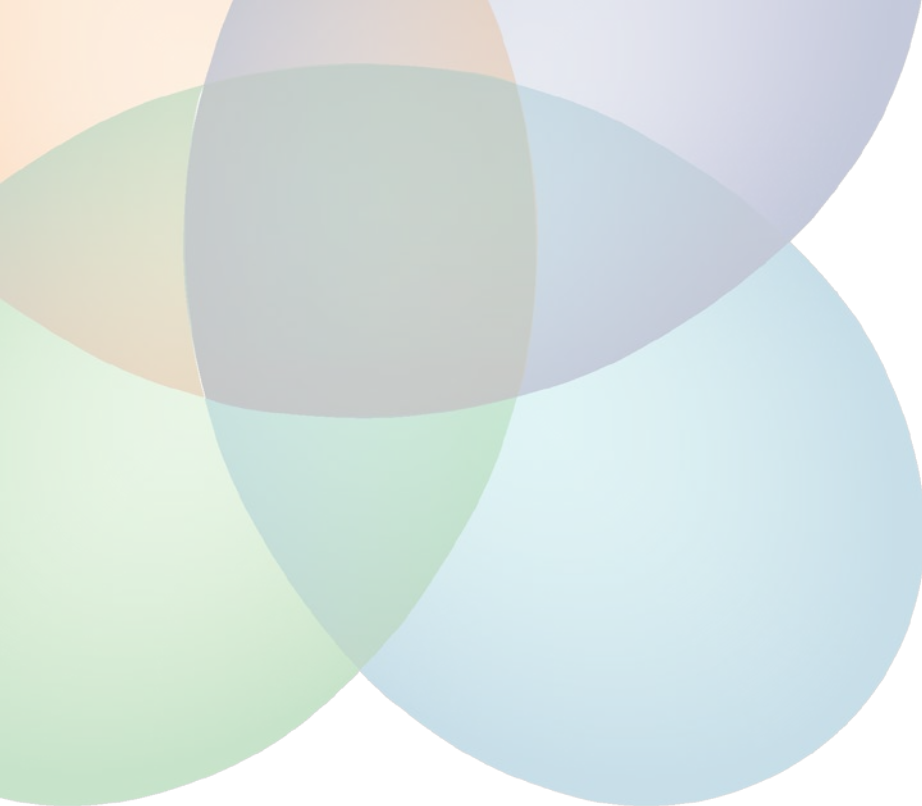
## Payment Models



ETC | KCF

CKCC Graduated  
CKCC Pro/Global





# REDUCING RISK



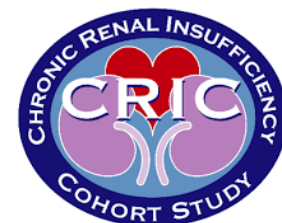
# Goal 1: Reducing Risk of Kidney Failure

## Objectives

- **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

## Past and Ongoing Initiatives to Improve Identification of CKD

- CKD Surveillance System
- NIH CKD phenotype
- NIH Funded Studies



# Future Initiatives to Improve Identification of CKD

- CKD Initiative
  - Cost-effectiveness studies of the long-term efficacy of public health interventions for CKD
  - Systematic Review on Barriers to CKD Screening Project
- CKD Epidemiology in the Military Health System

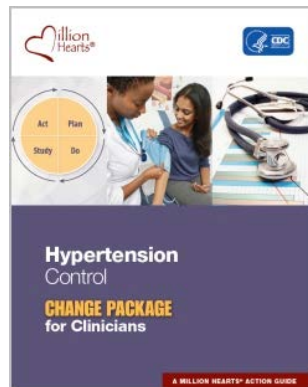


## Past and Ongoing Initiatives to Encourage Adoption of Interventions

- Special Diabetes Program for Indians
- National Diabetes Prevention Program
- National Institute of Diabetes and Kidney Diseases promotion of integrated health system model of team-based clinical care
- Medicare Diabetes Prevention Program expanded model

# Future Initiatives to Encourage Adoption of Interventions

- Hypertension Control Change Package for Clinicians
- Improving Chronic Diseases Management with Pieces (ICD-Pieces) Study
- ExaHealth





# ACCESS AND QUALITY

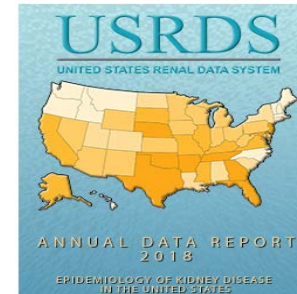


## Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

- **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

# Past and Ongoing Initiatives to Improve Access and Quality

- Annual U.S. Renal Data System (USRDS) Atlas
- Making Dialysis Safer for Patients Coalition
- ASPR and CMS have formed a collaboration to improve access to dialysis care during every disaster and have launched the emPOWER program



# Future Initiatives to Improve Access and Quality

## Innovation Center's New Kidney Care Models

- Mandatory:
  - End-Stage Renal Disease Treatment Choices (ETC) Model – Proposed Rule
- Voluntary:
  - Kidney Care First (KFC) Model
  - Graduated Comprehensive Kidney Care Contracting (CKCC) Model
  - Professional CKCC Model
  - Global CKCC Model



# Five Models

ESRD facilities and Managing Clinicians may participate in:

- The KCF Model *or* one of the CKCC Models
- If assigned to the ETC Model, they may still participate in KCF Model *or* one of the CKCC Models



# Proposed Rule for ETC Model

- Mandatory participation for 50% of country
- All Managing Clinicians and all ESRD facilities located in “selected geographic area(s)”
- “Selected geographic area(s)” will be Hospital Referral Regions (HRRs) selected by CMS



# Hospital Referral Regions (HRRs)

- 306 HRRs in U.S.
  - All 50 states and District of Columbia, stratified by region: Northeast, South, Midwest, and West (Maryland exception)
- 50% (153) HRRs in intervention group, equal number in comparison group
- Intended to capture 50% of adult ESRD beneficiaries
- HRRs derived from Medicare data based on hospital referral patterns and correlated with dialysis/transplant referral patterns to mitigate potential spillover effects





# ETC Model Payment Adjustment Period

Upward or downward performance adjustment on all dialysis claims and dialysis-related claims among the beneficiaries attributed to participating ESRD facilities and Managing Clinicians July 1, 2021 – June 30, 2026, depending on:

- Rates of home dialysis utilization
- Rates of kidney and kidney-pancreas transplantation



# ETC Model Payment Adjustments

- Home Dialysis Payment Adjustment (HDPA) would be a + payment adjustment on home dialysis/home dialysis-related claims during initial 3 years of the ETC Model
- Performance Payment Adjustment (PPA) would be a + or - payment adjustment, increasing over time, on dialysis/dialysis-related claims, both home and in-center, based on the ETC Participant's home dialysis rates and transplant rates during a Measurement Year in comparison to achievement and improvement benchmarks



# Home Dialysis Payment Adjustment (HDPA)

Upward adjustment on the MCP when billed for home dialysis  
January 1, 2020 – December 31, 2022:

- 3% upward adjustment year one
- 2% upward adjustment year two
- 1% upward adjustment year three

# Performance Payment Adjustment (PPA)

Upward or downward performance adjustment on MCP codes billed by Managing Clinicians July 1, 2021 – June 30, 2026, depending on:

- Rates of home dialysis utilization
- Rates of transplantation

**TABLE 12: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS**

	Measurement Year (MY)		Performance Payment Adjustment (PPA) Period	
Beginning CY 2020	MY1	1/1/2020 through 12/31/2020	PPA Period 1	7/1/2021 through 12/31/2021
	MY2	7/1/2020 through 6/30/2021	PPA Period 2	1/1/2022 through 6/30/2022
Beginning CY 2021	MY3	1/1/2021 through 12/31/2021	PPA Period 3	7/1/2022 through 12/31/2022
	MY4	7/1/2021 through 6/30/2022	PPA Period 4	1/1/2023 through 6/30/2023
Beginning CY 2022	MY5	1/1/2022 through 12/31/2022	PPA Period 5	7/1/2023 through 12/31/2023
	MY6	7/1/2022 through 6/30/2023	PPA Period 6	1/1/2024 through 6/30/2024
Beginning CY 2023	MY7	1/1/2023 through 12/31/2023	PPA Period 7	7/1/2024 through 12/31/2024
	MY8	7/1/2023 through 6/30/2024	PPA Period 8	1/1/2025 through 6/30/2025
Beginning CY 2024	MY9	1/1/2024 through 12/31/2024	PPA Period 9	7/1/2025 through 12/31/2025
	MY10	7/1/2024 through 6/30/2025	PPA Period 10	1/1/2026 through 6/30/2026



# Low-Volume Threshold Exclusions for the PPA

## Managing Clinicians:

- CMS proposes excluding Managing Clinicians who fall below the low-volume threshold of the bottom 5 % of Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY



# Low-Volume Threshold Exclusions for the PPA continued

## ESRD Facilities:

- CMS proposes excluding ESRD facilities that have fewer than 11 attributed beneficiary-years during a given MY from the application of the PPA meaning that the facility must have at least 132 total attributed beneficiary months for a MY





# Risk Adjustment

- For transplant risk adjustment, CMS will use the methodology of the Percentage of Prevalent Patients Waitlisted (PPPW) from the ESRD Quality Incentive Program (QIP) except over 75 years old, in skilled nursing facility, or on hospice
- For risk adjusting home dialysis rates, CMS proposes using the CMS-5 HCC (Hierarchical Condition Category) dialysis model approach

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

- **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

# Ongoing and Future Initiatives to Improve Access and Quality

## Focusing on Innovative Product Development

- Catalyzing rapid product development through public-private partnerships (particularly KidneyX)
- Creating clear and forward-looking guidelines for marketing approval for emerging technologies
- Prioritizing development of an artificial kidney in KidneyX Redesign Dialysis Phase III
- Providing next-generation organ preservation devices and systems

## 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

## Future Initiatives to Improve Deceased Donation

- Revising the guidelines to reducing risk of HIV, HBV, and HCV transmission while preserving high-quality organs
- Organizing a workshop to discuss use of HCV+ donor organs in recipients who do not have HCV
- Testing accelerated placement of kidneys at high risk for discard
- Reviewing the OPO conditions for coverage and proposing changes to the standards used to evaluate OPOs

## Future Initiatives to Improve Living Donation

- Expanding reimbursement of travel and other expenses related to living organ donation
- Considering also providing reimbursement for lost wages for donors
- Using findings from two ongoing HRSA studies to inform these decisions





**QUESTIONS?**