Federal Legislative and Regulatory Policy: A 365-day Overview

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ASN
American Society of Nephrology

Topics for Discussion

- Payment Update
- Centers for Medicare & Medicaid Innovation (CMMI) update
- Legislative Update
- Immigration Policy Update

Federal Legislative and Regulatory Policy in 2026

	Must/Likely to Happen	Unlikely/Won't Happen

Legislative Policy	• Discretionary funding for FY 2026
	  • Congress needs to pass 4 more appropriations bills by 1/30/26 to avoid partial government shutdown
	• Discretionary funding for FY2027
	  • Process begins February 2026
		• Living Donor Protection Act (S 1384)
		• Kidney PATIENT Act (HR 5074)
		• Honor Our Living Donors (HOLD) Act (HR 6020)
		• Living Donor Tax Credit Act (HR 6171)
		• New Era of Preventing End-Stage Kidney Disease Act (HR 6790)
		• RESTORE Act (HR 6860)
		• Preserving Seniors' Access to Physicians Act (HR 6683)
		• Parity of audio-only and audio-visual telehealth reimbursement
		• Officer of Kidney Health and Transplantation

Regulatory Policy	• Transplant system ongoing transformation (OPO, OPTN, IOTA) • CMS Proposed Rule: Medicare Advantage • CMS Proposed Rule: Medicare ESRD PPS and QIP • CMS Proposed Rule: Medicare Physician Fee Schedule • CMMI: IOTA updates, ACCESS Model	• USPSTF screening recommendation for kidney diseases • Medicare Advantage data gap in USRDS • Iteration of ESRD bundle

ESRD PPS QIP: 2026

- Base Rate: $281.71 ($7.89 or 2.2% increase from PY2025)
  - ESRD Market Basket Update: 2.1%
- Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Areas (Alaska, Hawaii, and U.S. Pacifici Territories)
  - Increase to the non-labor portion of ESRD PPS base rate, capped at 25%
- Removal of the Facility Commitment to Health Equity, Screening for Social Driers of Health, and Screen Positive Rate for Social Driver of Health reporting measures
- Reduced length of the ICH CAHPS survey from 39 questions to 23 questions
- Termination of ESRD Treatment Choices (ETC) Model

ESRD PPS QIP: What to expect in 2027

- MedPAC's December annual meeting on dialysis payment and draft Chair recommendation:
  - Calls for Congress to **eliminate** the update to the 2026 Medicare base payment rate for outpatient dialysis services
  - FFS Medicare payments 2026 project margin of 4% (down from 4.5% in 2024)
- ASN has opened a line of communication with MedPAC

CY2026 Medicare Physician Fee Schedule

- Two separate conversion factors (CF):
  - Alternative Payment Model (APM) Qualifying Participants (QP) CF: **$33.59** (projected increase of $1.24 or +3.83%)
  - Non-QP physician and practitioner CF: **$33.42** (projected increase of $1.17 or +3.62%)
- CY2026 PFS Impact on Total Allowed Charges: Nephrology

	Total: Non-Facility/Facility	Allowed Charges (mil)	Impact of Work RVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Nephrology	Total	**$1,623**	0%	0%	0%	1%
	Non-Facility	**$971**	1%	6%	0%	7%
	Facility	**$653**	0%	-9%	0%	-9%

Medicare Physician Fee Schedule: What to expect in CY2027

Ongoing concern regarding:

- **Efficiency adjustment:** -2.5% adjustment to work RVU and corresponding intraservice portion of non-time based services every three years
- **Practice expense methodology update:** reduce portion of indirect PE allocated to facility-based services beginning in 2026
- **Inflation & budget neutrality constraints**
  - In 2025, Congress provided a one-year, one-time 2.5% increase to Medicare physician payments under the PFS; **BUT it is time for a permanent solution**

Centers for Medicare & Medicaid Innovation (CMMI)

- **Increasing Organ Access and Transplantation Model:** proposed updates with open comment period
- **Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model:** ten-year long voluntary model aimed at increasing beneficiary access to innovative health technology through Outcome-Aligned Payments to Medicare Part B reimbursement for chronic disease management
  - **Cardiovascular-Kidney-Metabolic Syndrome (2 pathways-early stage and CKM). Achieving improved uACR and eGFR testing for CKD stage 3.**
  - Need further clarification on provider participation due to FFS exclusion language
- Upstream CKD Model?

Exhibit 14. KCC Model Impacts

Dialysis Care	Peritoneal dialysis, the predominant form of home dialysis, increased by 26% for KCF and 8% for CKCC relative to the comparison groups in the first year of the model. Home dialysis training increased 32% for CKCC. In-center dialysis decreased 4% for KCF.
Transplantation	Kidney transplant waitlisting increased by 11% for CKCC relative to the comparison group, driven by an increase in the active status waitlisting. There was no impact on kidney transplants overall for either model option or for living or deceased donor or preemptive transplants.
Utilization & Cost	There were no impacts on hospitalizations, ED visits, or readmissions for KCF or CKCC. The KCC Model did not impact Total Medicare Parts A & B payments. It also did not result in net savings or losses to Medicare. KCF peritoneal dialysis PPPM payments increased 23% relative to the comparison group. Total dialysis payments for CKCC increased modestly by 1%.
Quality of Care	Optimal ESRD Starts increased 16% for CKCC but were unchanged for KCF. KCF decreased AV fistula use by 9% and increased AV graft use by 20% relative to the comparison group. KCC had no impact on complication-related hospitalizations for patients with CKD or ESRD.

Notes: AV = arteriovenous; CKCC = Comprehensive Kidney Care Contracting; CKD = chronic kidney disease; ED = emergency department; ESRD = end-stage renal disease; KCF = Kidney Care First; PPPM = per patient per month

What's Next for Specialty Care- Mandatory Models

Opportunities within CMS TEAM across MGB

Co-create **optimal pathways for patients** that ensure pre-operative identification of risk factors, patient education and discharge planning to support discharge home.

MGB TEAM Hospitals Financial Opportunity	
Year 1 Maximum Upside	$15.4M
Year 2-5 Maximum Upside per Year	$24.7M
Year 2-5 Maximum Downside per Year	($22.2M)

Key System levers to improve TEAM Performance	How?
1. Manage PAC $3.75 – 6.5M	Prepare, optimize, + send patients home to recover
2. Site of Care $1.25 – 3.0M	Align with system SOC strategy for IP/OP cases
3. Readmissions, Risk Capture $0.6 - 1.3M	Capture patient complexity + credit via CMS target price

Patient Identification and Optimization

- Support patient engagement
- Complete condition capture to achieve optimal target price and identify conditions
- Optimize patients pre-operatively to ensure patients can be at home

High-quality Inpatient and Outpatient Surgical Episode

- Support inpatient episode and optimal discharge decision making with local teams

Post-Op Follow Up and Management

- Support post-discharge follow up calls within 48hrs of D/C
- Manage post-discharge patient needs and risk escalation

Government Funding & Shutdowns: Where are we now?

- Congress is operating a Continuing Resolution (CR) that is set to expire on January 30, 2026
  - 4 appropriations bills remaining to fund the Pentagon, **Health and Human Services (HHS),** Transportation, Housing and Urban Development, and the Department of Homeland Security
  - **Kidney Community success in LHHS appropriations language:** Kidney Advocacy efforts secured bipartisan support for expanded CKD prevention and education, KidneyX funding, and organ transplant system reform.
- **Research funding:**
  - Congress has advanced bill rejects White House's requested 40% cut to research funding
  - Senate bill calls for $188.3 billion in total scientific research funding (21.3% more than requested by the White House, but 3.6% below FY25 spending).

2026 Legislative Priorities & Bills to keep your eye on

- **Bills:**
  - Introduction of bill to expand remote patient monitoring (RPM) for patients with ESRD
  - Honor Our Living Donors Act
  - OPTN Fee Collection Authority Clarification
  - Referral for Organ Donation Improvement Act

- **Activities:**
  - Champion an HHS Officer of Kidney Health and Transplantation
  - Reimagine the ESRD PPS bundle
  - Address longstanding physician payment reform, back AMA-led bills
  - Call attention to workforce challenges, support community-wide legislation

Workforce: Immigration Related Issues

- **H-1B policy changes:**
  - “Restriction on Entry of Certain Nonimmigrant Workers” proclamation
  - “Weighted Selection Process for Registrations and Petitioners Seeking to File Cap-Subject H-1B Petitions” proposed rule
- **J-1 visa policy changes:**
  - “Establishing a Fixed Time Period of Admission and an Extension of Stay Procedure for Nonimmigrant Academic Students, Exchange Visitors, and Representatives of Foreign Information Media”

How to stay informed

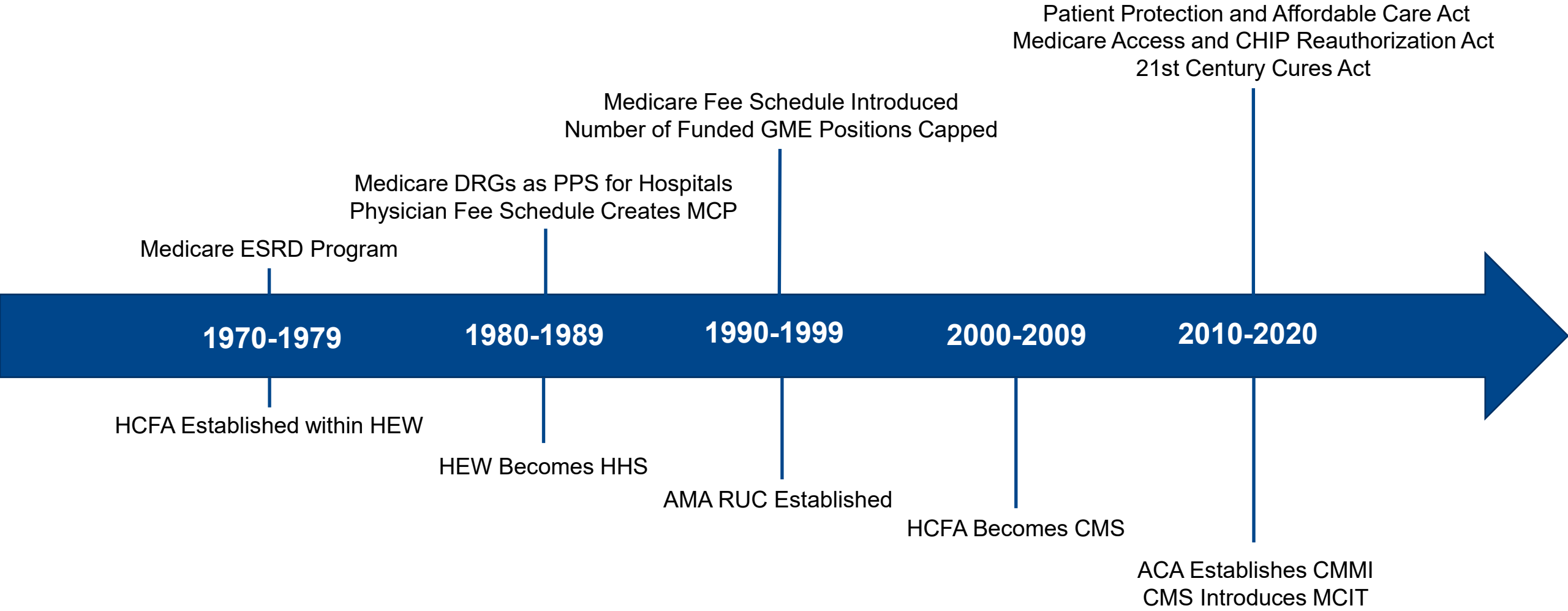
- ASN Health Advocacy Timeline
- ASN Policy Newsletter
- ASN Policy Podcast
- ASN Legislative Action Center

Contact us at policy@asn-online.org or lahearn@asn-online.org

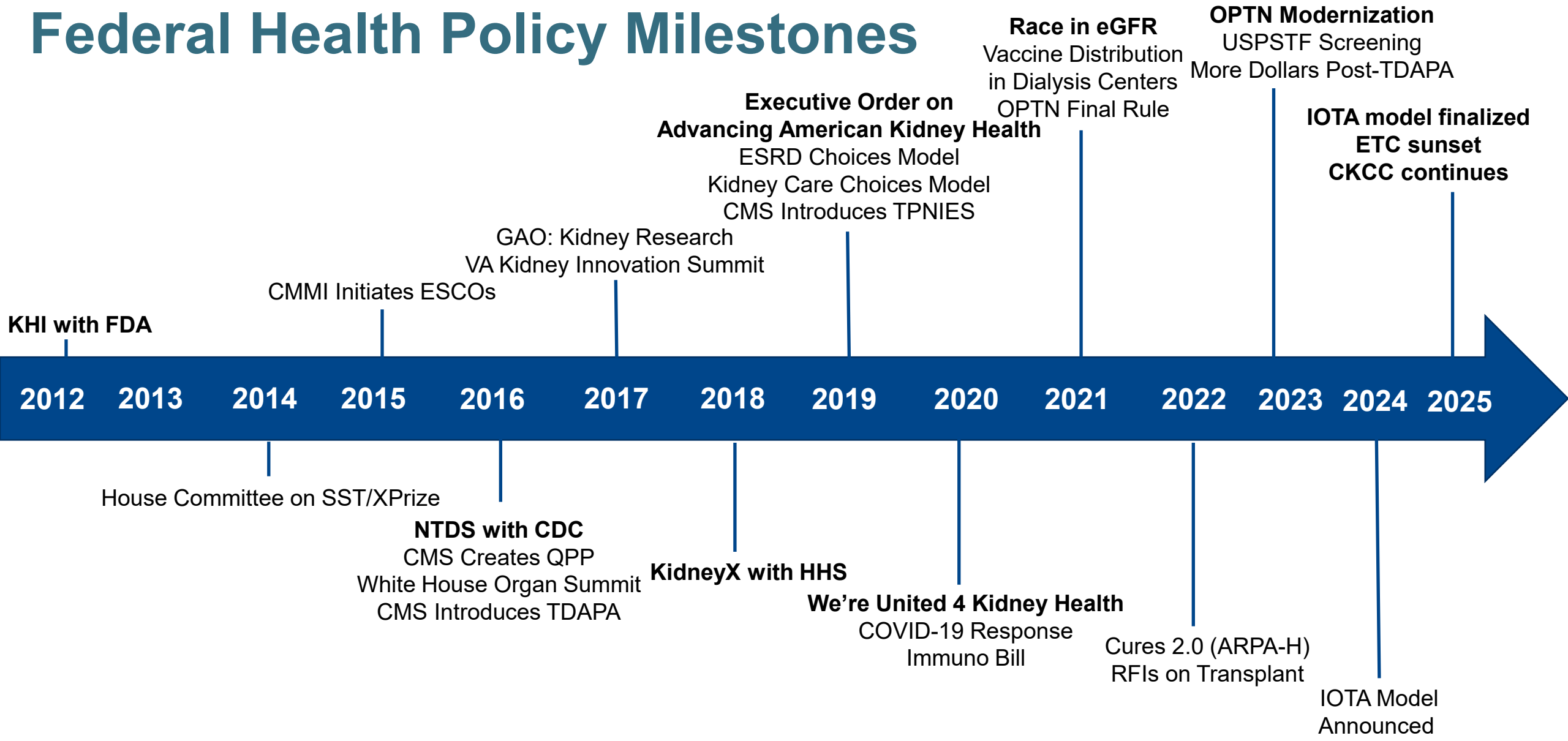
Additional Slides

The Federal Rulemaking Process

Federal Health Policy Milestones



Federal Health Policy Milestones



CY2025 Nephrology Policy Efforts

	Policy Achievements
February	ASN Congressional Advocacy for NIH funding
	Comment Letter for Medicare Advantage program including drug benefits
March	**ASN calls on Congress to increase NIH budget by $1.8 and $0.5B for AHRQ**
	ASN leads Congressional LHHS letter to fund SUS OPTN for $67M
May	**ASN submits letter to appropriation for $25M for KidneyX and $67M for transplant**
June	**ASN letter to Marco Rubio to avoid J1 visa pause for IMGs**
July	ASN affirms importance of USPSTF independence
	ASN provides guidance to the FDA on front of the label packaging
August	ASN asks for reinstating collection of race and ethnicity for CMS Form 2728
	Comment letter for ESRD PPS FY26 rule
September	**ASN requested exemption for H1b restrictions and new duration of status for J1 visa holders**
November	ASN advocates to FDA for addition of phosphorus content on food labels
December	ASN supports payment for physician RPM for home dialysis

AAKH Payment Models

Payment Models

ETC | KCF
CKCC Graduated
CKCC Pro/Global

Randomized

based on Hospital Referral Region

ESRD Treatment Choices (ETC)

- ↑ $ adjustment for patients receiving home therapy from 1/2020-12/2022
- ↑ or ↓ $ adjustment for patients receiving in-center or home dialysis

Mandatory randomization: no crossover/dropout allowed

Conventional Payment Model

- Payment not affected

↑ MANDATORY

↓ OPTIONAL

Nephrologist-only

Kidney Care First (KCF)

- Receive capitated payments for CKD 4-5 and ESRD patients
- Receive bonus $ for patients transplanted (distributed over 3 year period if transplant remains "successful")

Kidney Care Organization + Nephrologist

Comprehensive Kidney Care Contracting (CKCC)

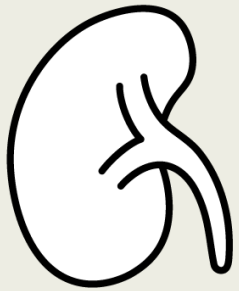
- Same as KCF
- Assume 50-100% risk as well as 50-100% of shared savings

JAMA Health Forum™

RCT: Financial Incentives to Facilities and Clinicians Treating Patients With End-Stage Kidney Disease and Use of Home Dialysis: a Randomized Clinical Trial

POPULATION

10 785 Men, 7836 Women



Medicare beneficiaries with end-stage kidney disease (ESRD) aged ≥66 y

Mean age, 74.8 y

SETTINGS / LOCATIONS

Dialysis facilities in the US

INTERVENTION

302 Hospital Referral Regions (HRRs)

91 Treatment group
ESRD facilities and managing clinicians received financial incentives for home dialysis use

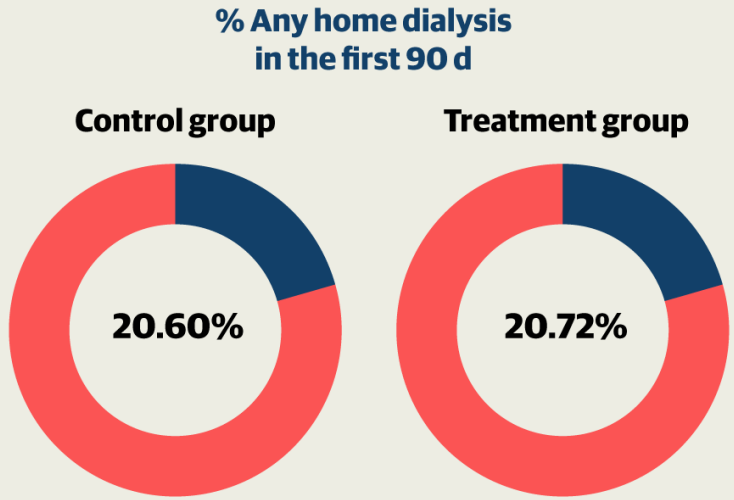
211 Control group
No intervention

PRIMARY OUTCOME

The percentage of ESRD patients receiving any home dialysis in the first 90 days of treatment

FINDINGS

The mean percentage of patients with any home dialysis in the first 90 days was not statistically significantly different in the treatment and control group



Any home dialysis in the first 90 days.
Mean difference between treatment and control HRRs, 0.12% (95% CI, -1.42% to 1.65%; *P* = .89)

Ji Y, Einav L, Mahoney N, Finkelstein A. Financial incentives to facilities and clinicians treating patients with end-stage kidney disease and use of home dialysis: a randomized clinical trial. *JAMA Health Forum*. 2022;3(10):e223503. doi:10.1001/jamahealthforum.2022.3503

Table 3. Effect of ETC During First Year of the Program in 2021[a]

Characteristic	Value in control HRRs, mean (SD)	Between treatment and control HRRs, mean difference (95% CI)	*P* value
Treatment modality			
Any home dialysis in first 90 d, %	20.60 (7.77)	0.12 (−1.42 to 1.65)	.89
Weeks receiving any home dialysis in first 90 d, %	16.67 (6.77)	0.17 (−1.24 to 1.58)	.82
Dialysis sessions at home in first 90 d, %	17.23 (6.81)	0.22 (−1.14 to 1.57)	.76
Patient characteristics and extensive margin outcomes			
Dialysis rate per capita[b]	0.01 (0.005)	−0.0001 (−0.0003 to 0.0002)	.44
Total No. of dialysis patients[c]	2388 (2521)	37.04 (−8.41 to 82.50)	.11
Predialysis Elixhauser index score	5.96 (0.75)	−0.02 (−0.18 to 0.13)	.77
Anticipatory effect			
Any home dialysis in first 90 d in 2020, %	20.00 (8.55)	−1.20 (−2.75 to 0.3382)	.13

Abbreviations: ETC, End-Stage Renal Disease Treatment Choice; HRRs, hospital referral regions.

[a] The table reports HRR-level average characteristics of ETC-eligible patients. The first column reports the means for the control HRRs. The second column reports the coefficient on the treatment indicator from estimating an HRR-level regression of the outcome variable on the treatment indicator, controlling for strata fixed effects, lagged outcome from 3 years prior, and HRR-level averages of patient demographic characteristics and baseline health. The regression is weighted by the average number of patients in the sample in 2018 and 2019. We report 95% CIs based on heteroskedasticity robust standard errors.

[b] This is the number of traditional Medicare patients 66 years or older who initiated treatment with dialysis in either modality in the baseline sample divided by the number of traditional Medicare patients 66 years or older.

[c] Includes all traditional Medicare patients who received dialysis between January 1 and October 3, 2021.

What are the early effects of the End Stage Renal Disease Treatment Choices Model on the kidney transplant waitlist?

CJASN
Clinical Journal of the American Society of Nephrology

Organ Procurement and Transplantation Network registry (Jan 2017 to Jun 2022)

Interrupted time series design

Compare slope changes in waitlist additions post-ETC, accounting for COVID-19

End Stage Renal Disease Treatment Choices Model

A mandatory randomized kidney payment model from the Centers for Medicare and Medicaid Services implemented on January 1, 2021

Waitlist Additions Post-ETC Implementation

Intervention arm
5,550 additions

Control arm
11,332 additions

Overall cohort

No difference in waitlist additions between the two arms

slope difference of 6.9 new listings/month, 95% CI: -7.4 to 21.1

Slope difference by race

Black 2.2/month (95% CI, -4.3 to 8.7)

Hispanic 0.2/month (95% CI, -4.5 to 4.9)

White 2.6/month (95% CI, -3.0 to 8.1)

The effect of COVID-19 was similar across both arms, with an estimated 6,259 fewer waitlist additions than expected during the study period after the COVID-19 pandemic (2,016 in the intervention arm; 4,243 in the control arm).

Conclusions: In the 18 months after ETC model implementation, there was no significant change in new kidney transplant waitlist additions, overall, or among Black or Hispanic patients.

Vishnu S. Potluri, Yuvaram N.V. Reddy, Sri Lekha Tummalapalli, et al, ***Early Effects of the ESRD Treatment Choices Model on Kidney Transplant Waitlist Additions by Race and Ethnicity***. CJASN, DOI: 10.2215/CJN.0000000000000571
Visual abstract by Cristina Popa, MD

Exhibit 4. Who Participates in the KCC Model

KCF Practices and KCEs 	30 KCF Practices and 55 KCEs joined the KCC Model in Cohort 1 and are distributed across the United States. Most CKCC Participants selected the Professional option (37 KCEs), followed by the Global (7) and Graduated Level 2 (7) and Graduated Level 1 (4) options. The majority (90%) of aligning providers that joined the KCC Model are participating in CKCC.
Providers 	291 nephrology professionals joined KCF and 2,565 nephrology professionals joined CKCC in Cohort 1. 133 transplant providers partnered with nephrology professionals to form KCEs, and 2,217 dialysis facilities opted to join KCEs. Nephrologists were the primary aligned providers in KCF (76%) and CKCC (73%). 39% of KCC providers were also attributed to the ETC Model.
Patients 	In PY 2022, KCC Participants provided care to 30% of the eligible Medicare FFS patients. KCF Practices and KCEs had similar proportions of patients with CKD (45%) and ESRD (51%). KCEs had a lower proportion of patients who are white and a higher proportion of patients who are Hispanic relative to KCF Practices and non-participating practices.
Markets 	KCC spanned 33 states and Washington, D.C. KCF Practices and practices in KCEs had a wider geographic reach than non-participant practices and provided services in more than one CBSA on average. There was a substantial amount of geographic overlap between participants and non-participants. The Midwest and West census regions are underrepresented in the model.

Note: CBSA = core-based statistical area; CKCC = Comprehensive Kidney Care Contracting; CKD = chronic kidney disease; ESRD = end-stage renal disease; FFS = fee-for-service; KCE = Kidney Contracting Entity; KCF = Kidney Care First.

Exhibit 7. Reasons Providers Joined the KCC Model

Reason	KCF	CKCC
Opportunity to Apply the Value-Based Care Approach	✓	✓
Desire to Improve Patient Care	✓	✓
Belief That Value-Based Care Is the Future of Kidney Care	✓	
Interest in Building on Practice's Previous Participation in CEC ESRD Seamless Care Organization Model of Care	✓	
Opportunity for Small Practice to Participate in Value-Based Care	✓	
Interest in Value-Based Design Models		✓
Belief That Participation Is the Best Way to Deliver Comprehensive Care to Increase Transplants and "Optimize Modality Choice"		✓
Opportunity to Extend Comprehensive Care Approach Upstream to Patients with CKD after Previous CEC Participation		✓

Note: CEC = Comprehensive End-Stage Renal Disease Care; CKD, chronic kidney disease; ESRD = end-stage renal disease; KCE = Kidney Contracting Entity; KCF = Kidney Care First.

Source: KCC Participant Implementation Survey, The Lewin Group, 2023.

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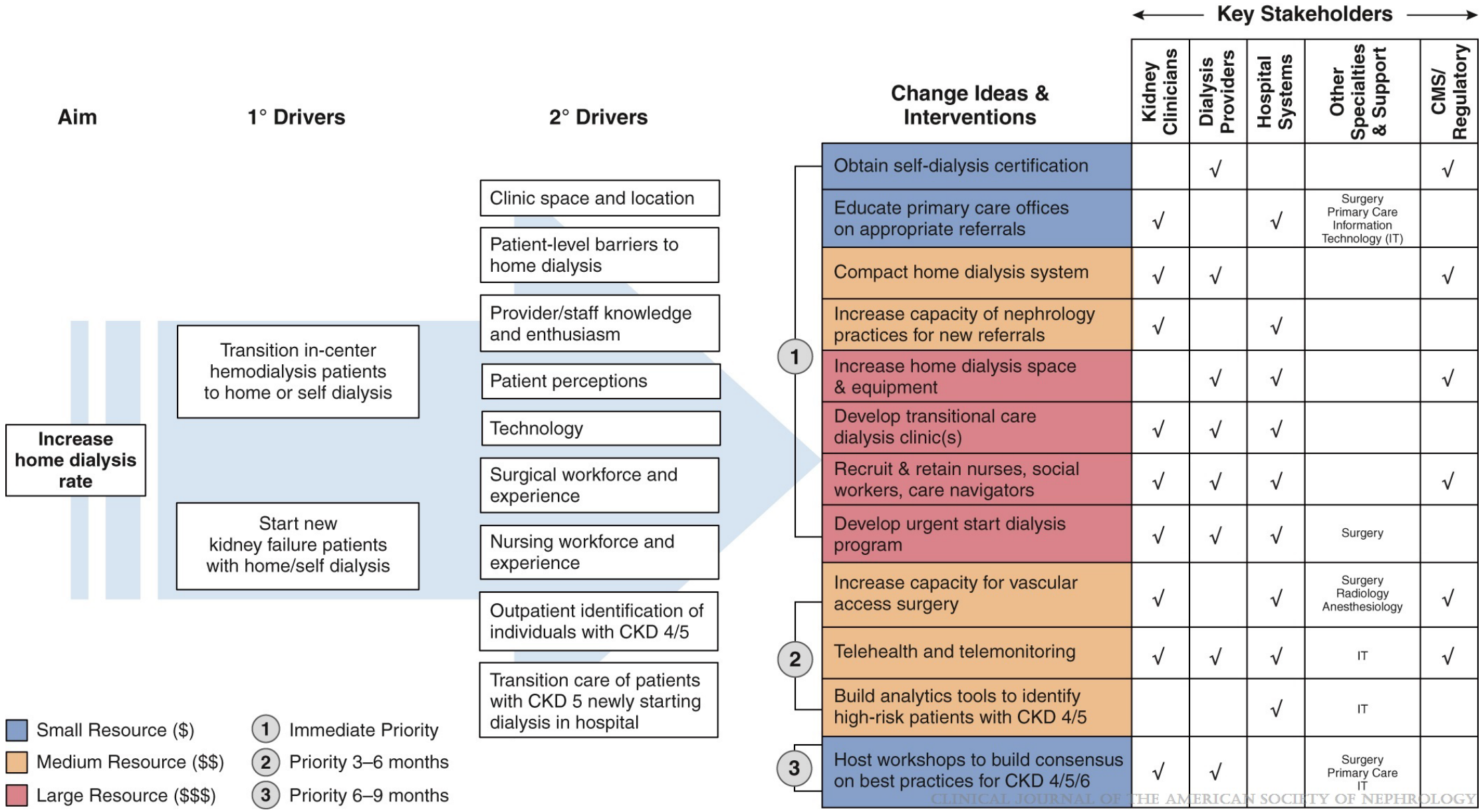
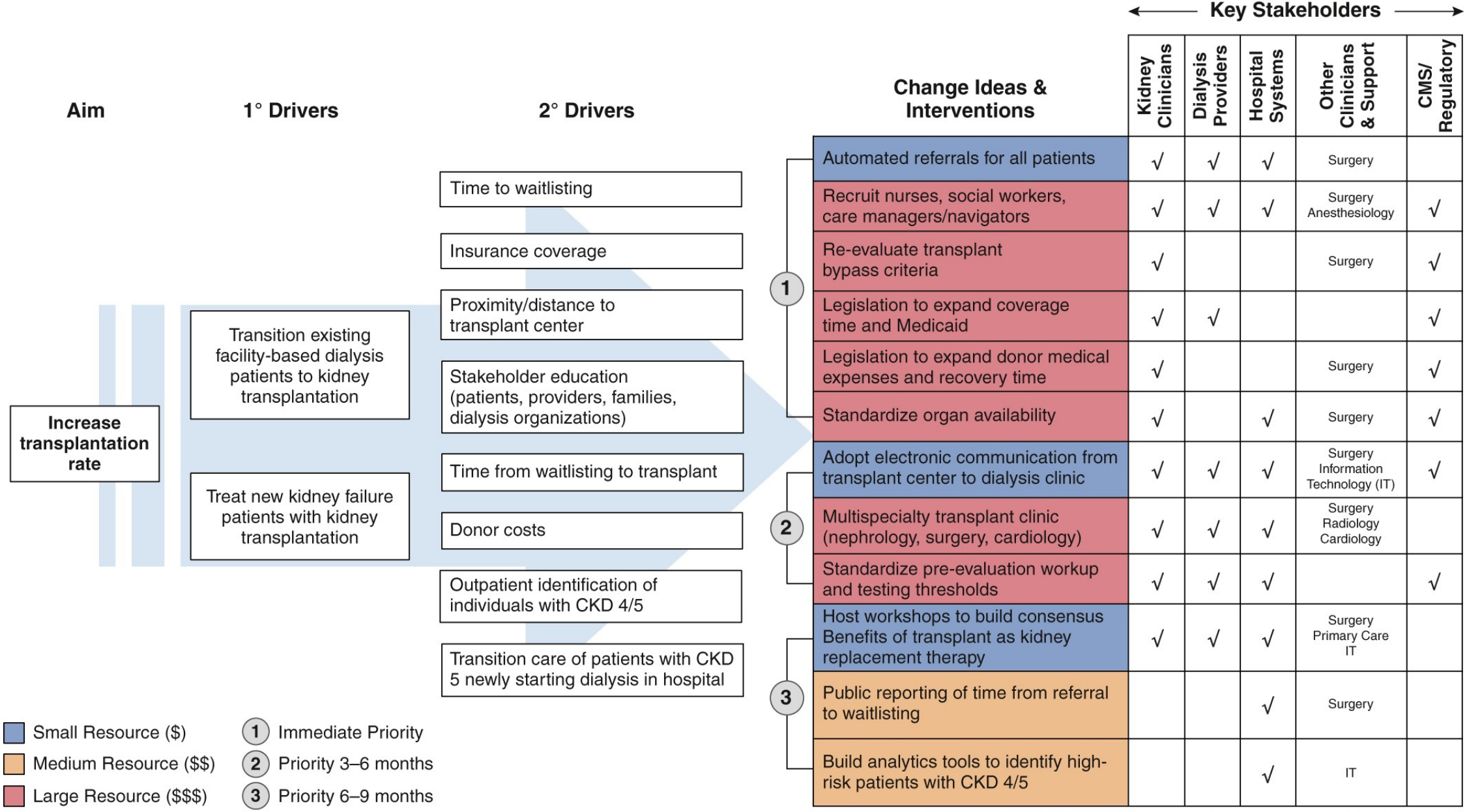


	Change Ideas & Interventions	Kidney Clinicians	Dialysis Providers	Hospital Systems	Other Specialties & Support	CMS/ Regulatory
		← Key Stakeholders →				
1	Obtain self-dialysis certification		√			√
1	Educate primary care offices on appropriate referrals	√		√	Surgery Primary Care Information Technology (IT)	
1	Compact home dialysis system	√	√			√
1	Increase capacity of nephrology practices for new referrals	√		√		
1	Increase home dialysis space & equipment		√	√		√
1	Develop transitional care dialysis clinic(s)	√	√	√		
1	Recruit & retain nurses, social workers, care navigators	√	√	√		√
1	Develop urgent start dialysis program	√	√	√	Surgery	
2	Increase capacity for vascular access surgery	√		√	Surgery Radiology Anesthesiology	√
2	Telehealth and telemonitoring	√	√	√	IT	√
2	Build analytics tools to identify high-risk patients with CKD 4/5			√	IT	
3	Host workshops to build consensus on best practices for CKD 4/5/6	√	√		Surgery Primary Care IT	

Keys to Driving Implementation of the New Kidney Care Models

Kshirsagar, Abhijit V.; Weiner, Daniel E.; Mendu, Mallika L.; Liu, Frank; Lew, Susie Q.; O'Neil, Terrence J.; Bieber, Scott D.; White, David L.; Zimmerman, Jonathan; Mohan, Sumit. Clinical Journal of the American Society of Nephrology17(7):1082-1091, July 2022.



CLINICAL JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY

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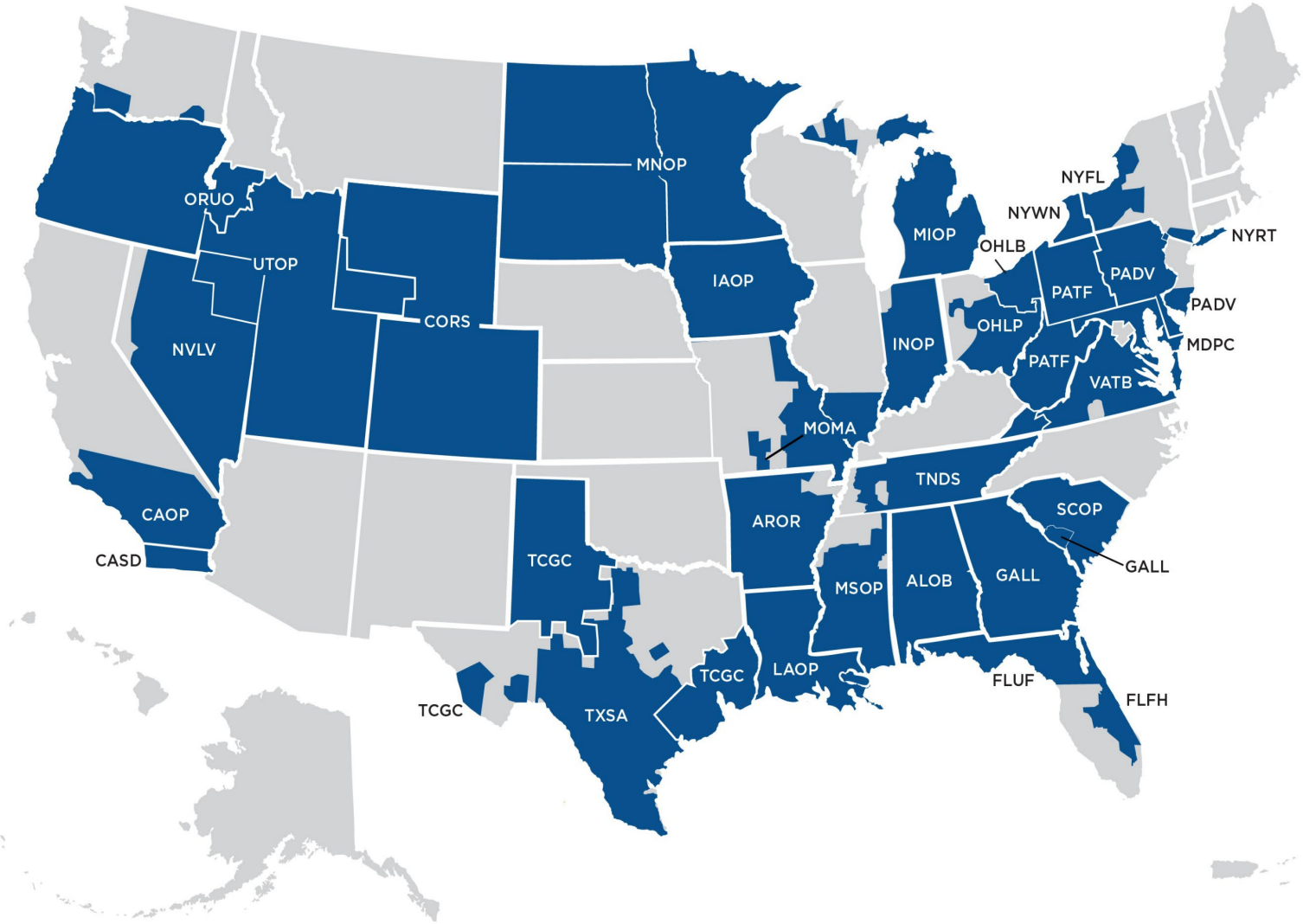
DSAs Selected for the Increasing Organ Transplant Access (IOTA) Model Participation



Basic Details: Participants

Florida:

‘FLUF’

- Hospital(s)

‘FLFH’

- Hospital(s)

ASN
American Society of Nephrology

Basic Details: Participants

- **Mandatory** model for transplant hospitals from **July 1, 2025-December 31, 2030**
  - Proposed baseline years: 2021-2023
- Focused solely on **adult kidney transplants**
  - Must perform 11 or more kidney transplants ages 18 and above and have >50% be adult kidney transplants to be eligible for participation
- **Randomized** by Donation Service Area (DSA) – 103 of 180 centers (relatively equivalent patient numbers)

Incentives Based on Points!

(Performance Assessed Over Three Domains)

Domain		Maximum Points
Achievement	Number of transplants relative to the target	60
Efficiency	Organ offer acceptance rate (O/E Ratio)	20
Quality	Composite Graft survival (not risk stratified..yet)	20
	Total	**100**

Basic Details: Performance and Payment

- Upside and downside risks
  - ➢$15,000 per transplant upside maximum, based on performance score
  - ➢$2,000 per transplant downside maximum, based on performance score
  - ➢200-patient program can bring in **~$1 million** (downside post y1~$130K)
- Performance score for payment adjustment based on performance for all attributed patients regardless of payer
- Payments for Medicare FFS patients **only** will be adjusted up or down based on performance score

What does it mean for me? Transplant Nephrologists

Potential Opportunities

- Transplant more waitlisted patients (and decrease discards)
- Elevate priority of kidney transplant within your center
- Focus on longer-term outcomes (vs. just 90-day and 1-year conditional)
- Lean into your program's strengths (minimally prescriptive model)

Potential Challenges

- Muster resources to evolve before IOTA $ (hopefully) comes in
- Capture attention of center leaders, hospital C-suite
- Secure partnership from community nephrologists to provide more care for patients
- Ensure additional $ from strong IOTA performance come back to kidney transplant program

Courtesy R Meyer

What does it mean for me? General Nephrologists

Potential Opportunities

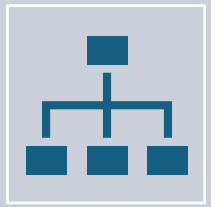
- Take advantage of expanded opportunities for your patients to get a transplant
- Help your patients pick program best-suited to meet their needs and advocate in organ offers made
- Improve your performance in KCC or ETC model
- Diversify your practice by caring for more transplant recipients

Potential Challenges

- Accessing the waitlist in the first place remains a barrier/black box for many
- Processing this newly-available info yourself and sharing with patients yourself or through team members
- Feeling confident in caring for more transplant patients long-term
- Remuneration for post-transplant care is less than for dialysis care

IOTA Summary

Significant CMS **incentives provided for transplant growth**



Growth requires optimization of team size, structure and related **resources**

Strong, proactive strategies can lead to an **increase in market share**

What's Next for Specialty Care- Mandatory Models

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Patient Identification and Optimization

- Support patient engagement
- Complete condition capture to achieve optimal target price and identify conditions
- Optimize patients pre-operatively to ensure patients can be at home

High-quality Inpatient and Outpatient Surgical Episode

- Support inpatient episode and optimal discharge decision making with local teams

Post-Op Follow Up and Management

- Support post-discharge follow up calls within 48hrs of D/C
- Manage post-discharge patient needs and risk escalation