

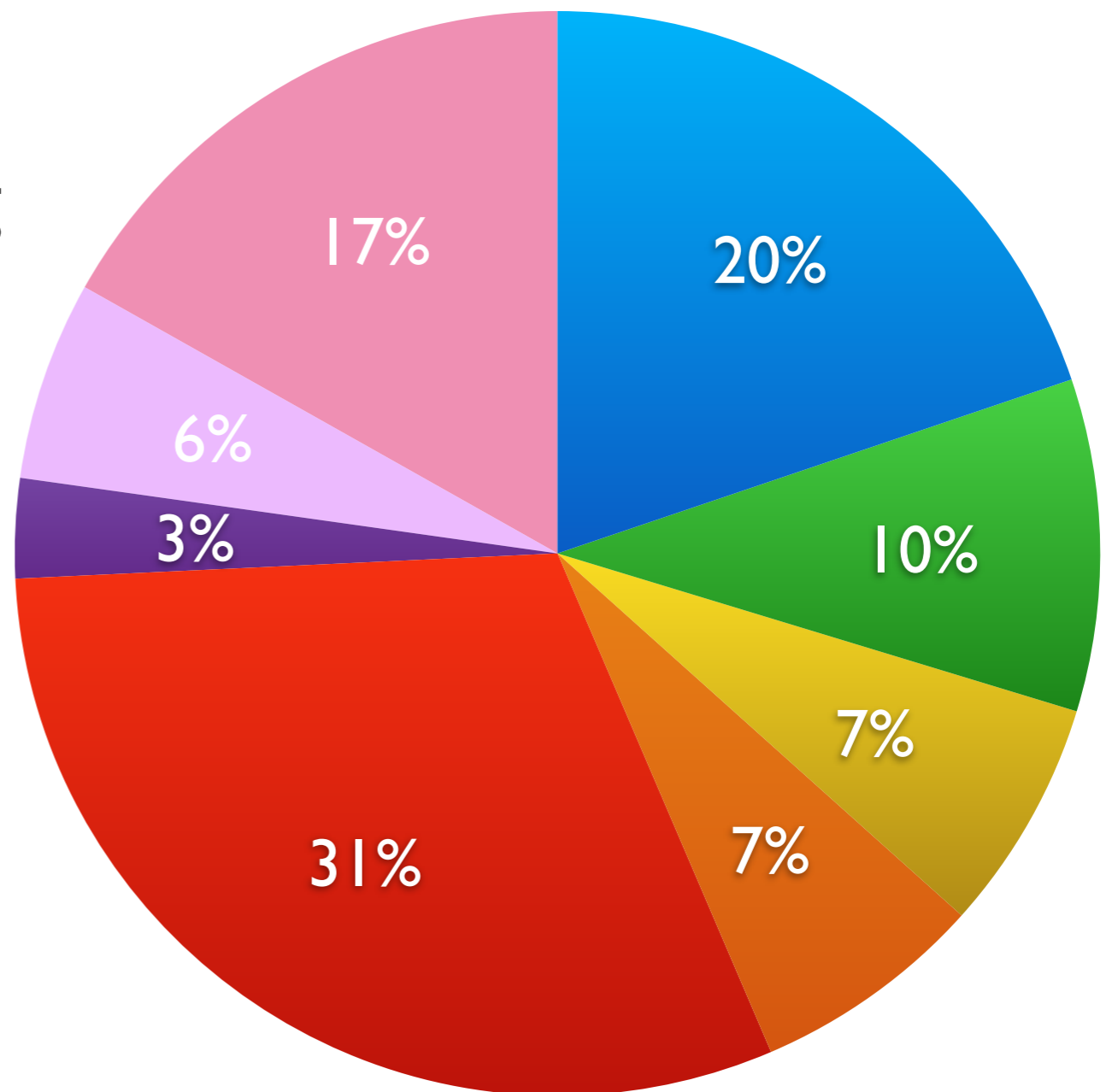
ESRD Reimbursement in the U.S.

Leslie V. Norwalk

U.S. Health Care: Where We Spend It

U.S. health care spending grew 3.9% in 2011, reaching \$2.7 trillion or \$8,680 per person.

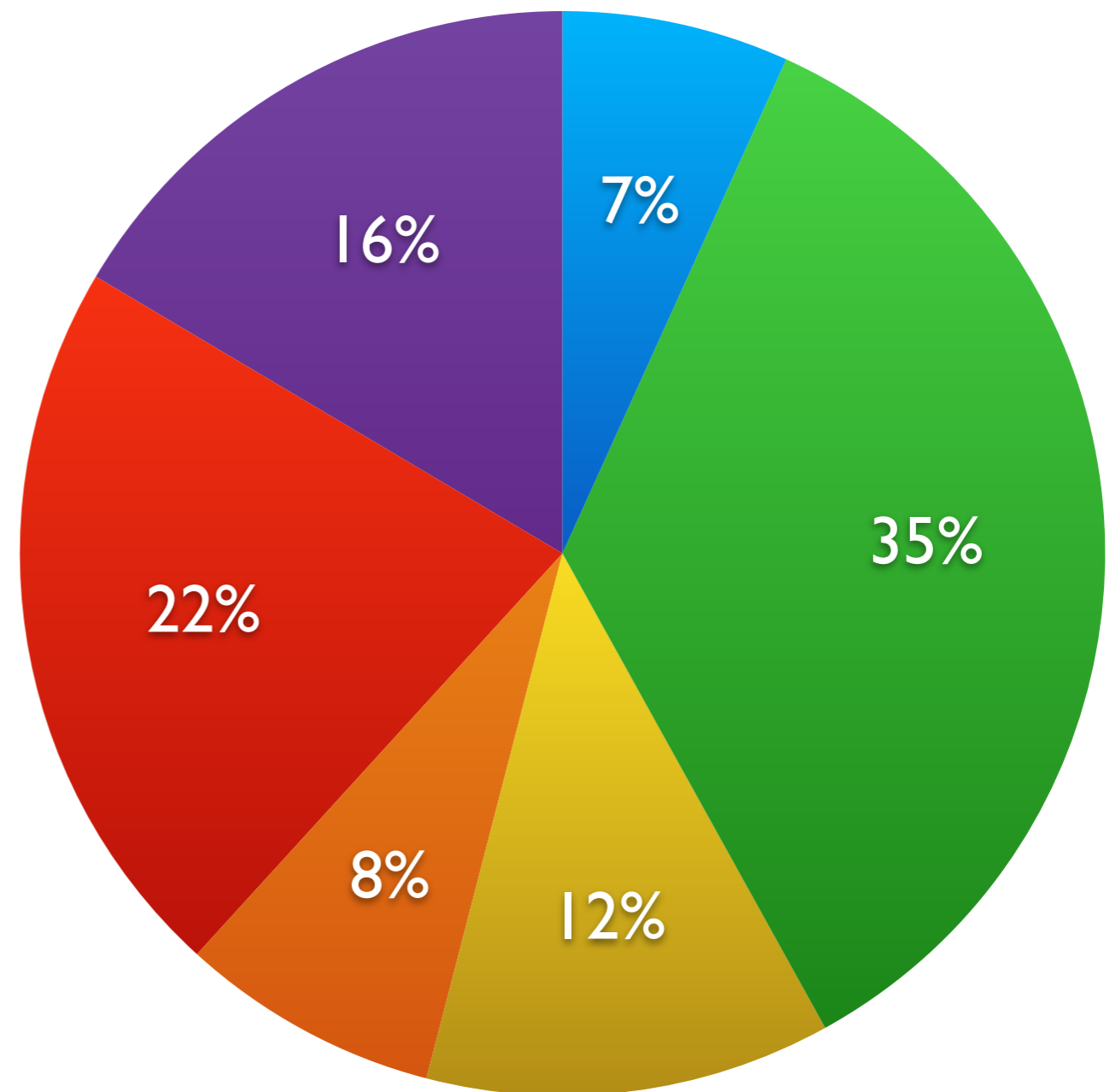
- Physicians / Clinics
- Prescription Drugs
- Dental / Other Professional
- Administration
- Hospital
- Home Health
- Nursing Homes
- Other



Who Pays for Health Care in the US, 2011

As a share of the nation's Gross Domestic Product, health spending accounted for 17.9%.

- Other Public Spending
- Private Health Insurance
- Out of Pocket
- Other Private Spending
- Medicare
- Medicaid/CHIP

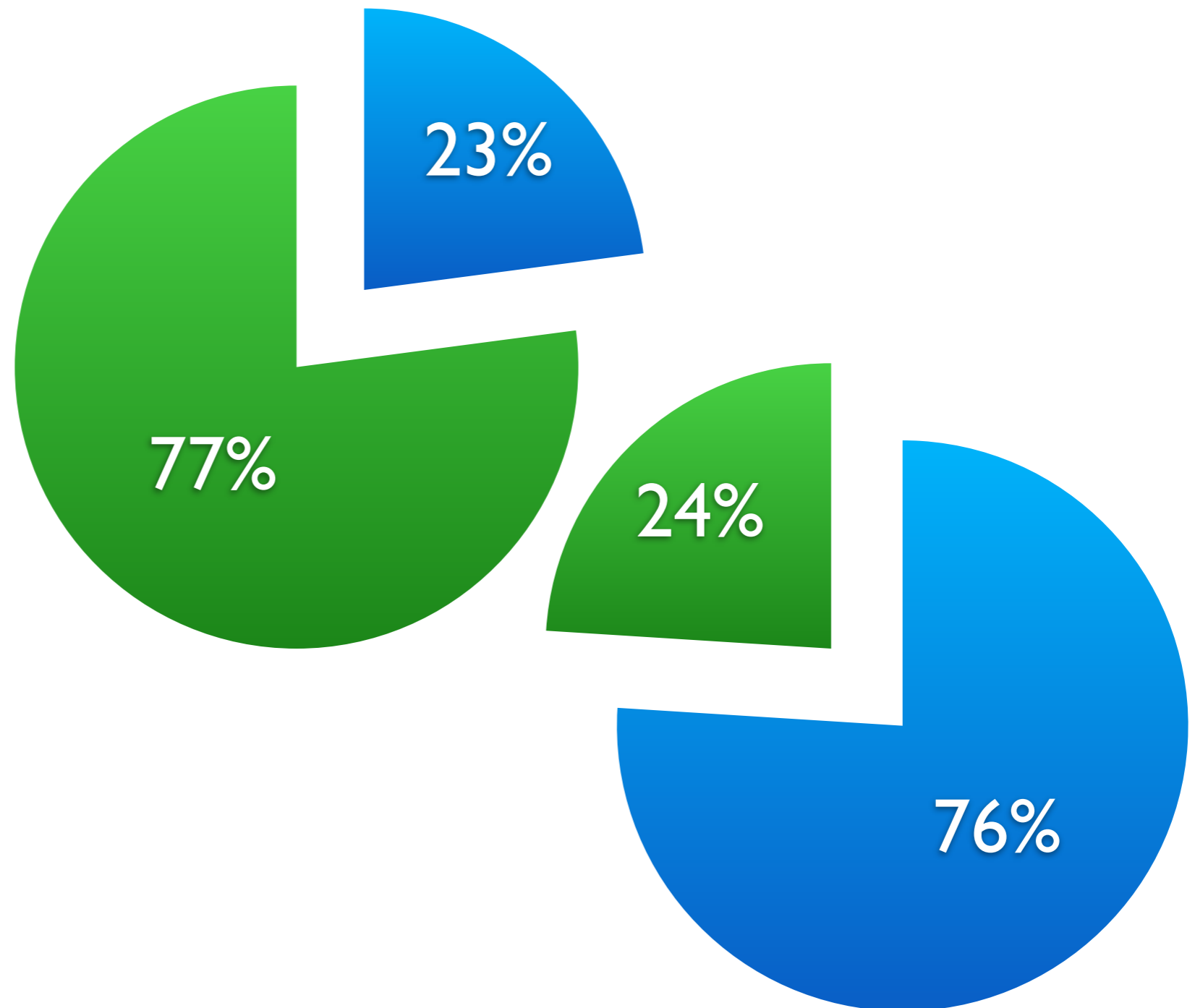


Medicare and Medicaid Enrollment

- 52 Million Medicare Beneficiaries
 - 43 Million Aged
 - 9 Million Disabled
 - \$590B a year
- 57 Million Medicaid (low-income) Beneficiaries
 - \$277B Federal Spending a year

Chronic Care Cost Concerns

- 23% of all Medicare Beneficiaries:
- Cost 76% of the Medicare Budget



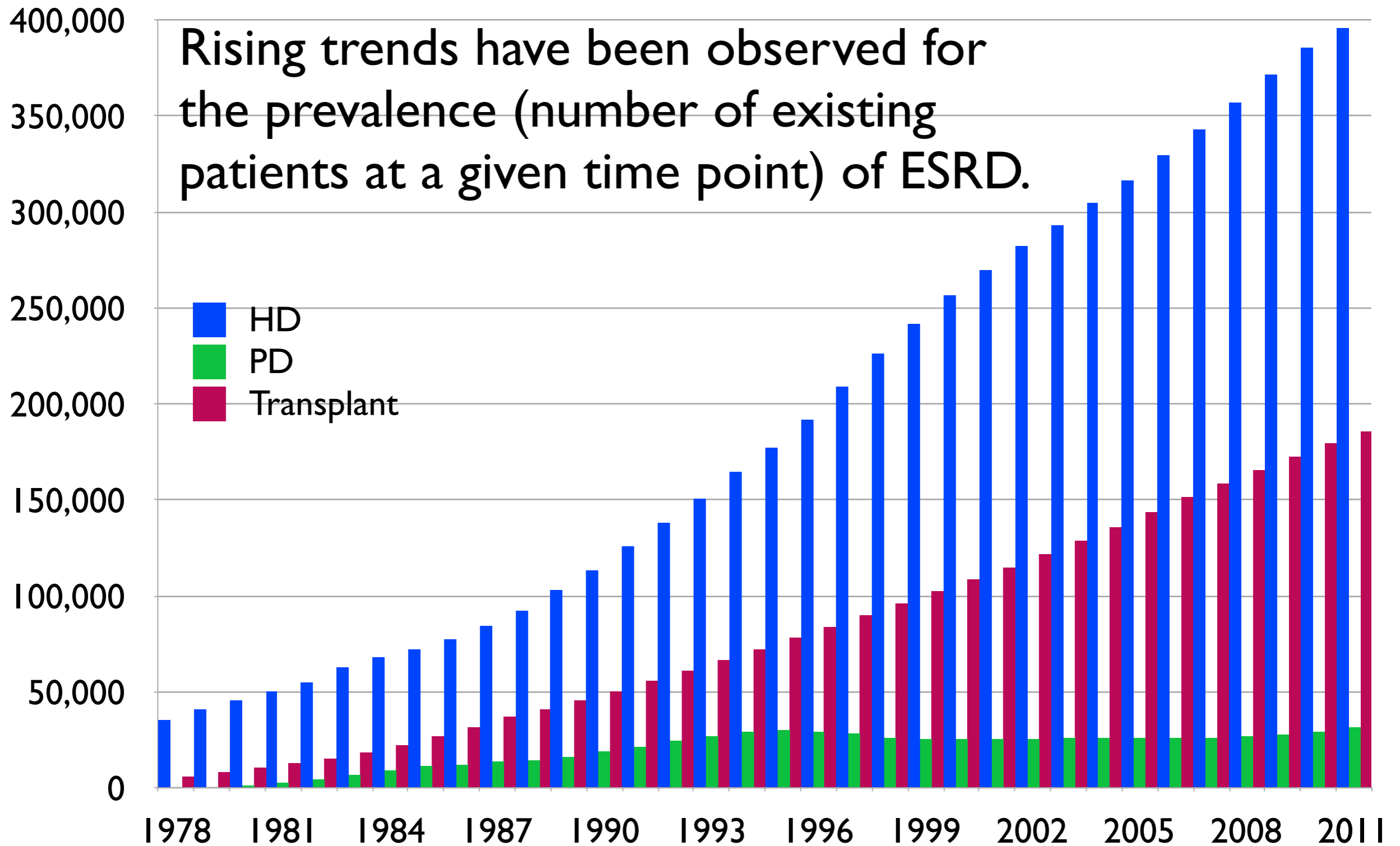
Chronic Care Costs Drive Medicare Spending

- 11 Million Medicare Beneficiaries:
 - Have 5 or more Chronic Conditions
 - See 12 or more physicians a year
 - Take 50 or more prescriptions a year
- Cost Medicare \$375B a year

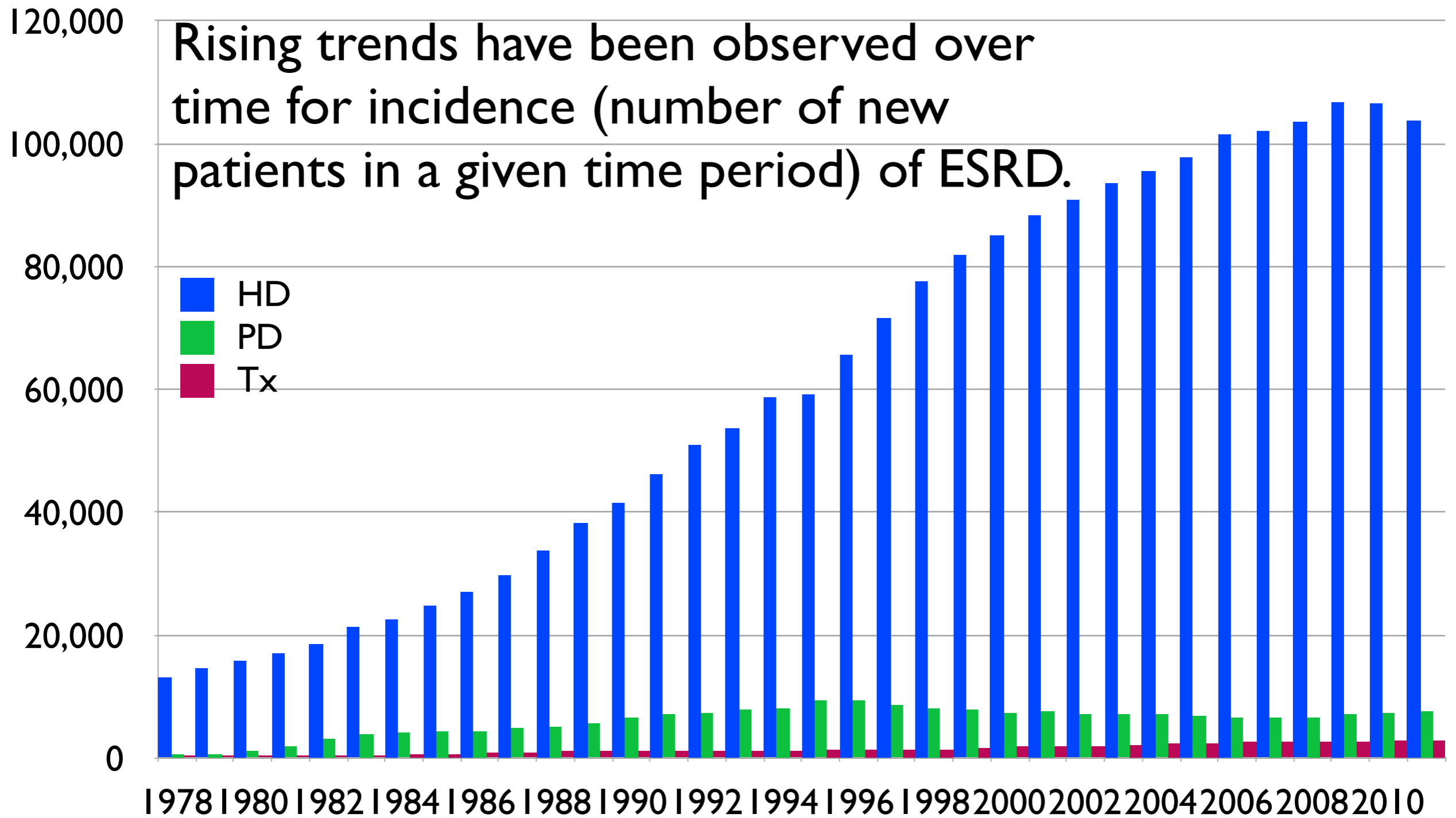
ESRD

- CMS defines ESRD as “permanent kidney failure treated with dialysis or a transplant.”
- The prevalence of CKD in the U.S. population is high, attributable in part to high rates of diabetes, hypertension, and obesity.
- It has been predicted that the number of ESRD patients in the U.S. will increase to more than 700,000 by 2015.

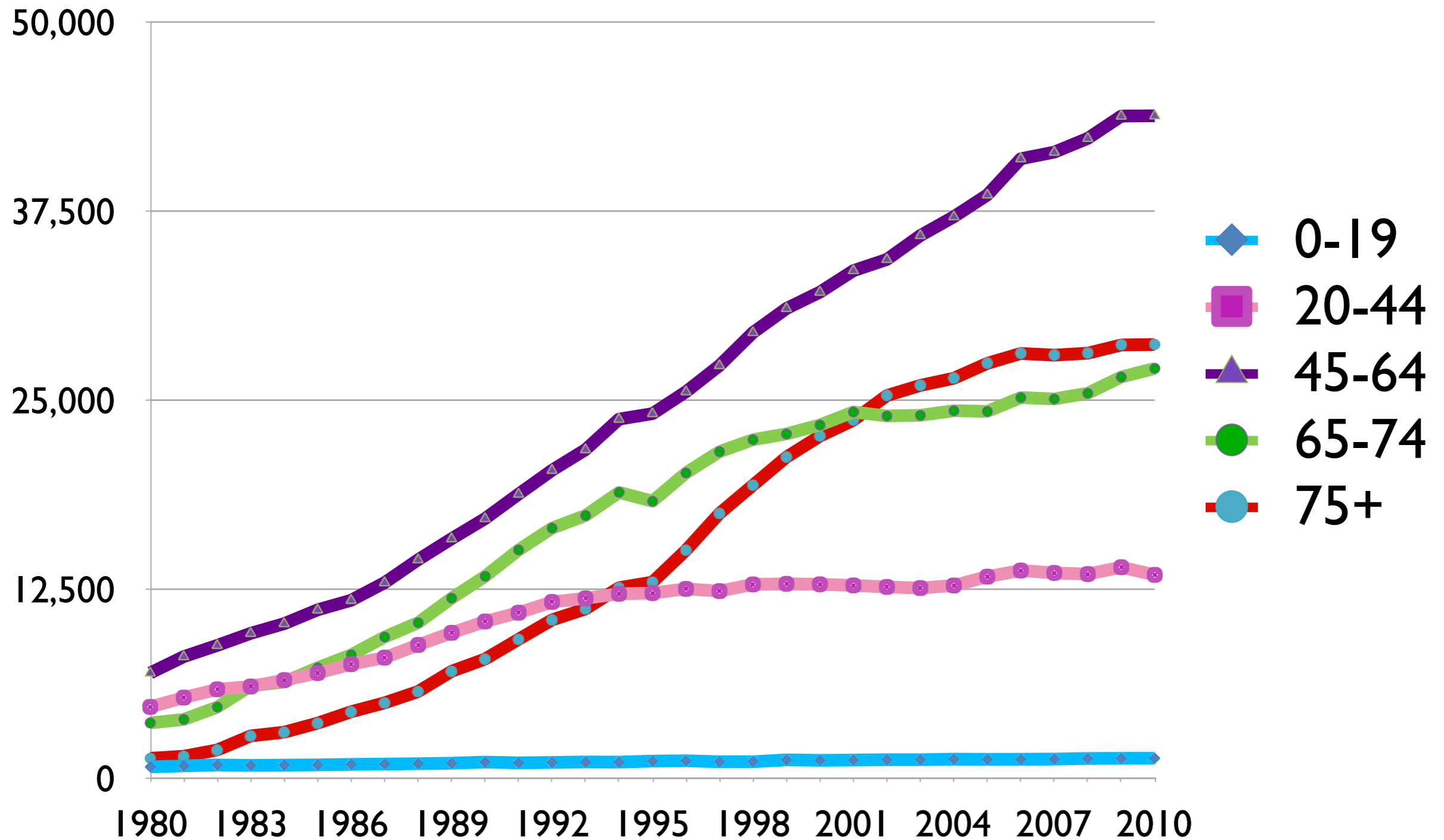
Prevalent Patient Counts



Incident Counts



ESRD Incident Counts by Age



ESRD Coverage

- In 1972 Medicare extended benefits to people with ESRD who are eligible for Social Security benefits, even those under age 65 years. ESRD patients entitled to Medicare due to kidney disease alone have the same benefits as other Medicare beneficiaries.
- Most US citizens (about 93%) can get Medicare when they start dialysis or have a transplant. About half of new ESRD patients each year are under age 65 and thus are entitled to Medicare because they have chronic renal failure.
- Medicare Part B covers dialysis after 4 months of in-facility treatment, or immediately if receiving dialysis at home. (In-home patients must start training before the 4th month of treatment).
- Medicare Part B pays 80% of Medicare's allowed charge for dialysis—at home or in a clinic—after the annual Part B deductible.

The Future of ESRD Spending

- There has been a dramatic rise in obesity, hypertension and diabetes across all age cohorts.
- These things often lead to chronic kidney failure and ESRD.
- Medicare covers a significant portion of all ESRD costs.
- The amount of Medicare outlays has grown over time and is likely to continue to grow at a fast pace.

Clinical Episode Groups that Account for Greatest Share of Spending, 2005

Rank	Episode treatment groups [®] base group	Number of episodes (in thousands)	Average spending per episode*	Share of total spending on episodes
1	Ischemic heart disease	6,504	\$4,296	14.0%
2	Congestive heart failure	2,493	3,437	4.3
3	Hypertension	14,166	562	4.0
4	Cerebral vascular accident	2,685	2,658	3.6
5	Chronic obstructive pulmonary disease	2,308	2,955	3.4
6	Diabetes	5,823	1,108	3.2
7	Joint degeneration, localized—knee & lower leg	2,272	2,681	3.1
8	Joint degeneration, localized—back	3,986	1,520	3.0
9	Chronic renal failure	1,170	4,844	2.8
10	Closed fracture or dislocation—thigh, hip & pelvis	347	13,229	2.3
11	Cataract	7,708	585	2.3
12	Bacterial lung infections	1,155	3,708	2.1
13	Malignant neoplasm of pulmonary system	284	10,895	1.6
14	Malignant neoplasm of prostate	1,025	2,787	1.4
15	Malignant neoplasm of breast	857	3,138	1.4
16	Psychotic & schizophrenic disorders	559	4,725	1.3
17	Malignant neoplasm of skin, major	2,688	882	1.2
18	Joint degeneration, localized—thigh, hip & pelvis	781	2,991	1.2
19	Other metabolic disorders	1,852	1,253	1.2
20	Atherosclerosis	1,036	2,056	1.1



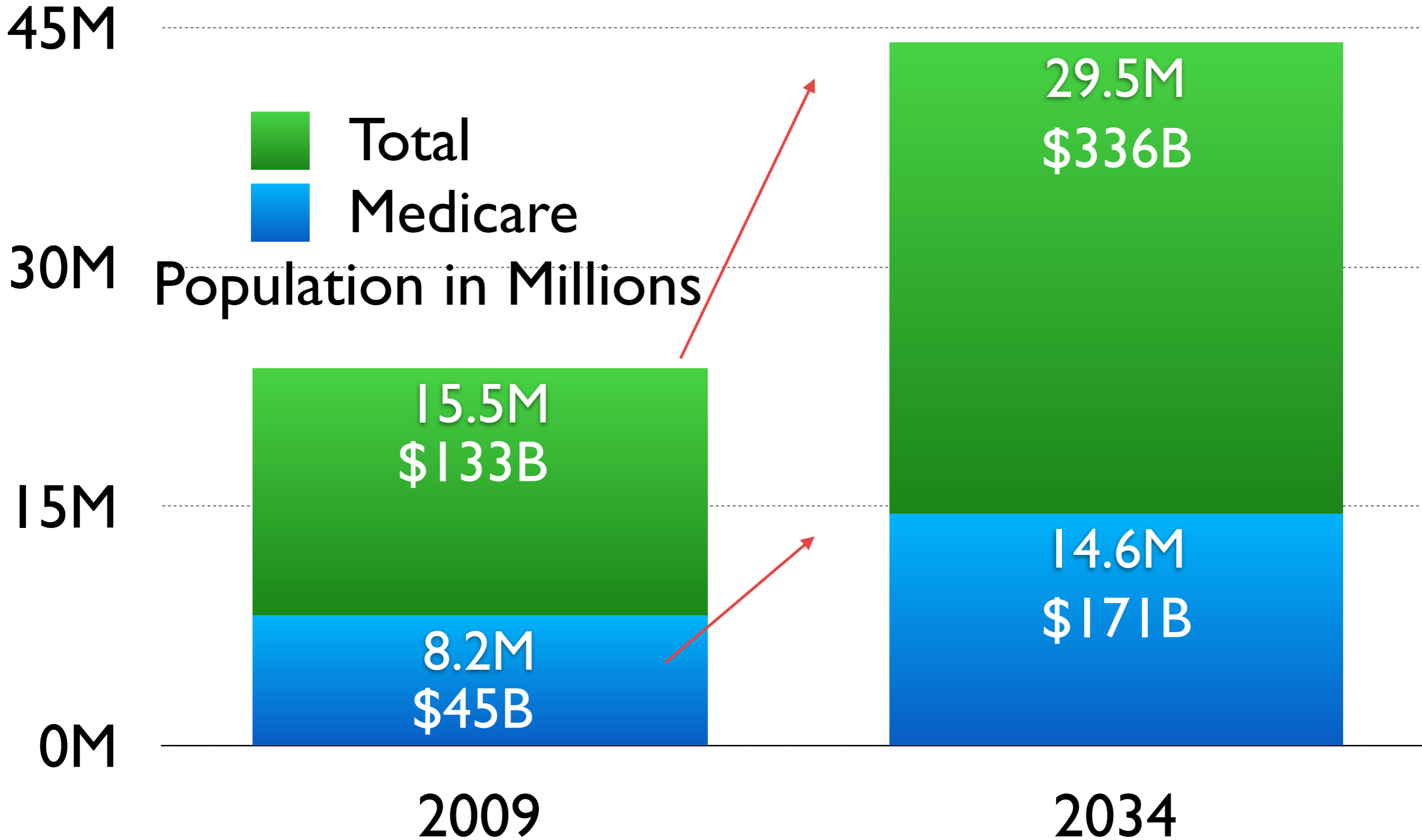
Note: Symmetry Episode Treatment Groups[®] (ETGs[®]) is an Ingenix, Inc., product. The number of episodes column represents an estimate of the number of cases in the entire Medicare population based on the number of cases in the 5 percent sample. *Spending is standardized to exclude variation in resource costs due to geographic differences in input costs or policy considerations (e.g., teaching hospital payments).

Source: MedPAC analysis of 5 percent sample of 2001–2006 Medicare claims using ETGs[®] version 7.5.1.

Diabetes Now

- The prevalence of diabetes more than doubled over 20 years (1986 to 2006), making diabetes the 5th deadliest disease in the US. \$176 billion in direct costs of treatment in 2012.
- Diabetes is the leading cause of kidney failure, accounting for 44% of new cases in 2008.
- In 2008, 48,374 people with diabetes began treatment for end-stage kidney disease in the United States.

Diabetes Later



Successfully controlling diabetes will be critical in keeping future costs down.

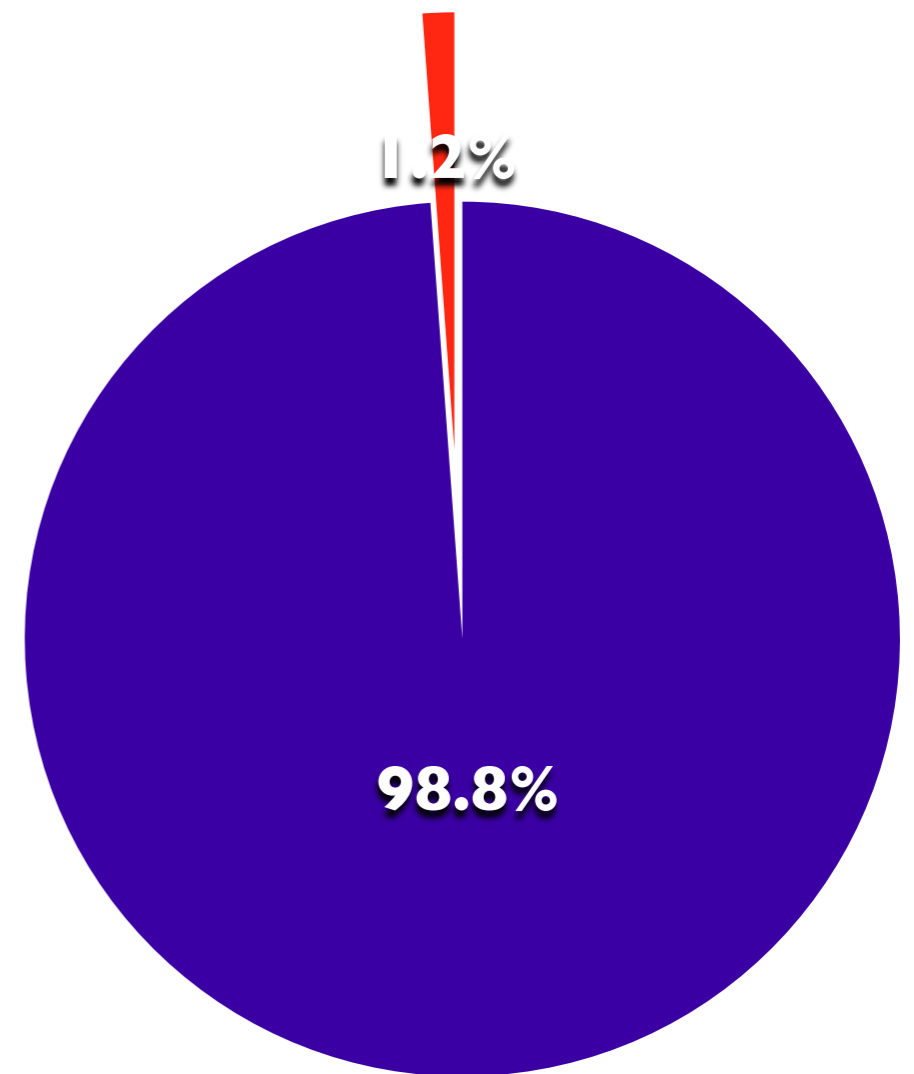
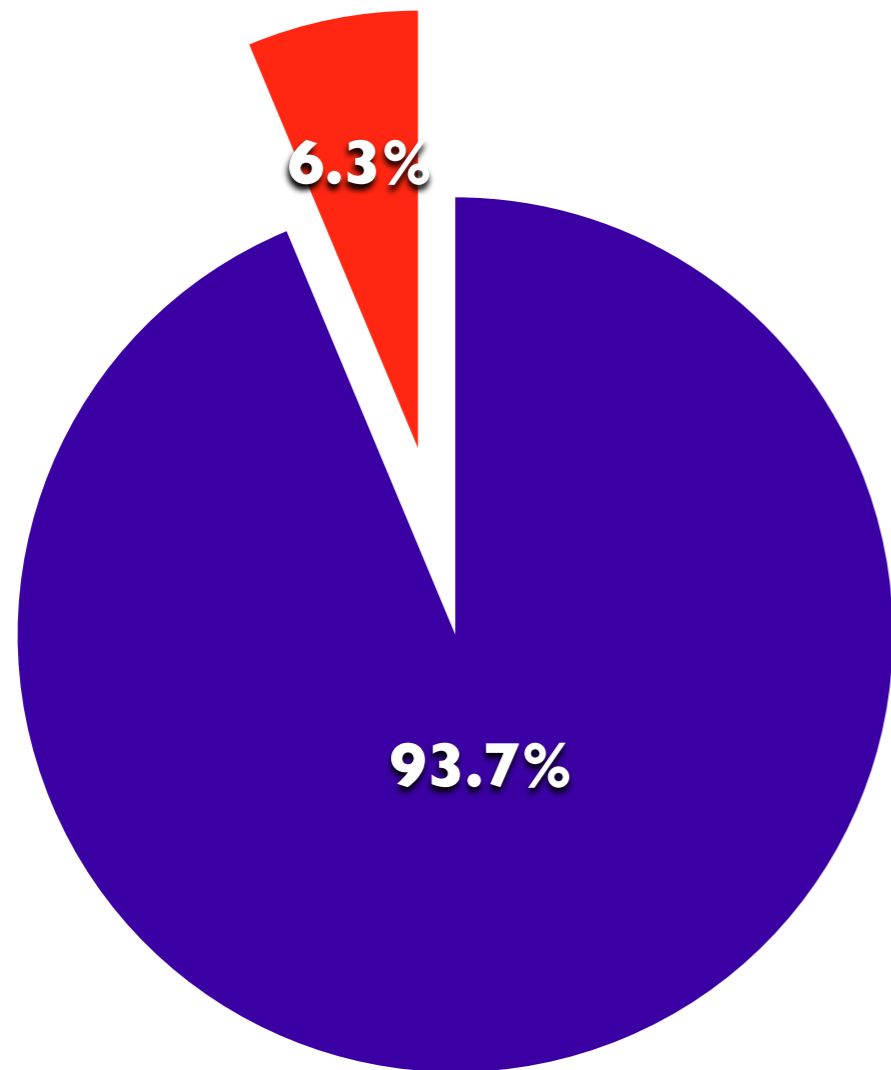
Medicare Spending for ESRD Services

- Medicare spending for ESRD beneficiaries exceeded original spending projections primarily because of unanticipated growth in the ESRD population. The over 600,000 enrolled ESRD beneficiaries in 2011 accounted for about 1% of total Medicare enrollment. By contrast, ESRD beneficiaries accounted for only 0.1% of enrollment in 1974.
- This enrollment growth reflects population aging, increased prevalence of diabetes—a major risk factor for ESRD—and improvements in clinical knowledge and techniques that have enabled successful treatment of older patients and those with coexisting illnesses who might not have been treated 30 years ago.

ESRD as a Portion of Medicare

Beneficiaries = 613,000

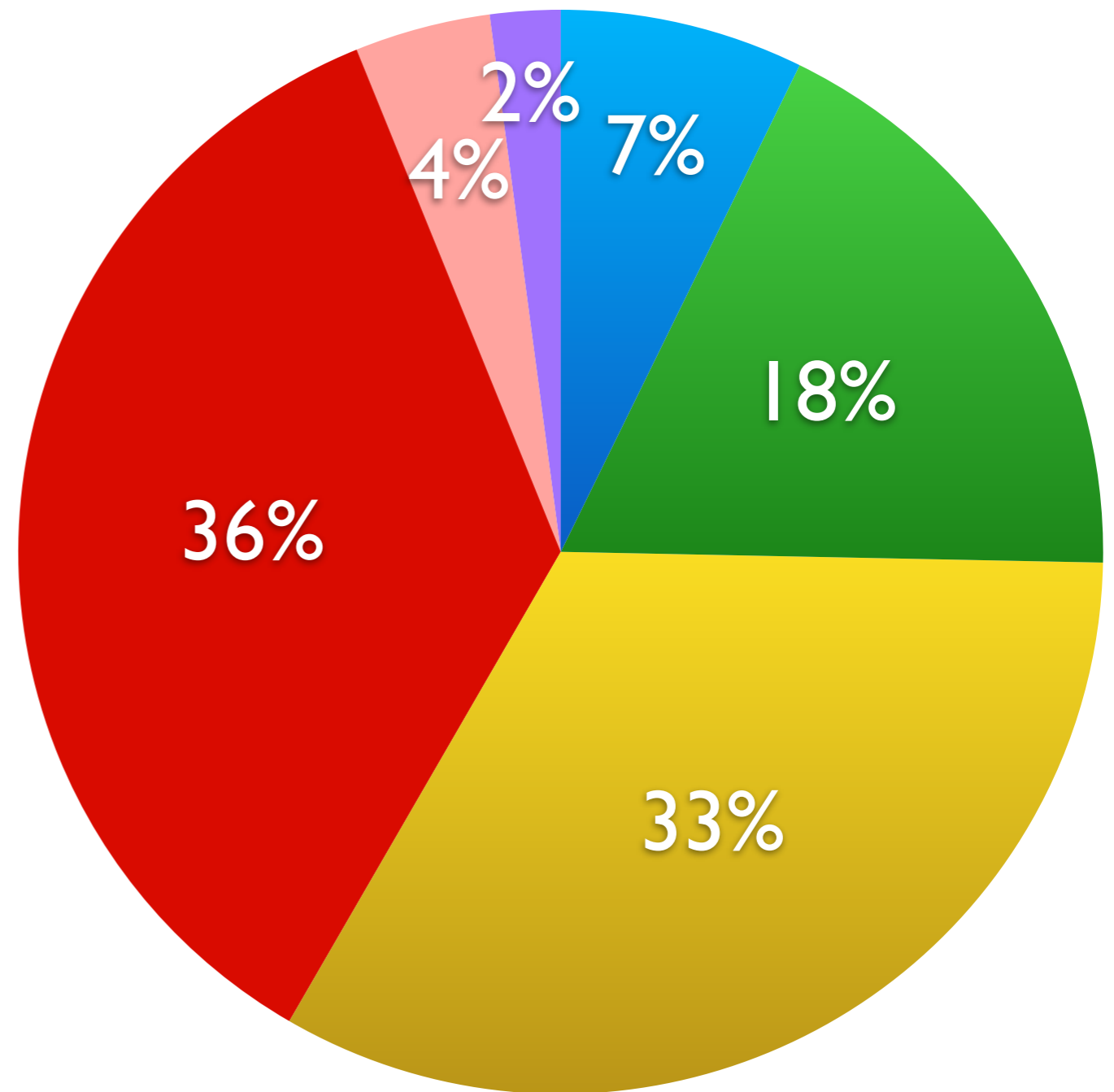
Cost



Medicare ESRD Spending, 2011

Total Spending
= \$29.8B

- Drug Benefit
- Physician
- Outpatient Hospital
- Inpatient Hospital
- Skilled Nursing
- Home Health



Medicare Reimbursement of ESRD Services

- Medicare covers two methods of dialysis—hemodialysis and peritoneal dialysis.
- The unit of payment is the dialysis treatment. Although different equipment, supplies, and labor are needed for hemodialysis and peritoneal dialysis, Medicare does not differentiate payment based on dialysis method.

Medicare Reimbursement of ESRD Services

Why has Medicare made changes to how it reimburses ESRD facilities over time?

- Take into account changes in the practice of medicine
- Provide incentives for more efficient and higher quality care
- Promote more efficient use of drugs commonly used in dialysis
- Encourage home dialysis
- Pay for improved quality

What Is Included in the Medicare “Bundle” to ESRD Facilities vs. Separately Payable?

	1983-2009: composite rate	2009-2010: adj. composite rate	2011-2013	2014-
Facility Services				
Home Dialysis				
ESAs				
Commonly Used ESRD IV Drugs				
ESRD Oral Drugs				
Lab Services				
Physician Services				
DME				
Dialysis Training Services				

Medicare Reimbursement of ESRD Services (1983-2009)

- Medicare pays dialysis facilities a predetermined payment or "Composite Rate" for each dialysis treatment they furnish, using a payment system first implemented in 1983.
- The composite rate is intended to cover the bundle of services, tests, certain drugs, and supplies routinely required for dialysis treatment and is adjusted to account for differences in case mix and local input prices.
- Medicare caps its payments to facilities at an amount equal to 3 dialysis sessions per week, although home dialysis may be given more frequently.

Setting the Composite Rate

- ESRD facilities receive composite rate payments for PD patients equal to 3 times the otherwise applicable composite rate per treatment, for each week a patient is on PD.
- For example, a facility's payment for a patient on PD for 21 days would be equal to $21/7 \times 3$ or 9 times the composite rate.
- This payment method for PD patients has existed since the beginning of the composite payment system in 1983.

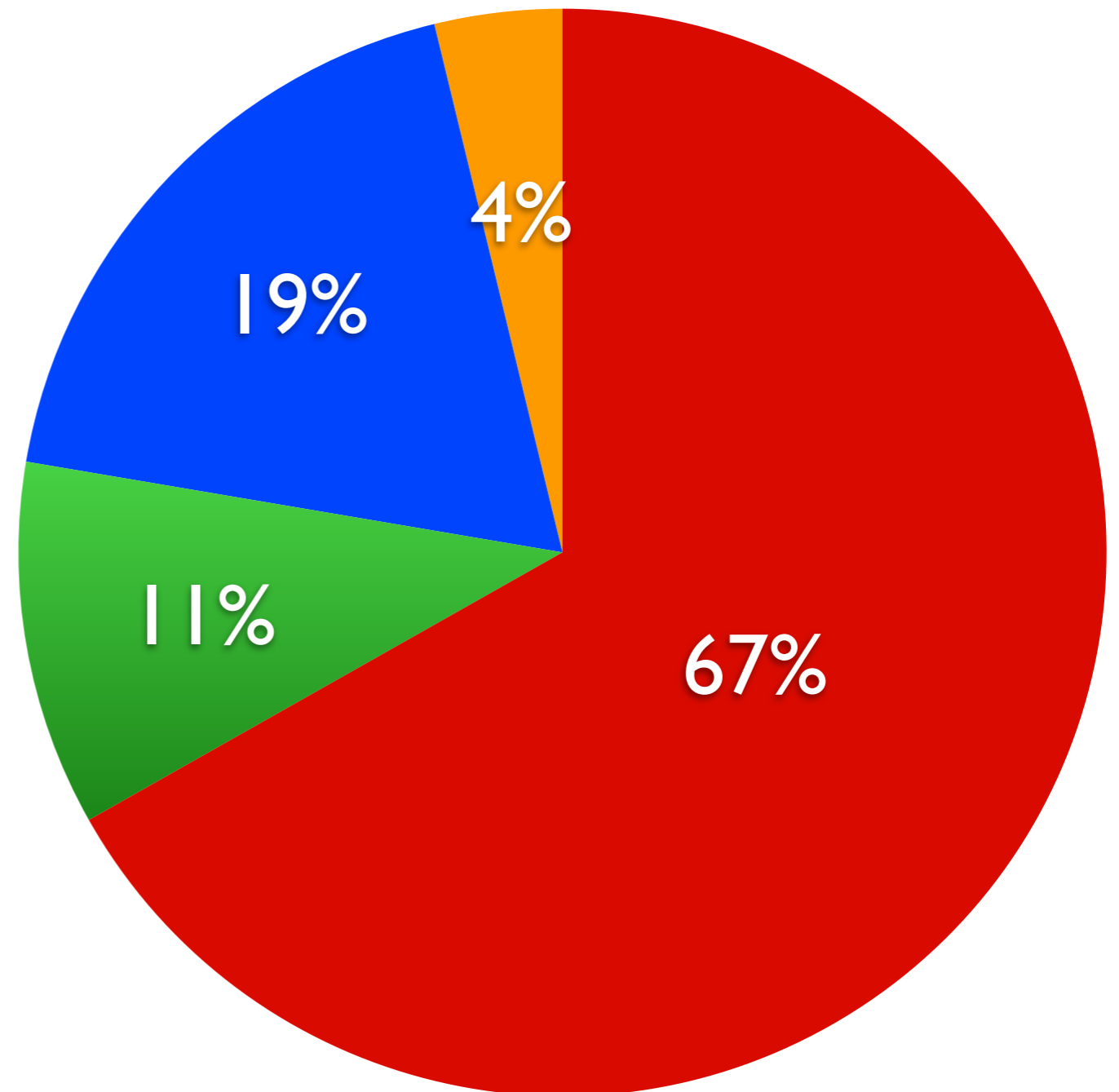
Medicare Reimbursement of ESRD Services 1983-2009

- Technological advances have changed the provision of dialysis care since the composite rate was established in 1983.
- The composite rate excluded several injectable drugs commonly provided to dialysis patients —such as erythropoietin, vitamin D, and iron.
- These drugs are now diffused widely into medical practice over the past decade.
- In 2007, drugs comprised about 33% of facilities' Medicare payments.

Medicare ESRD Drug Spending, 2011

Total Spending
for Injectables =
\$2.8B

- ESAs - \$1.87B
- Iron - \$304M
- Vitamin D - \$519M
- Other - \$106M



Medicare Reimbursement of ESRD Services 1983-2009

- Providers also separately billed Medicare for laboratory tests that were not included in the composite rate bundle from 1983-2009.
- Separately billable services (labs and IV drugs) represented about 40% of total Medicare payments per dialysis treatment.
- These high costs helped drive Congress to changes the ESRD reimbursement system.

Changes to the Composite Rate in 2009

- In 2008 a law passed requiring CMS to develop a modernized prospective payment system PPS that broadened the dialysis composite payment bundle beginning in 2011 and implemented a quality incentive program beginning in 2012.
- CMS adjusted the composite rate and the add-on payment for case mix using the following measures: age and two body measurement variables—body surface area and body mass index. CMS does not apply the body measurement variables when calculating payment for patients under 18.

Medicare Reimbursement of ESRD Services 2011 -

- Medicare incentivized facilities to control costs and promoted quality care by broadening the payment bundle and by linking payment to quality.
- The new bundled rate is designed to create incentives for facilities to furnish services more efficiently by reducing incentives inherent in the former payment method to overutilize drugs.

Medicare Reimbursement of ESRD Services 2011-

- Beginning in 2011, the dialysis payment bundle is expanded to include:
 - composite rate services,
 - Part B injectable dialysis drugs furnished by the facility and their oral equivalents paid for under Part D,
 - 53 ESRD-related laboratory services,
 - Part B separately billable equipment and supplies furnished by the facility,
 - selected ESRD-related oral-only Part D drugs, and
 - self-dialysis training services.

Medicare Reimbursement of ESRD Services 2011 -

- The bundled payment rate includes adjustments for patient case mix (e.g., patient weight, body mass index, co-morbidities, and other patient characteristics), high-cost patients, and low-volume facilities.
- Medicare can include adjustments for geographic factors, pediatric facilities, and for facilities located in rural areas.

Medicare Reimbursement of ESRD Services 2011-2014

- While the new prospective payment system substantially broadens the payment bundle, facilities will continue to be paid for each dialysis treatment they furnish. (CY13=\$240)
- CMS can augment the payment bundle over time when new medical innovations, including drugs and devices, related to the treatment of ESRD become available.

Quality Incentive Payment Program Goals

Medicare expects to:

- Promote efficiency;
- Improve quality and safety for beneficiaries;
- Minimize risks of unintended consequences related to a bundled payment system;
- Encourage meaningful use of health information technology; and
- Improve transparency for beneficiaries and other stakeholders

Quality Incentive Payment Program

- Connects Medicare payment rate to provider/facility performance based on specific measures
- Providers/facilities that do not meet **or** exceed the specified performance standards, will receive a payment reduction of up to **2.0%**
- Payment reductions will apply with respect to the year involved and **will not** be taken into account when computing future payment rates

Quality Incentive Program, Proposed Measures for 2015

Clinical Measures (75% weight, equally weighted)

Hemoglobin Greater Than 12 g/dL

Patient-Informed Consent for Anemia Treatment

A Kt/V measure for adult hemodialysis patients

A Kt/V measure for adult peritoneal dialysis patients

A Kt/V measure for pediatric hemodialysis patients

An arterial venous fistula measure

A catheter measure

Hypercalcemia

NHSN Bloodstream Infection in Hemodialysis

Outpatients

Quality Incentive Program, Proposed Measures

Reporting Measures (25% weight, each worth 5 points)

Anemia Management

Pediatric Iron Therapy

Mineral Metabolism

Patient Satisfaction Survey

Comorbidity

Quality Incentive Payment Program

- Currently, CMS measures quality of the following include anemia management, dialysis adequacy, patient satisfaction, iron management, bone mineral metabolism, and vascular access.
- Facility-level scores are publicly reported on-line and posted within dialysis facilities.
- Across all measurements of quality indicators, it appears that the new payment system improved most quality metrics or they were stable.

Facility Reimbursement vs. Physician Reimbursement

- Separate reimbursement for physicians and facilities is common in the Medicare fee-for-service program.
- Aligning incentives between facilities and physicians is critical.

Facility Reimbursement vs. Physician Reimbursement

- Physician services are not a part of the ESRD facility prospective payment.
- Medicare pays for dialysis-related physicians' services on a capitated basis, called the monthly capitation payment (MCP).
- The MCP is paid to a designated physician who is responsible for supervising a patient's ESRD care. MCP physicians manage patients with chronic renal failure by conducting assessments and care planning, monitoring laboratory results and the adequacy of dialysis treatment, and managing anemia and other conditions secondary to chronic renal failure.

Facility Reimbursement vs. Physician Reimbursement

- The MCP does not cover physicians' services unrelated to dialysis such as surgical services (repair of existing accesses) or interpretation of tests that have a professional component (e.g. electrocardiograms).
- Such services are separately billed by the physician who furnishes such services.

Cost Structures of PD and HD

Implications for a bundled payment system

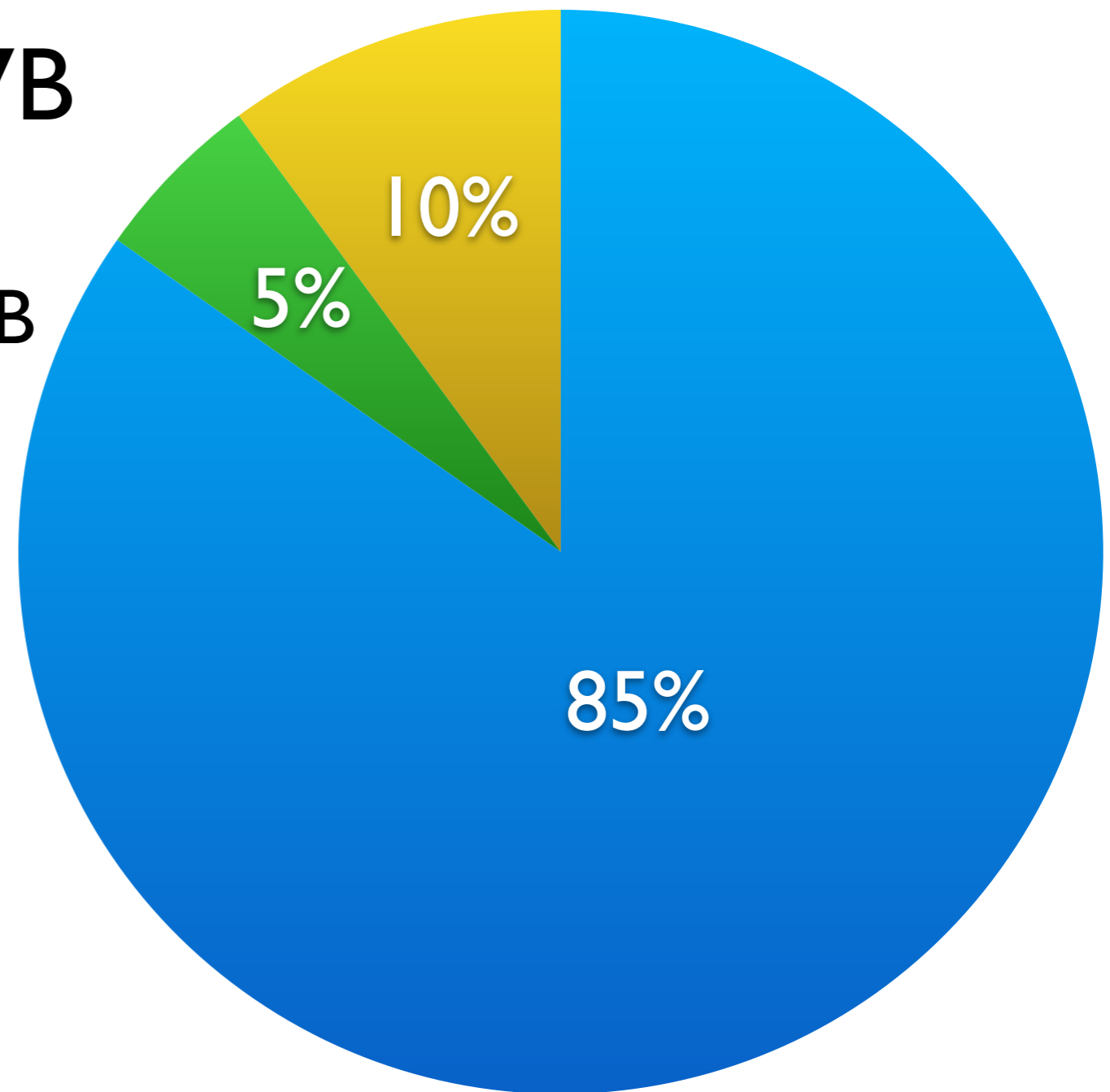
- On a per person per year basis PD is about \$6,000-\$7,000 less costly for outpatient service in a matched population
- ESA dosing is 40% less costly
- IV iron dosing is 80% less
- IV Vitamin D is 98% lower with few PD patients receiving this therapy

Medicare ESRD Spending, 2011

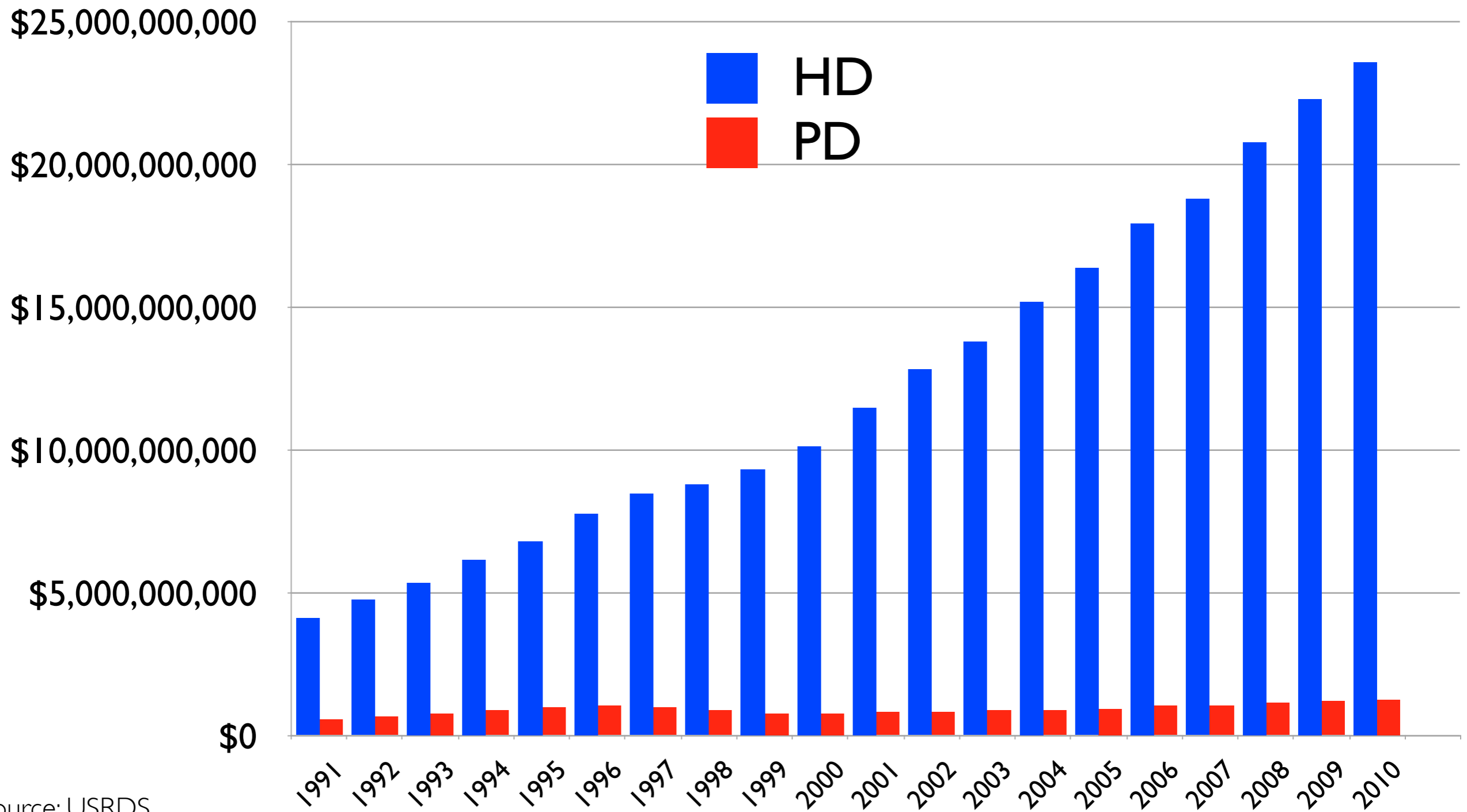
Total Spending = \$28.7B

- Hemodialysis - \$24.3B
- Peritoneal Dialysis - \$1.47B
- Transplant - \$2.9B

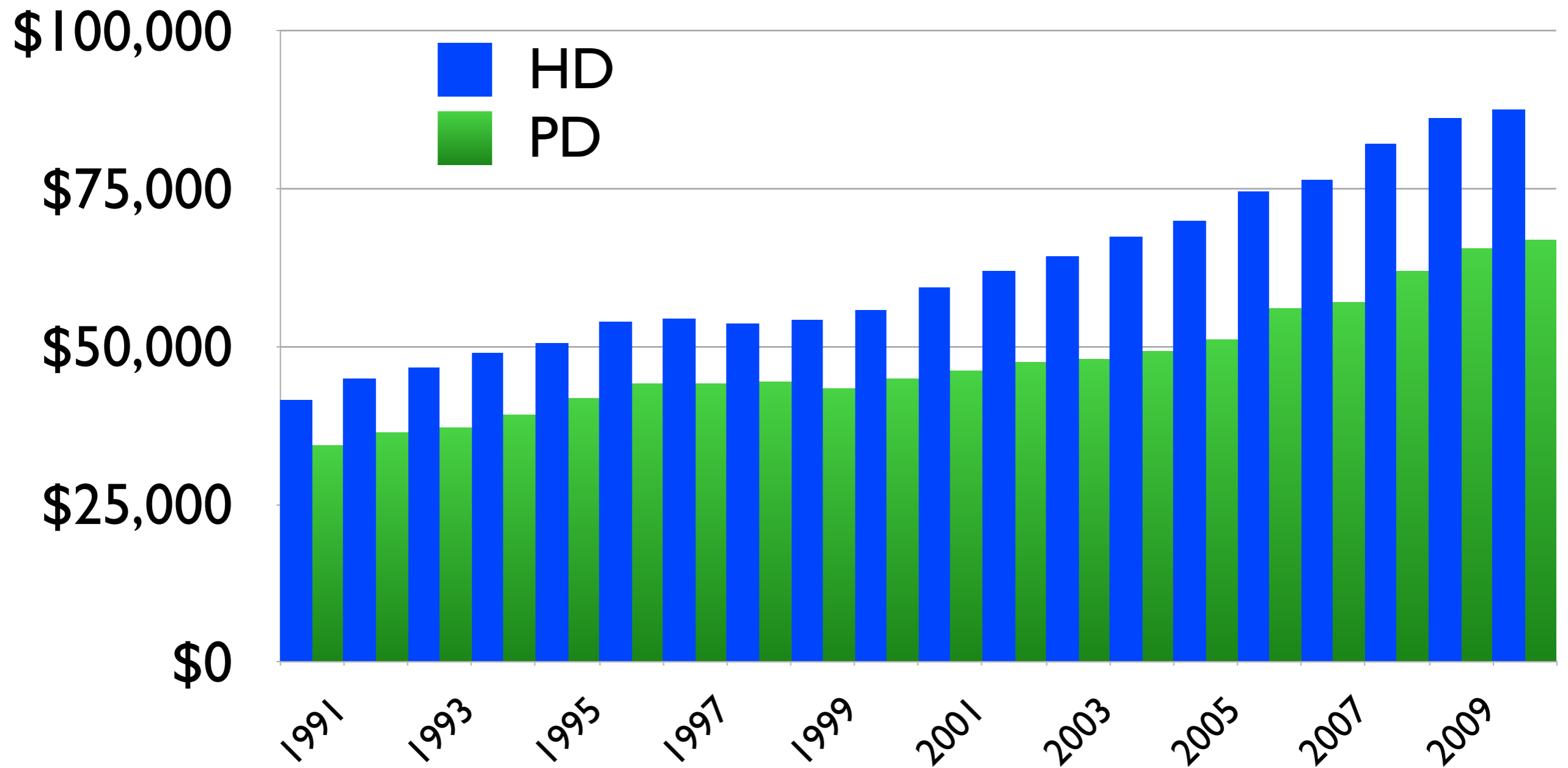
Per Person Spending
HD = \$87,945
PD = \$71,630
Transplant = \$32,922



Total Medicare ESRD expenditures, by modality



Total Medicare Expenditures per person



Quality of Life Benefits for Home Dialysis

- Individuals on Home Hemodialysis have a quicker recovery time after treatment and have an increased opportunity for rehabilitation.
- PD patients experience fewer negative side effects, such as nausea and weight gain, and dietary restrictions than in-center patients.
- Reduced relative risk of death for PD versus inpatient hemodialysis has been improving, tending to favor those on PD for longer and longer periods of time.
- Infectious complications for PD been markedly reduced.
- Greater autonomy and flexibility over when a patient dialyzes.
- Reduced dependence on transportation.
- Higher rates of employment among home dialysis patients.

Home Dialysis, Training, & the Onset of Dialysis

- As of 2008 <8% of prevalent ESRD patients in the United States are treated with PD, a modality mix that is significantly different from what is seen in other developed countries.
- Data suggest that the reasons for this seem to be caused by non-medical-related issues such as subtle differences in practice patterns and unintended financial considerations.
- It is anticipated that changes in government reimbursement, such as the bundling of dialysis-related services, will stimulate a renewed interest in home therapies.
- Currently most home dialysis units are small, and some have minimal clinical experience with PD.

Changes to Medicare Reimbursement of ESRD Services: What outcomes?

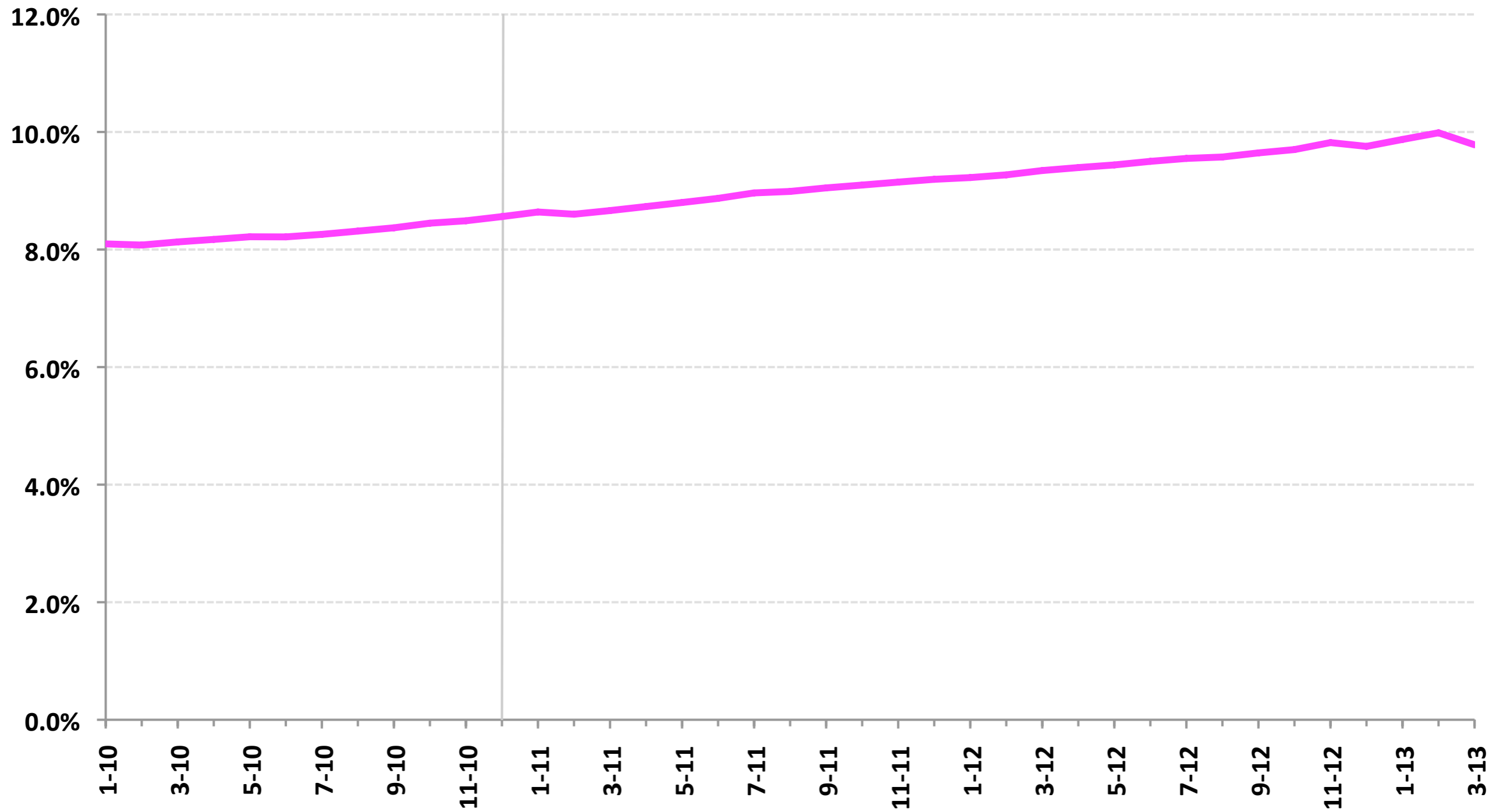
- Between 2009 and 2011 HD treatment billing increased 7.7%, however, PD treatments increased 16.8%.
- The percent of ESRD beneficiaries utilizing home dialysis steadily increased from a monthly average of 8.3% in 2010 to 8.9% in 2011, 9.5% in 2012, and 9.9% in 2013 Q1.
- The percent growth in PD was double compared to HD under the new Bundled payment system.

Utilization of PD

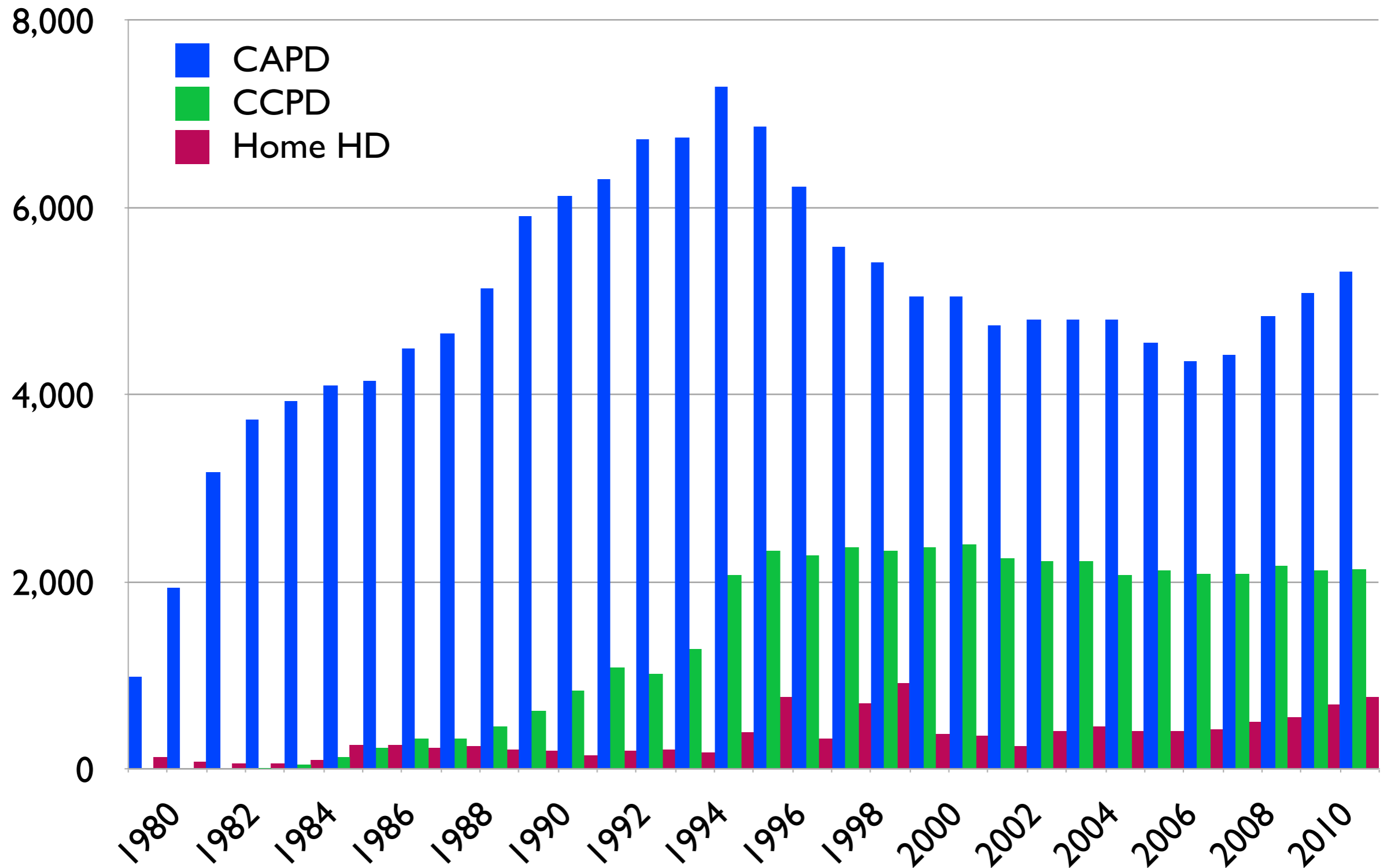
- Medicare's recent changes to the ESRD payment bundle and other regulations have been successful in promoting "patient independence and use of home dialysis whenever appropriate..." as the most recent data indicates it has led to an increase in the utilization of PD.
- An annual survey of the 10 largest providers found that between 2010-2012, home patients represented about 20% of the growth in ESRD patients, largely attributed to the growth in PD.

Percent of ESRD Beneficiaries Dialyzing at Home, by Month

Population: All ESRD Beneficiaries
Claims Processed by June 28, 2013



Home Dialysis by Therapy Type



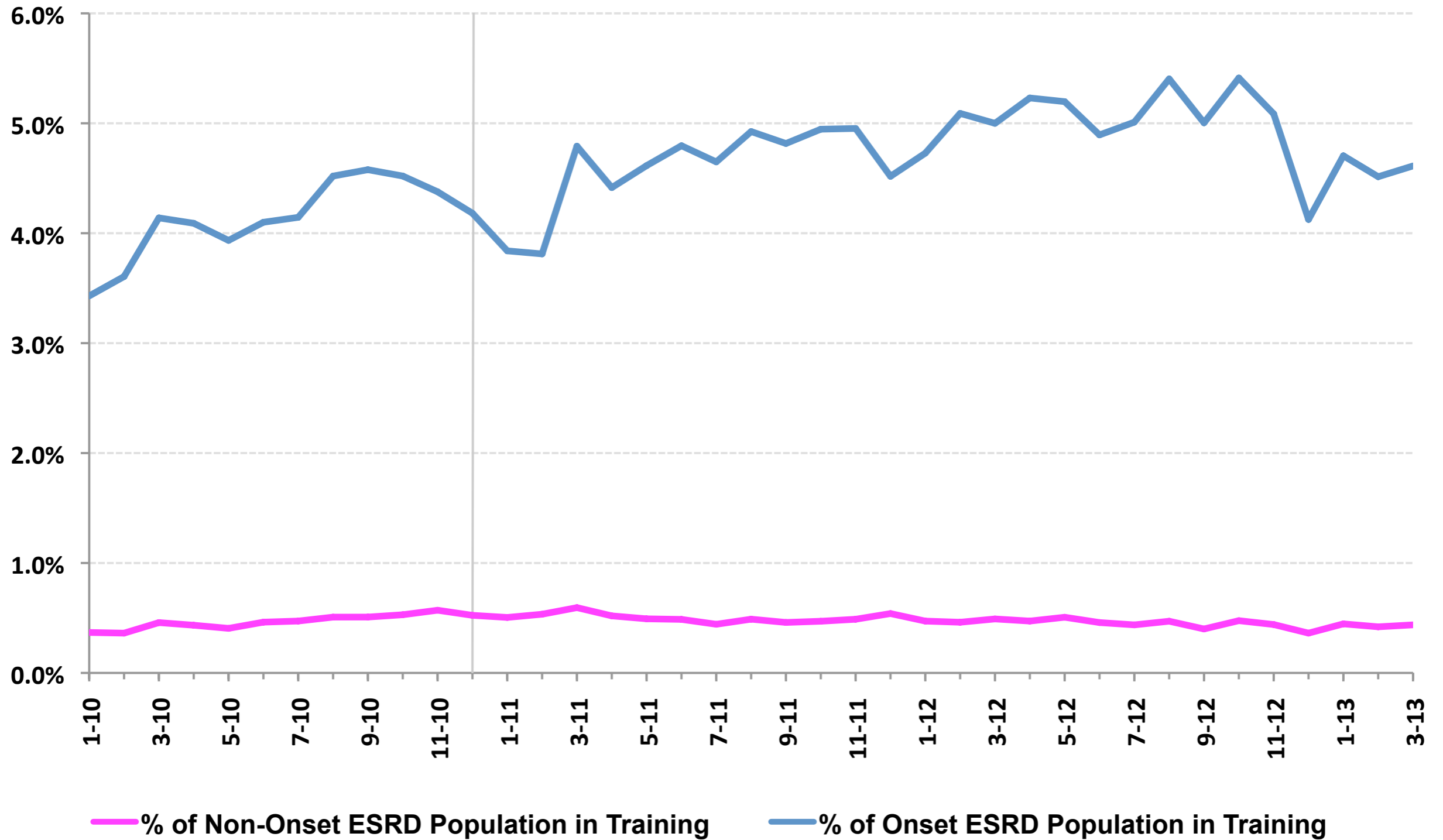
Importance of Training

- Data reveal that beneficiaries in onset undergo home dialysis training and transition to home dialysis at rates that are higher than rates among the non-onset population.
- Multiple U.S. studies demonstrate that when educated about the option, 40-50% of patients choose home dialysis.

Percent of ESRD Beneficiaries Participating in Home Training, by Month

Population: All ESRD Beneficiaries

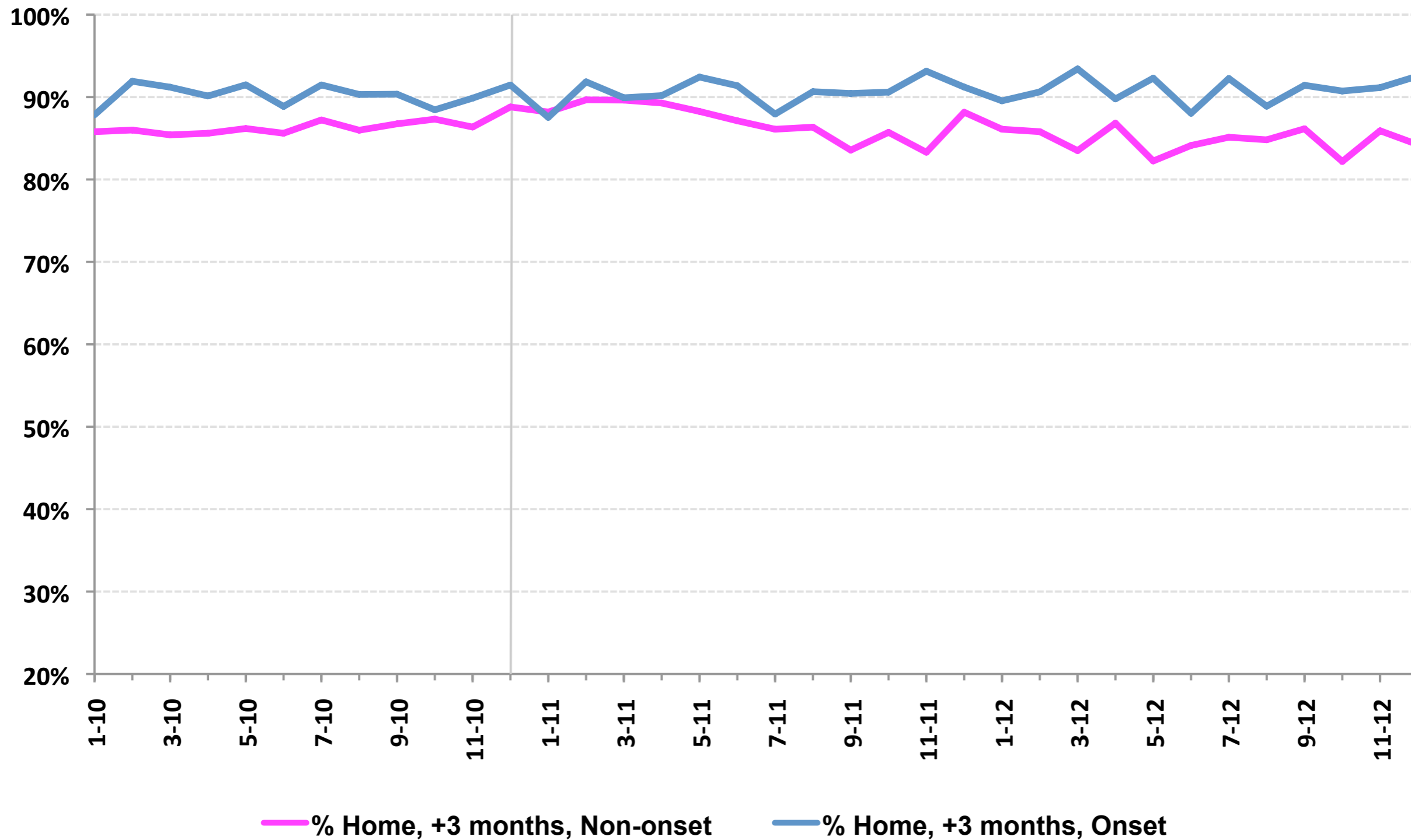
Claims Processed by June 28, 2013



Percent of Training ESRD Beneficiaries Participating in Home Dialysis after Three Months

Population: All ESRD Beneficiaries

Claims Processed by June 28, 2013



Utilization of PD

- While there has been momentum in recent years to increasing utilization of PD, data suggests that barriers still remain for optimizing the availability and utilization of HHD.
- Additionally, utilization of home dialysis varies widely by region and there are significant disparities by race.
- The current utilization rate suggests that there are an array of systematic barriers may be hampering efforts to optimize utilization of home dialysis for those patients who are appropriate candidates.

Accessibility

Barriers to expanding PD: Lack of patient awareness of home dialysis and limited number of providers that are trained and well-versed in home dialysis. Therefore -

- Support mentoring programs, particularly those that use existing patients as mentors
- Develop competency measures and benchmarks for PD within physician training programs to include in certification requirements
- Explore regionalization and partnership opportunities to bring economies of scale to home dialysis clinician training and patient services

Accountability

- Utilization can be improved through measures that are specifically designed to recognize and support excellence in the delivery of home dialysis services.
- Enforce existing Medicare Conditions for Coverage requirement to provide education on all modalities in a way that patients can understand
- Develop and adopt appropriate quality measures for home dialysis, including patient satisfaction measures specific to home patients

Align Incentives

Ensure that the reimbursement environment is aligned to support this underutilized treatment option.

- Maintain reimbursement parity for home and in-center dialysis in the ESRD Prospective Payment System
- Increase home dialysis training adjustment payment
- Update tracking and reimbursement codes for home hemodialysis
- Support more frequent home hemodialysis payment under Medicare
- Evaluate payment across the care continuum (primary care, surgeons, hospitals, nephrologists) to ensure incentives are properly aligned for home dialysis
- Advance demonstration programs for alternative payment methodologies for home dialysis

Align Incentives

Ensure that the Regulatory environment is aligned to support home dialysis

- Align federal and state regulatory requirements for home therapies, such as revising Medicare Conditions for Coverage requirements, to reflect differences in home and in-center dialysis

Summary

- CMS has worked to modernize the payment for ESRD by incorporating more goods and services into the bundles payment made to ESRD facilities
- The result has been a decrease in per patient reimbursement, in large part because of reduced use of common dialysis drugs.
- The quality indicators show general improvement or status quo relative to the prior payment system.
- There has been an increase in PD, largely because facilities are compensated the same amount as they are for HD, but costs are likely to be less.
- There still remain barriers to a greater uptake in PD.

Questions?

