

Using Policy to Address the Burden of Kidney Disease: Happenings at the State and Federal Level

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1965

Medicare and Medicaid are established as Title XVIII of the SSA

1967

Special Committee on Kidney Disease Established (The Gottschalk Committee)

1972

Medicare ESRD program established as part of the Social Security Amendments of 1972

1978

ESRD Networks are established

1983

Congress implements the first Medicare PPS (aka composite rate)

1984

National Organ Transplant Act passes and establishes OPTN

1986

ESRD Network responsibilities refined and 17 network areas established

1987

IOM study of ESRD program

1988

CMS begins to contract with ESRD Networks

1993

Medicare coverage of immunosuppressives for transplant extended to 36 mths.

1995

NKF launches DOQI

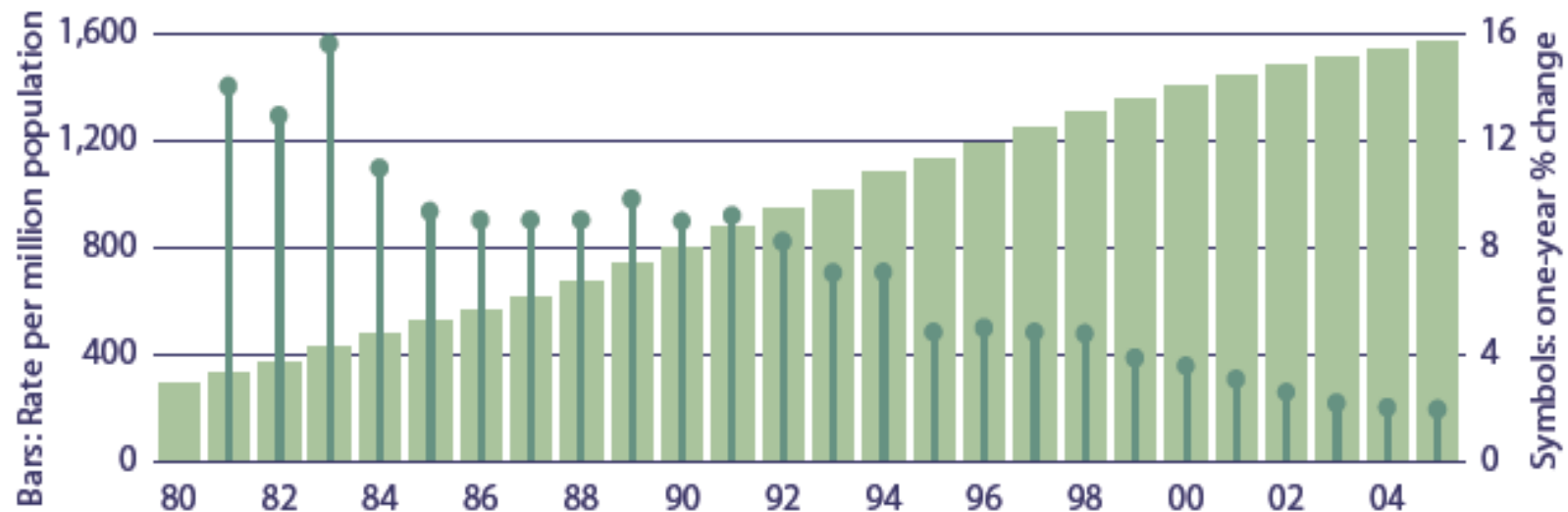
1999

DOQI expands to KDOQI
CKD gets its own focus area for Healthy People 2010

2003

Passage of the Medicare Modernization Act
Part D and composite rate changes

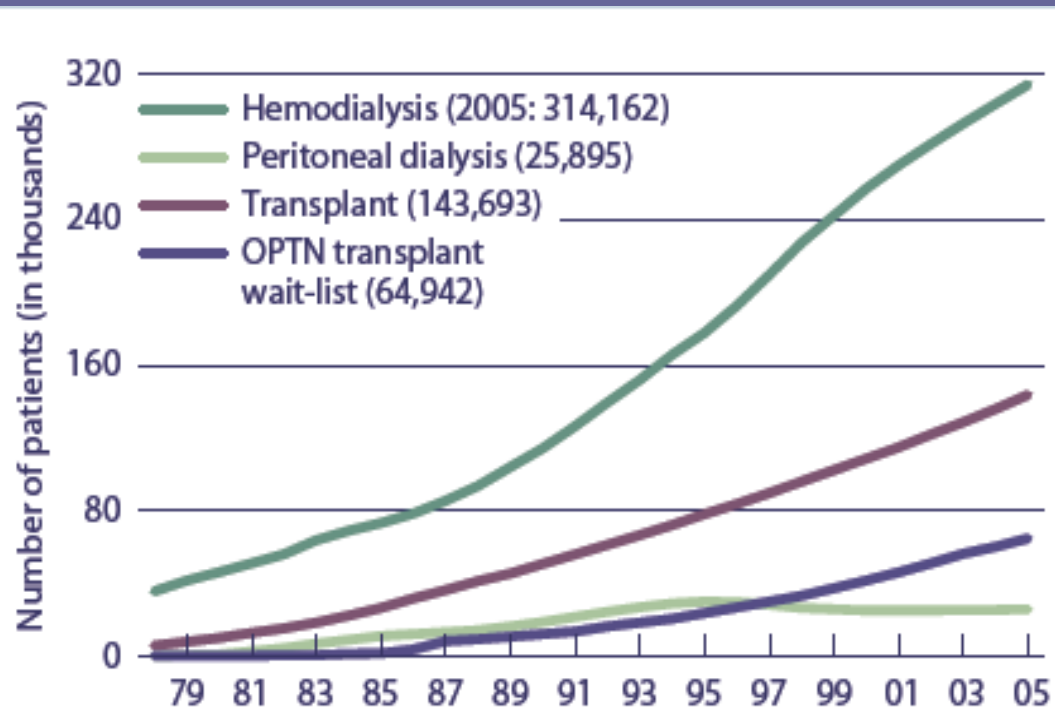
ESKD/CKD By The Numbers



2.22

Adjusted prevalent rates & annual percent change December 31 point prevalent ESRD patients

ESKD Modality and Costs



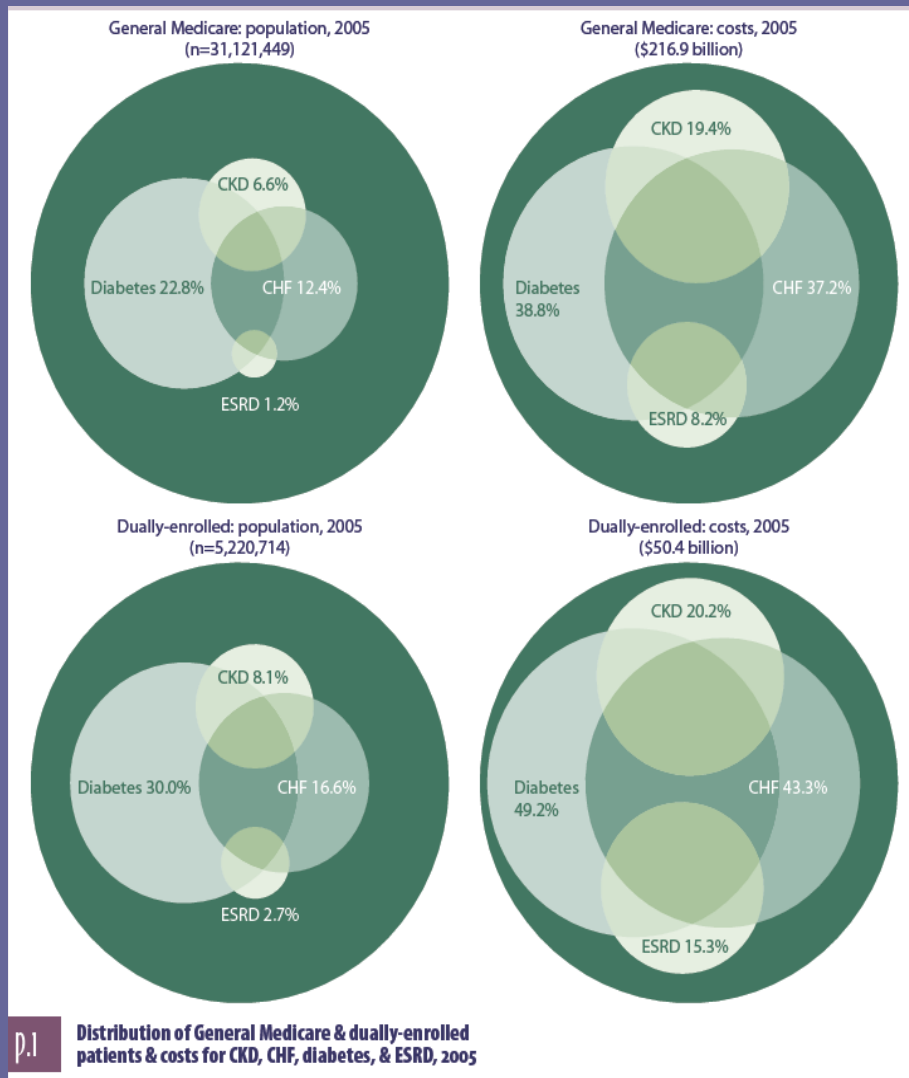
Medicare spending per patient year, 2005

| | |
|---------------------|--------|
| ESRD | 59,417 |
| Hemodialysis | 69,758 |
| Peritoneal dialysis | 50,847 |
| Transplant | 25,015 |

4.2

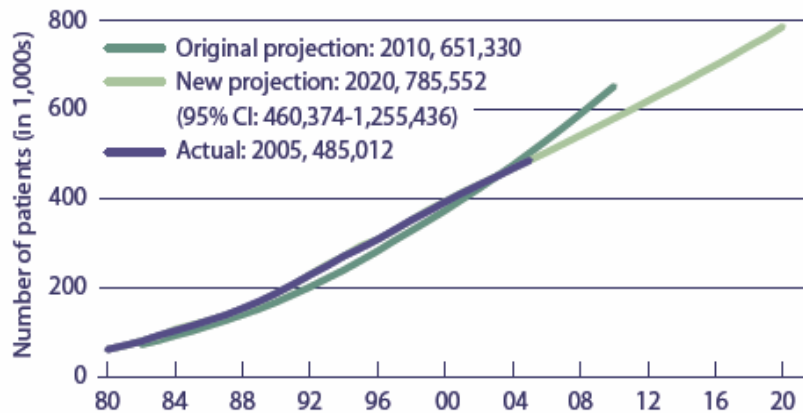
Prevalent patient counts (USRDS), by modality December
31 point prevalent ESRD pts; excludes pts w/unknown modality

Costs of ESKD and CKD



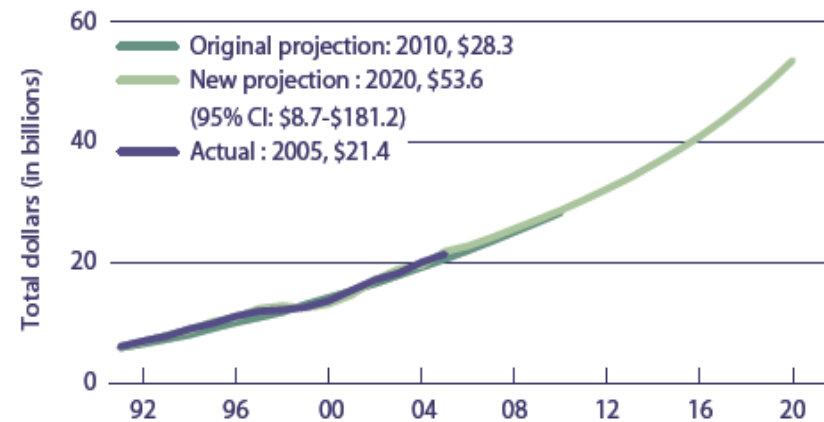
ESKD patients account for 1.2% of the Medicare population and 8.2% of total costs.

Projected Counts by 2020



2.32

Projected counts of prevalent ESRD patients through 2020 (autoregression model)



2.33

Projected ESRD expenditures through 2020 (autoregression model)

How is policy framed to promote cost containment and quality of care for ESKD and CKD?

- Better management of early CKD to slow progression to ESKD
 - Public health/Media campaigns
 - Prevention/Knowing the Risk Factors
 - Clinical guidelines for screening
 - Pre-Dialysis Education
- Focus on ESKD therapies that are less expensive
 - Better education on different treatment modalities
 - Increasing organ donation/donor pool
- Change the payment structure of dialysis providers and nephrologists
 - Implementing pay for performance measures
 - Composite rate increases
 - Change bundling design for dialysis services

North Carolina General Assembly

- 2006-2007 Session
 - SL 2006-248: The Studies Act of 2006
 - CKD Task Force
 - Study of rate-setting methodology for state funded kidney dialysis
- 2007-2008 Session
 - SL 2007-532: Organ Donation/The Heart Prevails



North Carolina General Assembly

- 2007-2008 Session
 - SL 2007-532: Organ Donation/The Heart Prevails
 - Uniform Anatomical Gift Act – 2006 Update
 - Adopted by 19 states and pending in 5 other states
 - Increased focus on personal autonomy in the donation process
 - Clearer rules on the role of family, friends, caregivers
 - Implementation of systems that make it easier for OPOs to look up potential donors



110th Congress

- HR710/S487:Charlie W. Norwood Living Organ Donation Act
- S432/HR1245: Kidney Disease Educational Benefits Act of 2007
- HR3282: Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007
- S691/HR1193: Kidney Care Quality and Education Act of 2007 (KCQEA)
- H3162: The Children's Health And Medicare Protection Act (CHAMP)

Some of the Lobbying Efforts

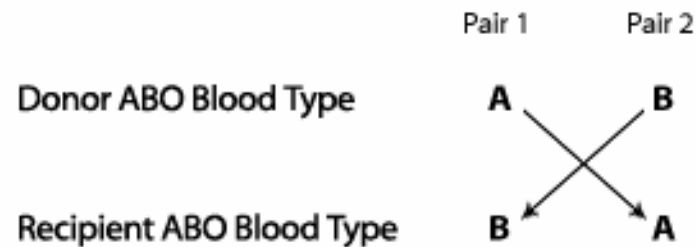
- Kidney Care Partners
(patient advocates, dialysis professionals, care providers and suppliers)
- Kidney Care Council
(dialysis providers)
- Renal Physicians Association
- National Kidney Foundation
- American Association of Kidney Patients
- RSN's Wellness & Education Kidney Advocacy Network (weKAN)
- AKF, DPC, Coalition for Patient Choice , Individual Companies, PhRMA, other trade organizations, other professional organizations

HR710/S487

Charlie W. Norwood Living Organ Donation Act

- Amended the National Organ Transplant Act to state that by stating that kidney paired counts as a viable transplant option and is NOT to be considered to involve the transfer of a human organ for valuable consideration.

Paired Donation for ABO Incompatibility



HR3282:

Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007

- Continuation of Part B Medicare coverage for transplant recipients not eligible for Medicare due to age or disability;
- Part B would ONLY cover immunosuppressives;
- Recipients would be responsible for Part B premium and deductible.

S432/HR1245 (*language now in CHAMP*)

Kidney Disease Educational Benefits Act of 2007

- Pre-dialysis educational classes reimbursed by Medicare (n=6);
- Educational sessions would include information on managing comorbidities, the prevention of uremic complications, each option for RRT (PD, HHD, HD, Transplant);
- Payment would be made by Medicare to physicians or dialysis facilities.

S691/HR1193 (*much of this is in CHAMP*) Kidney Care Quality and Education Act of 2007 (KCQEA)

Section 1: Improving Quality through Patient Education, Access, and Safety Initiatives

- CKD Demonstration Projects
- ESRD Self-Management Demonstration Projects
- Medicare Coverage of Kidney Disease Patient Education Services
- Blood Flow Monitoring Demonstration Projects
- IOM Evaluation and Report on Treatment Modalities for Patients with Kidney Failure
- Required Training for Patient Care Dialysis Technicians

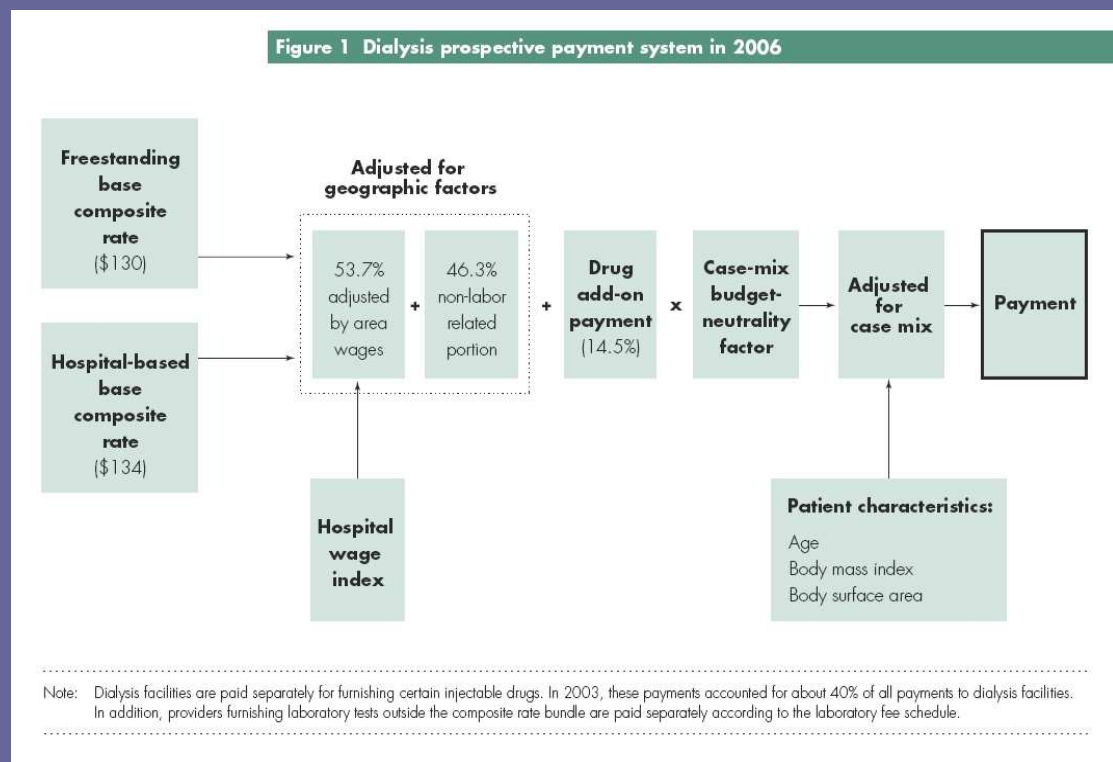
S691/HR1193

**Kidney Care Quality and Education Act of
2007 (KCQEA)**

Section 2: Assuring Quality of Care for Providers, Facilities,
and Physicians That Provide Services to Individuals With
ESRD Who Are Enrolled in Part B.

- Establishment of an ESRD Advisory Committee
- Update for Medicare Composite Rate for 2008, 2009, and 2010
- Continuous Quality Improvement Initiative in the Medicare ESRD Program
- Extension of Medicare Secondary Payer (MSP) from 30 to 42 months

The Composite Rate for Dialysis



The composite rate was established in 1983; pays for clinical/social services, equipment, supplies, some labs and some drugs; does NOT pay for injectable EPO, Vitamin D, or Iron. In 2006, composite rate was \$130 per treatment.

***There is NO Annual Update Framework for the composite rate.

The Composite Rate for Dialysis

- Separately billable injectibles:
 - In 2001 Medicare's payment was 11% lower on average than facilities' average costs to provide the items and services included in the composite rate, whereas Medicare's payment for separately billable drugs was 16% higher than facilities' average costs of acquiring these drugs.
 - Payments for separately billable dialysis-related drugs and biologics were changed to a determined acquisition cost in 2005. In 2006 and beyond, they would be reimbursed at the Average Sales Price (ASP) plus 6%.
 - Payments also now being focused on utilization with much debate over hemoglobin levels for anemia management in ESKD and CKD patients.

Erythropoiesis Stimulating Agents

- Erythropoietin is made by the kidneys and helps stimulate red blood cells.
- ESAs increase red blood cell production, and can be given subcutaneously or through a vein (most common)
- Target hemoglobin has averaged between 11-12 g/dl.
- Epogen introduced in 1983 – Procrit and Aranesp followed.
- By 2004, spending for Epoetin therapy was the single largest Medicare drug expenditure and is the 2nd largest source of dialysis facility income (22%).
- In 2005, total spending on Epogen was 2 billion; concerns over ASP +6% for Epo, as there are no competitor products.

Erythropoiesis Stimulating Agents

- **2006:**
 - 2 large trials published in NEJM demonstrate that targeting a higher hgb level (>12g/dl) probably has a negative impact on CVD morbidity and mortality; conflicting results on QOL measures.
 - Senate Ways & Means Committee holds a hearing on bundling payments for dialysis to curb the incentives for treatment.
- **2007**
 - FDA issues black box warning advising physicians to monitor red blood cell levels (hemoglobin) and to adjust the ESA dose to maintain the lowest hemoglobin level needed to avoid the need for blood transfusions.
 - CMS changes reimbursement policy : If patient's hemoglobin rises above 13 g/dL for 3 consecutive months, the dose must be decreased by 50% and a modifier statement regarding the reduction in dose is placed on the claims form (was 6 months and 25%). Policy to start 1/2008.
 - FDA holds a joint committee meeting and votes against setting a specific hemoglobin target for ESKD patients; re-labeling is still going to happen and the FDA's regulatory committee can change current decision.

H3162: The Children's Health And Medicare Protection Act (CHAMP)

- Main goal is to reauthorize the Children's Health Insurance Program

Many Provisions are similar to KCQEA:

- CKD Demonstration Projects
- Pre-ESKD education BUT no payment to dialysis facilities and only available to >65
- Training for dialysis technicians
- Report on treatment modalities BUT report done by MedPac instead of IOM
- MSP Extension to 42 months BUT only for large employers (>100 employees)

H3162: The Children's Health And Medicare Protection Act (CHAMP)

New Provisions:

- Payment adjustment of ESAs to 102% ASP (currently at 106% ASP for large dialysis providers)
- Equalize composite rate for hospitals and outpatient facilities (hospitals would lose \$4)
- ESRD Bundling to include more drugs and services and a MedPac report; bundling would pay 96% of total estimated payments if there were no bundling system (currently paying 100%)
- OIG Study and report on EPO
- Establishment of a Center for Comparative Effectiveness Research

What's Next

- Pushing to get bills out of Committee
 - KCQEA
 - Transplant coverage extension
- ?Medicare provisions to stay in CHAMP?- perhaps not, but will definitely resurface
- Increasing patient, caretaker, and provider participation in the advocacy process