Design of the ESRD PPS: *Technical Expert Panel*

Acumen, LLC

December 5, 2019

TEP Agenda

	Session	Time	Topic
Morning	Breakfast	8:00 to 8:15 AM	
	Session 1	8:15 to 8:30 AM	Introductions and Goals for this TEP
	Session 2	8:30 to 10:30 AM	Measurement of Costs for Determining Case-Mix Adjustment
	Break	10:30 to 10:45 AM	
	Session 3	10:45 to 11:30 AM	Wage Index
	Session 4	11:30 AM to 12:30 PM	Low Volume Payment Adjustment and Rural Adjustment
	Lunch	12:30 to 1:45 PM	
Afternoon	Session 5	1:45 to 2:30 PM	Transitional Drug Add-on Payment Adjustment
	Session 6	2:30 to 3:15 PM	Outlier Determination
	Break	3:15 to 3:30 PM	
	Session 7	3:30 to 4:00 PM	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
	Session 8	4:00 to 4:45 PM	Home Dialysis
	Session 9	4:45 to 5:30 PM	Open Discussion

Outline

No data	Sessions
1	**Introductions and Goals for this TEP**
2	Measurement of Costs for Determining Case-Mix Adjustment
3	Wage Index
4	Low Volume Payment Adjustment and Rural Adjustment
5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
9	Open Discussion

Session 1 Outline

Session Objective

- Introduce TEP participants, project team, and today's goals

Session Topics

- Introduce panelists and project team
- Explain project goals and scope of today's TEP

Session Time

- 15 minutes

Welcome

- CMS has contracted with Acumen, LLC to maintain the End Stage Renal Disease Prospective Payment System (ESRD PPS) and Acute Kidney Injury Payment System (AKI PS) and examine potential refinements to the design of these systems
- Acumen is convening this TEP to gather feedback on preliminary approaches to refining the ESRD PPS
- Introduction
  - Panelists
  - Project team representatives

Panelists

- **Eileen Brewer, MD**, Medical Director, Renal Transplant Program, Texas Children's Hospital
- **Mark Desmarais**, Consultant, The Moran Company
- **Johnie Flotte, RN**, Vice President, Clinical Services, US Renal Care
- **Derek Forfang**, Kidney Patient Advocate and Public Policy Committee Chair, National Kidney Foundation
- **J. Michael Guffey**, Treasurer, Dialysis Patient Citizens
- **John Hartman, MD**, CEO, Visonex
- **Alice Hellebrand, MSN, RN, CNN**, Chief Nursing Officer, Dialyze Direct
- **Andrew Howard, MD, FACP**, Nephrologist, The National Forum of ESRD Networks

Panelists (Cont'd)

- **Jeffrey Hymes, MD**, Senior Vice President, Clinical and Scientific Affairs, Fresenius Medical Care
- **Mahesh Krishnan, MD, MPH, MBA, FASN**, Group Vice President, Research and Development, DaVita
- **Keith Lester, MA**, Senior Vice President, Home Therapies/ Optimal Life, Satellite Healthcare
- **Chris Lovell, RN, MSN, CNN**, Director, Medical Informatics and Support Services, Dialysis Clinics, Inc.
- **Julie Williams, BSA**, President, National Renal Administrators Association
- **Jay Wish, MD**, Professor of Clinical Medicine, Indiana University School of Medicine
- **LeAnne Zumwalt, CPA**, Group Vice President, Government Affairs and Purchasing, DaVita

Project Team in Attendance

- Moderator
  - David Moore
- Active Participants/Session Leads
  - Kyle Buika
  - Myrna Cozen
  - Rose Do
  - Kevin Erickson
  - Bruno Garcia
  - Eugene Lin
  - Sriniketh Nagavarapu
  - William Vogt

Project Team in Attendance

- Additional Team Members
  - Rishav Bashyal
  - Andrew Etteldorf
  - Can Feng
  - Zhihang Lin
  - Taishu McLawhorn
  - Suraj Pant
  - Callie Richard
  - Dashi Xu

Acumen Is Examining Potential Revisions to the ESRD PPS

- ESRD PPS pays providers for 13 or 14 hemodialysis (or the equivalent peritoneal dialysis) sessions per month, either in the facility or at home
  - Includes adjustment for patient-level characteristics, facility-level characteristics, and outliers
- Stakeholders have voiced concerns with aspects of the ESRD PPS through public comments, the previous TEP, and other channels
- December 2018 TEP began exploring changes to claims and cost reports to collect more accurate cost information to ensure accuracy of payment adjustment
- This TEP builds on that discussion and presents preliminary approaches to revise payment adjustment in the ESRD PPS

Specific Goals of Today's TEP

- *Session 2*: Examine alternative approaches to measuring the cost of a dialysis session for use in a one-equation model for case-mix adjustment
- *Session 3:* Examine a method for constructing wage indexes that are more specific to dialysis facilities
- *Session 4:* Assess potential changes to the Low Volume Payment and Rural Adjustments
- *Session 5:* Examine how to transition drugs from TDAPA status into the ESRD PPS bundle
- *Session 6:* Consider an alternative approach to the outlier adjustment to meet the 1% target
- *Session 7:* Discuss the criteria for establishing TPNIES eligibility for innovative equipment and supplies
- *Session 8:* Discuss methods of capturing the costs of home dialysis
- *Session 9:* Open discussion

Each Session Follows a Similar Format

- Describe how the topic is handled in the current ESRD PPS
- Summarize stakeholder concerns relative to the topic
- Suggest a preliminary approach, or multiple approaches, to refine the ESRD PPS to address concerns in a manner consistent with legislative requirements and policy goals
- Obtain feedback from TEP members through a series of discussion questions
- Additional notes:
  - Sessions 1-8 will not discuss the overall budget allocated to the ESRD PPS, as this is out of Acumen's scope
  - Session 9 is an open discussion period for both TEP members and observers to provide comments on topics from the previous sessions or other topics

Outline

No data	Sessions
1	Introductions and Goals for this TEP
2	**Measurement of Costs for Determining Case-Mix Adjustment**
3	Wage Index
4	Low Volume Payment Adjustment and Rural Adjustment
5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
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Session 2 Outline

Session Objective

- Examine alternative approaches to measuring the cost of a dialysis session, for use in a one-equation model for case-mix adjustment

Session Topics

- Describe current two-equation model for case-mix adjustment
- Summarize stakeholder feedback on the current model
- Suggest two approaches to creating a new one-equation model
- Gather TEP feedback on the relative merits of each approach
- Consider changes to cost reports and claims to support additional refinements, for both adult and pediatric dialysis

Session Time

- 2 hours

Statutory Requirement for Implementing Case-Mix Adjustment in ESRD PPS

- Section 1881(b)(14) of Social Security Act requires a bundled payment system for ESRD PPS
  - Bundle is comprised of all essential renal dialysis services, including drugs, labs, supplies and capital costs related to the dialysis treatment
  - Base rate required to include a payment adjustment based on case-mix to account for patient comorbidities
- Goal of case-mix adjustment is to ensure payment accuracy – i.e., that payment for a treatment tracks expected resource use/cost for that treatment
  - Protects access to care for least healthy beneficiaries and adequately compensates facilities with high proportion of those beneficiaries
- ESRD PPS also includes facility-level adjustments designed with the same goal

Current Case-Mix Adjustment Model for Adult Dialysis Uses Two Equations

1. Facility-level equation for Composite Rate (CR) costs
   - Estimates the effect of case-mix factors on CR cost per treatment
   - CR costs calculated from cost reports
2. Patient-level equation for Formerly Separately Billable (FSB) costs
   - Estimates the effect of case-mix factors on FSB cost per treatment for each provider-beneficiary month
   - FSB costs calculated using reported units from 72x claims

- Case-mix factors include:
  - Age categories, BSA, low BMI, onset status, comorbidities (pericarditis, GI tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome)
  - Additional facility adjusters: low volume status and rural status

Current Case-Mix Adjustment Model for Adult Dialysis Uses Two Equations (Cont'd)

- Final case-mix adjusters for adults are the weighted average of estimated coefficients from these two equations
  - Weights are the fraction of costs that are composite rate versus formerly separately billable
- Regression equations and weighted averages are calculated using 2012-2013 claims and cost report data
- Current case-mix adjusters were implemented in the CY2016 rule and have been in effect since January 2016

Case-Mix Adjustment Model Is Adapted for Pediatric Dialysis

- Central challenges in statistical analysis are the small number of pediatric dialysis patients and the difficulty in disentangling the portion of composite rate costs for adult versus pediatric patients
- ESRD PPS addresses these challenges by taking the following steps:
  - Use patient-level model for formerly separately billable (FSB) costs to obtain estimated effect of age and dialysis modality
  - Construct ratio of pediatric costs to adult costs
  - Find the average payment multiplier for adults
  - Find the fraction of pediatric costs that are composite rate vs. FSB
  - Combine the above to create the final case-mix adjusters
- Current adjusters were calculated using 2012-2013 claims and cost report data and were implemented in CY2016 rule

Stakeholders Have Expressed Concerns with the Current Case-Mix Adjustment Model

- Stakeholders have critiqued the two-equation methodology, citing:
  - Difficulty in inferring patient case-mix adjustments from facility-level data
  - Size and magnitude of age, BMI, and BSA effects that are surprising
  - Implications of taking the weighted average of estimates across the two equations when the joint distribution of composite rate and formerly separately billable costs is not accounted for
- Logistical challenges in obtaining accurate comorbidity data
  - Diagnoses made by medical providers contained in medical records and may not be readily available to dialysis facility
  - Operational costs of obtaining these data may exceed value of the adjustment
- Costs unique to pediatric dialysis may not be adequately represented in cost reports and therefore not accounted for in pediatric adjustments

Stakeholder Comments Point to Persistent Interest in Creating a "One-Equation" Model

- One equation would be used to estimate the effect of case-mix factors and low-volume status on total costs per treatment – including both composite rate (CR) and FSB costs
- Estimated coefficients from the one-equation model would be used to adjust payments for patient case-mix directly, with no weighting
  - Analogous to other payment systems with case-mix adjustment, such as Home Health, Inpatient Rehabilitation Facility, Skilled Nursing Facility, and Inpatient Psychiatric Facility PPS
- Fundamental problem: How to identify meaningful patient-level variation in CR costs?
  - CR costs include capital, labor, administrative, drug, lab and supply costs
  - Many of these costs are difficult to assign to individual patients

Two Approaches to a One-Equation Model Under Consideration in Today's TEP

- Approach 1:
  - Use dialysis session charges from claims and cost-to-charge ratios (CCRs) from cost reports and claims to calculate composite rate (CR) costs per treatment
- Approach 2:
  - Use cost reports for CR items/services and additional information (e.g. time on dialysis) to calculate CR costs per treatment
- Both approaches then:
  - Use FSB charges on claims and CCRs from cost reports and claims to calculate FSB costs per treatment
  - Sum CR and FSB costs per treatment for each provider-beneficiary month
  - Use total costs per treatment as a dependent variable in a single regression model
  - Use the coefficients to set the case-mix adjustment factors

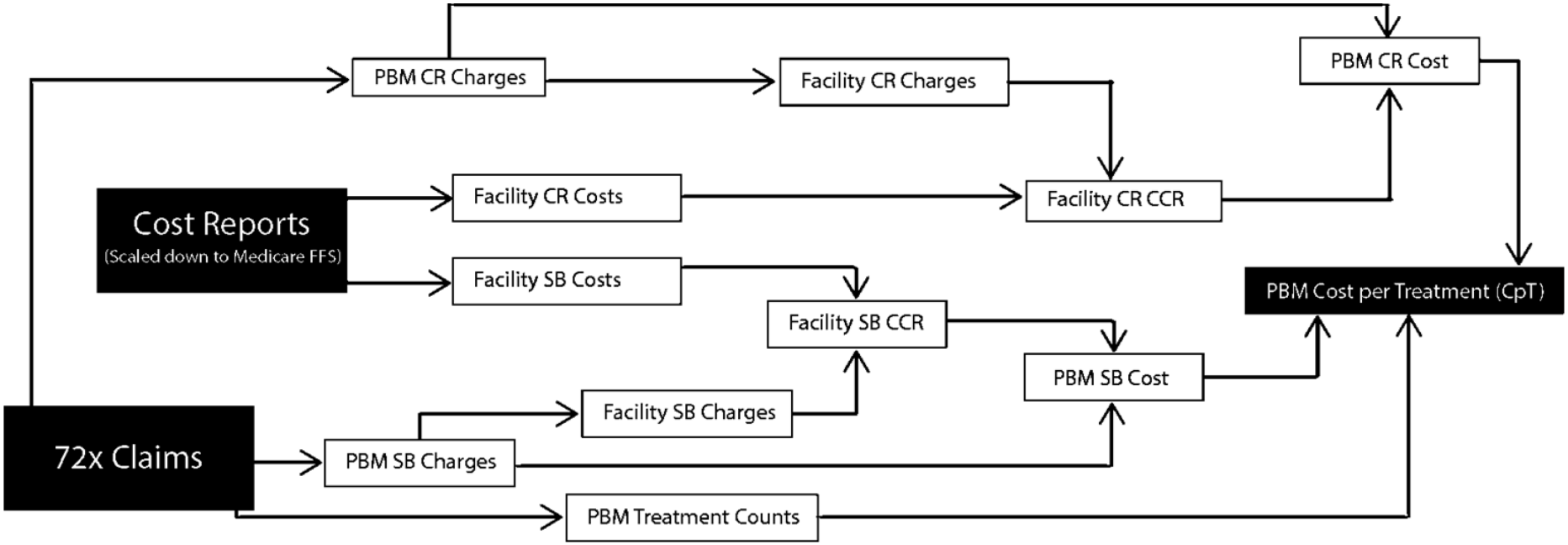
Remainder of Session 2 Explores These Two Approaches and Potential Refinements

- For each approach:
  - Describe the suggested methodology
  - Present the implications for case-mix adjustment factors and compare to the current ESRD PPS
  - Discuss the limitations and potential changes to cost reports/claims to address these limitations
- Analysis is meant to illustrate the two approaches concretely and obtain TEP feedback on the advantages and disadvantages of pursuing either one in greater detail

Approach 1 Utilizes Charges and CCRs from Claims and Cost Reports

- For each provider:
  - Obtain total composite rate (CR) costs from cost reports for each modality, applying an adjustment to remove non-Medicare costs
  - Obtain total charges from corresponding dialysis session lines on 72x claims
  - Divide costs by charges to obtain provider-level CCRs for CR costs, by modality
- Calculate CR cost for each provider-beneficiary month
  - CR cost = charges from dialysis session lines * provider-level CCR for given modality
- Use FSB charges on claims and cost-to-charge ratios specific to FSB items to calculate FSB costs per treatment
- Add CR cost to FSB cost to obtain total cost per treatment for each beneficiary/month
- Estimate a regression model of total cost per treatment for each provider-beneficiary-month on case-mix characteristics and facility characteristics using data from 2016-2017

Approach 1 Utilizes Charges and CCRs from Claims and Cost Reports (Cont'd)



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Dialysis Treatment Costs Vary by Modality and Location

National average Cost per Treatment by modality and location - computed in Approach 1 (2017)

Modality	Type	HD-equivalent Treatment Count	Relative to In-center HD - CR	Relative to In-center HD - SB	Relative to In-center HD - total	Relative to Total Per-Treatment Cost - CR	Relative to Total Per-Treatment Cost - SB
HD	In-center	39,852,837	*100%*	*100%*	*100%*	89%	11%
HD	Home	1,018,413	86%	102%	88%	87%	13%
HD	Training	42,042	280%	102%	260%	96%	4%
PD	In-center	496	490%	134%	450%	97%	3%
PD	Home	4,076,334	87%	81%	86%	89%	11%
PD	Training	78,752	302%	99%	279%	96%	4%

- Home hemodialysis (HD) and peritoneal dialysis (PD) have lower CR costs than in-center HD
- Treatment costs for training sessions (HD and PD) are significantly higher than in-center HD

Average Cost Per Treatment Shows Limited Variation by Beneficiary Characteristics

Average Cost per Treatment (CpT) by beneficiary characteristics - computed in Approach 1 (2017), weighted by treatment counts, scaled relative to adults mean

Beneficiary characteristics		Avg SB CpT	Avg CR CpT	Avg SB + CR CpT
Adults				
Age	18 - 44	1.109	0.994	1.007
	45 - 59	1.021	0.989	0.993
	60 - 69	0.993	0.998	0.997
	70 - 79	0.970	1.009	1.005
	>= 80	0.921	1.018	1.007
BSA (m^2)	Q1: < 1.67	0.990	1.007	1.005
	Q2: 1.67 - 1.83	0.992	1.000	0.999
	Q3: 1.83 - 1.96	0.994	0.999	0.998
	Q4: 1.96 - 2.14	0.998	0.996	0.996
	Q5: >= 2.14	1.025	0.999	1.002
Low BMI	No	1.003	1.000	1.000
	Yes	0.902	0.999	0.988
Onset	No	0.994	0.996	0.996
	Yes	1.120	1.081	1.086

Average Cost Per Treatment Shows Limited Variation by Beneficiary Characteristics (Cont'd)

Average Cost per Treatment (CpT) by beneficiary characteristics - computed in Approach 1 (2017), weighted by treatment counts, scaled relative to adults/pediatric mean

Beneficiary characteristics		Avg SB CpT	Avg CR CpT	Avg SB + CR CpT
Adults				
Gastro-intestinal tract bleeding (acute)	No	0.999	1.000	1.000
	Yes	1.349	0.991	1.031
Hereditary hemolytic or sickle cell anemia (chronic)	No	0.998	1.000	1.000
	Yes	1.932	0.989	1.093
Myelodysplastic syndrome (chronic)	No	0.999	1.000	1.000
	Yes	1.542	0.983	1.045
Pericarditis (acute)	No	1.000	1.000	1.000
	Yes	1.162	1.091	1.099
Pediatric				
Age	<13	0.828	0.936	0.932
	13 - 17	1.172	1.064	1.068

Approach 1 Case-Mix Adjusters Are Generally Smaller in Magnitude Than Current ESRD PPS

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers
Age	18 - 44	**1.257**	1.015
	45 - 59	**1.068**	1.005
	60 - 69	**1.070**	1.003
	70 - 79 (reference)	**1.000**	1.000
	>= 80	**1.109**	0.997
	Onset	**1.327**	1.048
	BSA (per 0.1 m2)	**1.032**	1.002
	Underweight (BMI < 18.5)	**1.017**	1.003
Comorbidities	Pericarditis (acute)	**1.040**	1.044
	Gastro-intestinal tract bleeding (acute)	**1.082**	1.039
	Hereditary hemolytic or sickle cell anemia (chronic)	**1.192**	1.104
	Myelodysplastic syndrome (chronic)	**1.095**	1.049
Facility	Low Volume	**1.239**	1.252
	Rural	**1.008**	1.020

- All New Multipliers are significant ($p < 0.0001$). Current Multipliers are combination of two regressions, and without associated significance level.
- Current Multipliers are estimated by KECC on 2012 and 2013 data.
- New Multipliers are estimated on 2016 and 2017 data using proposed one-equation method.

December 2018 ESRD PPS TEP Proposed Several New Case-Mix Adjusters

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers (Same Case-Mix)	New Multipliers (New Case-Mix Added)
Age	18 - 44	**1.257**	1.015 ****	1.019 ****
	45 - 59	**1.068**	1.005 ****	1.006 ****
	60 - 69	**1.070**	1.003 ****	1.003 ****
	70 - 79 (reference)	**1.000**	1.000	1.000
	>= 80	**1.109**	0.997 ****	0.998 ****
Comorbidities	Onset	**1.327**	1.048 ****	1.047 ****
	BSA (per 0.1 m2)	**1.032**	1.002 ****	1.002 ****
	Underweight (BMI < 18.5)	**1.017**	1.003 ****	1.001
	Pericarditis (acute)	**1.040**	1.044 ****	1.042 ****
	Gastro-intestinal tract bleeding (acute)	**1.082**	1.039 ****	1.034 ****
	Hereditary hemolytic or sickle cell anemia (chronic)	**1.192**	1.104 ****	1.102 ****
	Myelodysplastic syndrome (chronic)	**1.095**	1.049 ****	1.044 ****
Facility	Low Volume	**1.239**	1.252 ****	1.251 ****
	Rural	**1.008**	1.02 ****	1.021 ****

- New adjusters have minimal impact on multipliers for existing adjusters
- Significance level:
  - * $p < 0.05$
  - ** $p < 0.01$
  - *** $p < 0.001$
  - **** $p < 0.0001$

December 2018 ESRD PPS TEP Proposed Several New Case-Mix Adjusters (Cont'd)

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers (Same Case-Mix)	New Multipliers (New Case-Mix Added)
New Adjusters	Current Disability			1.003 ****
	HBV (acute or chronic) in prev 12 months			1.012 ****
	Cancer			1.016 ****
	Diabetes			1.004 ****
	Liver Disease/Cirrhosis			1.024 ****
	Dementia			1.009 ****
	Neurologic Muscular Diseases			1.009 ****
	Strokes/Coma			1.007 ****
	Paralytic Syndromes			1.007 ****
	Respiratory Problems			1.029 ****
	Psychiatric Disorders			1.012 ****
	Drug/Alcohol Use Disorder			1.021 ****
	Ulcers			1.015 ****
	Autonomic Neuropathy			1.004 ****
	Blindness			1.001
	Hearing Loss			0.998 ****

- New adjusters have minimal impact on multipliers for existing adjusters

Significance level:

- * $p < 0.05$
- ** $p < 0.01$
- *** $p < 0.001$
- **** $p < 0.0001$

Extremely Small Values for Case-Mix Adjusters Reflect Limited Variation in Charges on Claims

- While the small size of certain case-mix adjusters – e.g. age – are consistent with stakeholder critiques, other effect sizes may be unexpectedly small
- This is a direct effect of the fact that providers' reported charges exhibit little variation
  - In 2017, about 90 percent of all providers report 1-4 unique charges per dialysis session regardless of modality

Providers with one or more unique dialysis charge per session values on 72x claims (2017) - % of providers reporting each modality

Number of unique dialysis charge per session values	Hemodialysis (0821)	IPD (0831)	CAPD (0841)	CCPD (0851)	Ultrafiltration (0881)	all
1	69.0%	85.7%	24.7%	18.6%	99.6%	46.0%
2 - 4	29.7%	14.3%	74.5%	79.5%	0.4%	43.8%
5 - 10	1.0%	0.0%	0.7%	1.6%	0.0%	9.7%
10 +	0.3%	0.0%	0.1%	0.2%	0.0%	0.6%

Components of Dialysis Treatment Costs

Capital	Buildings and fixtures, movable equipment, operating and maintenance of plant and equipment, dialysis treatment equipment, housekeeping
Labor	Salaries and benefits for direct patient care
Administrative	Facility costs not directly related to the provision of dialysis care, such as accounting, legal services, and recordkeeping
Drugs	Drugs used to treat or manage a condition associated with dialysis treatment
Labs	Routine laboratory tests for dialysis patients
Supplies	All supplies used to furnish direct dialysis care, such as tubes, syringes, and dialysate

Revisions to Claims and Cost Reports Needed to Support Approach 1

- Improve reporting of dialysis session charges on 72x claims, assuming current reporting does not reflect true variation
- Ensure costs from cost reports are comprehensive
  - Standardize the reporting of capital costs related to dialysis machines and other supportive equipment
    - E.g., add cost of maintaining isolation room for HBV+ patients, patient assist devices, etc.
  - Include all relevant labor categories (e.g. nurse practitioners)
  - Include lines for operational costs such as network fees, CROWNWeb fees and ICH-CAHPS administration fee
- Ensure allocation of costs by modality is meaningful
  - Cost report allocates each cost component to modality and pediatric/adult only indirectly, using various cost accounting rules
    - Capital: Based on square footage and treatment counts
    - Machines: Based on fraction of time
    - Salaries: Based on hours of work
    - Benefits: Based on gross salaries
    - Drugs, labs and supplies: Based on acquisition costs

Revisions to Claims and Cost Reports Needed to Support Approach 1 (Cont'd)

- Differentiate composite rate (CR) labs and supplies from formerly separately billable (FSB)
- Improve the specificity with which Medicare treatment counts are reported
  - Number of Medicare treatments on 72x claims diverges sharply from number reported on cost reports for substantial subset of facilities
  - Consequence is that constructed costs per treatment cannot accurately reflect true costs per treatment

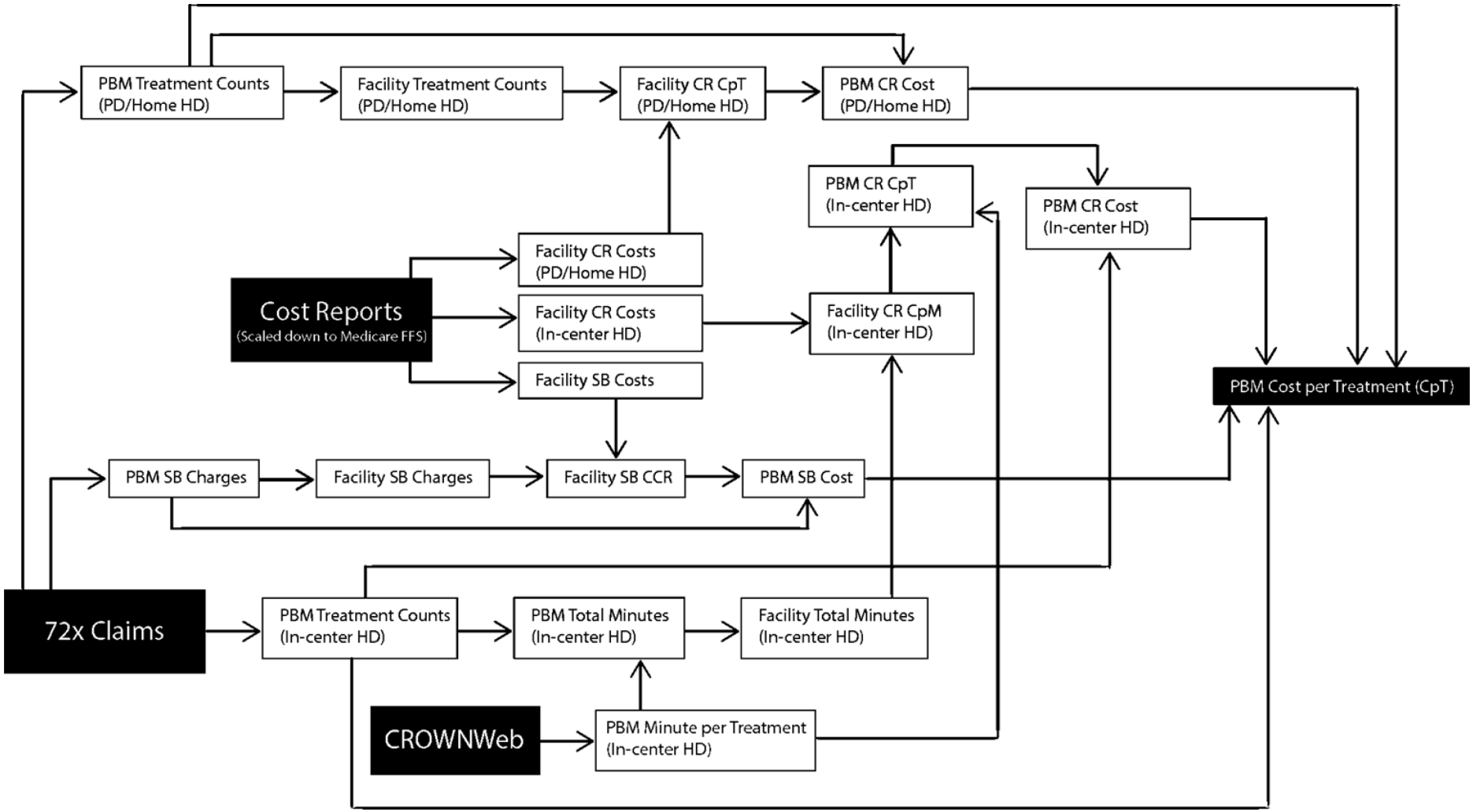
Distribution of provider-level metrics:
Medicare FFS treatment count (from 72x claims) / reported total Medicare treatment count
2017

	Facilities	Mean	P5	P10	P20	P30	Median	P70	P80	P90	P95
Overall	**7068**	**2.59**	**0.92**	**0.95**	**0.98**	**0.98**	**0.99**	**1.00**	**1.00**	**1.00**	**1.02**
Hemodialysis (in-center)	6660	2.68	0.94	0.97	0.98	0.99	0.99	1.00	1.00	1.00	1.02
Hemodialysis (home or SNF home)	1440	0.91	0.61	0.66	0.75	0.81	0.99	1.00	1.00	1.00	1.05
Hemodialysis (self dialysis training/retraining)	995	0.91	0.12	0.65	0.79	0.88	1.00	1.00	1.00	1.00	1.20
Peritoneal (in-center)	97	0.73	0.00	0.00	0.00	0.00	0.66	1.00	1.00	1.34	3.97
Peritoneal (home or SNF home)	3115	1.05	0.87	0.96	0.99	1.00	1.00	1.00	1.01	1.03	1.06
Peritoneal (self dialysis training/retraining)	2625	0.99	0.60	0.79	0.91	0.97	1.00	1.00	1.00	1.07	1.27

Approach 2 Uses Differences in Modality and Treatment Times to Infer Patient-level Variation

- For each provider:
  - Obtain composite rate (CR) cost per treatment from cost reports for each modality
  - Obtain total dialysis minutes for in-facility HD
    - From 72x claim treatment counts and HD minutes from CROWNWeb
- For each provider-beneficiary-month with in-facility HD:
  - CR cost per treatment = provider-level CR cost per minute * minutes per treatment
- For home HD, home PD, and in-facility PD:
  - CR cost per treatment = provider-level CR cost per treatment for given modality
- Use formerly separately billable (FSB) charges on claims and CCRs specific to FSB items to calculate FSB costs per treatment
- Add CR cost to FSB cost from claims to obtain total cost per treatment
- Estimate a regression model of total cost per treatment for each provider-beneficiary-month on case-mix characteristics and facility characteristics using data from 2016-2017

Approach 2 Uses Differences in Modality and Treatment Times to Infer Patient-level Variation (Cont'd)



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Dialysis Treatment Costs Vary by Modality and Location

National average Cost per Treatment (CpT) by modality and location - computed in Approach 2 (2017)

Modality	Type	HD-equivalent Treatment Count	Relative to In-center HD - CR	Relative to In-center HD - SB	Relative to In-center HD - Total	Relative to Total CpT - CR	Relative to Total CpT - SB
HD	In-center	39,927,811	*100%*	*100%*	*100%*	89%	11%
HD	Home	1,029,203	86%	102%	88%	87%	13%
HD	Training	42,886	274%	100%	255%	96%	4%
PD	In-center	818	700%	163%	640%	97%	3%
PD	Home	4,124,824	87%	81%	86%	90%	10%
PD	Training	80,021	303%	98%	280%	96%	4%

- Home hemodialysis (HD) and peritoneal dialysis (PD) have lower CR costs than in-center HD
- Treatment costs for training sessions (HD and PD) are significantly higher than in-center HD

Average Cost Per Treatment Shows Limited Variation by Beneficiary Characteristics

Average Cost per Treatment (CpT) by beneficiary characteristics - computed in Approach 2 (2017), weighted by treatment counts, scaled relative to adults mean

Beneficiary characteristics		Avg SB CpT	Avg CR CpT	Avg SB + CR CpT
Adults				
Age	18 - 44	1.108	1.016	1.026
	45 - 59	1.021	1.015	1.015
	60 - 69	0.993	1.000	0.999
	70 - 79	0.971	0.990	0.988
	>= 80	0.922	0.970	0.965
BSA (m^2)	Q1: < 1.67	0.990	0.936	0.942
	Q2: 1.67 - 1.83	0.992	0.967	0.970
	Q3: 1.83 - 1.96	0.995	0.993	0.993
	Q4: 1.96 - 2.14	0.998	1.019	1.016
	Q5: >= 2.14	1.025	1.083	1.077
Low BMI	No	1.003	1.002	1.002
	Yes	0.903	0.915	0.914
Onset	No	0.994	0.996	0.996
	Yes	1.120	1.078	1.083

Average Cost Per Treatment Shows Limited Variation by Beneficiary Characteristics

Average Cost per Treatment (CpT) by beneficiary characteristics - computed in Approach 2 (2017), weighted by treatment counts, scaled relative to adults/pediatric mean

Beneficiary characteristics		Avg SB Cpt	Avg CR CpT	Avg SB + CR CpT
Adults				
Gastro-intestinal tract bleeding (acute)	No	0.999	1.000	1.000
	Yes	1.349	0.983	1.024
Hereditary hemolytic or sickle cell anemia (chronic)	No	0.998	1.000	1.000
	Yes	1.933	0.965	1.072
Myelodysplastic syndrome (chronic)	No	0.999	1.000	1.000
	Yes	1.545	0.971	1.034
Pericarditis (acute)	No	1.000	1.000	1.000
	Yes	1.151	1.091	1.098
Low Volume	No	1.001	0.995	0.996
	Yes	0.910	1.348	1.300
Pediatric				
Age	<13	0.808	0.922	0.917
	13 - 17	1.218	1.088	1.094

Approach 2 Exhibits Larger Effects from Most Case-Mix Factors Than Approach 1

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers (Approach 1)	New Multipliers (Approach 2)
Age	18 - 44	**1.257**	1.015	1.035
	45 - 59	**1.068**	1.005	1.024
	60 - 69	**1.070**	1.003	1.012
	70 - 79 (reference)	**1.000**	1.000	1.000
	>= 80	**1.109**	0.997	0.986
	Onset	**1.327**	1.048	1.058
	BSA (per 0.1 m2)	**1.032**	1.002	1.018
	Underweight (BMI < 18.5)	**1.017**	1.003	0.99
Comorbidities	Pericarditis (acute)	**1.040**	1.044	1.035
	Gastro-intestinal tract bleeding (acute)	**1.082**	1.039	1.043
	Hereditary hemolytic or sickle cell anemia (chronic)	**1.192**	1.104	1.097
	Myelodysplastic syndrome (chronic)	**1.095**	1.049	1.051
Facility	Low Volume	**1.239**	1.252	1.252
	Rural	**1.008**	1.02	1.015

* All New Multipliers are significant ($p < 0.0001$). Current Multipliers are combination of two regressions, and without significance level associated.
* Current Multipliers are estimated by KECC on 2012 and 2013 data.
* New Multipliers are estimated on 2016 and 2017 data using proposed one-equation method.

Approach 2 Shows Small, Positive Effects of Case-Mix Factors Suggested by TEP

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers (Same Case-Mix)	New Multipliers (New Case-Mix Added)
Age	18 - 44	**1.257**	1.035 ****	1.041 ****
	45 - 59	**1.068**	1.024 ****	1.024 ****
	60 - 69	**1.070**	1.012 ****	1.011 ****
	70 - 79 (reference)	**1.000**	1.000	1.000
	>= 80	**1.109**	0.986 ****	0.988 ****
	Onset	**1.327**	1.058 ****	1.056 ****
	BSA (per 0.1 m2)	**1.032**	1.018 ****	1.018 ****
	Underweight (BMI < 18.5)	**1.017**	0.99 ****	0.988 ****
Comorbidities	Pericarditis (acute)	**1.040**	1.035 ****	1.033 ****
	Gastro-intestinal tract bleeding (acute)	**1.082**	1.043 ****	1.038 ****
	Hereditary hemolytic or sickle cell anemia (chronic)	**1.192**	1.097 ****	1.096 ****
	Myelodysplastic syndrome (chronic)	**1.095**	1.051 ****	1.046 ****
Facility	Low Volume	**1.239**	1.252 ****	1.252 ****
	Rural	**1.008**	1.015 ****	1.016 ****

- New adjusters do not affect multipliers for existing adjusters
- Significance level:
  - * $p < 0.05$
  - ** $p < 0.01$
  - *** $p < 0.001$
  - **** $p < 0.0001$

Approach 2 Shows Small, Positive Effects of Case-Mix Factors Suggested by TEP (Cont'd)

Category	Case-Mix Adjusters (Adults)	Current Multipliers	New Multipliers (Same Case-Mix)	New Multipliers (New Case-Mix Added)
New Adjusters	Current Disability			1.006 ****
	HBV (acute or chronic) in prev 12 months			1.015 ****
	Cancer			1.014 ****
	Diabetes			1.013 ****
	Liver Disease/Cirrhosis			1.032 ****
	Dementia			1.013 ****
	Neurologic Muscular Diseases			1.011 ****
	Strokes/Coma			1.008 ****
	Paralytic Syndromes			1.003 ****
	Respiratory Problems			1.032 ****
	Psychiatric Disorders			1.01 ****
	Drug/Alcohol Use Disorder			1.019 ****
	Ulcers			1.021 ****
	Autonomic Neuropathy			1.006 ****
	Blindness			1.001
	Hearing Loss			1.000

- New adjusters do not affect multipliers for existing adjusters
- Significance level:
  - * $p < 0.05$
  - ** $p < 0.01$
  - *** $p < 0.001$
  - **** $p < 0.0001$

Revisions to Claims and Cost Reports Needed to Support Approach 2

- As with Approach 1:
  - Ensure costs from cost reports are comprehensive
  - Ensure the rules for the allocation of costs by modality are meaningful
  - Improve the reporting specificity of Medicare treatment counts
  - Differentiate composite rate (CR) labs and supplies from formerly separately billable (FSB)
- Collect information on components of capital and labor costs that are used particularly heavily by clearly defined patient types
  - Examples of improved data collection for cost reports to consider
    - Cost of equipment specific to home dialysis
    - Cost of specific types of dialyzers
    - Cost of particular labor categories used more extensively by clearly defined patients (e.g. social workers or administrative staff)
    - Cost of maintaining an isolation room (HBV patients)
    - Cost of patient assist equipment (patients with mobility issues)

Revisions to Claims and Cost Reports Needed to Support Approach 2

- Illustration of how collecting information on specific cost components can support Approach 2 using example of onset patients
- Have small case-mix adjustments in the Approach 2 results above because they exhibit little difference in treatment times
- However, onset patients may be more costly to treat for a variety of reasons
  - Some costs are formerly separately billable and identifiable on claims (E.g. injectable medications)
  - Others are composite rate costs related to capital, labor, or administration and are not identifiable from claims or cost reports (E.g. greater use of staffing time from social workers, nutritionists, nurses, and administrative staff)
- If cost reports separately identify these key components of composite rate costs, then these costs can be compared to the share of onset patients to infer the distinct costs associated with onset
- Note that this is distinct from the current facility-level equation in the two-equation model because this approach explicitly identifies cost components that are highly correlated with an important patient type

Revisions to Claims and Cost Reports Needed to Support Approach 2

- Simple reporting change to dialysis treatment lines could capture treatment time in minutes using a revenue code
  - Would replace the current reported line for a dialysis treatment
  - 2018 TEP preferred reporting on claims over CROWNWeb
    - Time on dialysis from CROWNWeb is only reported once per month and data are not available for all beneficiaries/months

Missing Rates in CROWNWeb HD Treatment Duration, And Imputation Steps - 2017

Imputation Steps For Missing Information	# Provider-Bene-Month	%
Same provider-bene-month found - No imputation	3,270,075	92.00
Imputed from same bene-month at other providers	101,332	2.85
Imputed from same provider-bene in other months	110,539	3.11
Imputed from same bene and other provider-months	19,063	0.54
Remained missing after imputation	53,453	1.50

With Either Approach 1 or 2, Similar Challenges Involved for Pediatric Beneficiaries

- Pediatric patients constitute tiny fraction of total ESRD population, limiting the ability to precisely estimate costs
- Pediatric patients disproportionately receive treatment in hospital-based facilities, but hospital cost report (CMS Form 2552-10) does not distinguish pediatric and adult dialysis costs

% of Treatments in Two Types of Facilities
Adults vs. Pediatric, 2017

	% Treatments in Hospital-Based Facilities	% Treatments in Freestanding Facilities
Adults	5%	95%
Pediatric	59%	41%

- Cost reports for freestanding facilities do provide a breakdown of pediatric and adult dialysis, but this faces several limitations

Approach 1 Version for Pediatric Dialysis Measures Costs Relative to Adults

- Include pediatric patients in the same one-equation model
- For pediatric patients, assign 0 to all explanatory variables in the adult model, and create 4 pediatric-specific variables:
  - Age < 13
  - Age 13 – 17
  - PD Treatment Interacted with Age < 13
  - PD Treatment Interacted with Age 13 - 17
- For adult patients, use the same explanatory variables in the adult model, and assign 0 to all 4 pediatric-specific variables
- This regression shows cost per treatment for different categories of pediatric patients relative to the reference adult group
- We then reconstruct multipliers for each category of pediatric patients

Approach 1 Version for Pediatric Dialysis Measures Costs Relative to Adults

Category	Case-Mix Adjusters (Adults + Indicators for Pediatric)	Current Multipliers	New Multipliers (Approach 1)
Age	18 - 44	**1.257**	1.015 ****
	45 - 59	**1.068**	1.005 ****
	60 - 69	**1.070**	1.003 ****
	70 - 79 (reference)	**1.000**	1.000
	>= 80	**1.109**	0.997 ****
	Onset	**1.327**	1.048 ****
	BSA (per 0.1 m2)	**1.032**	1.002 ****
	Underweight (BMI < 18.5)	**1.017**	1.003 ****
Comorbidities	Pericarditis (acute)	**1.040**	1.044 ****
	Gastro-intestinal tract bleeding (acute)	**1.082**	1.039 ****
	Hereditary hemolytic or sickle cell anemia (chronic)	**1.192**	1.104 ****
	Myelodysplastic syndrome (chronic)	**1.095**	1.049 ****
Facility	Low Volume	**1.239**	1.252 ****
	Rural	**1.008**	1.02 ****
Pediatric	Age < 13		1.869 ****
	Age 13 - 17		1.666 ****
	PD Treatment Interacted with Age < 13		0.652 ****
	PD Treatment Interacted with Age 13 - 17		0.748 ****

* All New Multipliers are significant ($p < 0.0001$). Current Multipliers are combination of two regressions, and without significance level associated.
* Current Multipliers are estimated by KECC on 2012 and 2013 data.
* New Multipliers are estimated on 2016 and 2017 data using proposed one-equation method.

Approach 1 for Pediatric Dialysis Exhibits Significant Multipliers

Multipliers For Pediatric Population From One-Equation Model (2016 - 2017 data)

HD/PD	Case-Mix Adjusters (Pediatric)	Current Multipliers	New Multipliers (Approach 1)
HD	Age < 13	1.306	1.869 ****
HD	Age 13 - 17	1.327	1.666 ****
PD	Age < 13	1.063	1.219 ****
PD	Age 13 - 17	1.102	1.247 ****

* Significance level: * p < 0.05, ** p < 0.01, *** p < 0.001, **** p < 0.0001
* New Multipliers are estimated on 2016 and 2017 data using proposed one-equation method.

Limitations of Freestanding Facility Cost Reports in Capturing Cost of Pediatric Dialysis

- Cost report allocates each category of expenses to pediatric/adult only indirectly, using various cost accounting rules described previously
- This method does not directly acquire information on the dimensions along which pediatric costs differ from adult costs:
  - Pediatric patients require items and services not currently reflected in cost reports (e.g. stocks of more types/sizes of supplies and special equipment, special training for nurses)
  - Several relevant labor categories are not reflected in cost reports
    - School Liaison, Creative Art Therapist, Child-Life Specialist, Developmental Psychologist
  - Specialized direct patient care required for reasons such as:
    - Vascular access options differ
    - One-on-one staffing required for patients less than 2 years old

Discussion Questions

- What are the relative advantages and disadvantages of Approaches 1 and 2 for a one-equation model?
- For Approach 1:
  - Is it feasible to obtain improved reporting of dialysis session charges on claims?
  - If so, how can CMS best encourage this?
  - Can cost reports be restructured to allow for calculation of cost-to-charge ratios similar to other Medicare settings?
- For Approach 2:
  - What are the distinct types of patients served by dialysis facilities, in terms of the costs of treatment?
  - What types of costs must be collected on cost reports to better infer differences in treatment costs across these patient types?
  - What are the strengths and limitations of using time on dialysis to calculate patient-level variation in capital and labor costs?
  - Are there challenges to collecting time on dialysis information on claims?

Discussion Questions

- Are there distinct categories of dialysis session costs that cannot be captured through either charges or treatment time?
  - If so, how can these costs be reported?
- Are there other approaches to building total per-treatment costs for use in a one equation model that should be considered?
  - Which approaches are feasible with current data?
  - What data collection is necessary for remaining approaches?
- Is it sufficient to assess the distinct costs of pediatric dialysis using freestanding facility cost reports, or are revisions required to hospital cost reports?
- What pediatric-related elements missing from the current ESRD PPS cost reports should be added to adequately account for distinct costs of pediatric dialysis care?

Outline

No data	Sessions
1	Introductions and Goals for this TEP
2	Measurement of Costs for Determining Case-Mix Adjustment
3	**Wage Index**
4	Low Volume Payment Adjustment and Rural Adjustment
5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
9	Open Discussion

Session 3 Outline

Session Objective

- Examine issues with the current ESRD PPS wage index and ways to create a wage index more specific to dialysis facilities

Session Topics

- Describe the current ESRD PPS wage index
- Summarize stakeholder comments on the current wage index
- Suggest an alternative construction of the wage index for dialysis facilities
- Show implications of the alternative wage index
- Gather TEP feedback on the alternative

Session Time

45 minutes

ESRD PPS Uses the Hospital Wage Index to Adjust for Geographic Wage Differences

- Wage index is based on hospitals subject to the Inpatient Prospective Payment System (IPPS)
  - Derived from wage and employment data from hospital cost reports (Form CMS 2552-10)
- All else equal, ESRD PPS payments are higher for facilities in areas with a higher wage index
  - Payments depend on the product of the wage index with (i) Labor-related share of the base rate, and (ii) Training add-on payment

Stakeholders Have Expressed Two Main Concerns with the Existing Wage Index

- Data delays limit applicability
  - IPPS wage index is computed using data from 4 fiscal years prior
  - Data lag may result in underestimation of relative wages because data do not capture recent state and municipality minimum wage increases and overall economic growth
- IPPS hospitals and outpatient dialysis facilities may have different labor costs and occupational mixes
  - IPPS wage index construction includes wage data for many occupations seldom or not utilized by dialysis facilities
  - Data gathered from occupational mix survey include five categories: Registered Nurse, Licensed Practical Nurse, Nurse Aides, Medical Aides, and All Other
  - Examples of categories grouped to *All Other* include, but are not limited to: non-physician anesthetist, teaching physician, interns & residents, home office personnel

Hospitals and Dialysis Facilities Have Different Occupational Mixes and Average Wages

Occupational Mix and Average Hourly Wages

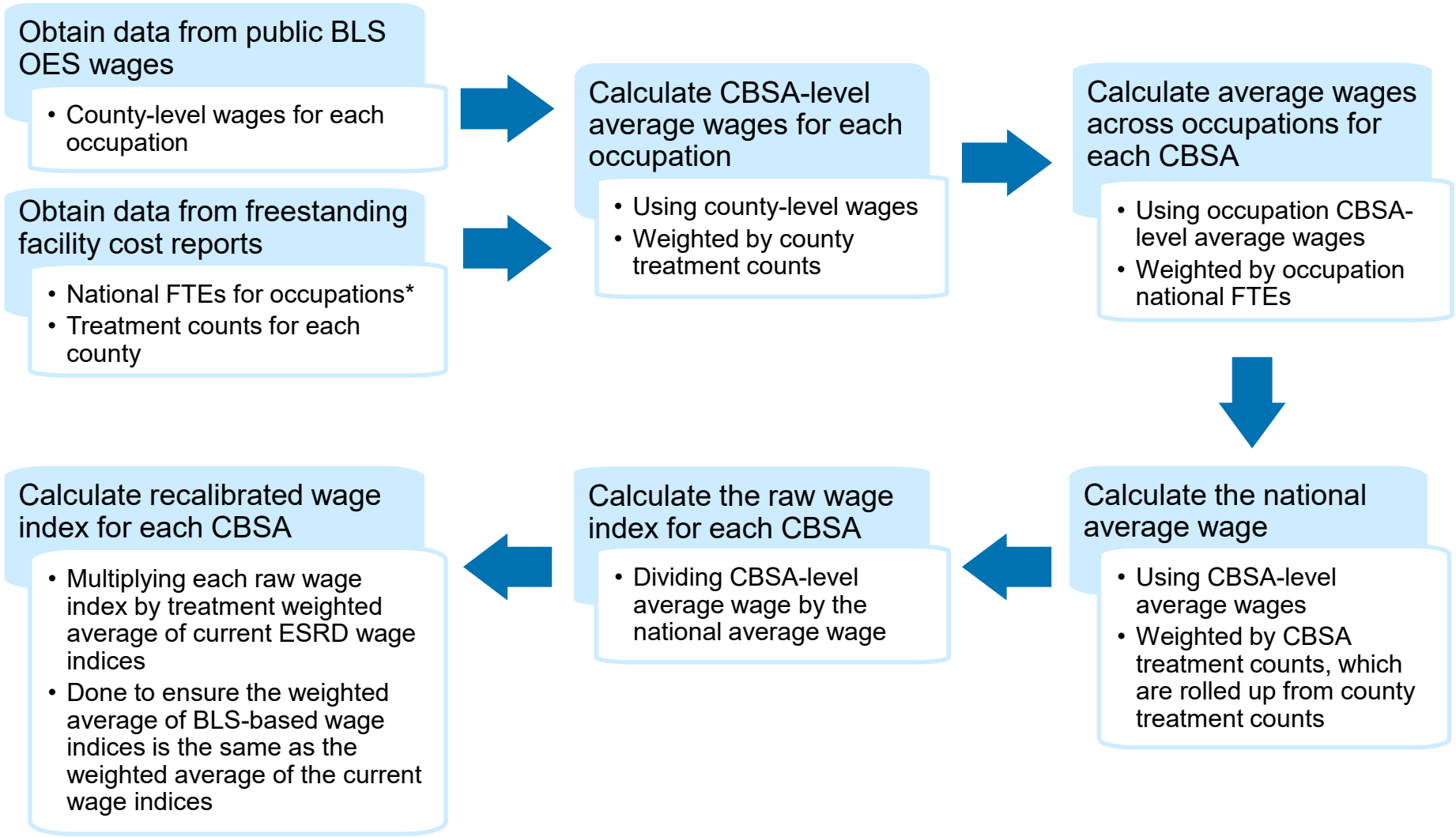
	IPPS Hospitals		Dialysis Facilities	
Occupation	**Occupational Mix***	**Average Hourly Wage ($)***	**Occupational Mix****	**Average Hourly Wage ($)*****
Registered Nurse	28.40%	41.7	28.74%	35.6
Licensed Practical Nurse	2.64%	24.7	4.63%	22.5
Nurse Aides	7.54%	17.0	2.32%	13.7
Medical Aides	1.45%	18.1	N/A	-
Other (Total)	59.97%	32.1	N/A	-
Technicians	N/A	-	39.68%	25.5
Social Workers	N/A	-	4.51%	27.5
Dieticians	N/A	-	4.41%	28.7
Administrative	N/A	-	10.96%	17.9
Management	N/A	-	4.76%	52.8
Additional Occupations	N/A	-	N/A	-

* Source: FY_2019_S3_and_OccMix_Final_Rule_PUF_07182018 downloaded from: https://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page. The All Other occupation category includes these subcategories, along with a variety of other occupations including, but not limited to: non-physician anesthetist, teaching physician, interns & residents, home office personnel.
** Source: Independent facility cost reports (Form CMS-265-11)
*** Source: BLS OES wage data (May 2017)

Suggested Approach to Revising Wage Index Aims to Address Concerns Raised by Stakeholders

- Alternative approach combines two sources of data
  - Information on occupational mix from freestanding facility cost reports
  - Wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) on occupation-specific wages in each county
    - OES program conducts a semiannual survey to produce estimates of employment and wages for numerous occupations
    - E.g., May 2017 OES wage estimates are based on data from six surveys, spanning from November 2014 to May 2017
- Approach is more specific to dialysis facilities and uses somewhat more recent data than the IPPS wage index
  - Requires no additional administrative burden and can be accomplished with currently available data

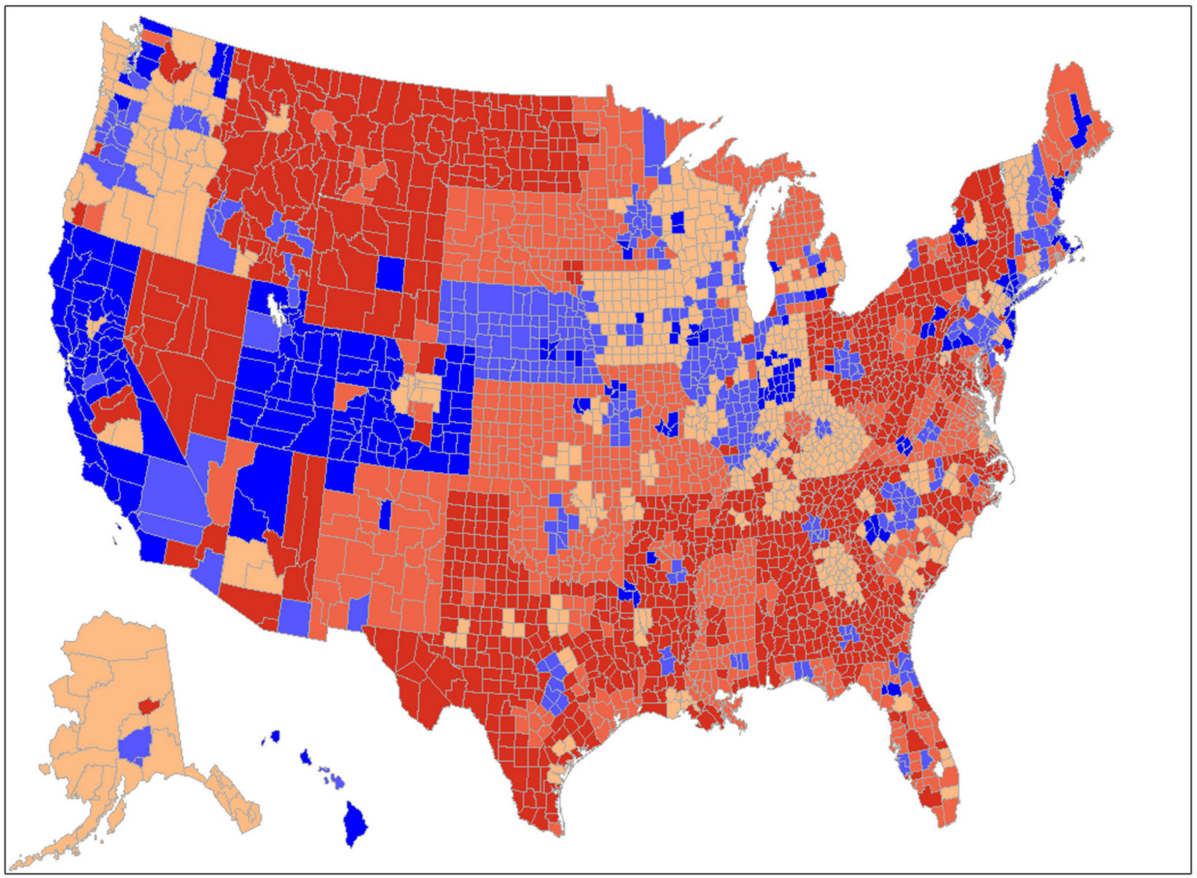
Methodology Combines Cost Reports and BLS OES Wages to Calculate a Wage Index for Dialysis Facilities



*Occupations chosen correspond to those on freestanding facility cost reports: RNs, LPNs, Nurses' Aides, Technicians, Social Workers, Dieticians, Administrative Staff, and Management

Majority of Counties Experience a Significant Change by Applying the Alternative Wage Index

Percent Change from IPPS to BLS Wage Index

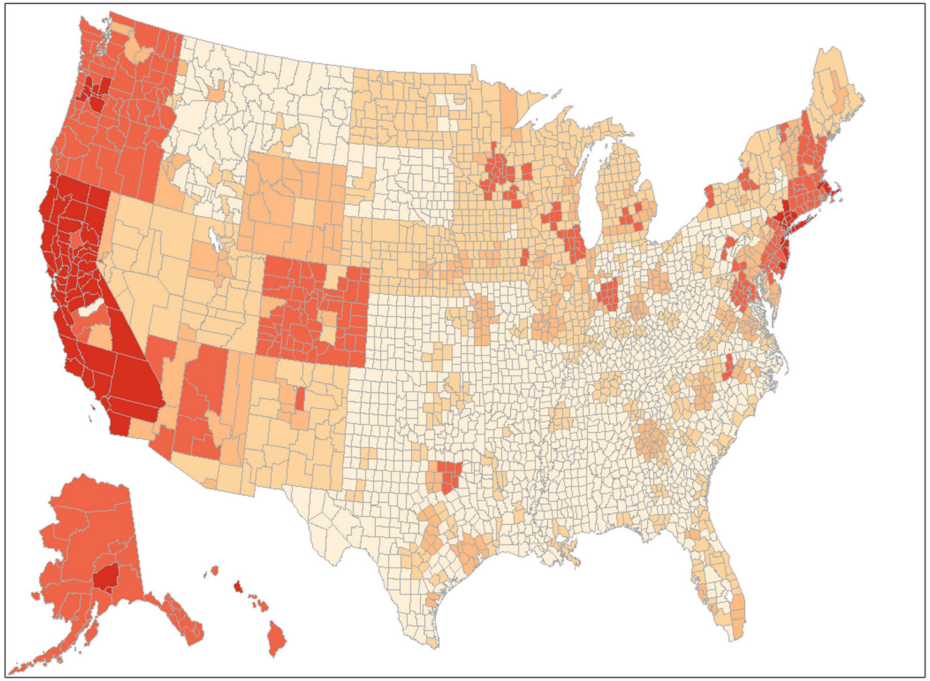


Bin	% Change
	< -5%
	-5% to 0%
	> 0% to 4%
	4% to 8%
	> 8%

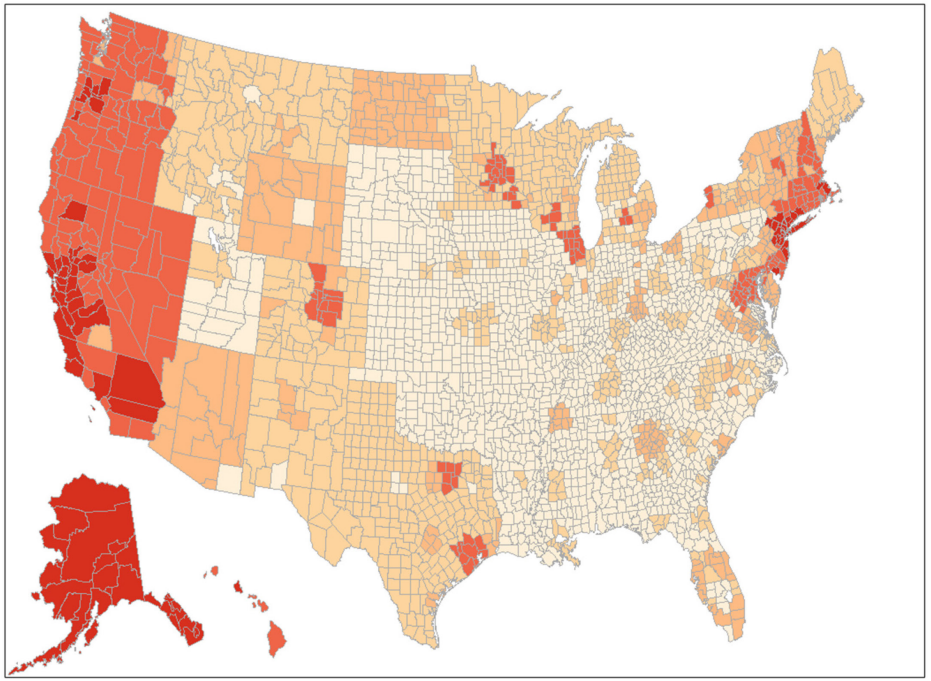
- 60 percent of counties experience an increase of more than 4 percent or a decline of more than 5 percent

Relative Rankings of Counties Are Similar Across the Two Wage Indexes

IPPS Wage Index Quintile by County



BLS Wage Index Quintile by County



- Counties often remain in the same quintile or change by at most one quintile

Bin	Quintile
	1st to 20th percentile
	21st to 40th percentile
	41st to 60th percentile
	61st to 80th percentile
	81st to 100th percentile

Largest Increases in Wage Indexes Targeted to Rural Areas

Facility Type	Number of Providers	Ratio of Proposed Wage Index to Current Wage Index			
		Average	25th Pctl	50th Pctl	75th Pctl
All Facilities	7,099	1.027	0.976	1.029	1.075
Geographic Location					
Rural	1,271	1.072	1.036	1.075	1.104
Urban	5,828	1.017	0.970	1.024	1.072
Census Region					
East North Central	1,145	1.016	0.975	1.004	1.055
East South Central	572	1.094	1.038	1.088	1.120
Guam, AS, MP	8	0.978	0.938	0.938	1.044
Middle Atlantic	777	1.002	0.953	0.973	1.063
Mountain	400	1.030	0.968	1.024	1.056
New England	191	1.009	0.968	1.012	1.053
Pacific*	837	0.915	0.876	0.906	0.970
Puerto Rico and Virgin Islands	51	1.319	1.254	1.278	1.394
South Atlantic	1,622	1.055	1.024	1.056	1.087
West North Central	497	1.009	0.983	1.007	1.039
West South Central	999	1.065	1.037	1.072	1.079

*Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

Distribution of Wage Index Changes Is Similar Along Several Facility Characteristics

Facility Type	Number of Providers	Ratio of Proposed Wage Index to Current Wage Index			
		Average	25th Pctl	50th Pctl	75th Pctl
All Facilities	7,099	1.027	0.976	1.029	1.075
Type					
Hospital Based	418	1.027	0.975	1.024	1.071
Freestanding	6,681	1.027	0.976	1.029	1.075
Ownership Type					
Large dialysis organization	5,400	1.029	0.979	1.030	1.076
Regional chain	881	1.021	0.971	1.029	1.072
Independent	485	1.015	0.953	1.007	1.072
Hospital based*	327	1.030	0.973	1.024	1.075
Unknown	6	0.999	1.003	1.028	1.037
Facility Size					
Less than 4,000 treatments	1,245	1.031	0.987	1.030	1.072
4,000 to 9,999 treatments	2,666	1.038	0.997	1.037	1.087
10,000 or more treatments	3,147	1.016	0.961	1.023	1.072
Unknown	41	1.022	0.974	1.040	1.075

*Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership

Average Regional Payment Changes Generally Mirror Average Wage Index Changes

Facility Type	Number of Providers	Ratio of Payments Using Proposed Wage Index vs Current Wage Index			
		Average	25th Pctl	50th Pctl	75th Pctl
All Facilities	7,099	1.006	0.984	1.010	1.033
Geographic Location					
Rural	1,271	1.028	1.013	1.030	1.044
Urban	5,828	1.001	0.979	1.008	1.031
Census Region					
East North Central	1,145	1.003	0.984	0.998	1.022
East South Central	572	1.038	1.014	1.039	1.050
Guam, AS, MP	8	0.985	0.965	0.965	1.018
Middle Atlantic	777	0.995	0.969	0.983	1.026
Mountain	400	1.010	0.980	1.008	1.024
New England	191	1.000	0.977	1.003	1.023
Pacific*	837	0.943	0.921	0.941	0.979
Puerto Rico and Virgin Islands	51	1.098	1.078	1.109	1.119
South Atlantic	1,622	1.022	1.008	1.023	1.041
West North Central	497	0.999	0.987	0.999	1.014
West South Central	999	1.027	1.014	1.030	1.033

*Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

Payment Changes Are Attenuated Relative to Wage Index Changes, by Facility Type

Facility Type	Number of Providers	Ratio of Payments Using Proposed Wage Index vs Current Wage Index			
		Average	25th Pctl	50th Pctl	75th Pctl
All Facilities	7,099	1.006	0.984	1.010	1.033
Type					
Hospital Based	418	1.007	0.984	1.008	1.029
Freestanding	6,681	1.006	0.984	1.010	1.033
Ownership Type					
Large dialysis organization	5,400	1.007	0.986	1.011	1.033
Regional chain	881	1.002	0.980	1.011	1.033
Independent	485	1.001	0.970	0.999	1.028
Hospital based*	327	1.008	0.983	1.008	1.033
Unknown	6	0.991	0.998	1.010	1.012
Facility Size					
Less than 4,000 treatments	1,246	1.009	0.990	1.011	1.033
4,000 to 9,999 treatments	2,666	1.012	0.995	1.014	1.039
10,000 or more treatments	3,147	1.000	0.975	1.007	1.031
Unknown	40	1.006	0.982	1.016	1.033

*Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership

Refinements to Suggested Approach Are Possible With Access to Additional BLS Data

- Approach implemented above uses publicly available BLS OES data
  - Publicly available data provide wages by occupation for each broad geographic area
  - Not further broken down by type of healthcare facility
- Access to confidential BLS OES data would facilitate two further refinements to the suggested approach
  - Determine average occupation-specific wages for specific types of healthcare facilities most analogous to dialysis facilities
  - Examine wages specific to smaller geographic areas

Selected Cost Report Changes Would Refine the Suggested Approach

- Increase specificity of labor categories to better reflect current staffing patterns and associated labor costs
  - Current cost report includes limited number of categories:
    - Physicians, RNs, Licensed Practical Nurses, Nurses Aides, Technicians, Social Workers, Dieticians, Administrative, Management, and Other
  - Additions to labor categories could include:
    - Intermediate providers such as nurse practitioners
    - Specialists treating pediatric patients
    - Further breakdown of administrative and management (e.g., management, business and financial operations, office and administrative support, computer systems analysts)
- Clarify instructions for reporting of FTEs by labor category
  - Current cost report asks for a given staff member's hours to be allocated across categories according to the type of activity performed (e.g. administrative work performed by a physician)

Discussion Questions

- What are the advantages of the suggested approach to constructing wage indexes, relative to the current system?
- What are the main limitations of the suggested approach?
- Can any limitations be addressed through the use of confidential BLS OES data and/or changes to the cost reports?
- If confidential BLS OES data were available, what types of healthcare facilities should be used to calculate average wages relevant to dialysis facilities?
- What additional labor categories, if any, should be added to cost reports to support the revision of the wage index? Are any other changes to the cost reports required for this purpose?

Outline

No data	Sessions
1	Introductions and Goals for this TEP
2	Measurement of Costs for Determining Case-Mix Adjustment
3	Wage Index
4	**Low Volume Payment Adjustment and Rural Adjustment**
5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
9	Open Discussion

Session 4 Outline

Session Objective

- Assess changes to the Low Volume Payment and Rural Adjustments to maintain/improve access to dialysis for beneficiaries in regions with limited dialysis options

Session Topics

- Describe existing LVPA and Rural Adjustments
- Summarize stakeholder comments on the LVPA and Rural Adjustments
- Present a preliminary approach to revise the LVPA Adjustment
- Gather TEP feedback on the approach and compare with the existing rural adjustment

Session Time

- 1 hour

Current ESRD PPS Includes Separate Adjustments for Low Volume Status and Rural Location

- Section 1881(b)(14)(D)(iii) of Social Security Act requires a payment adjustment to "reflect the extent to which [renal dialysis] costs incurred by low-volume facilities […] exceed the costs incurred by other facilities…"
  - Effective January 1, 2011
  - LVPA methodology was refined in 2016 to update payment adjustment and reduce opportunities for gaming
- Low Volume Payment Adjustment (LVPA)
  - Provided to facilities with less than 4,000 treatments per year over the previous three years
  - Includes additional requirements related to ownership status and proximity to other dialysis facilities
  - 23.9 percent payment adjustment to all treatments
- Rural Adjustment
  - The ESRD PPS also includes a 0.8 percent adjustment for all facilities located in rural areas

Stakeholders Call for Improvements in Low-Volume and Rural Adjusters

- Agree that the ESRD PPS should include adjustment for low-volume facilities
  - Should be targeted at small and independent facilities
- Recommend the LVPA be refined to better target facilities that are critical to beneficiary access
  - Under the current LVPA, all facilities below the treatment threshold receive an adjustment regardless of whether they are necessary for access
- Concerned that strict treatment count threshold introduces a "cliff-effect" and could allow gaming
- Commenters split regarding rural adjustment
  - Some stated that the two adjusters were "overlapping"
  - Others maintained rural adjustment accounts for costs not covered by the current LVPA

Novel Approach to LVPA Should Support Policy Goals and Address Stakeholder Concerns

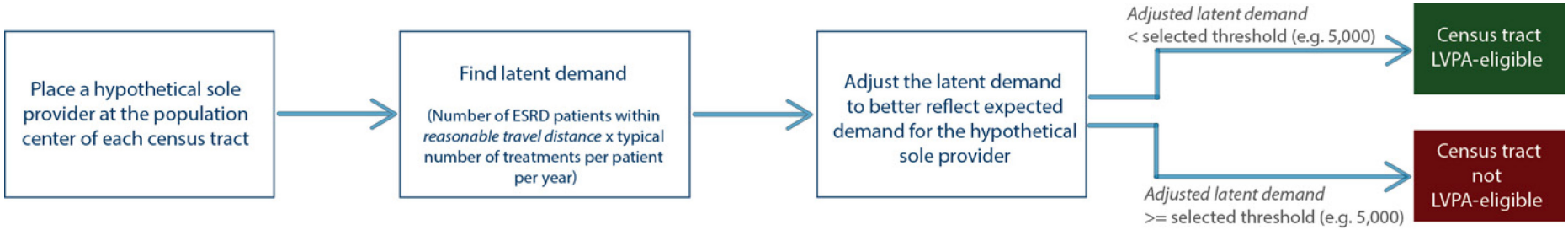
- Policy Goals:
  - Encourage (1) currently operating facilities to continue providing access to care and (2) entry of facilities into areas at risk for limited access to care, due to prohibitively low demand for dialysis treatment and high marginal treatment cost
  - Reduce provider burden associated with LVPA attestation process
- Stakeholder Concerns:
  - Discussed on previous slide

Novel Approach to LVPA

- Divide US into market areas based on willingness to travel
  - More willingness/ ability to travel longer distances in rural areas
  - Less willingness/ ability to travel a given distance in urban areas where socioeconomic status and other factors impede access to transportation
- Calculate expected demand for dialysis in each area
  - Identify areas where expected demand is so low that a facility would be forced to operate on a small scale and thus at high cost per treatment
- The size of the LVPA payment could be calculated as the difference between average cost to provide care in these low demand areas and higher demand areas
- Consider use of tiers
  - No reason to confine to single subsidy

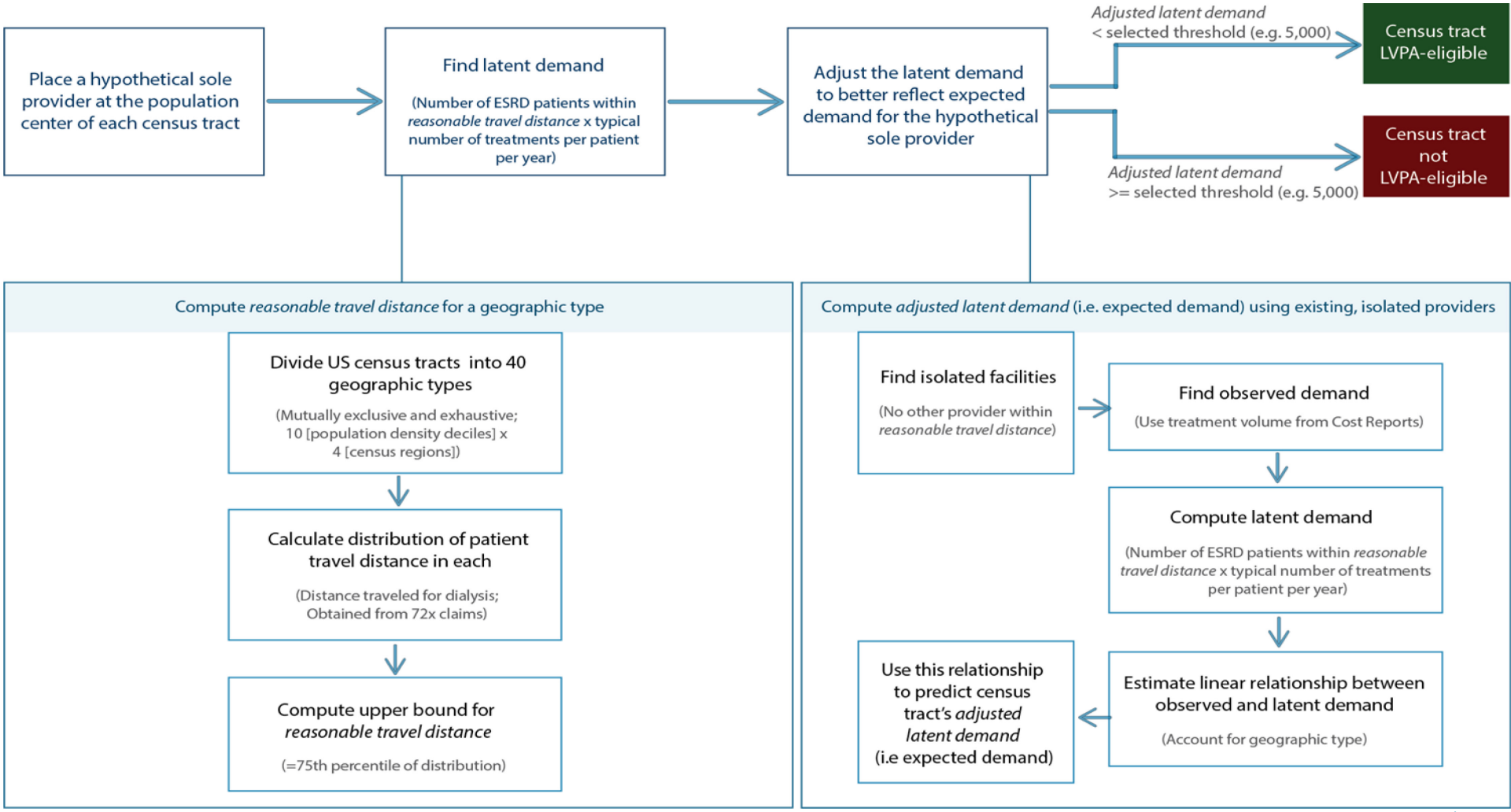
Proposed LVPA Status to Low-Volume Regions, Not Facilities

All facilities in a LVPA-eligible region receive LVPA



Proposed LVPA Status to Low-Volume Regions, Not Facilities

All facilities in a LVPA-eligible region receive LVPA



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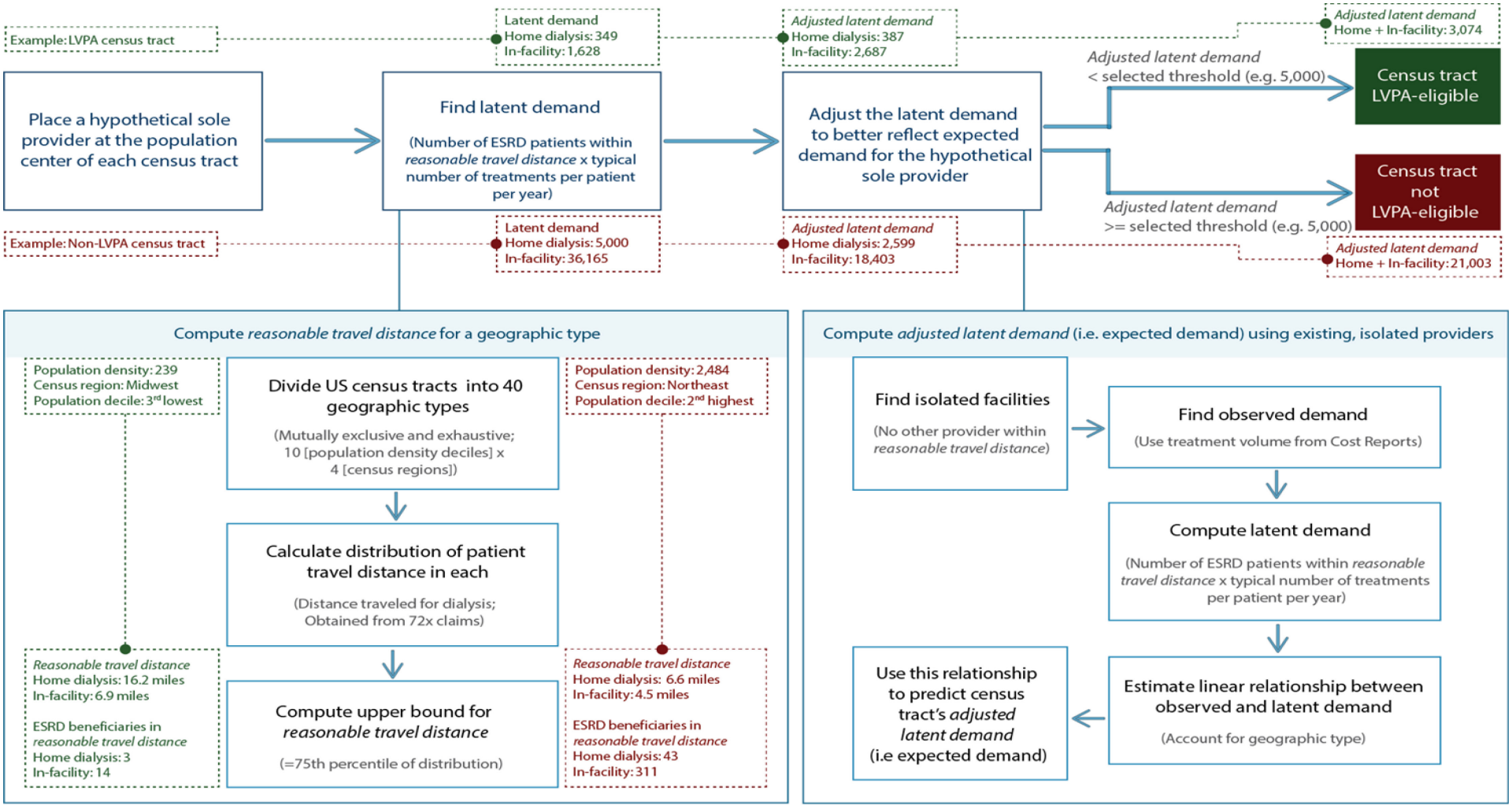
Proposed LVPA Status to Low-Volume Regions, Not Facilities

All facilities in a LVPA-eligible region receive LVPA



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Set the Threshold for LVPA Status at Adjusted Latent Demand of 5,000 or Fewer Treatments

- Selecting a threshold is necessary to compare the proposed methodology to the existing LVPA
  - An alternative threshold can be chosen
- Today, a threshold of 5,000 or fewer treatments selected for two primary reasons:
  - Freestanding facility cost-per-treatment differential stabilizes around proposed LVPA threshold of 5,000
  - Existing provider count to receive LVPA under proposed LVPA (333) is most similar to the current LVPA (335)

Value of Adjusted Latent Demand (Number of Treatments)

	< 3000	>=3k and < 4k	>=4k and < 5k	>=5k and < 6k	>=6k and < 7k	>=7k and < 8k	>=8k and < 9k	> 9000
Count of US Census Tracts	**1,233**	**1,016**	**1,324**	**1,712**	**1,944**	**2,134**	**2,165**	**62,587**
Tracts with Providers	67	117	135	192	196	194	212	4,923
Number of Providers	68	125	140	201	213	206	233	5,624
Provider Cost Per Treatment ($)								
Freestanding	305	284	268	254	247	246	245	250
Hospitals	344	339	353	322	355	347	320	348

Proposed Methodology Targets More Rural Facilities

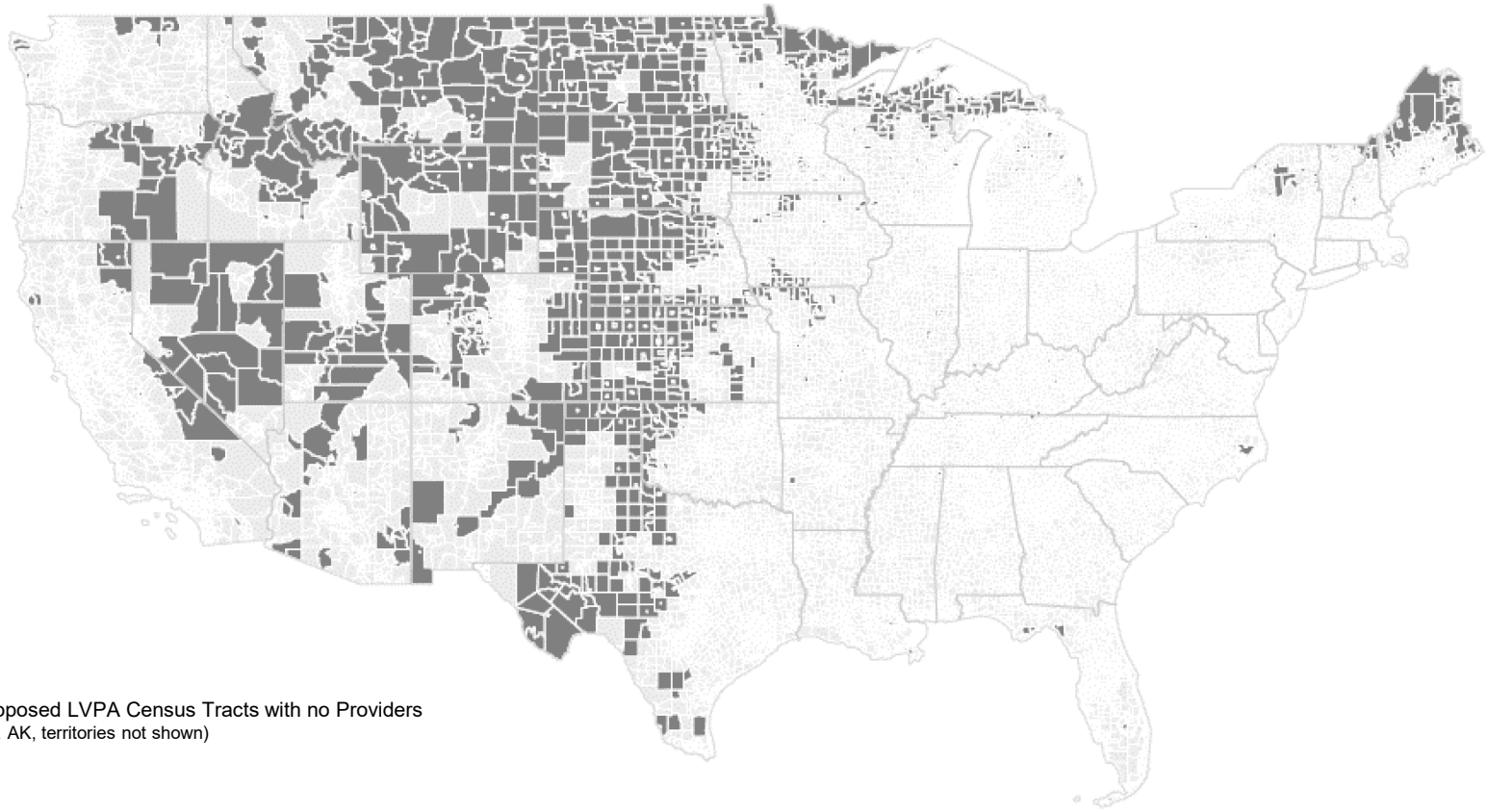
Count of Rural vs Urban Facilities Receiving Current LVPA – Yes/No

Proposed LVPA Tiers	All Facilities - Yes	All Facilities - No	Rural - Yes	Rural - No	Urban - Yes	Urban - No
Tier1: Lowest Predicted Demand (<3000)	37	**31**	33	**27**	4	**4**
Tier2: Medium Predicted Demand (3000-5000)	70	**195**	59	**169**	11	**26**
Tier3: No LVPA (>5000)	**228**	6249	**78**	877	**150**	5372

- 86% of proposed LVPA facilities are rural, 51% in current LVPA
- 23% of all rural facilities operate in proposed LVPA regions
- 68% of rural proposed LVPA facilities do not have current LVPA status
  - 196 would receive LVPA, 78 lose LVPA

Proposed Approach Incentivizes Provider Relocation to Underserved Areas

- Majority (92%) of proposed LVPA census tracts have no providers



Proposed LVPA Census Tracts with no Providers
(HI, AK, territories not shown)

- 5% of census tracts receive proposed LVPA status

Facilities Receiving the LVPA under Proposed Methodology Are More Isolated

- Proposed LVPA facilities are 29.7 miles on average from their nearest provider, relative to 4.7 miles for proposed non-LVPA facilities

Facility Type	Proposed LVPA = No	Proposed LVPA = Yes
All Facilities	6,477	333
Nearest Provider		
Number of Providers within Standard Travel Distance	6.0	0.1
Mean Distance to Nearest Provider*	4.7	29.7
Local Population Density		
Mean Total Population Per Square-Kilometer	1,598	303
Geographic Location		
Rural	15%	86%
Urban	85%	14%
Avg Local Capacity (Num Seats x2.5)		
Daily Capacity - Own	48	43
Cumulative Daily Capacity - Neighboring Providers**	293	6

*Nearest provider defined using shortest straight line distance between 2 providers
**Neighboring providers defined by drawing a radius around a provider based on applicable standard travel distance

Proposed LVPA Facilities Have Characteristics Similar to a Subset of Current LVPA Facilities

- Facilities newly designated LVPA under proposed method have very similar geographic characteristics as facilities that receive LVPA under both the Current and Proposed Methodologies

Facility Type	Current LVPA = No Proposed LVPA = No	Current LVPA = Yes Proposed LVPA = Yes	Current LVPA = No Proposed LVPA = Yes
All Facilities	6,249	107	226
Nearest Provider			
Number of Providers within Standard Travel Distance	6.1	0.1	0.2
Mean Distance to Nearest Provider*	4.5	35.0	27.2
Local Population Density			
Mean Total Population Per Square Kilometer	1,637	277	316
Geographic Location			
Rural	14%	86%	87%
Urban	86%	14%	13%
Avg Local Capacity (Num Seats x2.5)			
Daily Capacity - Own	48.8	47.5	41.5
Cumulative Daily Capacity - Neighboring Providers**	299.6	3.8	7.5

*Nearest provider defined using shortest straight line distance between 2 providers

**Neighboring providers defined by drawing a radius around a provider based on applicable standard travel distance

Facilities not Receiving LVPA under Proposed Methodology Are Less Isolated

- Current LVPA facilities that are not in proposed LVPA census tracts:
  - Have characteristics similar to facilities that have never received LVPA status
  - Do not have characteristics similar to proposed LVPA facilities

Facility Type	Current LVPA = No Proposed LVPA = No	Current LVPA = Yes Proposed LVPA = Yes	Current LVPA = Yes Proposed LVPA = No
All Facilities	6,249	107	228
Nearest Provider			
Number of Providers within Standard Travel Distance	6.1	0.1	2.3
Mean Distance to Nearest Provider*	4.5	35.0	8.1
Local Population Density			
Mean Total Population Per Square Kilometer	1,637	277	522
Geographic Location			
Rural	14%	86%	34%
Urban	86%	14%	66%
Avg Local Capacity (Num Seats *2.5)			
Daily Capacity - Own	48.8	47.5	34.5
Cumulative Daily Capacity - Neighboring Providers*	299.6	3.8	101.7

*Nearest provider defined using shortest straight line distance between 2 providers
**Neighboring providers defined by drawing a radius around a provider based on applicable standard travel distance

Facilities in Proposed LVPA Census Tracts are More Hospital-Based and Less LDO

- Facilities that are designated LVPA under proposed methodology but do not currently receive LVPA have very similar treatment and ownership characteristics compared to facilities that always receive LVPA

Facility Type	Current LVPA = No Proposed LVPA = No	Current LVPA = Yes Proposed LVPA = Yes	Current LVPA = No Proposed LVPA = Yes
All Facilities	6,249	107	226
Type			
Hospital Based	5%	36%	21%
Freestanding	95%	64%	79%
Home Dialysis Provider			
Furnishing Home Treatment	48%	18%	39%
In-Facility Only	52%	82%	61%
Ownership Type			
Large dialysis organization	76%	54%	67%
Regional chain	13%	17%	9%
Independent	7%	6%	7%
Hospital Owned	4%	23%	17%

Note: Type indicates whether the facility submitted a freestanding or hospital based cost report. Ownership Type is self-reported and unrelated to cost reports. Thus the misalignment of hospital-based and hospital owned statuses

Current LVPA Facilities Not in Proposed LVPA Census Tracts Are Less Hospital-Based and More LDO

- Facilities that are not designated LVPA under proposed methodology but receive LVPA currently have very similar treatment and ownership characteristics compared to facilities that never receive LVPA

Facility Type	Current LVPA = No Proposed LVPA = No	Current LVPA = Yes Proposed LVPA = Yes	Current LVPA = Yes Proposed LVPA = No
All Facilities	6,249	107	228
Type			
Hospital Based	5%	36%	11%
Freestanding	95%	64%	89%
Home Dialysis Provider			
Furnishing Home Treatment	48%	18%	29%
In-Facility Only	52%	82%	71%
Ownership Type			
Large dialysis organization	76%	54%	72%
Regional chain	13%	17%	10%
Independent	7%	6%	10%
Hospita-Owned	4%	23%	9%

Note: Type indicates whether the facility submitted a freestanding or hospital-based cost report. Ownership Type is self-reported and unrelated to cost reports. Thus the misalignment of hospital-based and hospital-owned statuses

A Tiered Approach: The Most Isolated Facilities Have Highest Cost Per Treatment

- Estimates of the cost differential between providers vary across proposed LVPA tiers
- With the addition of the rural indicator, LVPA payments increase modestly

Model: Facility Log(cost/treatment) regressed on proposed LVPA tiers

Log Linear Regression - Excludes Rural Indicator

Variable	2-Tiered LVPA		3-Tiered LVPA		4-Tiered LVPA	
	Multiplier	P Signf	Multiplier	P Signf	Multiplier	P Signf
Predicted Demand <3000	1.22	***	1.23	***	1.24	***
Predicted Demand 3-4000	N/A		1.12	***	1.13	***
Predicted Demand 4-5000	N/A		N/A		1.07	*

Log Linear Regression - Includes Rural Indicator

Variable	2-Tiered LVPA		3-Tiered LVPA		4-Tiered LVPA	
	Multiplier	P Signf	Multiplier	P Signf	Multiplier	P Signf
Predicted Demand <3000	1.24	***	1.26	***	1.28	***
Predicted Demand 3-4000	N/A		1.16	***	1.17	***
Predicted Demand 4-5000	N/A		N/A		1.10	**
Rural Indicator	0.96	**	0.95	***	0.94	***

- Based on dialysis facilities that billed 72x during 2016 and corresponding 2016 cost report information
- The outcome is logged facility cost-per-treatment while predictors are binary indicators for whether provider is located in tracts that meet the proposed LVPA tiers. Also included are controls for geographic regions and population density of the corresponding census tract in which the provider is located

Rural Proposed Non-LVPA Facilities Are Less Isolated

- Table limits to the 1,243 rural facilities

Facility Type	Current LVPA = No Proposed LVPA = No	Current LVPA = Yes Proposed LVPA = Yes	Current LVPA = No Proposed LVPA = Yes	Current LVPA = Yes Proposed LVPA = No
All Facilities	877	92	196	78
Nearest Provider				
Number of Providers within Standard Travel Distance	0.7	0.1	0.2	0.9
Mean Distance to Nearest Provider	14.2	37.9	28.5	13.3
Local Population Density				
Mean Total Population Per Square Kilometer	294	260	304	155
Type				
Hospital Based	5%	37%	22%	10%
Freestanding	95%	63%	78%	90%
Home Dialysis Provider				
Furnishing Home Treatment	46%	16%	39%	26%
In-Facility Only	54%	84%	61%	74%
Ownership Type				
Large dialysis organization	80%	52%	65%	71%
Regional chain	10%	16%	10%	10%
Independent	6%	7%	8%	13%
Hospital Owned	4%	25%	17%	6%

- The lower cost estimate for rural status on previous slide (0.94) is primarily driven by the 955 facilities not in proposed LVPA census tracts

Discussion Questions

- Is there agreement that the LVPA should focus on ensuring or improving access to dialysis services for beneficiaries with the most limited access?
- Are there concerns about the use of a geographically-based LVPA designation, knowing that the result is still that an individual facility receives or doesn't receive the LVPA?
  - Should a distinction other than census tract be considered?
- What criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine eligibility?
  - E.g., a threshold of high average cost per treatment

Discussion Questions

- What are the concerns for facilities that will lose LVPA?
- Acknowledging that the proposed LVPA methodology focuses on isolated (and most often rural) facilities, should a separate rural adjustment be maintained, even if it is negative?
- What are the TEP's concerns about how providers may try to game the proposed LVPA?

Outline

No data	Sessions
1	Introductions and Goals for this TEP
2	Measurement of Costs for Determining Case-Mix Adjustment
3	Wage Index
4	Low Volume Payment Adjustment and Rural Adjustment
5	**Transitional Drug Add-on Payment Adjustment**
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
9	Open Discussion

Session 5 Outline

Session Objective

- Examine how to transition drugs from Transitional Drug Add-on Payment Adjustment (TDAPA) status into the ESRD PPS bundle

Session Topics

- Describe the TDAPA policy
- Summarize stakeholder comments on moving from TDAPA status to the ESRD PPS bundle
- Present options for incorporating monies after TDAPA period

Session Time

45 minutes

TDAPA Temporarily Offers Additional Payments for New Drugs

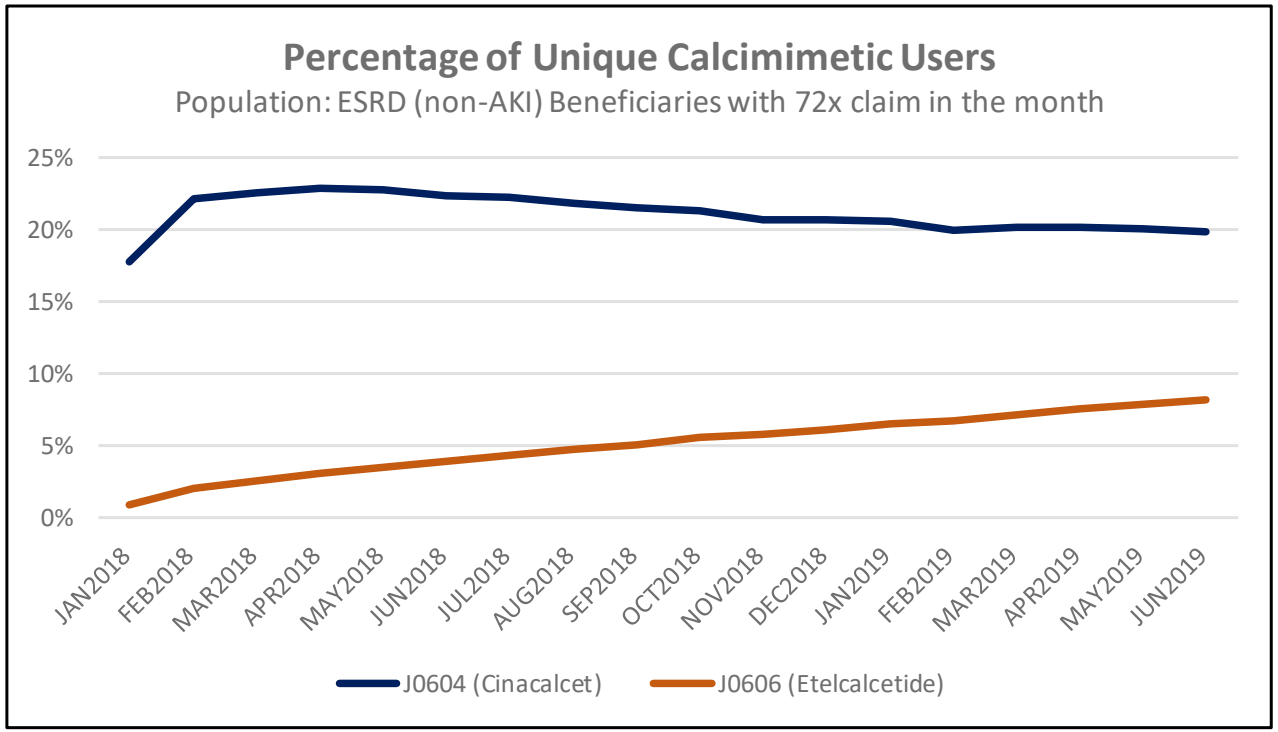
- Proposed in the CY2016 ESRD PPS rule and effective January 1, 2018 for oral and injectable calcimimetics
- Designed to facilitate beneficiary access to new renal dialysis drugs until sufficient data are collected to price these drugs into the bundle (two years) if the drug does not fall into an existing ESRD PPS functional category
  - New drugs that do fall into an existing functional category can still receive a TDAPA, but the base rate will not be adjusted when the TDAPA expires
- CY2020 Final Rule extended TDAPA coverage for calcimimetics through CY2020
- Payment is based on the Average Sales Price (ASP)
- Discussion will focus on calcimimetics as an example

Stakeholders Emphasize Need to Adjust Bundle to Incorporate Calcimimetics

- Stakeholders agree that new and innovative treatments should be incentivized separately from the bundle
- Calcimimetics need to be added to the bundle when the TDAPA expires
  - Commenters believe the base rate should be expanded to account for the additional cost of calcimimetics
- Current billing problems related to Medicare Advantage and other payers discourage use of drugs and other items without HCPCS codes
- Some commenters suggested that the TDAPA period for calcimimetics be extended past the third year

About 25% of ESRD Beneficiaries Received Calcimimetics in 2018

- Percentage of ESRD beneficiaries using cinacalcet has ranged from 20% to 25% since TDAPA was implemented
- Percentage of ESRD beneficiaries using etelcalcetide has steadily risen from 1% to about 8% since January 2018



Two Options for Incorporating Calcimimetics into the ESRD PPS Base Rate

- Option 1: Add calcimimetics into base rate
  - Cost of calcimimetics averaged across base rate increase for all dialysis treatments
- Option 2: Add calcimimetics into base rate with case-mix adjustment to account for calcimimetic use
  - Payment increase targeted at patients with past clinical indicators correlated with calcimimetic use
- Both options leverage utilization data collected during TDAPA period

Option 1 Distributes Calcimimetics Payments Evenly across All Treatments

- Consistent with a single payment for a bundle of services
- Consider a simplified example, with fabricated data for illustration, where the patients receiving calcimimetics account for 25 percent of all Medicare covered ESRD patients, and they account for 25 percent of 40,000,000 Medicare treatments
- Consider also that total costs for TDAPA drugs are $956,000,000, or roughly $95 per treatment, and the ESRD PPS base rate is $239
- In this example, Option 1 results in a $23.9 increase to the base rate
- Since 100 percent of beneficiaries would receive an increased payment in this option, payment under this option would agree with realized calcimimetic use 25 percent of the time

Option 2 Uses Case-Mix Adjustment to Target Potential Calcimimetic Use

- Monies still added to the bundle, but use of case-mix adjustment concentrates a larger portion to likely recipients of calcimimetics
- Risk adjusters can be diagnoses/conditions, or other prescriptions/medications/procedures that are correlated with calcimimetics use
- Case-mix adjusters then included in the ESRD PPS case mix model, values reported in rulemaking, and the base rate adjusted using the PPS Pricer

Option 2 Example Uses Joint Indicators for Case-mix Adjustment

- Presence of both in prior months:
  - Secondary Hyperparathyroidism (N2581)
  - Prescription of Vitamin D Analog
- Indicator driven largely by extent of Vitamin D Analog Prescription:
  - Hyperparathyroidism Diagnosis widely prevalent, vitamin D prescription less prevalent, possibly correlated with provider type

Frequency of Indicators for Calcimimetic Use Across Patient-Months in 2018 (IP, OP and PB Claims)

Individual Indicators	Freq	Pct
Vitamin D Prescription in Patient-Month (HCPCS)	1,680,238	45.0%
Vitamin D Prescription in Patient-Month (NDC)	2,499,559	67.0%
Hyperparathyroidism DGN in Patient-Month	3,370,246	90.3%

Proposed Indicator Positive for 80 Percent of Months with Use of Calcimimetics

- Recall that 25 percent of ESRD PPS beneficiaries received calcimimetics in CY 2018
- 66 percent of patient-months in 2018 had both vitamin D prescription and a diagnosis for hyperparathyroidism during 2018 in prior 2 months

	Freq	Pct	Agreement with Calcimimetic Use in Month				
			Accuracy	True positive	True negative	False positive	False negative
Vitamin D Prescription & Hyperparathyroidism in prior 2 Patient-Months	2,481,942	66.5%	50.4%	21.2%	29.2%	45.3%	4.3%

Potential Methodology for Pricing TDAPA Drugs Directly in the Bundle

- Estimate model predicting a beneficiary's future use of calcimimetics based on proposed indicator from previous slide involving secondary hyperparathyroidism and prescription for vitamin D analog
- A beneficiary with a positive value for the proposed indicator is 2.8 times more likely to receive calcimimetics, after controlling for other ESRD PPS risk adjusters

Logit Model: Predicting Calcimimetic Usage at Provider-Beneficiary-Month

Binary Outcome - Use of calcimimetic during a Provider-Patient-Month in 2018

Variable	Odds Ratio	Significance
Proposed Indicator	**2.8**	***
Age < 18	0.2	***
Age 18-44	1.8	***
Age 45-59	1.7	***
Age 60-69	1.3	***
Age 70-79		Reference
Age >= 80	0.7	***
Low BMI	0.8	***
Onset	0.1	***

*Not shown - controls for the months of the year

Proposed Risk Adjuster Is Conditionally Correlated with Use of Calcimimetics

- After factoring in age/BMI/onset status, use of the proposed case-mix adjuster results in an agreement rate of 75 percent, compared to 25 percent in Option 1

Logit Model: Agreement Between Actual and Predicted Outcome

Label	Value
Percent in Agreement*	75%
Percent in Disagreement	25%
Provider-Patient-Months	3,889,561

*Agreement occurs when the predicted probability of calcimimetic use exceeds (does not exceed) 50% and calcimimetics are (not) used.

Use of the Case-Mix Adjuster Increases Payment for Beneficiaries that Receive Calcimimetics

- Recall the example used in Option 1
  - Patients receiving calcimimetics account for 25 percent of all Medicare covered ESRD patients, and they account for 25 percent of 40,000,000 Medicare treatments
  - Total costs for TDAPA drugs are $956,000,000, or roughly $95 per treatment, and the ESRD PPS base rate is $239
- Proposed risk adjuster distributes calcimimetics payments over roughly 66 percent of treatments, instead of 100 percent in Option 1
- Results in an increased ESRD PPS payment of $36 for patients with a positive value of the proposed risk adjuster,
  - 50 percent increase in per-treatment payment relative to Option 1

Implications of Methodology for Payment by Provider Type

- Small, independent and hospital-based facilities have fewer patient-months with the proposed risk-adjuster

Percent of Time Calcimimetic Indicator Present (Patient-Months)

Facility Type	# Providers	Average	25th Pctl	50th Pctl	75th Pctl
All Facilities	7,442	64%	55%	69%	78%
Type					
Hospital based	392	38%	12%	40%	59%
Freestanding	7,050	65%	57%	69%	78%
Ownership Type					
Large dialysis organization	5,698	67%	59%	70%	79%
Regional chain	930	61%	52%	67%	76%
Independent	502	43%	12%	50%	67%
Hospital based[1]	304	36%	9%	37%	59%
Unknown	8	75%	62%	89%	97%
Facility Size					
Less than 4,000 treatments	1,385	53%	37%	58%	72%
4,000 to 9,999 treatments	2,804	64%	55%	68%	78%
10,000 or more treatments	3,219	68%	61%	71%	79%
Unknown	34	56%	46%	59%	69%

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership

Discussion Questions

- What are the perceived pros/cons of Option 1 and Option 2?
- Should claims from other (non-72x) settings be used for a potential indicator if it results in improved agreement?
- What are Panel's concerns about how such a risk adjuster could be gamed?
- Should cost reports be revised to include calcimimetics costs, relative to payments? Could cost reports include alternative ways to prospectively identify calcimimetic use?

Discussion Questions

- Are there any expected or possible trends in utilization of calcimimetics over the next few years (e.g. increased utilization or use of generics) that should be considered when incorporating calcimimetics into the bundle?
- Are there additional options distinct from Options 1 and 2 which should be considered?
- Are there other potential indicators of calcimimetic use that should be considered?

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Session 6 Outline

Session Objective

- Consider an alternative approach to the outlier adjustment to meet the 1% target

Session Topics

- Describe current approach to outlier payments
- Summarize stakeholder concerns regarding the current outlier adjustment
- Examine adjustment to calculating the outlier thresholds
- Gather TEP feedback on the proposed approach

Session Time

45 minutes

Outlier Payment Mitigates Losses for Unusually High-Cost Patients

- Outlier pays 80 percent of treatments costs above a given outlier threshold

$$ESRD\ PPS\ Outlier = 0.8 * (MAP_0 - (hat(MAP_0) + FDL))$$

MAP_0 = Per Treatment Outlier Medicare Allowable Payment (MAP) Amount from Claims
$hat(MAP_0)$ = Predicted per Treatment Outlier MAP Amount
FDL = Fixed Dollar Loss

- Each year, the FDL and Imputed MAP amounts for adult and pediatric beneficiaries are updated using claims data from two Calendar Years prior

Current Outlier Threshold Methodology Results in Total Outlier Payments Less than 1 Percent Target

- Current methodology assumes constant utilization over time
- CY 2018 Rule was finalized in late 2017
- Rule used data from 2016 to set an adult FDL amount of $77.54 that was added to the predicted MAP to determine the outlier threshold
- MAP Amount continued to fall from 2016 to 2018
- In 2018, FDL amounts were calculated in 2017 using 2016 data with the aim of making outlier payments 1 percent of total ESRD PPS payments in 2018
- In 2018, outlier payments constituted 0.5 percent of total ESRD PPS payments
  - In 2018, outlier payments constituted 0.6 percent of total non-TDAPA ESRD PPS payments

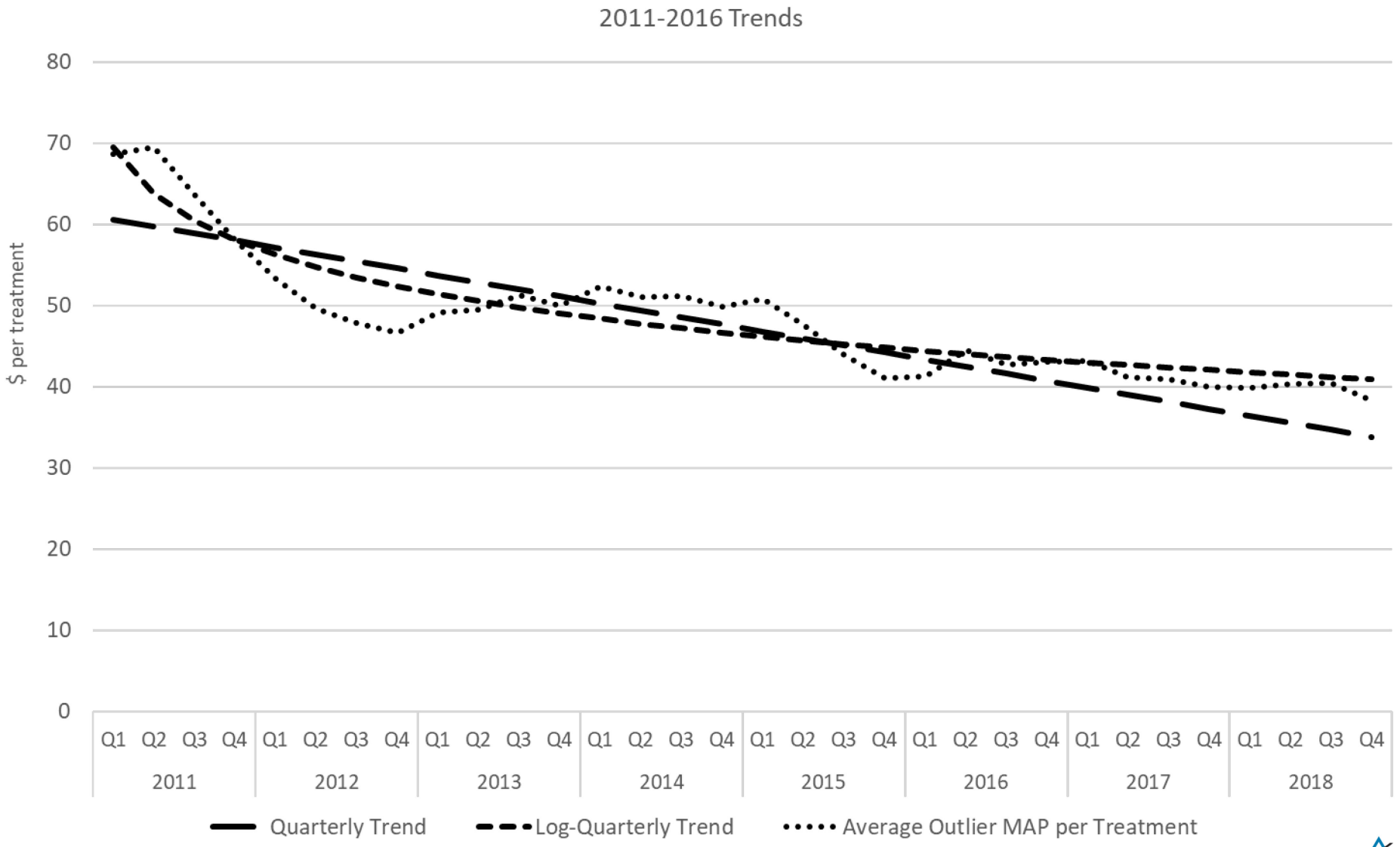
Stakeholder Comments Note Shortcomings in Current Methodology

- Originally intended for a small number of beneficiaries with high utilization of Erythropoietin Stimulating Agents (ESAs)
- Underpayment of the outlier results in significant losses to providers
- Future outlier thresholds should be established using alternative modeling approaches that reflect trends in separately billable spending over time

Alternative Methodology to Achieve 1 Percent Outlier Target

- Relax the assumption of constant utilization over time
- From 2011-2016 claims, determine the average monthly MAP amount for each beneficiary
- Determine quarterly time trends for outlier-eligible MAP amount per session
- Apply the trend to 2016 claims data to project 2018 values
- Using the projected 2018 data, proceed with current FDL algorithm to get an FDL for 2018

Predicted and Average Outlier Eligible MAP Amount Per Treatment for Adults, 2011-2016



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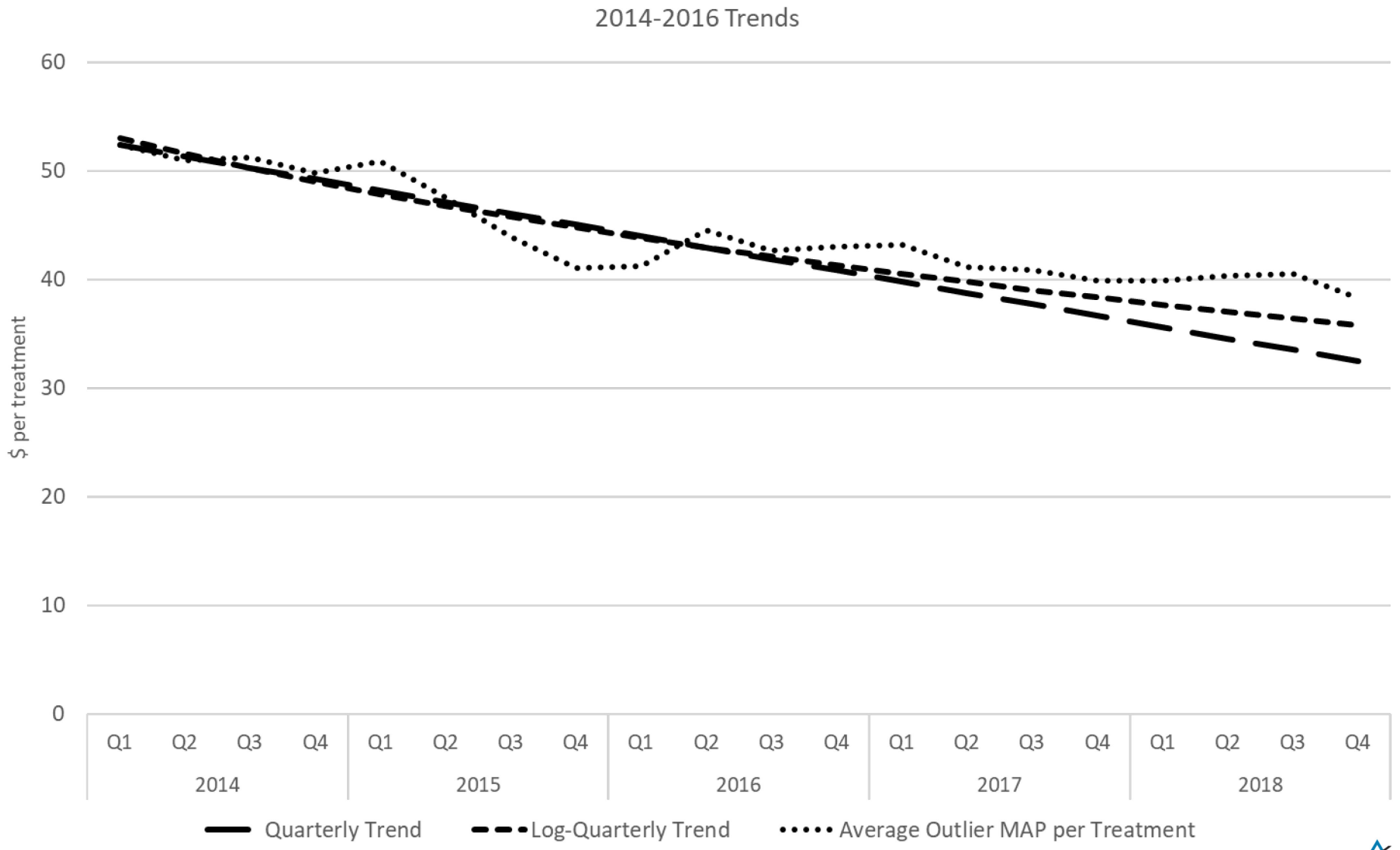
Alternate Model Can Lower FDL and Increase Outlier Payments Toward Target Percent

Using 2011-2016 Trends

Method	FDL Adult	FDL Pediatric	% Outlier of Total Payments in 2018
Current Method	77.54	47.79	0.52%
Quarterly Trend	50.11	38.61	0.93%
Log-Quarterly Trend	67.84	45.74	0.62%

Predicted and Average Outlier Eligible MAP Amount Per Treatment for Adults, 2014-2016



Both the Selection of Trend Functional Form *and* the Time Period Affect the FDLs

Using 2014-2016 Trends

Method	FDL Adult	FDL Pediatric	% Outlier of Total Payments in 2018
Current Method	77.54	47.79	0.52%
Quarterly Trend	44.73	65.23	1.06%
Log-Quarterly Trend	54.60	59.22	0.84%

Average Payments Increase for Facilities in Each Region

Payment Ratio (Revised/Historical) in 2018

Facility Type	2011-2016 Trends		2014-2016 Trends	
	Quarterly	Log-Quarterly	Quarterly	Log-Quarterly
All Facilities	1.004	1.001	1.005	1.003
Geographic Location				
Rural	1.004	1.001	1.005	1.003
Urban	1.004	1.001	1.005	1.003
Census Region				
East North Central	1.004	1.001	1.005	1.003
East South Central	1.004	1.001	1.005	1.003
Middle Atlantic	1.005	1.001	1.006	1.004
Mountain	1.003	1.001	1.004	1.002
New England	1.004	1.001	1.005	1.003
Pacific*	1.004	1.001	1.005	1.003
Puerto Rico and Virgin Islands	1.002	1.001	1.003	1.002
South Atlantic	1.004	1.001	1.006	1.003
West North Central	1.005	1.001	1.007	1.004
West South Central	1.004	1.001	1.005	1.003

*Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

Average Payments Increase for All Facility Types

Payment Ratio (Revised/Historical) in 2018

Facility Type	2011-2016 Trends		2014-2016 Trends	
	Quarterly	Log-Quarterly	Quarterly	Log-Quarterly
All Facilities	1.004	1.001	1.005	1.003
Type				
Freestanding	1.004	1.001	1.005	1.003
Hospital based	1.009	1.003	1.012	1.007
Ownership Type				
Large dialysis organization	1.004	1.001	1.005	1.003
Regional chain	1.005	1.001	1.006	1.004
Independent	1.005	1.001	1.006	1.004
Hospital owned*	1.010	1.003	1.012	1.008
Profit Status				
For-profit	1.004	1.001	1.005	1.003
Non-profit	1.007	1.002	1.009	1.006
Facility Size				
Less than 4,000 treatments	1.005	1.001	1.006	1.004
4,000 to 9,999 treatments	1.004	1.001	1.006	1.003
10,000 or more treatments	1.004	1.001	1.005	1.003

*Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

Discussion Questions

- What are the specific concerns about adjusting rulemaking year claims data to make predictions of future utilization of outlier eligible items?
- What time period should be used to determine the trend? E.g. a five year window like 2011-16, a three year window like 2014-16, or some other window?
  - 2011-14 involve the PPS transition period
- Should the functional form of the trend be changed each rulemaking cycle to best fit the data, or should a pre-determined functional form be used each year for clarity, even if this results in a higher FDL?

Discussion Questions

- Do panelists acknowledge that this approach may lead to an increase in the FDL if future years of claims reveal an increasing trend in utilization of outlier eligible items?
- Are there alternative approaches or changes to the existing outlier policy that should be considered?
- Some Stakeholders have commented that the set of outlier eligible items be expanded to capture all of the services pediatric ESRD patients require, including management of comorbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder
  - What are the specific items/services which should be considered?
  - Are each of these items/services separately itemized on claims?
  - If not, how can reporting be adjusted so that these costs can be allocated to specific treatments/patients?

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1	Introductions and Goals for this TEP
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5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	**Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies**
8	Home Dialysis
9	Open Discussion

Session 7 Outline

Session Objective

- Discuss the application process for payment through the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), particularly how to define *substantial clinical improvement (SCI)*

Session Topics

- Describe TPNIES policy
- Present application process used for new-tech add-on payments in IPPS/OPPS
- Review substantial clinical improvement criteria
- Gather TEP feedback on proposed approaches

Session Time

30 minutes

TPNIES Supports Uptake of New, Innovative Equipment and Supplies

- Provides separate payment for innovative equipment and supplies with substitutes included in the bundle
  - Payment based on 65 percent of price established by Medicare Administrative Contractors (MACs)
- Temporary payment for 2 years to allow items to gain competitive foothold with dialysis providers
- After 2 years, providers choose whether to switch to the new equipment and supplies, which are now solely covered under the ESRD PPS bundle
  - After TPNIES expires, items will qualify as outlier services
- Stakeholders support TPNIES to spur innovation for new equipment and supplies but expressed concern that capital-related assets are not eligible

TPNIES Closely Tied to the IPPS New Technology Add-On Payment (NTAP)

- Program was created to adjust for delays between current MS-DRG weighting and introduction of new technologies
- Applications to this program are usually for technologies that would be used for, and paid in the inpatient setting
- CMS has paid up to 50% of the estimated costs of a new technology in addition to the full DRG payment or up to 50% of the costs of the new technology
- Starting in FY 2020, add-on payment will increase to 65% and for certain anti-microbials, will increase to 75%

OPPS Has a Similar Program - New Device Pass-Through Status

- Incorporates costs of new devices into the procedure APC rate
- If required by the FDA, it must have received FDA approval or clearance
- The device must be:
  - An integral part of the service furnished
  - Used in one patient only
  - Come into contact with human tissue
  - Be surgically implanted or inserted, or applied in/on a wound or other skin lesion
- The device cannot be:
  - Equipment for which financing expenses are recovered as depreciable assets
  - Material furnished incident to a service (i.e. suture, customized surgical kit)
- Criteria:
  - FDA approved if required by the FDA for use
  - Not already described by existing transitional device pass-through
  - Not already described by current outpatient service categories
  - Meets substantial clinical improvement

TPNIES Applications for CY2021 Payment Year Must Be Submitted by February 1, 2020

- Six Criteria for TPNIES eligibility
  - CMS-designated renal dialysis service
  - FDA marketing authorization granted on or after January 1, 2020 and by September 1 prior to the payment calendar year
  - Commercially available by January 1 of the payment calendar year
  - HCPCS application submitted by September 1 of the previous calendar year
  - Meet substantial clinical improvement (SCI) criteria specified in Inpatient Prospective Payment System (IPPS)
  - Not capital-related assets
- CMS developing website for TPNIES applications for CY2022 payment year. For CY2021 payment year, providers should respond to questions published in the CY2020 Final Rule.
- CMS Plans to Convene Workgroup to Review TPNIES Applications, NTAP SCI criteria

Substantial Clinical Improvement Criteria from IPPS New Technology Add-on Payment

- (1) Offers a treatment option for patients unresponsive to or ineligible for existing treatments
- (2) Offers the ability to diagnose a medical condition earlier than existing methods or in patients where the condition is currently undetectable
  - Also requires evidence that use of the technology to make a diagnosis affects the management of the patient
- (3) Significantly improves clinical outcomes relative to existing technologies, including
  - Reduction in mortality or a clinically significant complication
  - Decreased rate of at least one subsequent diagnostic or therapeutic intervention
  - Decreased number of future hospitalizations or physician visits
  - Reduced length of stay or recovery time
  - Improvement in one or more activities of daily living or quality of life
  - Greater medication adherence or compliance
- Or the totality of the circumstances otherwise demonstrates that the new technology substantially improves the diagnosis or treatment of Medicare beneficiaries relative to existing technologies

Two Examples of Applying SCI Criteria

- Discuss two examples of the determination of SCI in past IPPS NTAP applications
  - CAR T-cell Therapy
    - SCI criteria met
  - Supersaturated Oxygen (SSO2) Therapy
    - SCI criteria not met

Two CAR T-Cell Immunotherapies Were Awarded IPPS NTAP for FY2019

- CD-19-directed T-cell immunotherapies used for the treatment of patients with aggressive variants of non-Hodgkin's lymphoma (NHL)
- KYMRIAH (tisagenlecleucel)
  - Novartis Pharmaceuticals Corporation
  - FDA approval May 1, 2018
  - Earlier FDA approval for a different indication
- YESCARTA (axicabtagene ciloleucel)
  - Kite Pharma, Inc.
  - FDA approval October 18, 2017

CMS Determined the CAR T-Cell Technologies Represented SCI over Existing Technologies

- Manufacturers provided peer-reviewed research on their technologies in application to CMS
- CMS determined that the technologies allowed treatment options for patients who are unable to receive standard-of-care treatments
  - Meets first SCI criterion
- CMS also noted that both technologies appear to significantly improve clinical outcomes and allow for a manageable safety profile
  - Meets third SCI criterion

New Supersaturated Oxygen (SSO2) Therapy for FY2020 Not Approved for NTAP

- Application submitted by TherOx, Inc.
- Proposed indication is for patients receiving treatment for an ST-segment elevation myocardial infarction (STEMI), a type of AMI which carries a substantial risk of death and disability
- Applicant asserted that the therapy reduces the size of the infarction
- Applicant proposed that if this occurred, it could
  - Lower the risk of heart failure and mortality
  - Improve quality of life for STEMI patients

CMS Determined that SSO2 Therapy Did Not Meet CMS' SCI Requirement for NTAP

- CMS expressed concern that the standard-of-care for STEMI has evolved since studies cited in TherOx's application were conducted
  - Unclear whether the therapy would demonstrate the same clinical improvement as compared to the current standard-of-care
- CMS also had concerns with the data in the application
  - Lack of long-term data
  - Insufficient controls for certain studies
- Overall, the treatment did not meet SCI criteria 1 or 2, and there was insufficient evidence for criterion 3

Discussion Questions

- Does the IPPS NTAP definition of SCI fully apply to the ESRD PPS?
  - If not, what revisions should be considered for an ESRD-specific SCI criterion?
- How, if at all, should TPNIES criteria differ for equipment/supplies targeted for the pediatric population?
- What, if any, barriers to use of TPNIES covered equipment/supplies do facilities expect to encounter?
- How could capital-related assets, which are used for multiple treatments and/or multiple beneficiaries, be incorporated into TPNIES?
  - TPNIES payments are per-treatment. Capital-related assets are owned/rented, depreciate and thus their costs are not easily translated into per-treatment costs
  - Would require disclosure of stratified capital-related expenses on cost reports using a uniform methodology

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7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	**Home Dialysis**
9	Open Discussion

Session 8 Outline

Session Objective

- Discuss improved methods of capturing the costs of home dialysis

Session Topics

- Describe CMS's current approach to home dialysis
- Summarize stakeholder feedback on home dialysis costs versus in-facility costs
- Present potential revisions to the cost report to separately identify costs related to home dialysis
- Obtain TEP feedback on the proposed changes

Session Time

45 minutes

Current Issues in Home Dialysis Costs and Payments in ESRD PPS

- Providers maintain that home dialysis costs exceed those for in-facility treatments
- Adjusted payment for maintenance home dialysis treatment not currently included in the ESRD PPS bundle
- Analysis of currently available cost report data indicate that home treatment costs may be lower than in-facility costs
- Especially with regard to capital expenses, cost reports do not sufficiently differentiate home from in-facility costs
- Since recent policy initiatives incentivize increased use of home dialysis, important to know true costs
  - And how home dialysis costs differ from other modalities

Home Dialysis Payment in ESRD PPS

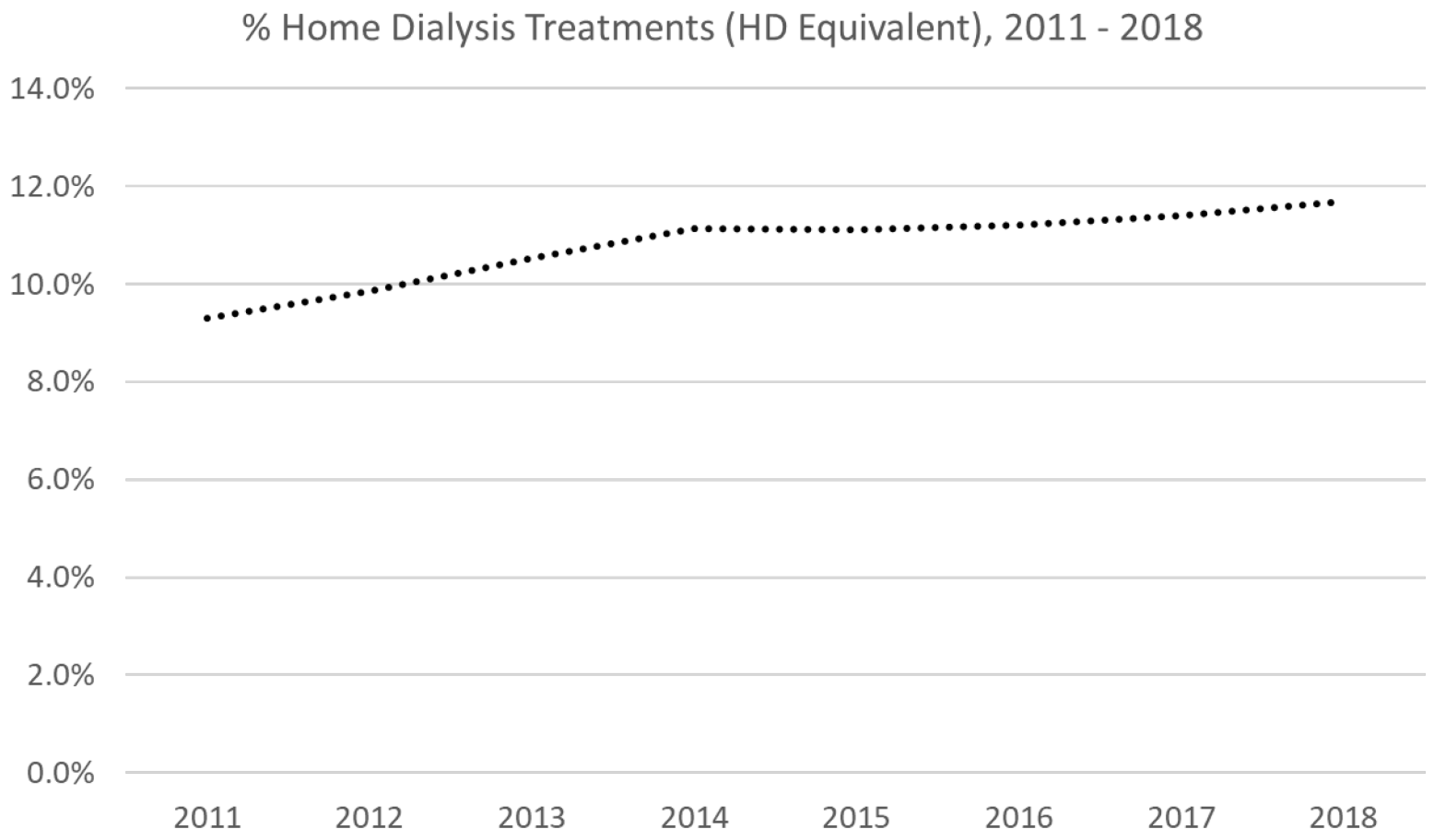
- ESRD PPS pays for home and in-facility hemodialysis (HD) at the same rate
  - Home peritoneal dialysis (PD) sessions paid at 3/7 of the hemodialysis rate to equate average weekly payments
  - For pediatric patients, there is a case-mix adjustment distinguishing PD and home HD payments
- ESRD PPS includes a home dialysis training add-on payment
  - Pays for a maximum of 25 sessions of HD training and 15 sessions of PD training
  - Payment amount based on 1.5 hours of nursing time per session and an average hourly wage from national BLS data on nurses' wages
    - Adjusted for geographic differences using the wage index

Recent Policy Initiatives Mandate and Incentivize Increased Use of Home Dialysis

- Recent Executive Order calls for a payment model to incentivize the use of home dialysis
  - Aims to have 80% of ESRD patients receiving transplants or home dialysis by 2025
- ESRD Treatment Choices (ETC) Model operationalizes this incentive structure
  - ETC Model takes effect in 2020

Marginal Uptake of Home Dialysis since 2011

- Claims data indicate only modest growth from 9.3% in 2011 to 11.7% in 2018



Current Home Dialysis Use is Limited and Skewed to Certain Sub-Populations

- A small proportion of beneficiaries utilize home dialysis
  - Peritoneal dialysis is the predominant modality in home dialysis representing greater than 80% of home dialysis use
- Beneficiaries more likely to be younger, white, urban, and not dual-eligible

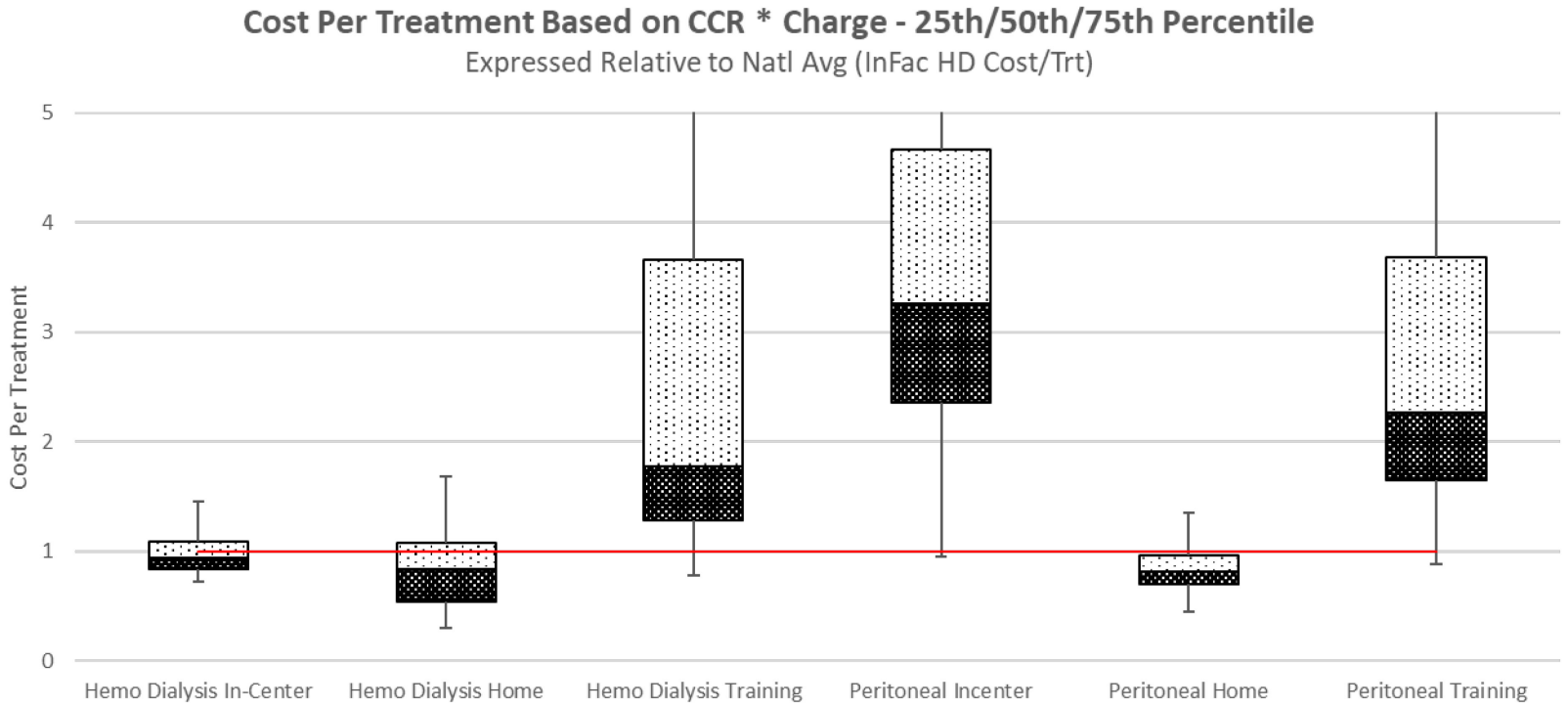
Beneficiary Characteristics		In-Facility	Home HD	Home PD
Total Beneficiary Count		**277140**	**5673**	**28534**
Average Age		63	57	59
Male		55.7%	61.7%	53.9%
Race	White	44.5%	60.0%	56.6%
	Black	38.4%	29.3%	25.5%
	Hispanic	7.9%	3.8%	7.1%
	Other Races	9.2%	6.9%	10.9%
Rural		6.8%	8.5%	8.9%
Dual-eligible		51.3%	34.7%	34.5%

Stakeholders Maintain that Home Dialysis Entails Unique and Higher Costs

- Some home dialysis treatment costs differ from in-facility costs
  - Each home patient requires a separate dialysis machine, whereas in-facility machines can be utilized by multiple patients
  - Home dialysis requires highly skilled nursing support
    - Caseload for nurses dedicated to home dialysis care limited to 6-7 patients/week
  - Training costs for home dialysis nurses
  - Survey and certification requirements
- Home dialysis costs have risen significantly in recent years
  - Higher costs attributed to inputs such as supplies, equipment, and water treatment
  - Limited competition among suppliers
- Logistical challenges also affect facility-level uptake
  - Limited resources may force facilities to choose between offering a home dialysis program and other priorities

Treatment Charges on Claims Indicate Home Sessions Are Marginally Less Expensive

- Per treatment charge data indicate in-facility treatment costs are higher than in-home treatment, except in the case of home training sessions
- Home HD training, PD training and in-center PD sessions show higher cost per treatment and greater variation



*Bottom (top) of dark (light) box is 25th (75th) percentile.

Cost Reports Also Indicate Lower Costs for Home Dialysis

- Results presented to previous TEP also examined the correlation between costs per treatment and the proportion of home dialysis users by facility, and found inconclusive results
  - Facilities with higher PD use had lower per-treatment costs
  - Facilities with higher home HD use had higher per-treatment costs
- Inconsistency between the data and stakeholder concerns suggest the importance of ensuring that cost reports are accurately capturing the costs of home dialysis and training

Components of Dialysis Treatment Costs

Capital	Buildings and fixtures, movable equipment, operating and maintenance of plant and equipment, dialysis treatment equipment, housekeeping
Labor	Salaries and benefits for direct patient care
Administrative	Facility costs not directly related to the provision of dialysis care, such as accounting, legal services, and recordkeeping
Drugs	Drugs used to treat or manage a condition associated with dialysis treatment
Labs	Routine laboratory tests for dialysis patients
Supplies	All supplies used to furnish direct dialysis care, such as tubes, syringes, and dialysate

Current Cost Reports Do Not Adequately Capture Costs Specific to Home Dialysis

- Component costs are not collected separately for home and in-facility dialysis
  - One worksheet (A) collects information on component costs overall and applies adjustments to ensure consistent definitions
    - Does not differentiate between home and in-facility costs
  - Another worksheet (B) allocates component costs for each modality using various rules, but leaves unanswered key questions about unique home dialysis costs
    - Rules include:
      - Capital: Based on square footage and treatment counts
      - Machines: Based on fraction of time
      - Salaries: Based on hours of work
      - Benefits: Based on gross salaries
      - Drugs, labs and supplies: Based on acquisition costs
    - Unclear whether component costs are allocated by treatment number or reflect true costs of treatment for each modality

Current Cost Reports Leave Unanswered Key Questions About Relative Costs of Capital

- What are the purchase or leasing costs of machines used for home dialysis versus in-facility dialysis?
- Does depreciation differ when machines are used in the home? Do manufacturers provide an expected lifetime?
- Does the cost of ancillary equipment or supplies used with home dialysis machines differ from in-facility dialysis?
- What equipment, if any, can be reused for other patients?
- How do the answers differ for home HD versus home PD?

Current Cost Reports Leave Unanswered Key Questions About Relative Costs of Labor

- Do the hours allocated to home dialysis on cost report worksheets reflect an accurate accounting of how labor time is used?
  - Or is it rule-based, i.e., allocated by number of treatments?
  - If rule-based, how reliable are these data and is the rule consistently applied across facilities?
- Does the allocation of staff by labor category differ for home dialysis versus in-facility (e.g. greater use of RNs in one or the other)?
- Do reported hours include travel time?
- How are labor costs reported when staff time is split between training sessions and maintenance sessions in a facility?

Cost Report Changes Can Better Identify Home Dialysis Capital Costs

- Differentiate the cost of machines and support equipment used in home dialysis from those used for in-facility dialysis
  - Include number and type of machines, and distinguish HD and PD
  - Differentiate rental from purchases, and track depreciation amounts
- Implementing these changes would provide needed detail on relative capital costs for home versus in-facility treatment

Cost Report Changes Can Identify Home Dialysis Costs: Labor, Drugs, Labs, and Supplies

- Provide explicit instructions regarding what hours of effort to include (e.g. travel to the patient's home) in the allocation of salaries to home dialysis care vs. training vs. in-facility dialysis
  - Use an alternative metric (e.g. number of nursing visits) that is easier to track than hours
  - Delineate the fraction of hours or visits performed by various occupations (e.g. RNs, social workers, med techs, etc.)
- Use another metric to allocate drugs, lab and supply costs if charge information is difficult to distinguish by home vs. in-facility or because it reflects suppliers' pricing and not true costs
- Improve cost report instructions for reporting of in-facility back-up sessions for home dialysis
  - Make explicit that these are single sessions for patients who will return to in-home dialysis

Discussion Questions

- What are the primary sources of cost differences between home dialysis and in-facility dialysis? Between home HD and PD?
  - Does the cost of machines and support equipment differ in their purchase price, depreciation, or ability for reuse? What are the main support equipment items to consider?
  - Are the differences in labor cost driven by time spent on patient care or the occupational mix or the level of training required?
  - Are there any other important differences besides machine and labor costs? If so, what are they?
- Do these cost differences vary by home modality? Do they vary by beneficiary characteristics?
- Do dialysis session charges adequately reflect the differences between in-facility and home dialysis costs?
  - If not, is it feasible to better differentiate these charges on claims?
  - Is it feasible to report distinct home HD from PD charges on claims?

Discussion Questions

- Are the suggested changes to improve accounting for home dialysis costs feasible and an acceptable tradeoff for increased burden?
- Are the suggested changes on cost reports comprehensive? If not, what are other items that would be useful to collect data on and how should this be done in a way that minimizes burden?
- What is a reliable method for distinguishing the labor costs associated with training from those for in-facility dialysis and routine home dialysis support, when staff may split time between both?

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8	Home Dialysis
9	**Open Discussion**

Session 9 Outline

Session Objective

- Provide opportunity for all TEP participants to offer feedback and thoughts

Session Topics

- Open Discussion

Session Time

45 minutes*

*May be adjusted to accommodate overtime in earlier sessions

Open Discussion

- All attendees are encouraged to comment on the day's discussion
- Speakers may offer comments or direct technical questions to project team representatives
- Please limit remarks to allow time for everyone to participate

Thank You