End Stage Renal Disease Prospective Payment System Proposed Rule

Presentation to
Office of Management and Budget
May 27, 2010

Overview

- Providers support bundling as proposed in MIPPA
  - 2% cut was understood and agreed to
- Economic reality is that the Proposed Rule proposes deep cuts beyond the 2%
  - Vast majority of beneficiaries government funded
  - Fragile economics: system is reliant on 10% of patients with commercial insurance
- Issues are straight-forward and solvable
- Providers support a properly implemented bundle

Discussion Framework

- 3 Percent Transition Adjustment
  - Based on assumptions, not data
  - Flawed methodology discourages early adoption of PPS
- Patient Level Adjusters
  - Co-morbidity adjusters
  - Race-based adjuster
  - First 120 days of dialysis
- Oral Drugs
  - If CMS includes oral drugs in PPS, they must be fully funded
  - If CMS lacks sufficient data, it should defer inclusion to conduct a pilot and review GAO study
- Laboratory Services
  - CMS must include 100% of payments for lab services
  - Adopt discrete list of lab tests "for the treatment of ESRD"

Transition Adjustment: Flawed Logic

CMS rationale	Counter arguments
• Facilities that delay entry into the bundle are high utilizers	• CMS is guessing • Even transitioning facilities will probably implement efficiencies given bundled portion of transition payment • Providers will not increase utilization given how quickly they will be fully bundled and how transparent any change will be
• 3% is right level	• Rule assumes one-third will opt in – but two largest providers will likely opt in and they account for 60% of centers • Adjustment applies to all centers, those who transition and those who fully opt in; contrary to MIPPA • Adjustment does not decline as PPS % decreases • If all centers opt in, 2% improvements is guaranteed, yet 3% penalty still applies
• Policy does not create disincentive to opt in	• Policy creates a disincentive to participate: – Most facilities are interested in opting in day 1 for administrative reasons, etc. – Rule applies "cut" to all facilities vs. transition facilities only – Lack of data driven assumptions

Transition Adjustment: Consequences

- Economic problem
  - Facility margins ~0.5% given 2% MIPPA adjustment (MedPAC 2010)
  - 3% is significant reduction in addition to 2% required by MIPPA
- If 3% is overstated, how will funding be added back to PPS?

Transition Adjustment: Recommendation

- Apply adjustment only to transitioning facilities
- Materiality dictates no guessing
  - Implement as a "look back" to minimize risk
  - Base adjustments on actual experience
- Adjust years 2-4 to reflect increasing percentage of PPS payment

Guessing is High Risk Strategy for Fragile Patient Population;
Look Back Eliminates Risk

Patient Level Adjusters

- Cormorbidity data largely unavailable to dialysis providers
  - Most data reside with hospitals or MDs
    - Not routinely shared or shared timely with facilities
    - No requirement that providers supply data despite community's requests in proposed legislation over years - longstanding frustration
    - Collection costs for facilities could be significant
    - If required, have CMS supply from its data sources
- CMS analysis cannot be replicated
  - Lack of information = inability to report adjustors = inadequate reimbursement
- Proposed adjustors not powerful predictors of cost
  - Currently explain only 6% of variance

Patient Level Adjusters: Recommendations

- Add a race adjuster
  - Patient race correlates most closely to cost and resource use
    - More accurate, stronger predictive power than proposed comorbidities
    - African-Americans are higher utilizers of ESAs
  - Rectifies correlation between negative impact of PPS in Proposed Rule and high African-American population in those areas
- Eliminate co-morbidity adjusters
  - If required, have CMS supply information to providers from its data sources (those used in development of NPRM, e.g.)
- Looking ahead, CMS should:
  - Collect data to determine meaningful adjusters that are available to providers
  - Evaluate application of the Medicare HCC risk scoring methodology for beneficiaries on dialysis as basis for case mix adjustment

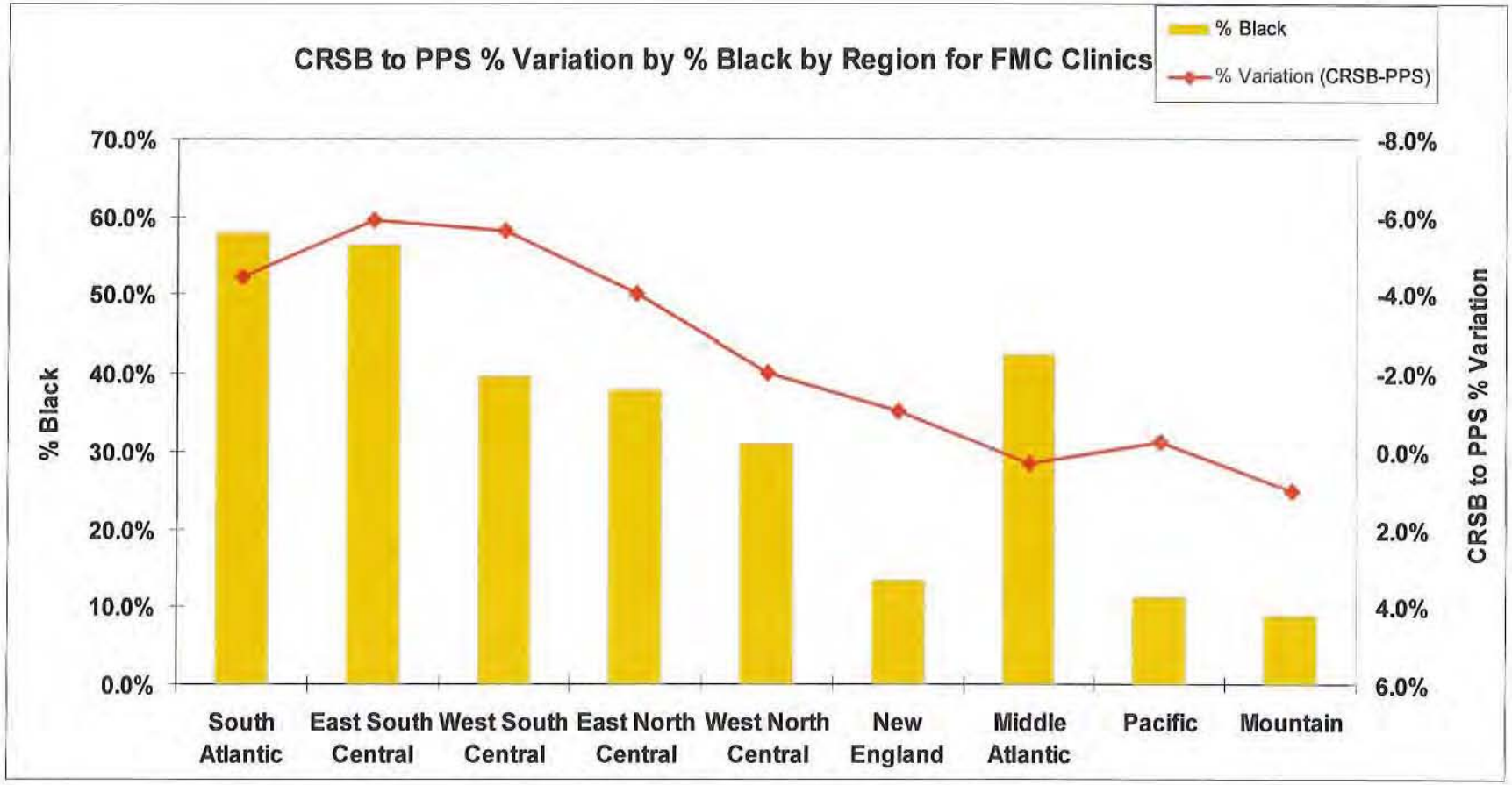
Patient-Level Adjusters: LDO Impact

ESRD-PPS Adjuster	LDO	KECC	Difference	Adjuster Weight	Base Rate Per Tx	Adjuster Impact	
						Per Tx	LDO (mm)
Co-Morbidities:							
Septicemia	3.0%	10.1%	-7.2%	1.234	$198.64	($3.32)	($91.0)
HIV/AIDS	1.5%	4.1%	-2.7%	1.316	$198.64	($1.66)	($45.6)
Hep B	0.6%	7.6%	-7.1%	1.089	$198.64	($1.25)	($34.1)
Cancer	13.4%	16.5%	-3.2%	1.128	$198.64	($0.80)	($21.9)
Hereditary hemolytic or sickle cell ane	0.5%	2.4%	-2.0%	1.226	$198.64	($0.88)	($24.0)
Myelodysplastic syndrome	0.2%	1.1%	-0.9%	1.084	$198.64	($0.15)	($4.1)
Pericarditis in ≤ 3 months	0.1%	0.4%	-0.4%	1.195	$198.64	($0.14)	($3.7)
Monoclonal gammopathy	0.8%	1.4%	-0.6%	1.021	$198.64	($0.03)	($0.7)
GI bleed in ≤ 3 months	1.8%	1.2%	0.6%	1.316	$198.64	$0.35	$9.5
Cardiac arrest	5.3%	3.1%	2.2%	1.032	$198.64	$0.14	$3.8
Bacterial or other pneumonia or OI	3.0%	1.7%	1.3%	1.307	$198.64	$0.79	$21.7

Substantial difference between KECC estimate and provider experience leads to high probability of "leakage;" especially problematic given limited impact on payment (<6%)

LDO Data Sources: NNI Feb 2010 publication. 100 DVA centers, 7,340 patients reporting (DVA Informatics Survey Fall 2009); FMCNA Fall 2009 Clinical Survey
Note: Calculated as individual case-mix adjuster impact. Results not cumulative.

Impact of PPS on Reimbursement to Regions with High African-American Population



New Patient (120 Day) Adjuster

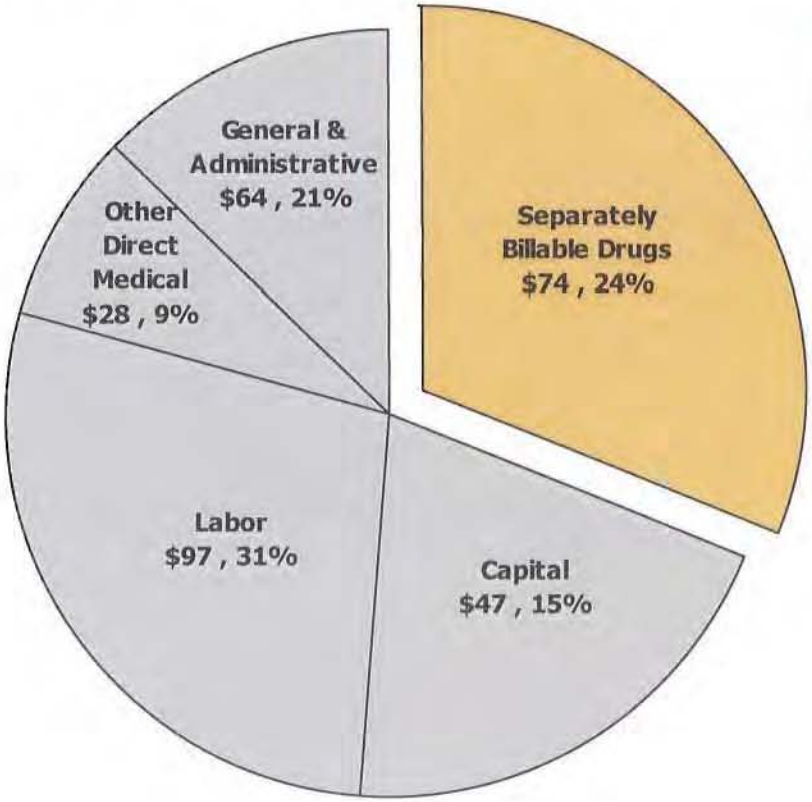
- Significant size of adjuster increases likelihood of gaming
- Decreases base rate for all prevalent patients
- May discourage retention of patients >120 days and affect referral patterns
- Creates negative care incentives
  - Septicemia adjuster conflicts with catheter reduction goals for incident patients
- No current issue with admission of new patients
- Proportion of new patients highly variable across facilities
  - Facilities at capacity or slower growing (rural) will be disadvantaged
- Recommendation:
  - Eliminate the 120 day adjustor

New Patient Adjuster: Methodology

- CMS adjustor has 2 components:
  - Composite rate
  - Separately-billable services – drugs, lab tests, etc.
- Composite rate:
  - Only cost data available to CMS is facility-specific for all payors
  - Unclear how adjustor was determined to be 1.5
  - Fixed nature of composite rate costs indicate limited patient variation; well below 1.5
- Separately-billable payments:
  - Patient-level claims data
  - Costs tracked from months 1 through 12 following onset of dialysis
  - Straight-forward analysis:
    - Results: Drop in the amount of separately-billable payments after 4 months on dialysis
  - Adjuster of 1.47 is reasonable and data driven for separately billable payments only
- Combined adjuster = 1.11
  - Composite rate adjuster is negligible; addressed through patient characteristic adjusters
  - Separately billable adjuster = 1.47

New Patient Adjuster: Data Limitations

Cost Per Dialysis Treatment = ~$240



Composite Rate = ~$165 per treatment

Fixed costs to facilities regardless of individual patients' consumption of resources or length of time on dialysis

Separately Billable Drugs = ~$75 per treatment

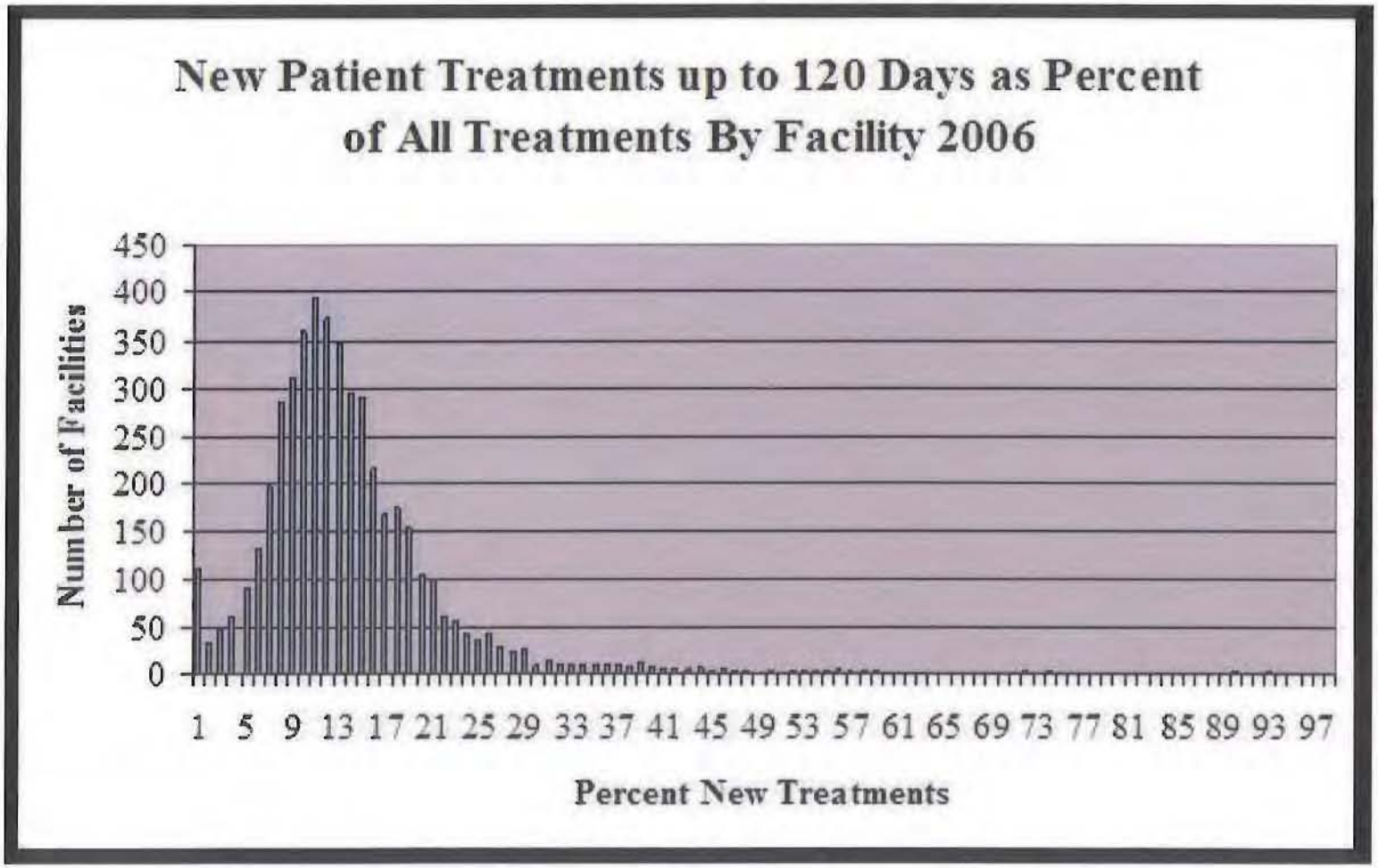
Evidence of correlation with length of time on dialysis;

LDO experience has been ~35-40% higher use during first 120 days after onset of dialysis

Source: MedPAC March 2010 Report to Congress, CMS ESRD-PPS Proposed Rule, DaVita and Fresenius data

New Patient Adjuster

Problematic for <u>all</u> types of facilities



Analysis by The Moran Company using 100% Outpatient Hospital Standard Analytic File for 2006. Patients 65 years old and older and those on disability.

Oral Drugs

- If oral drugs are included in the PPS, they must be fully funded
- Proposed rule underfunds orals by $30+/treatment
  - Represents 16% of proposed base rate
  - Deficit is too large to overcome through efficiencies
- Proposed Rule fails to take into account:
  - Coverage – Ignores 45% of beneficiaries who get drugs outside Part D
  - Utilization – current utilization will increase as compliance with optimal standard of care improves, unless prevented by inadequate funding
  - Inflation
    - CMS estimates 12.24% inflation from 2007 to 2011
    - Wolters Kluwer data estimates 19% increase from 2007 to 2008 alone
- If CMS has inadequate data to fully fund orals, it should defer inclusion and conduct a pilot
  - DaVita and FMCNA ready to participate in large-scale pilot
  - Wait for results of GAO study required by Section 10336 of PPACA

Fully Fund Laboratory Services

- Proposed Rule fails to fully fund lab services
  - MIPPA requires inclusion of all lab payments that otherwise would have been paid under current system (subject to 98% adjustment)
  - Medicare pays 100% for CLFS labs
  - Proposed Rule includes only 80%, violating MIPPA
- MIPPA requires inclusion of lab tests "for the treatment of ESRD"*
  - Proposed Rule goes beyond treatment of ESRD by including all laboratory tests ordered by the MCP
  - MCPs frequently function as PCPs and order tests unrelated to treatment of ESRD

* SSA§1881(b)(14)(B)(iv)

Rationale for Discrete Set of Labs

- ~ 50 lab tests are "furnished for the treatment of ESRD," as required under MIPPA
  - These tests account for ~95% of MCP-ordered lab tests (through dialysis facilities) and associated dollars
- CMS already created a specific list of ESRD-related lab tests when it exempted such tests from the Medicare SNF Part A consolidated payment
- Will promote coordination of care, avoid additional lab draws that are risky for dialysis patients, and will allow dialysis facilities to make informed arrangements for the provision of ESRD-related lab services
- A defined list of lab CPT codes will promote a more accurate capture of dollars associated with those specific tests

JOHN KERRY
MASSACHUSETTS

COMMITTEES:
COMMERCE, SCIENCE, AND TRANSPORTATION
FINANCE
FOREIGN RELATIONS
SMALL BUSINESS

United States Senate
WASHINGTON, DC 20510-2102

May 25, 2010

Mr. Jonathan Blum
Deputy Administrator and Director, Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Room C5-15-12
Baltimore, MD 21244-1850

Dear Mr. Blum:

I am writing to inquire about the Centers for Medicare and Medicaid Services' (CMS) End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule. I understand that the intention of the Proposed Rule represents a significant advancement in care, and to that end, I would like to raise concerns with the implementation of the proposed transition adjustment and the inclusion of a payment adjuster for new patients.

I understand that the Proposed Rule includes a three percent reduction in reimbursement for all dialysis facilities, whether or not they participate in the four-year transition period. I am told that such an approach may create a disincentive for facilities to fully opt in to the new payment system and that applying the adjuster only to those facilities that participate in the transition would correct the incentive structure. In addition, I ask that you reconsider several of the Proposed Rule's assumptions with respect to provider behavior. For example, the Proposed Rule estimates that only 36 percent of facilities will elect to forego the transition period. The two largest dialysis organizations, however, account for approximately 60 percent of our nation's outpatient dialysis facilities. If both organizations opt into the new PPS – which I understand is likely – the Proposed Rule's estimates would appear to be significantly skewed on this basis alone. Rather than taking a speculative prospective approach to determining the transition adjustment, CMS should consider calculating any transition adjustment only after facilities have made their payment system elections for the phase-in period.

I have been informed that the Proposed Rule's inclusion of an increased reimbursement rate for treatment of beneficiaries during the first 120 days of dialysis may unwittingly create incentives for undesirable behavior, such as the steering of certain patients from one treatment setting to another based on payment considerations. I also understand that the new patient adjuster does not appear to be independent of the other proposed adjusters, meaning its inclusion would be duplicative of other adjusters that may more accurately predict treatment costs. I encourage CMS to reconsider any payment methodology that creates a risk of misaligned incentives and opt instead for opt instead for adjusters that are more predictive of actual treatment costs.

As CMS moves forward with finalizing the ESRD PPS, I understand and appreciate the time and effort it has put forth in developing this new bundled payment system.

Thank you in advance for your consideration of this request.

Sincerely,

John F. Kerry