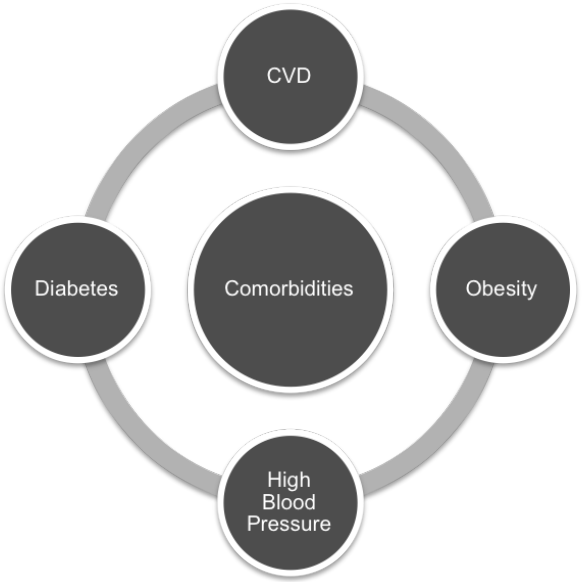
KIDNEY CARE PARTNERS

Promoting Innovation in ESRD

Meeting with the Office of Management and Budget

June 28, 2019

Diverse, Complex, High Need Population: Vast Majority of Patients Live with Multiple Comorbidities



80%+ Medicare beneficiaries

45% dual-eligible

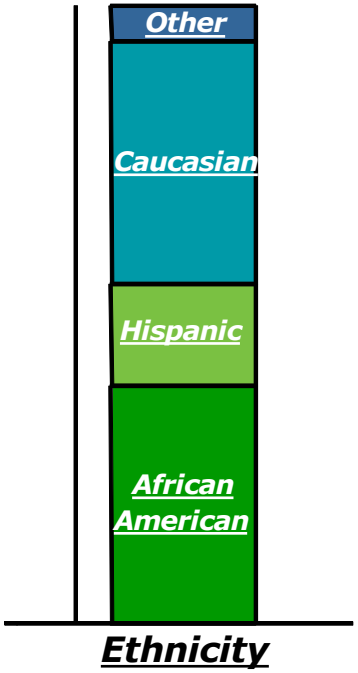
50%+ minority

86% of ESRD patients have at least one comorbidity; many have 3 or more (e.g., diabetes/hypertension)

~8+ medications

2 hospitalizations per year

Primarily low-income; difficult to remain working



Source: Gullion CM, Keith DS, Nichols GA, Smith DH. Impact of comorbidities on mortality in managed care patients with CKD. Am J Kidney Dis. 2006;48:212-220

Medicare Underfunding Will Not Support Innovation

Medicare disproportionately covers ESRD beneficiaries

- 90% of ESRD beneficiaries rely on government coverage, which is underfunded
  - Medicare pays ~$60/hour for intensive, hands-on patient care; Medicaid pays less
  - MedPAC continues to report negative margins

The consequences of underfunding this payment system are many

- Further consolidation
- Limited innovation
- Further cost shift to the private sector with a very limited patient population

Underfunding creates inappropriate pressure on the private sector to fund the government shortfall

- 1 out of 10 patients make a difference if a facility can survive
- The private sector is taking actions to reduce their contribution to the system
  - Attacking charitable premium assistance and implementing plan designs that discriminate against ESRD beneficiaries

Federal government should take actions to improve the bundle

- Implement recommendations on the bundle adjustors
- Protect patients right to access private coverage
- Establish a permanent pathway for new products and technologies

Quality Indicators Demonstrate a Plateauing of Improvements, which Results from Underfunding

Historically positive track record for quality improvement

- Reduced hospitalizations reduces Part A Medicare spending
- Reduced patient mortality mean patients living longer, require ongoing services

Continued improvements require greater investments: current rates do not provide a sustainable pathway

- Additional labor
- Innovating care with new drugs, biologicals, and devices
- Adopting new technologies
- Investing in care coordination and patient assessments (e.g., mental health assessments)
- Understanding the impact of social determinants and addressing them

To address patient needs and reduce overall Medicare spending for patients with kidney failure, we need innovation and new technologies

- Innovation can only be transforming if Medicare accounts for the increase in costs

Improvements in quality have occurred, but the next level of improvement and innovation require investment and adequate payment for new drugs, biologicals, devices, new technologies, and transformative services

Patient Should Have Right to Select the Coverage that Best Meets Their Needs

- Charitable Premium Assistance (CPA) for patients with kidney failure is a long-standing program
  - Created more than 20 years ago
  - Affirmed by the Office of the Inspector General in 1997
  - Plays a critical role in supporting a financially vulnerable patient population
- CPA allows some patients to maintain commercial insurance; has not destabilized the individual market
  - Most patients have government insurance as primary
  - Exchange plans have been highly profitable for payors the last few years
- More than half of Qualified Health Plan participants using CPA have no other insurance option; most others using CPA to maintain coverage they had before kidney failure
  - For patients on Medicare, annual costs to patients are higher and transplant rates lower

New Drug Payment Policies Create the Wrong Incentives; Will Not Support Long-Term Adoption of Innovative Products

- Two-years of dollars for new products with no new dollars in bundle for truly innovative products does not provide a long-term pathway

Dollar Amounts for ESRD Bundle Drug
for Functional Category Other than Anemia Management on a Per Treatment Basis

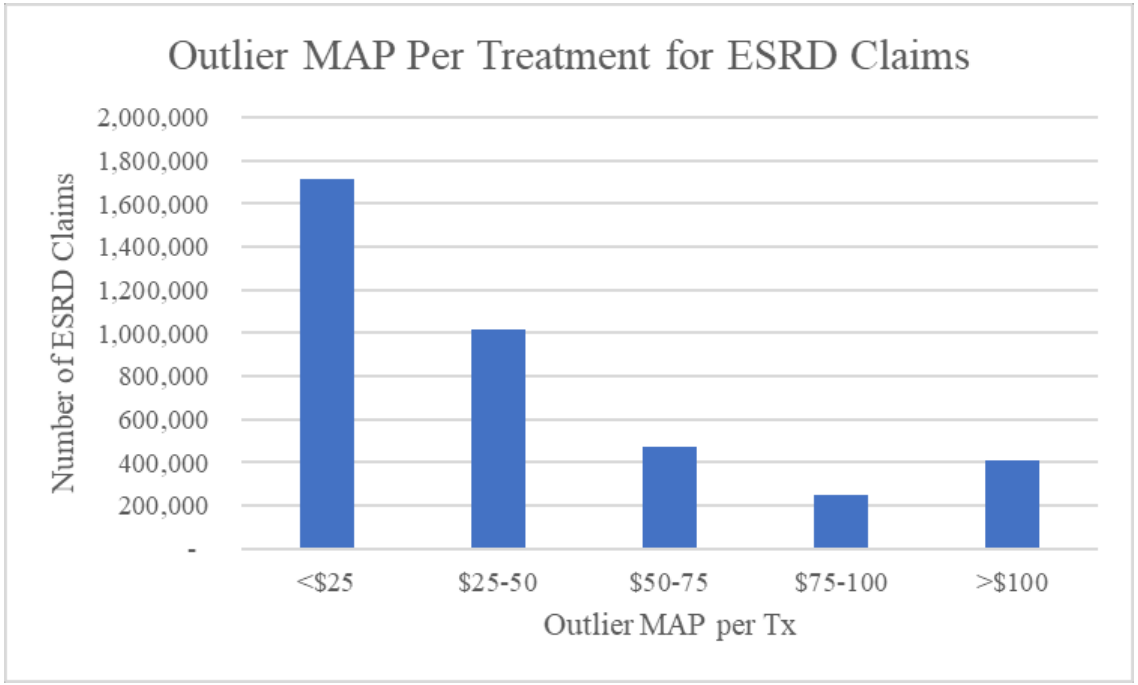
	2017 Utilization by Facilities Priced at ASP+6	
Functional Category	Avg. MAP per Tx	
Bone and Mineral Metabolism	$	1.09
Cellular management	$	0.02
Access Management	$	0.18
Anti-infective	$	0.12
Other injectables	$	1.37

Assumption that quality will overcome lack of reimbursement is not a practical reality because the entire bundle is underfunded and the assumed dollars are not sufficient

CMS Solution of Using the Outlier Pool Will Not Provide Adequate Funding for Innovative Products

83 percent of patients have MAP amounts less than $75 per treatment

Figure 1. Distribution of Average MAP per Treatment for ESRD Patients in 2017



- If CMS bundled a new drug costing $25 more per treatment than existing alternative therapies without adding new money, these 83 percent of patients would remain ineligible for outlier payments

Community's Consensus Recommendation

- Provide new money for truly innovative products, regardless of functional category status
  - Not every new product should receive new money when enter the bundle
  - KCP shared recommendations on a measured approach to evaluating new drugs and adding new money when appropriate
- Use TDAPA to collect two full years of claims data before determining how to incorporate into the ESRD PPS
  - CMS needs to understand the utilization and cost of a drug to establish an appropriate adjustment the bundle
- For low-utilization drugs, use an adjustment/add-on to allow the money to follow the patient
  - Drugs would still be bundled, but instead of spreading dollars across all patients, the dollars could be targeted to those patients who medically require the product
  - Would not create separately payable drugs outside of bundle

Investment in Medicare benefits just as critical as investing in research and development of innovative products and technologies

Conclusion: The Federal Government Should Take Actions to Improve the Bundle

- Implement recommendations on the bundle adjustors
- Protect patients right to access private coverage
- Establish a permanent pathway for new products and technologies

Kidney Care Partners

- Voice of the vast majority of the kidney care community
  - Patients and patient advocates
  - Dialysis facilities and providers
  - Physicians and nurses
  - Pharmaceutical companies and device manufacturers

- Our mission is to ensure that
  - Chronic kidney disease (CKD) patients receive optimal care
  - CKD patients are able to live quality lives
  - Dialysis care is readily accessible to all those in need
  - Research and development leads to enhanced therapies and innovative products

Appendix: KCP Members

- Akebia Therapeutics
- American Kidney Fund
- American Nephrology Nurses' Association
- American Renal Associates, Inc.
- Ardelyx
- American Society of Nephrology
- American Society of Pediatric Nephrology
- Amgen
- AstraZeneca
- Atlantic Dialysis
- Baxter Healthcare Corporation
- Board of Nephrology Examiners and Technology
- Cara Therapeutics
- Centers for Dialysis Care
- Corvidia Therapeutics
- DaVita, Inc.
- Dialysis Clinic, Inc.
- DialyzeDirect
- Dialysis Patient Citizens
- Fresenius Medical Care North America
- Fresenius Medical Care Renal Therapies Group
- Greenfield Health Systems
- Kidney Care Council
- National Kidney Foundation
- National Renal Administrators Association
- Nephrology Nursing Certification Commission
- Otsuka
- Renal Physicians Association
- Renal Support Network
- Rockwell Medical
- Rogosin Institute
- Satellite Healthcare
- U.S. Renal Care