RENAL ECONOMICS:
"THE BUNDLE" EXPLAINED

Facilities Prepare for 2011 and Beyond

J.G. BHAT, M.D.

ATLANTIC DIALYSIS MANAGEMENT SERVICES, L.L.C

RIDGEWOOD, NEW YORK 11385

Learning Objectives

- Understand the historical perspective of dialysis reimbursement system in the USA
- Understand the structure and rationale for the proposed Prospective Payment System for End Stage Renal Disease (ESRD)
- Understand the impact of the new system as it relates to care of patients with ESRD

Disclosures

- Research grants:
  - Amgen
  - Rockwell
- Speaker's Bureau:
  - Amgen
  - Genzyme
  - Roche

Disclosures

Dr. Bhat is a member of New York State Public Health Council. The views and opinions expressed today are his personal views and opinions and not to be construed as representing the New York State Public Health Council or Department of Health.

Four Important Questions

- How did we get here?
- Where are we now?
- What do we do now?
- Where do we go from here?

How Did We Get Here?

ESRD Program

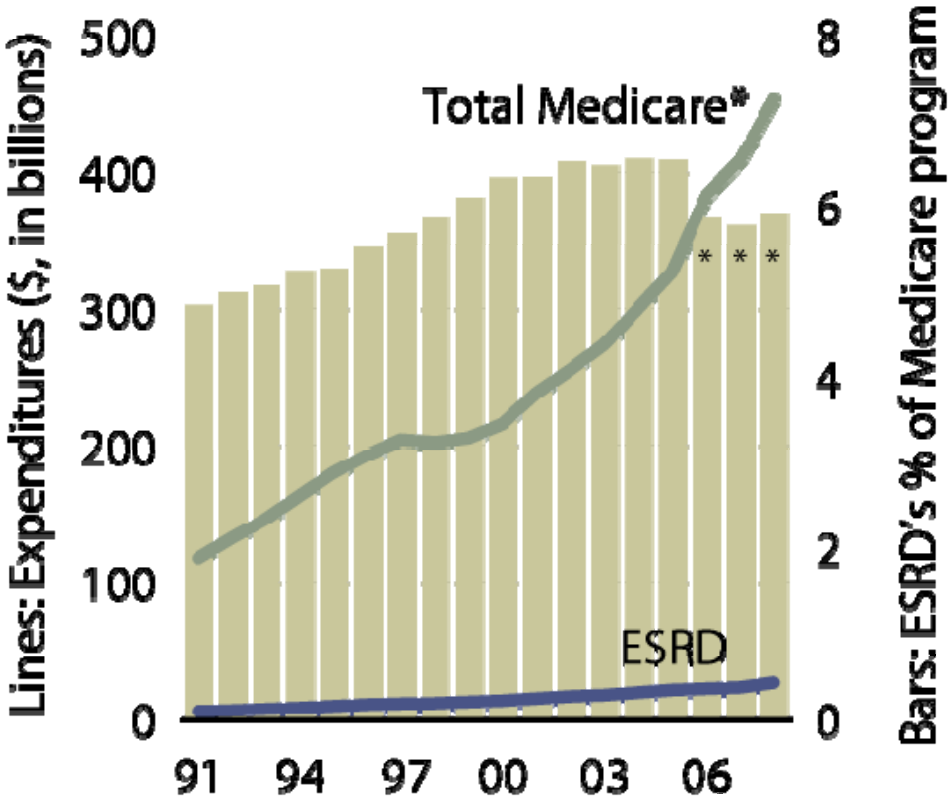
- The Social Security Act (1972) was amended (*section 2991 of Public Law 92–603, 1972 Amendments to the Social Security Act*) to extend all Medicare Part A and Part B benefits to all individuals with ESRD who are entitled to receive Social Security benefits.

- ESRD entitlement under Social Security Act is nearly universal, covering more than 90% of people with ESRD

- ESRD is the *only* health condition covered under Medicare in the absence of age over 65 or other disability

Costs of the Medicare & ESRD Programs

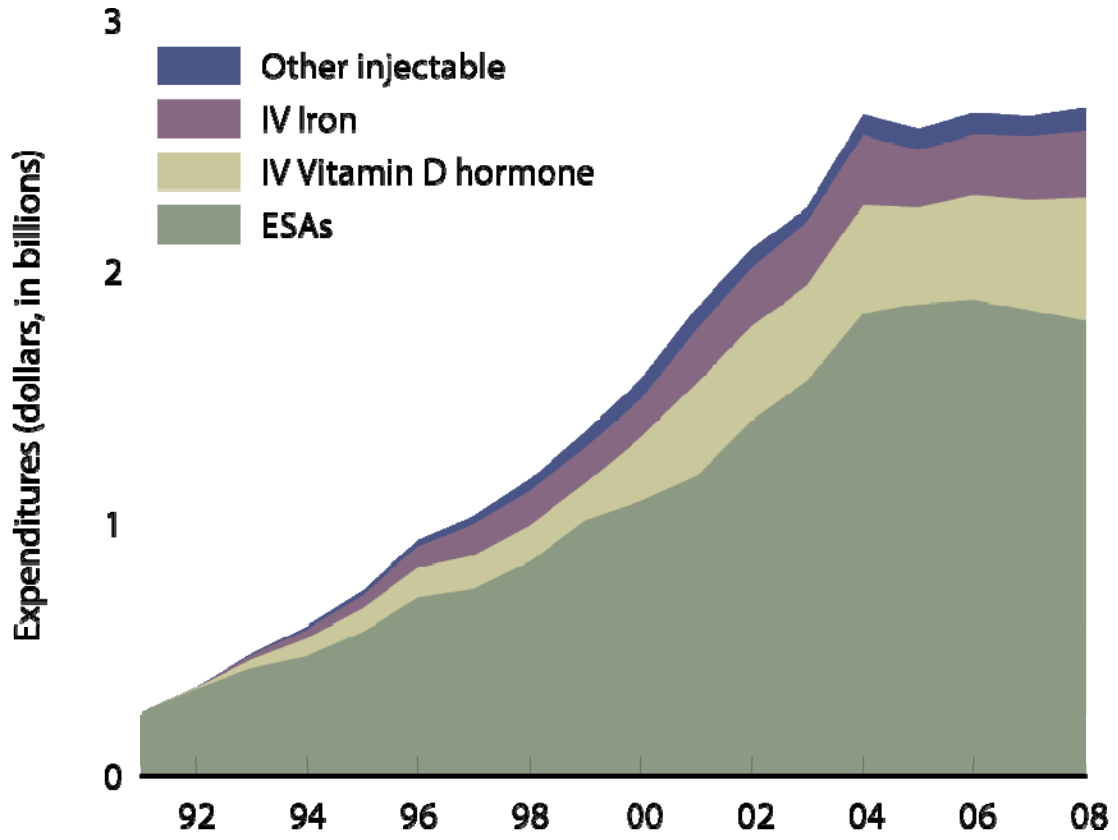
USRDS Annual Report 2009, Figure 11.2 (Volume 2)



Total ESRD expenditures are from paid claims (Table K.2) as well as estimated costs for HMO & organ acquisition. ESRD costs in 2008 are inflated by 2 percent to account for costs incurred but not reported. Total Medicare expenditures obtained from the CMS Office of Financial Management, Division of Budget. *Data for 2006-2008 include Part D amounts for total Medicare, but no Part D amounts for ESRD.

Total Medicare spending for injectables

USRDS Annual Report, 2009 - Figure 11.1 (Volume 2)



Period prevalent dialysis patients.. ESAs: erythropoiesis stimulating agents.

ESRD Payment System:

Inception and Evolution

- Early 1970s: Medicare approved $150 per dialysis treatment and paid 80% of this amount excluding physician fee

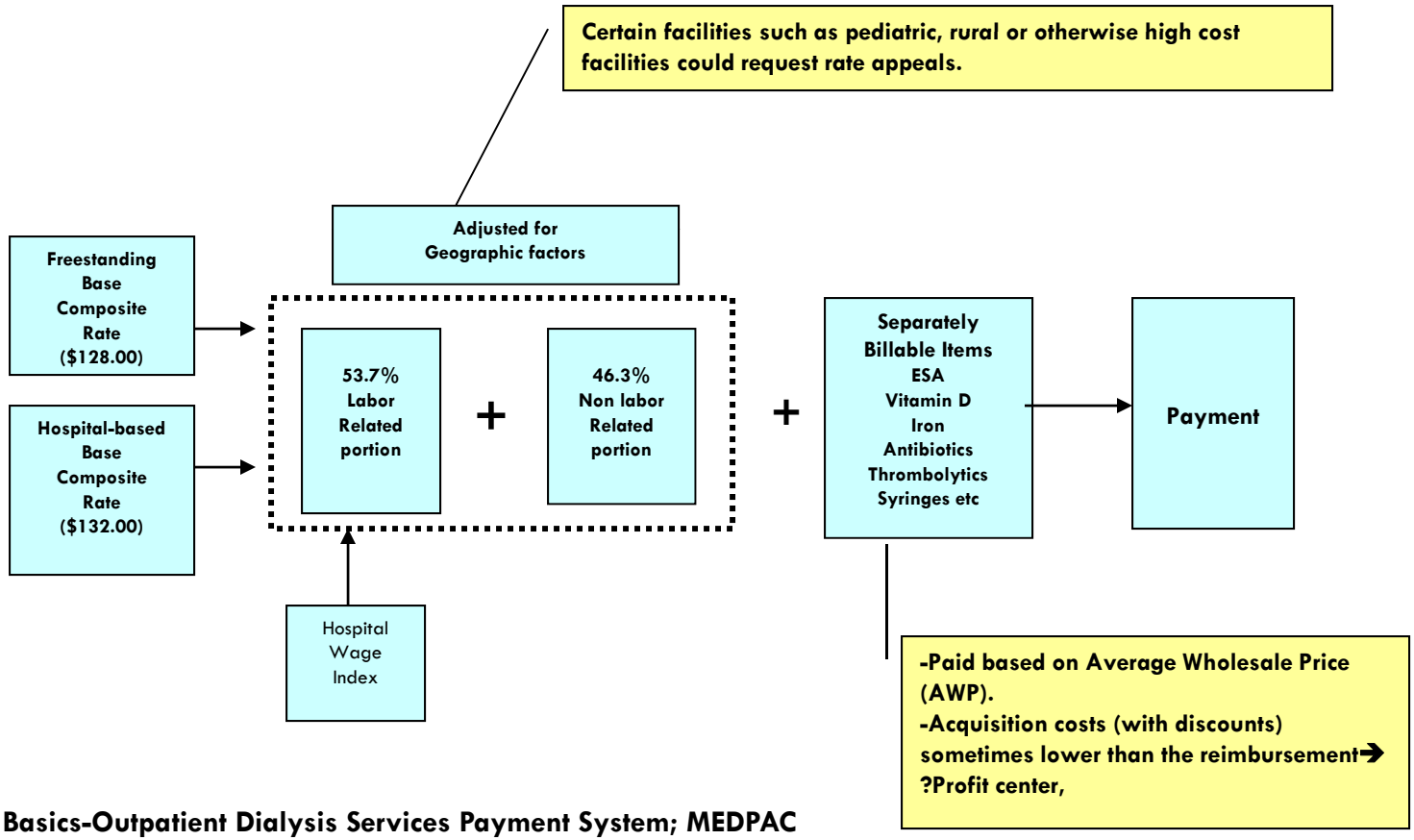
- 1983: Medicare introduced a Prospective Payment System (PPS) called Composite Rate for dialysis services
  - Covered the bundle of services, tests, certain drugs and supplies routinely required for dialysis treatment
  - This Composite rate was adjusted to account for differences in case mix and local input prices
  - Composite rate remained unchanged throughout 1990s with adjustments made to Epogen reimbursement and addition of other separately billable drugs

Current Composite Rate Payment System: Inception and Evolution

- No "automatic" adjustments to composite rate unlike other Medicare funded health services
- Each update of composite rate requires an "act of congress"
- From 1983 to 2003 there have been 5 adjustments to composite rate
  - 1986 -$2.00 and an additional -$0.50 to defray the cost of USRDS
  - 1991 +$1.00
  - 2000 +1.2%
  - 2001 +2.4%
  - 2004 +2.4%
  - 2006 +1.6%

Peter B DeOreo, Hemodialysis Horizons: Reimbursement for hemodialysis 29-33

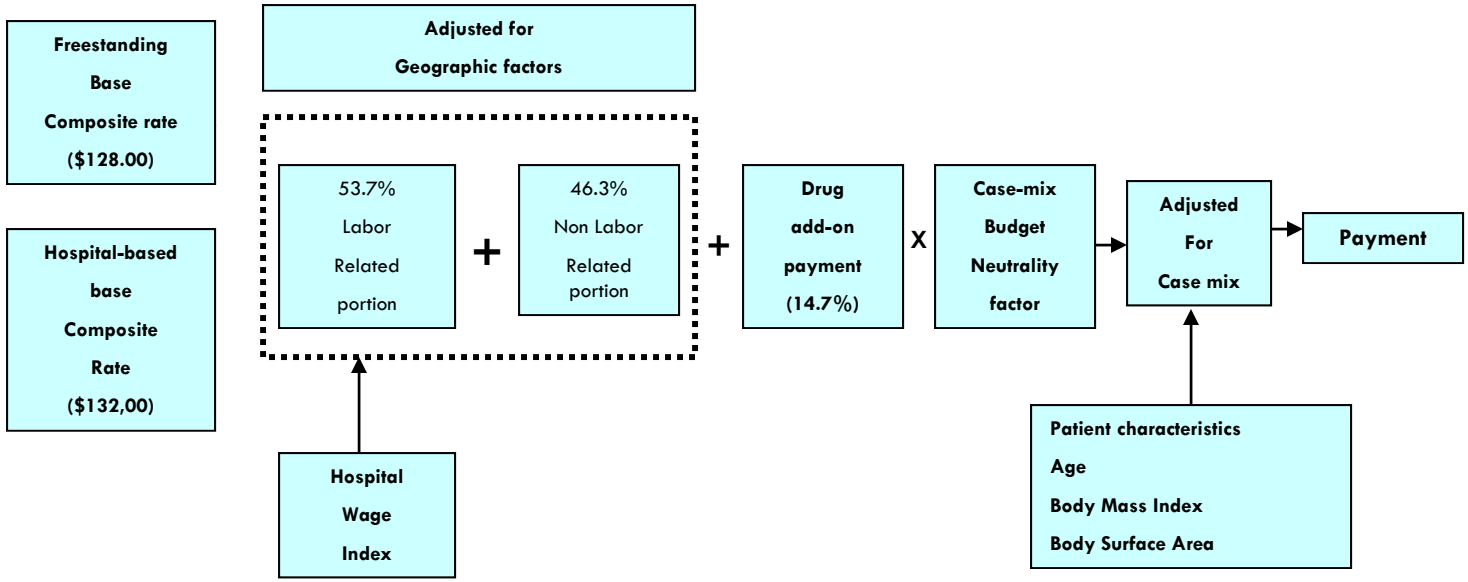
Anatomy of Dialysis Payments:
Circa 2005



Adapted from: Payment Basics-Outpatient Dialysis Services Payment System; MEDPAC

Anatomy of Dialysis Payments:

Dialysis Prospective Payment System in 2006



Adapted from: Payment Basics-Outpatient Dialysis Services Payment System; MEDPAC

Composite Rate: Definitions

Adapted from *Peter B DeOreo* : Dialysis Horizons: Reimbursement for hemodialysis

Composite Rate	Definition
Base	Established by Congress, it is the rate against which percentage increases (or decreases) are applied. Contains a labor and non-labor component. Initially 40%, the labor factor is increased to 53.7% in 2006. The hospital rate is $4 more than independent facility rate
Wage Adjusted	Results from applying an adjustment to the labor component of the base rate
Drug Add on Factor	Percentage increases to the Wage Adjusted Composite Rate that compensates for the difference between revenue obtained from facilities being paid 95% of the average wholesale price of ancillary drugs (EPO, iron etc.) and the reimbursement based on average sales price+6%
Budget Neutrality Adjustment	Only increases in the base composite rate can cause an increase in total Medicare spending for ESRD. All other adjustments must be budget neutral. Increases in one component will be matched by deceases in another component
Case mix Adjustment	An adjustment made to the Wage Adjusted CR with Drug Add on Factor composite rate for an individual patient based on demographics (age, body surface area and body mass index) thought to capture the cost of providing care to that patient

What is in the Base?

Everything except what can be billed separately

- Labor related: Wages, salaries, fringe benefits etc.
- Non labor related:
  - Occupancy costs: rent, utilities etc.
  - All dialysis supplies: dialyzers, saline, fistula needles, heparin, oral medications etc.
  - Waste management, reuse costs,
  - Routine labs such as monthly chemistries, hemoglobin,
  - Other allowed expenses

Wage Adjuster

- Estimated base payment represents national average without regard to case-mix adjustments where the wage index is equal to 1.0
- For geographic areas with higher or lower wage index values, the labor related portion of the base is multiplied by the wage index corresponding to the geographic location where facility is located

Drug Add on Factor

- In 2006, Medicare moved away from fixing the drug reimbursement based on AWP to ASP+6%
- This was an attempt to reduce the drug usage for profit, reimbursement rate was always higher than the AWP (with discounts)
- To offset the revenue loss from the spread between acquisition cost and reimbursement to facilities, Medicare proposed a drug add on factor

Budget Neutrality Factor

- ESRD Medicare spending can be increased only by increasing the base rate
- Increasing the base rate will require an act of Congress
- All other adjustments must be revenue neutral
- Increase in one component will be matched by equal decrease in another component/s.

Case Mix Adjusters, 2006:
Age, BSA and BMI

Age	Factor
< 18	1.620*
18 - 44	1.223
45 - 59	1.055
60 - 69	1.000
70 - 79	1.094
80 and above	1.174
* No BMI or BSA adjustment	
Body Surface Area (BSA) (per 0.1 m^2 change in BSA from national average of 1.84)	1.037
Low Body Mass Index (BMI) (< 18.5 kg/m^2)	1.112

Rationale for Case Mix Adjusters

- Based on the retrospective Medicare-claims based research done by University of Michigan Kidney Epidemiology and Cost Center (UM-KECC),
  - Facilities with a larger proportion of patients with a greater than average BSA, or with a BMI lower than 18.5 were found to have greater composite rate costs
  - When the reference age group (composite rate multiplier 1.000) was between the ages of 60 – 69, oldest ($\geq$ 80) and youngest ($\leq$ 44) patients incurred higher composite rate costs

HR 6331: Enter MIPPA

(Medicare Improvements for Patients and Providers Act of 2008)

- Requires "Bundling" of all costs for ESRD care into a single Medicare payment effective January 1, 2011
- Modernization of the payment system will remove incentives for facilities to overuse items and services that are currently separately billed.
- Protect patients while providing incentives for more efficient provider behavior, consistent with the philosophy governing many of Medicare's other payment systems.

MIPPA Highlights

- **Protects Patients with More Complex Needs.** The bill takes several steps to ensure proper care for Medicare beneficiaries with more complex needs.
  - First, the bill *requires* case mix adjustment, which adjusts payments upwards for more complex patients with higher costs of care.
  - Second, the bill *requires* additional reimbursement to help providers cover high-cost outlier patients.
  - Third, the legislation *requires* providers of ESRD services to meet a certain standard for quality of care.
- Providers may meet performance standards by demonstrating improvement or high levels of achievement.
- The bill authorizes cuts in payments to ESRD providers who do not meet specified quality targets

MIPPA Highlights

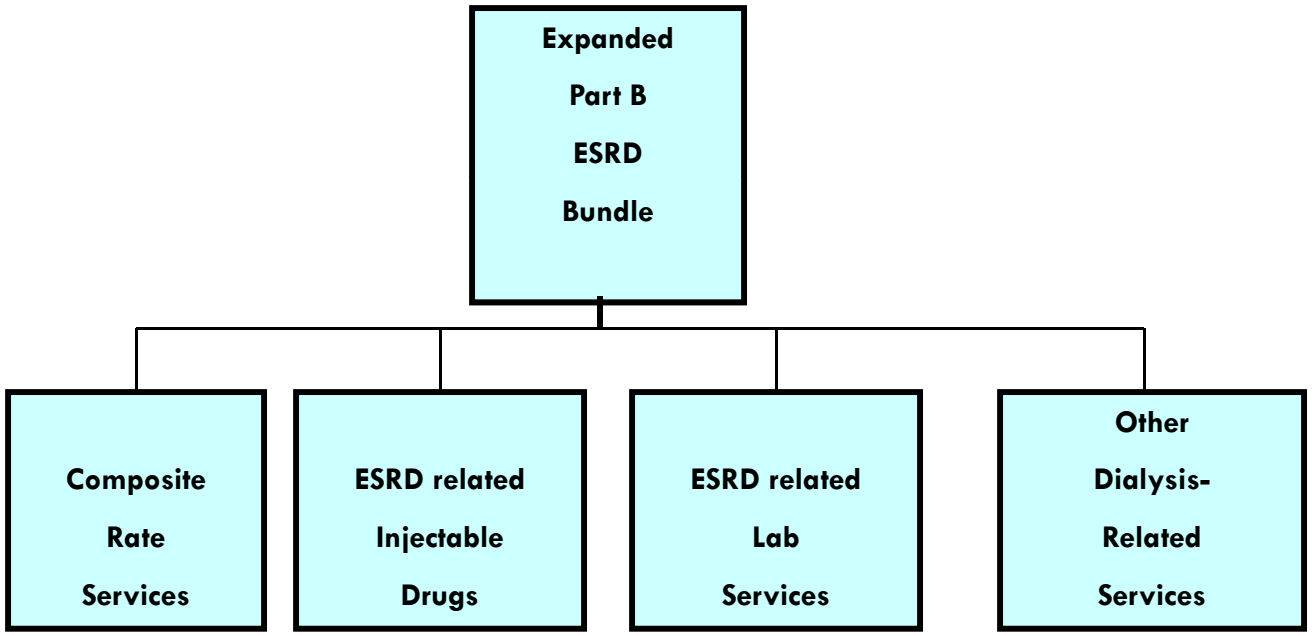
- **Increases payments to providers of ESRD services.**
  - The bill provides a permanent market-based update to providers of renal dialysis services.
  - The bill also takes additional steps to ease the transition to a bundled payment system, such as providing for a four-year phase-in and requiring additional payments for low-volume facilities.
  - In addition, MIPPA allows for extra payments to pediatric, rural, or other providers that may require additional resources to provide high-quality care to their patients.

MIPPA Highlights

- **Increases outreach and education programs for patients with kidney disease.**
  - The legislation requires the establishment of pilot programs to track, screen for, and increase awareness of chronic kidney disease.
  - It also requires Medicare to pay for kidney disease education services that will help beneficiaries manage health problems that come along with the disease, prevent additional complications, and understand their dialysis options.

Where Are We Now?

Proposed Expanded Bundle
As of January 1, 2011



Base Payment

Witch's Brew?

How did CMS Calculate Base Rate?

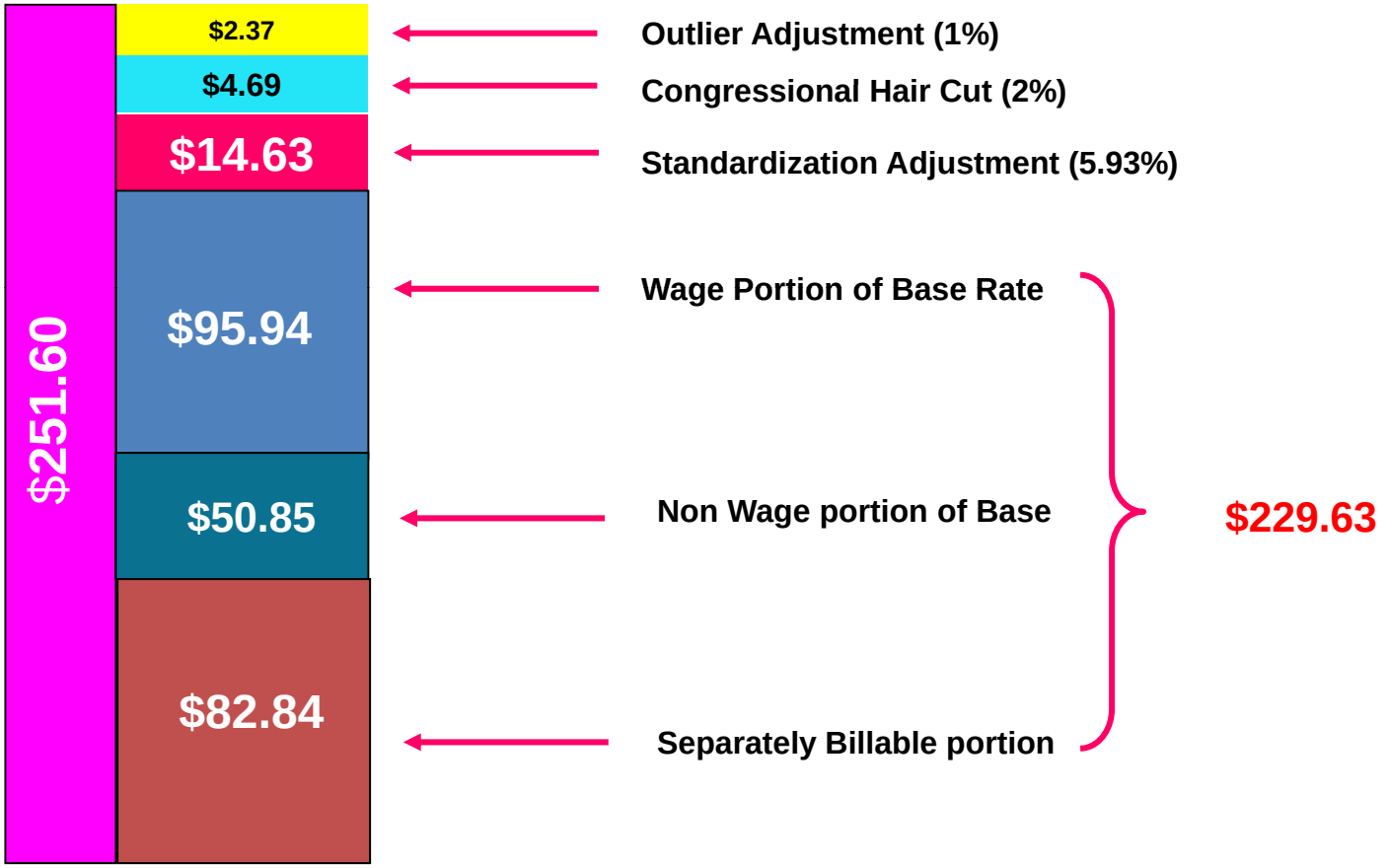
Description	Actual MAP for 2007
Outpatient dialysis	$5,719,657,831
Part B drugs and biologicals	
Erythropoiesis Stimulating Agents (Epogen, Darbepoetin)	$2,044,862,543
Injectable Vitmain D	$ 402,876,683
Iron	$ 234,306,045
Other (Levocarnitine, Alteplase, Vancomycin, Daptomycin and other drugs)	$ 41,485,610
Lab tests billed by dialysis facility or ordered by MCP physician	$ 295,508,409
DME supplies and equipment	$ 18,060,483
Other supplies and support services	$ 42,274,380
Part D drugs	$ 10,700,084
Total (Part B and Part D services)	$8,809,732,068
Total Medicare hemodialysis equivalent sessions	36,747,662
Average Medicare allowable payment	$239.88

Federal Register/ vol. 75,No 155 Page 49131, Table 26

How did CMS arrive at the 2011 Base Rate?

Description	
Average Medicare Allowable Payment in 2007	$239.88
Unadjusted Base Rate reflecting price inflation 2009 (includes Part D drugs)	$243.65
Unadjusted base rate 2011	$251.60
Standardization adjustment (Case Mix Effect)	(0.9407)
Post Case Mix Base Rate (Unadjusted Base Rate * Case Mix Effect)	$236.68
(Outlier Effect)	(0.99)
Post Outlier Base Rate (Post Case Mix Base Rate* Outlier Effect)	$234.31
(2% mandatory Congressional Haircut)	(0.98)
Post Haircut Base Rate (Post Outlier Base Rate* Congressional Haircut)	$229.63

Base Payment

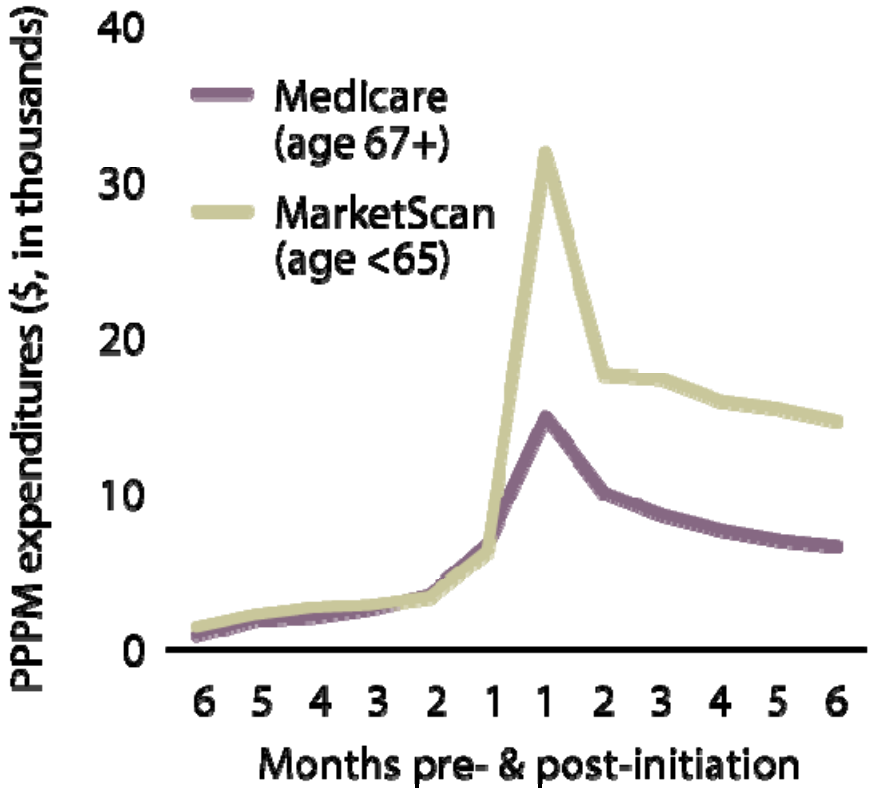


Expanded Bundle:
Composite Rate Multipliers

- Age
- Gender
- Body Surface Area
- Body Mass Index
- Duration of Renal Replacement Therapy
- Clinical Case Mix Adjusters
- Small facility

Overall per person per month costs during the transition to ESRD, 2007

USRDS Annual Report, 2009 - Figure 11.8 (Volume 2)



Medicare: patients 67 years & older, initiating in 2007, with Medicare as primary payor.
MarketScan: ESRD patients age <65, initiating in 2007.

Case Mix Adjustment Multipliers:

Demographic Factors

Variable	Current	Proposed	Final
Age Groups			
< 18	1.620		1.067 – 1.277 [1]
18 – 44	1.223	1.194	1.171
45 – 59	1.055	1.000	1.013
60 - 69	1.000	1.012	1.000
70 - 79	1.094	1.057	1.011
80+	1.174	1.076	1.016
Female		1.132	
Body Surface Area (per 0.1m^2)	1.037	1.034	1.020
Underweight (BMI < 18.5)	1.112	1.020	1.025
Duration of RRT (< 4 months)		1.473	1.510
Low Volume Facility (< 4000 Tx) [2]		1.202	1.189

[1] Based on two age groups, < 13 and 13-17 and modality

[2] During each year between 2006-2008. No. of Tx increased from < 3000 in the proposed rule

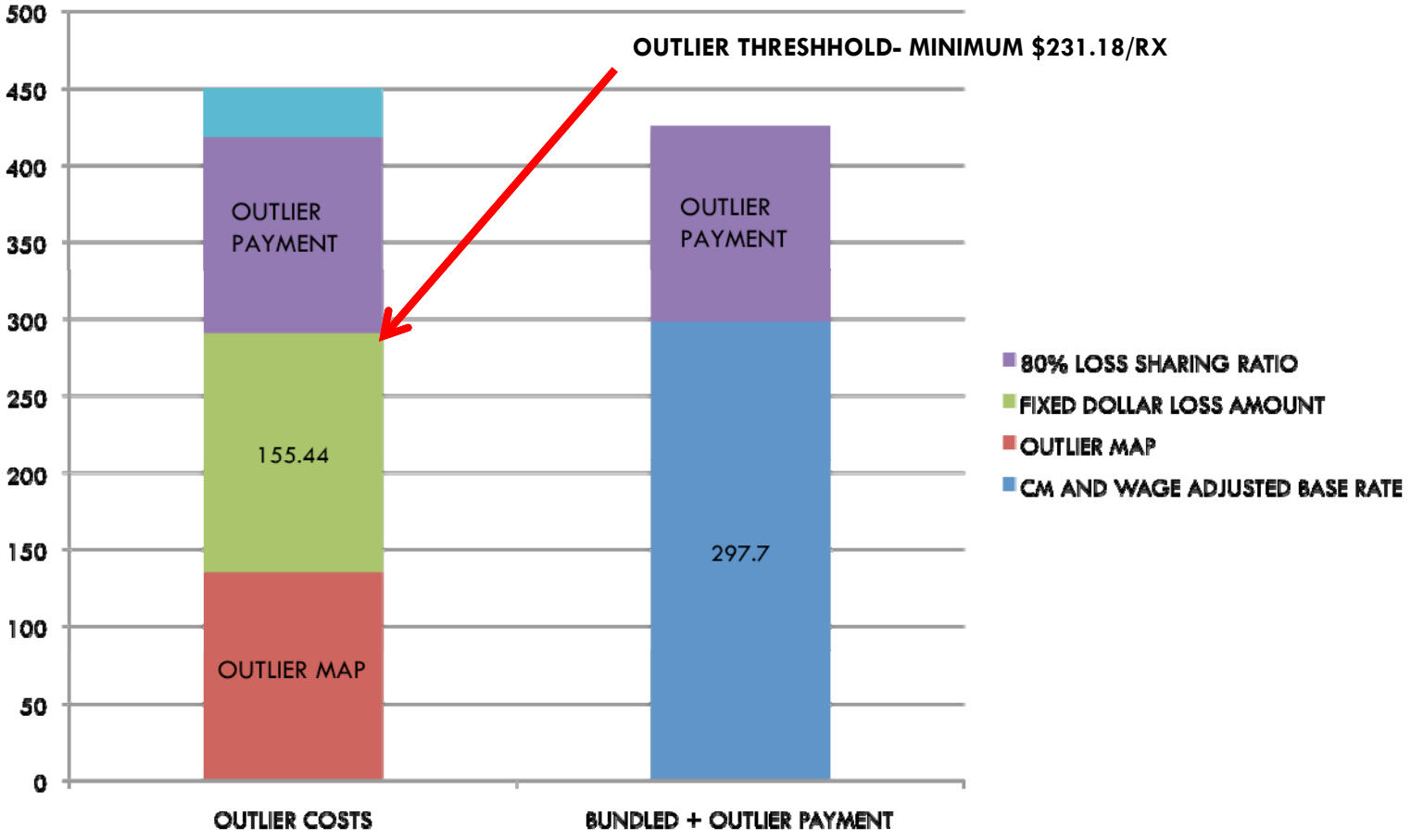
Case Mix Adjustment Multipliers:

Co-morbid conditions

Variable	Case Mix Adjustment Multiplier	
	Proposed	Final
Alcohol/Drug dependence	1.150	
Cardiac arrest (any)	1.032	
Pericarditis (during prior 0-3 months)	1.195	1.114
HIV/AIDS (any)	1.316	
Hepatitis B (any)	1.089	
Specified infections (during prior 0–3 months)		
Septicemia	1.234	
Pneumonia	1.307	1.135
G. I. bleeding (during prior 0-3 months)	1.316	1.183
Hereditary hemolytic or sickle cell anemia (any)	1.226	1.072
Cancer (since 1999) except non melanoma skin cancer	1.128	
Myelodysplastic syndrome (any)	1.084	1.099
Monoclonal gammopathy	1.021	1.024

Anatomy of outlier payment system

Applies to ONLY 1% of total payments



What's included? Medications:

Category	Examples
Access Management	Heparin Alteplase and other Thrombolytics
Anemia Management	All Erythropoiesis Stimulating Agents (ESAs) All Invtravenous (IV) Irons
Anti-infectives for Access-related Infection	Vancomycin Daptomycin Any other antimicrobial given for access-related infection
Bone and Mineral Metabolism	Vitamin D, administered orally or IV
Miscellaneous	Pain medications, Antiemetics, and Anxiolytics given at the dialysis facility Levocarnitine

What's out?

- Non-ESRD related medications given at the facility are to be billed and paid separately through modifiers. Examples:
  - Immunosuppressives
  - Antibiotics given for NON-access related infections
  - Desmopressin

Oral-only drugs: **Out** (For Now)

- Delayed until 2014
- Issues:
  - Inadequate data regarding pricing of oral drugs
  - More time needed to evaluate potential impact on small dialysis facilities
  - Operational and safety issues
  - Need to allow sufficient time for ESRD facilities to establish a pharmacy in accordance with state licensure requirements or to establish an arrangement with pharmacies to provide oral-only drugs

What's included? Lab tests:

Category	Tests
Basic serum and urine chemistries	BMP, Albumin, Phos, Magnesiumm, Urine urea nitrogen and creatinine for clearances
Nutritional Markers	Albumin, Prealbumin, Transferrin
Bone Disease	Phos, Parathyroid Hormone, Vitamin D testing, Alkaline Phosphatase
Anemia Management	CBC, Iron Indices (Iron, Iron Binding, Tsat, Ferritin), Vitamin B12, Folate, reticulocyte count, Epo levels
Infection control	Hepatitis B assays
Cultures	Blood and other cultures sent from dialysis

What's out?

- Tests not listed above are to be separately billed and paid through modifiers
- Clotting times, prothrombin times, AST, ALT, LDH are not in the list

Secondary Payers / Medicaid

- On the whole, beneficiaries will see their copays rise by 1.2%, largely related to copayment liability for lab tests
- The first 120 days may also be a period of increased copayment liability
- Since some medications that were included in Part benefit will now be covered under Part B, there may be increase coinsurance obligation for some patients

Low-volume Adjuster

- For facilities that furnished <4,000 adult treatments in each of the 3 years preceding the payment year; AND have not opened, closed, or had a change in ownership in the 3 years preceding the payment year.
- For new facilities, the number of treatments is the aggregate number of treatments furnished by the facility and the number of treatments furnished by other ESRD facilities that are both:
  - Under common ownership with, and
  - 25 miles or less from the ESRD facility
- 1.9% of facilities will be eligible

Home Dialysis

- No case-mix adjuster for modality
  - This is GOOD, since PD is associated with lower CR and SB costs, so a modality adjustment would have yielded LOWER payments for home therapy
- No Method II billing, since ESRD facility will pay DME suppliers
- Training add-on adjustment
  - $33.88 per session adjusted by area-wages and added to base rate after all other adjustments
  - Cannot be applied during 1st 120 days

What Do We Do Now?

Opt-in, Transition in?

- We proposed a concept of “Naked Bundle” which would give the facility the absolute minimum payment taking into consideration Area Wage Index, Age Group, BSA and BMI and 120 day adjuster
- Outlier payments and Clinical Case Mix Adjusters, if any will increase this revenue
- If your “Naked Bundle” revenue is equal to greater than current expected revenue, your facility may decide to “Opt In”

Naked Bundle[1]

Facility	Separately Billable (SB)	Total Current Revenue (TCR)	Opt in "naked bundle"	Phase in "Naked Bundle"	SB/TCR
A	$167,922	$706.591	$850,488	$742.565	23.77%
B	$422,162	$1,403,272	$1,495,999	$1,422,627	30.00%
C	$487.376	$1,382,158	$1,348,064	$1,366,827	35.26%
D	$508,541	$1,309,761	$1,206,169	$1,283,863	38.83%

[1] Treatments done between January 1, 2010 through June 30 2010

Uncontrolled Epogen Use

"Epo Gluttony" can Ruin a Facility

Facility	# Of Tx	Average Epo Use[1]	Revenue Impact [2]	Opt in/ Phase In
A	3,300	$36.11	$143,897	Opt In
B	5,7,94	$56.26	$92,728	Opt In
C	5,223	$65.26	($34,094)	Phase In
D	4,676	$81.30	($103,592)	Phase In/Out?

[1] Current Average expected Epogen reimbursement used as a proxy

[2] Revenue differential if the facility decided to "Opt In"

Erythropoiesis Stimulating Agents (ESA) – the Achilles Heel

"Not you again Achilles."

Where Do We Go From Here?

The ESRD PPS: A clinician's perspective

Premila Bhat, M.D

Pharmacy Cost Management Under The "Bundle"

Tracy Mayne, Ph.D.