

ESRD Payment policy changes: The New “Bundled” Dialysis Prospective Payment System (PPS) in the United States

Allan J. Collins, MD, FACP
Professor of Medicine
University of Minnesota

Director, United States Renal Data System
Coordinating Center

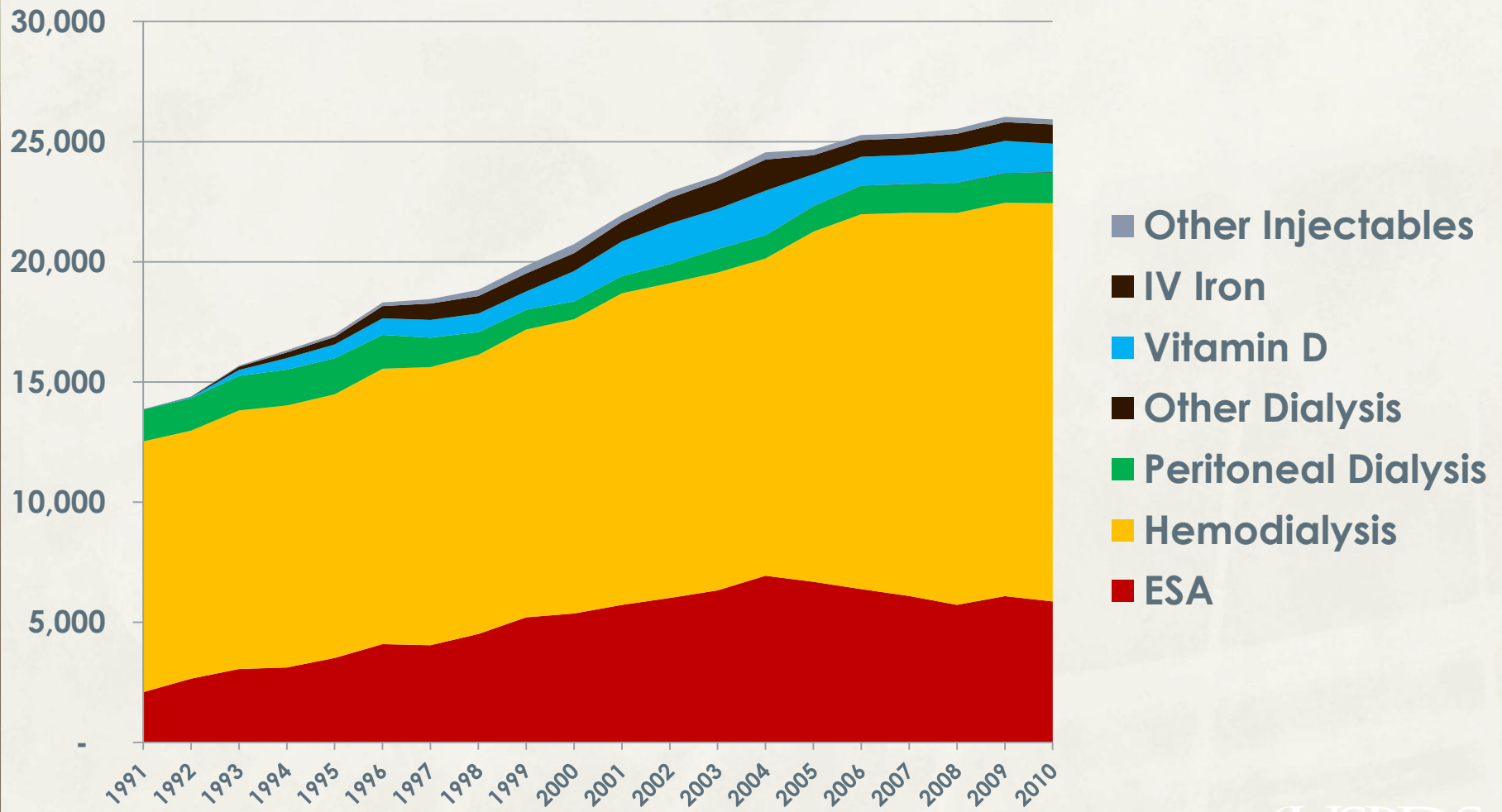
Disclosures

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- Epidemiology consulting: Takeda, NxStage, Amgen, Merck, Affymax, GSK, Reata, Abbott

Health Care policy for ESRD in a time of economic challenges

- The prevalent US dialysis population was 400,000 in 2009 growing at 3-4% per year
- The increasing dialysis costs led Congress to mandate payment reform with updating of the Composite Rate Bundled payment first introduced in 1983.

Expenditures Per Person Per Year for dialysis services



The New CMS “Bundled” payment system- key elements (January 1, 2011)

- The new CMS payment system pays one amount of money per person per treatment for all dialysis, EPO, Vitamin D, IV iron, all ESRD lab tests and oral medications with IV equivalents
- The new Bundle builds on the same principles that led to the original “Composite Rate” dialysis payment introduced in 1983.

Dialysis Bundle payment: old vs new

- Old bundled system

- Dialysis procedure labor & supplies (HD/PD paid the same)
- Monthly routine labs: K, Ca, PO₄, Creat, CO₂, AST, BUN, KT/V, CBC, INR

- Outside Bundle

- Injections: ESAs, IV Fe, IV Vitamin D, Antibiotics, Carnitine
- All other lab tests for CVD, DM, risk factor monitoring, cultures, PRAs for Tx

- New Bundle with adjusters

- Same as old plus
- All dialysis labs done by nephrologists
- All injections included (ESAs, Vit D, IV Fe, Carnitine, Antibiotics, cultures)
- PO medications: Fe, Vitamin D
 - Sensipar and phosphate binders by 2014

Medicare Bundled Dialysis Prospective Payment System: components (for 2011)

- Total dollars on all dialysis services divided by the total number of Medicare HD (PD)-equivalent sessions in CY2007 and adjust for CY2011 prices = \$251.60 per treatment
- Reduce by 5.94% to account for average case-mix adjustment = \$236.68 per treatment
- Reduce by 1% to create outlier payment pool = \$234.31 per treatment
- Reduce by 2% per MIPPA for budget neutrality = \$229.63 per treatment

Adjusters to Base payment: \$229.63/Trt

- Low volume adjustment: 1.202
 - <4000 treatments x 3 years
- Onset of dialysis ≤ 4 months: 1.51
- Acute: current month + 3 months
 - Pericarditis: 1.114
 - Bacterial pneumonia: 1.135
 - GI bleed with hemorrhage: 1.183
- Chronic† added on the current month until death or Tx
 - Hereditary hemolytic or sickle cell anemias: 1.072
 - Myelodysplastic syndrome: 1.099
 - Monoclonal gammopathy: 1.024

Cost structures of PD and HD: Implications for a bundled payment system (USRDS 2011 ADR, Matched HD and PD Cohorts)

- On a per person per year basis PD is about \$6-7000 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

USRDS Special Study: Assessing the New CMS Dialysis Bundled Payment System

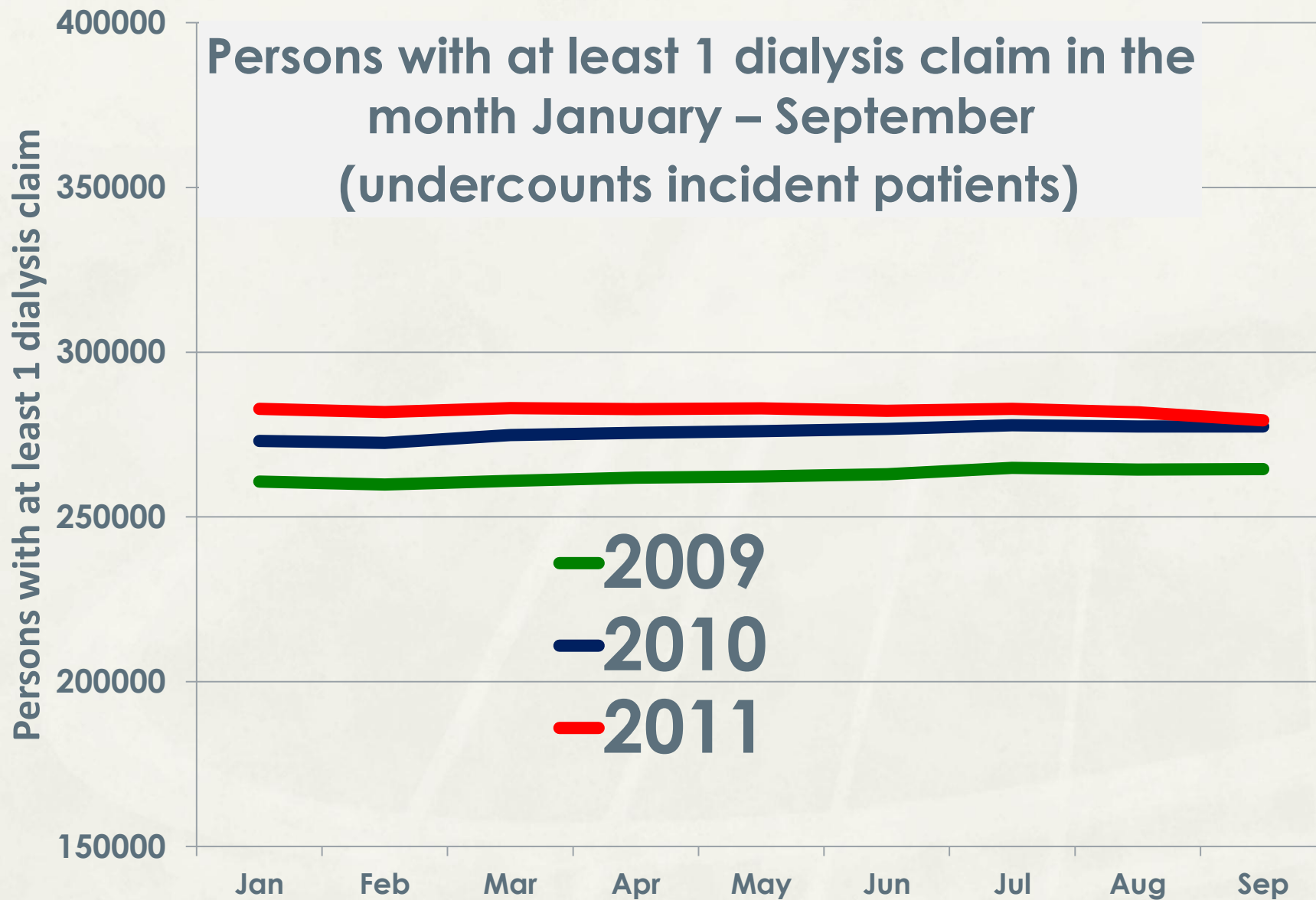
- Special Study from early data available within a current year after the first nine calendar months: 2011 CMS quarterly SAFs (QSAFs)
- Finder file generated from the quarterly SIMS/Crown Data submitted by networks/dialysis providers (4th quarter)
- The finder file is cumulative throughout the year capturing prevalent patients as well as incident patients from submitted ME Form 2728s (delays in submitted ME Forms need to be considered).
- The data starts with a claim level definition to determine dialysis patients

Switching to the New Bundled payment system- data thru June 2011

- 96% of providers that use EPO switched to the bundled payment system
- 76% of providers that use DPO switched to the bundled payment system
- EPO doses decreased 19.2% in the first 9 months of 2011 vs same period in 2009
- Mean Hb fell 3.8% from 2009 (11.39 gm/dl) to first nine months of 2011 (10.96 gm/dl)
- 3% increase in Patients using IV iron

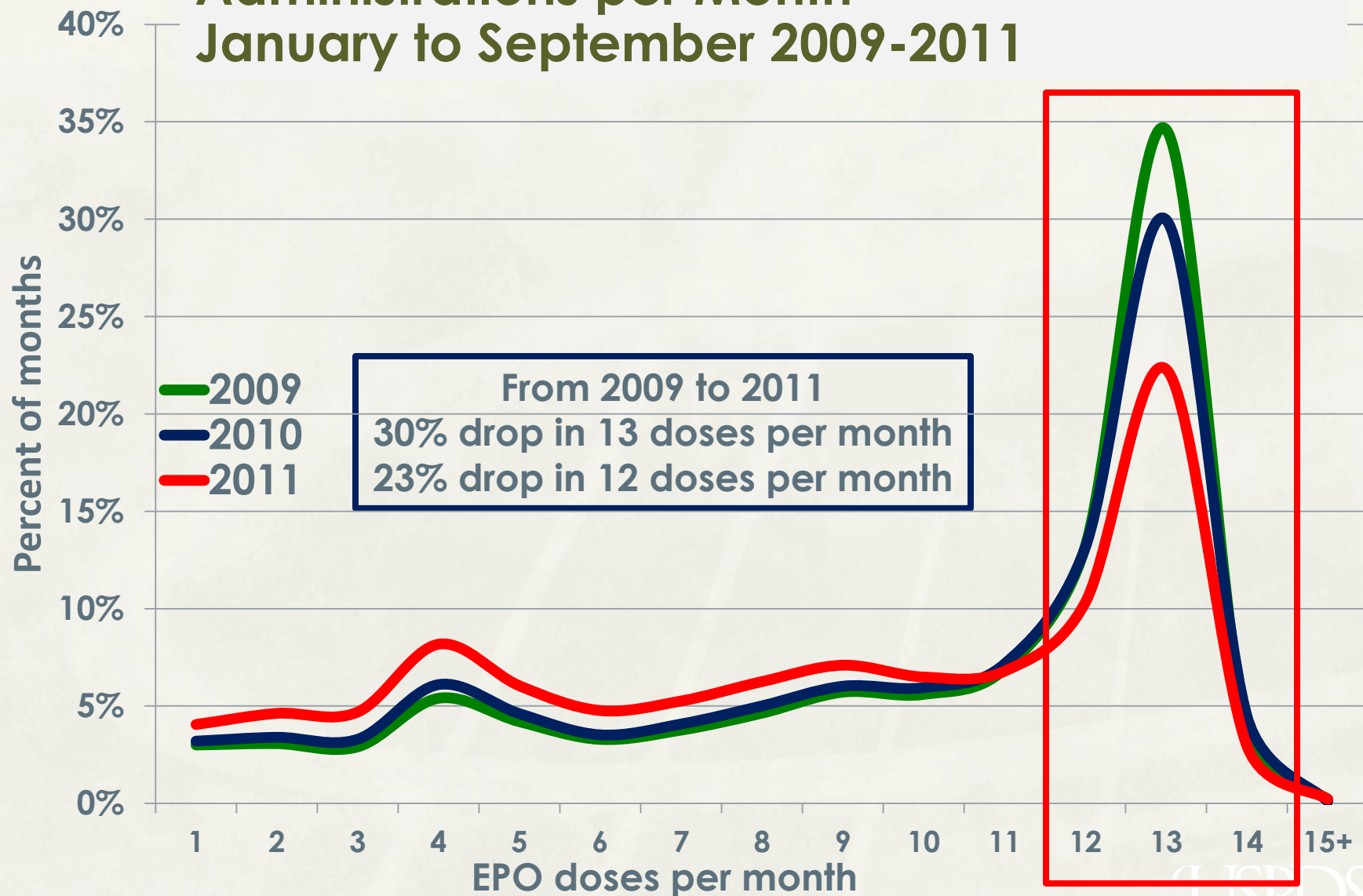
Switching to the New Bundled payment system-2

- HD treatment billing increased 7.7%, however, PD treatments increased 16.8% between 2009 and 2011
- Therefore, the percent growth in PD was double compared to HD under the new Bundled payment system.

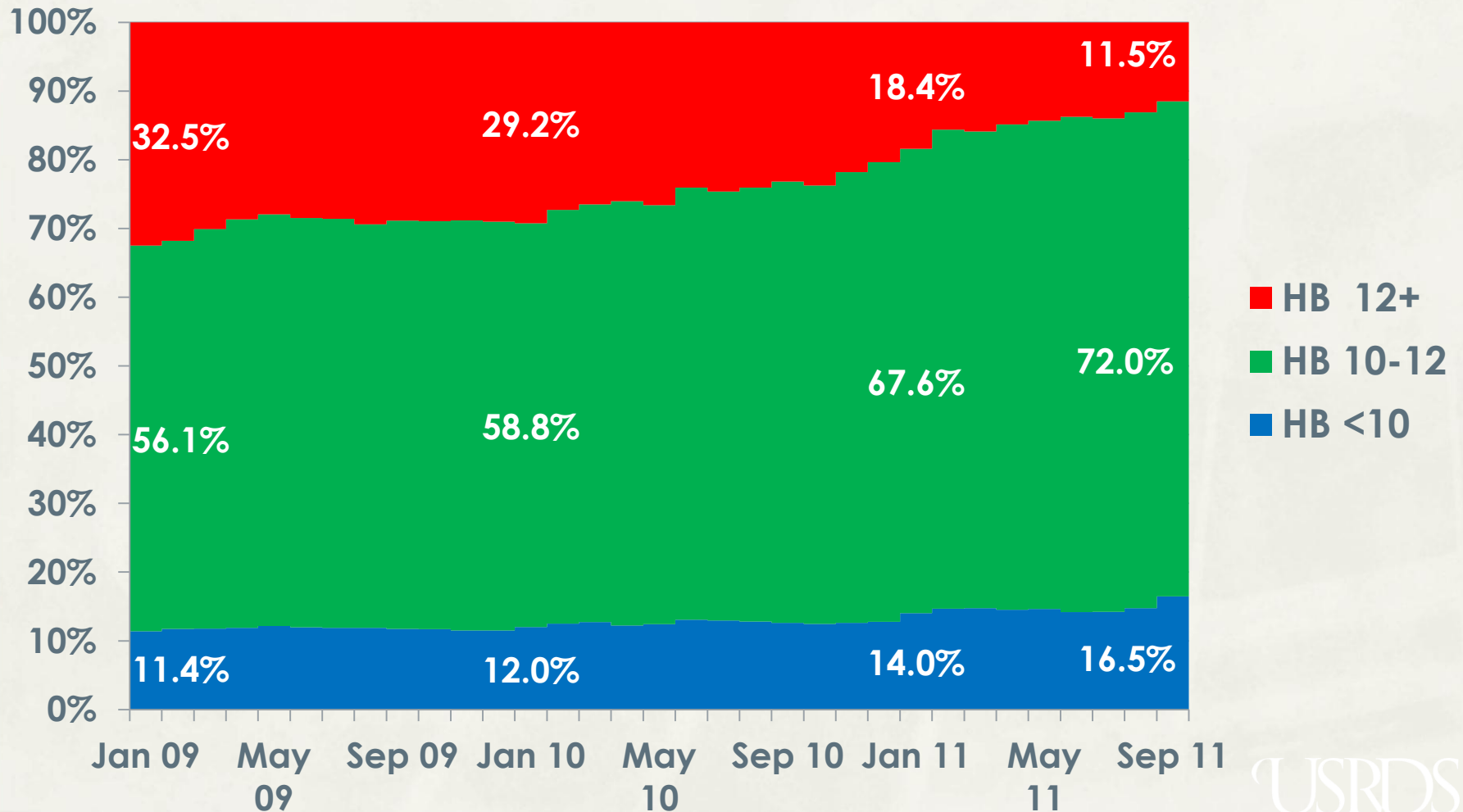


***2011 QSAFs, finder file 4th quarter 2011**

% of Patients by the Mean Number of EPO Administrations per Month January to September 2009-2011



Hb Distribution before and after the New Bundled Dialysis Payment System

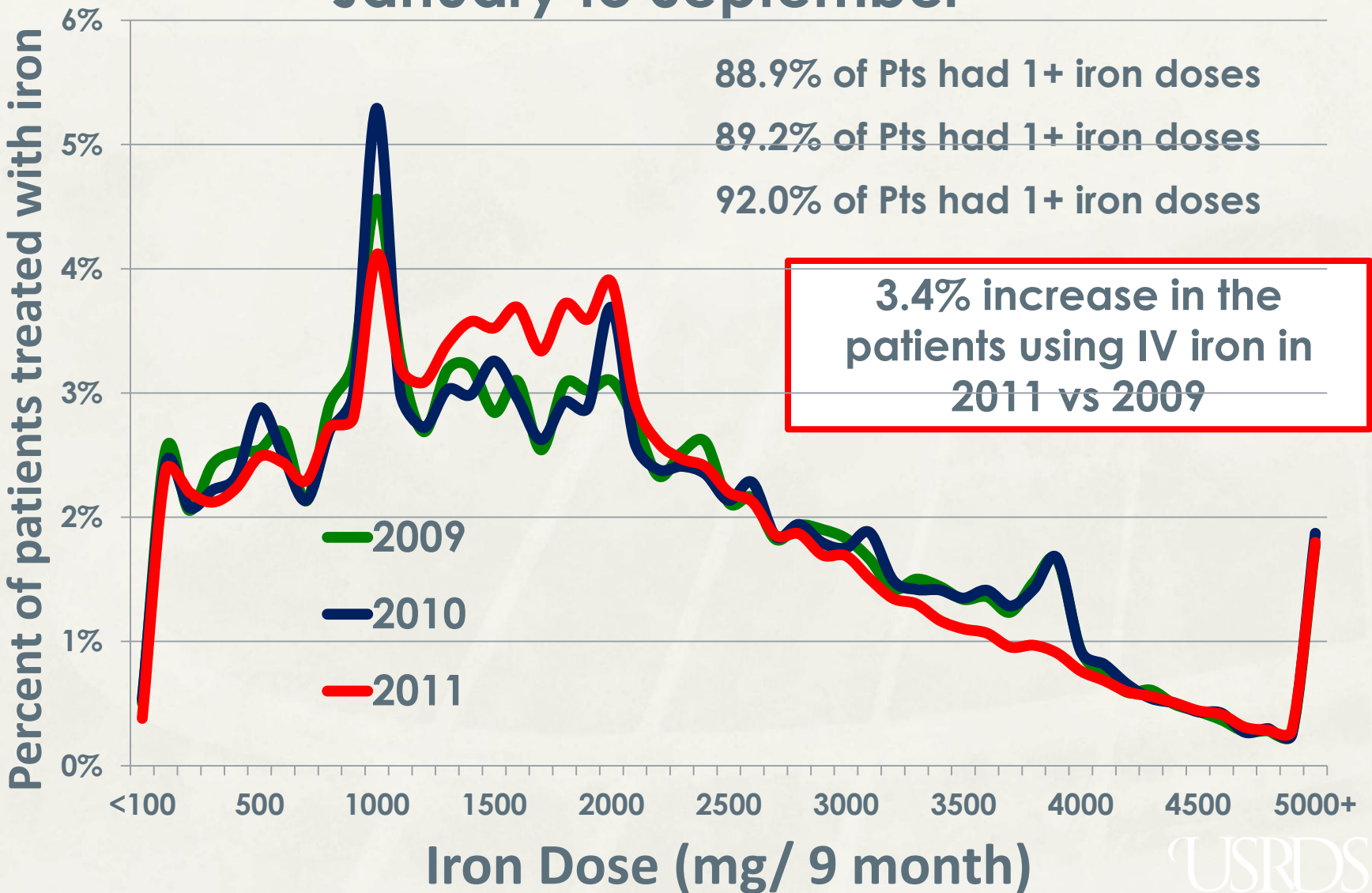


Distribution of Dose of IV Iron January to September

88.9% of Pts had 1+ iron doses

89.2% of Pts had 1+ iron doses

92.0% of Pts had 1+ iron doses

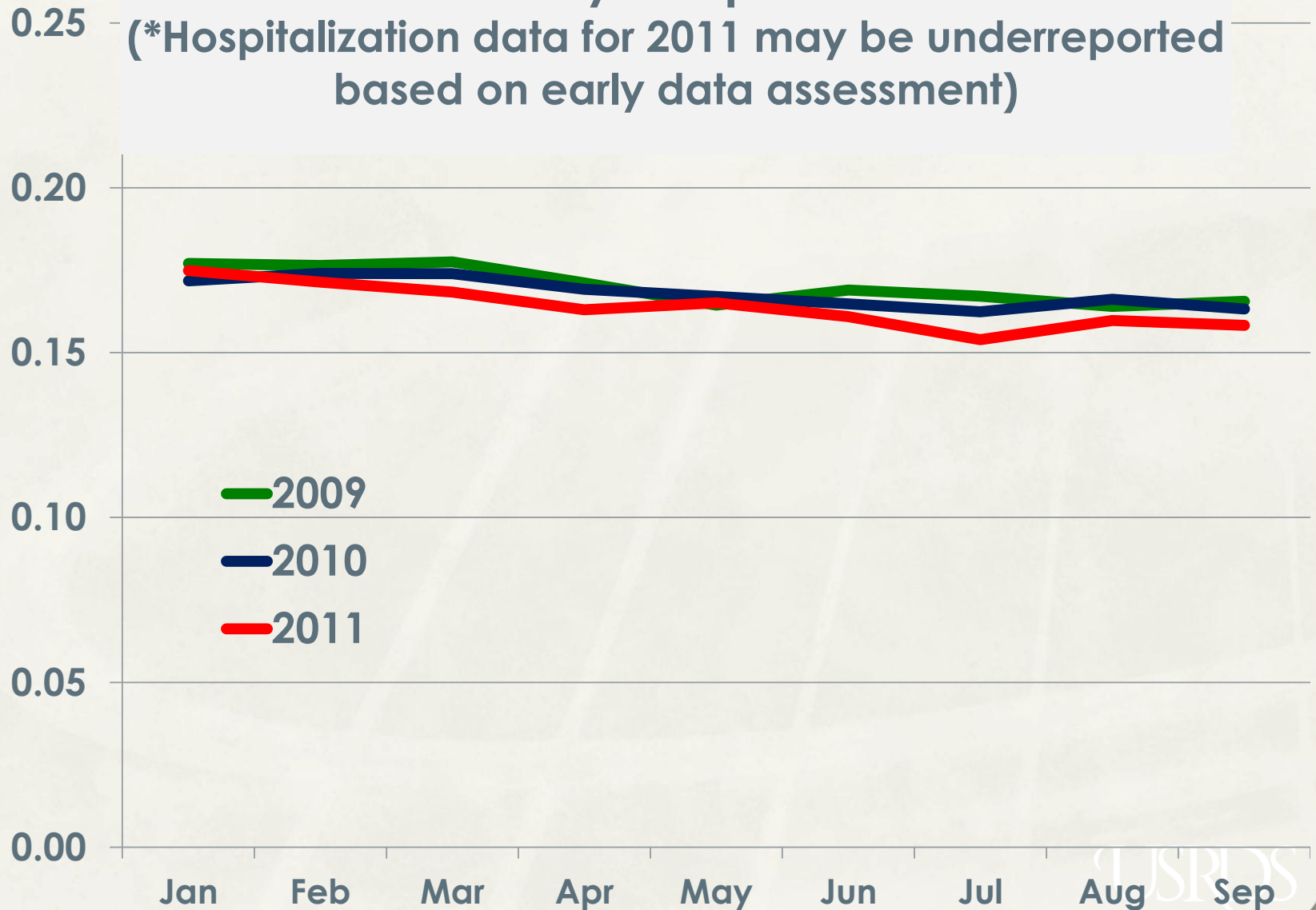


Monthly Admission Rate*

January - September

(*Hospitalization data for 2011 may be underreported based on early data assessment)

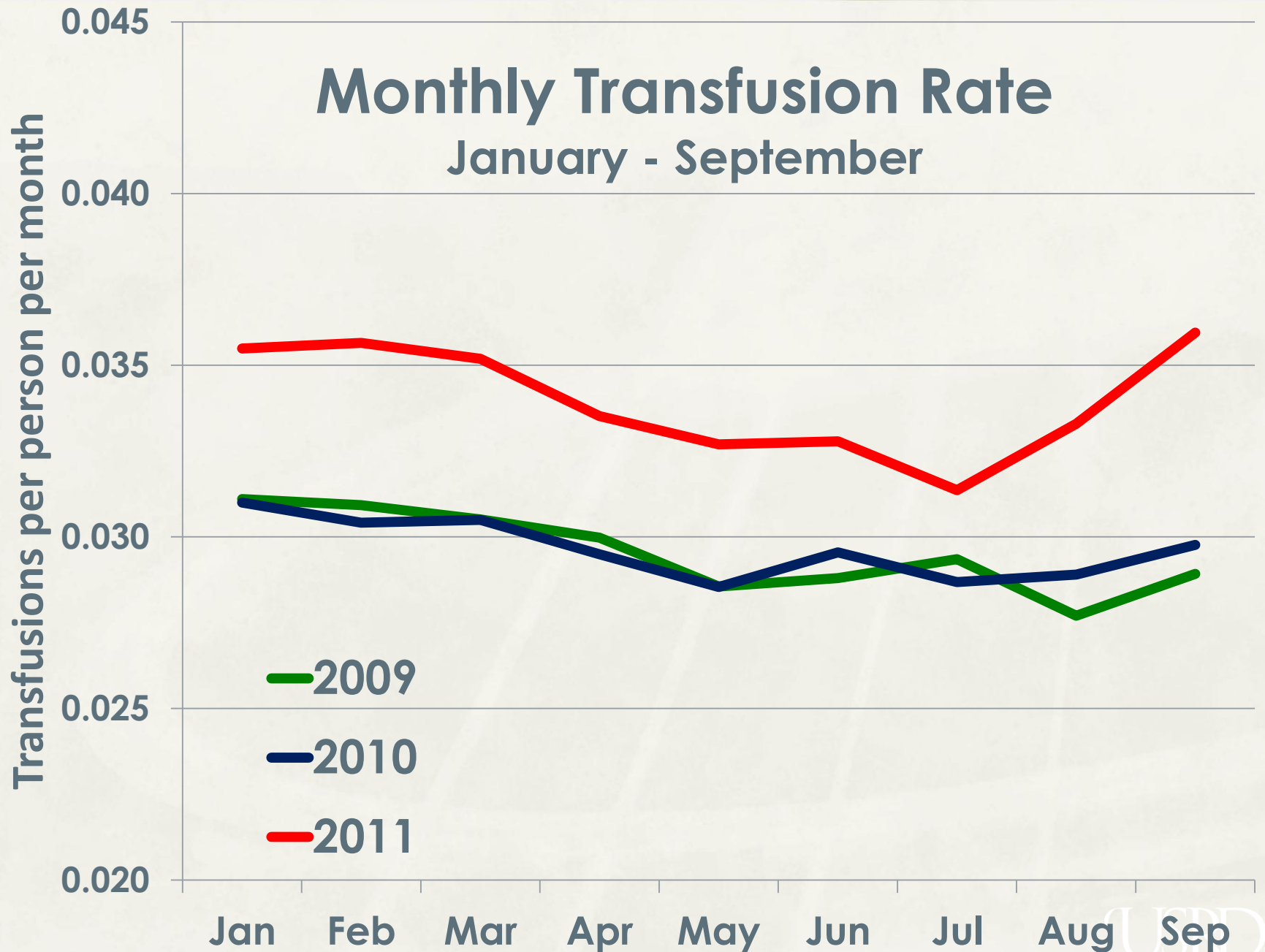
Admissions per person per month



- 2009
- 2010
- 2011

Monthly Transfusion Rate

January - September



Major changes under the new dialysis Bundled Prospective Payment System

- Providers adopted the new Bundled payment system (93+%)
- The use of peritoneal dialysis has increased
- ESA treatment has changed with reduced dosing and greater held doses in 2011 vs 2009
- Hb levels have fallen which is a continuation of changes noted under the new FDA labeling for ESA treatment over several years
- IV iron usage has increased

Assessing the New CMS Dialysis Bundled Payment System: Data Considerations

- Outpatient dialysis claims are paid on a timely basis based on rapid electronic submission from providers
- Data within 2011 needs to be validated for the potential for incurred but not reported hospitalization events
- Delayed hospitalization data may be vulnerable to slower claim submission for complex admissions.
- Transfusion data may be underreported based on most transfusion events occur during hospitalizations.

USRDS Special Study: Assessing the New CMS Bundled Dialysis Payment System

- USRDS will be receiving quarterly updates (QSAFs) for 2012 to assess ongoing changes after implementation of the new Bundled Payment System
- USRDS ASN presentation will focus on the transitions in care from 2009-2011
- The USRDS 2012 ADR will have data on the Bundle as well as Medicare Part D trends