

End Stage Renal Disease Prospective Payment System Technical Expert Panel Summary Report

Date of TEP: December 10-11, 2020

Date of Report: April 2021

CONTENTS

In	trodu	ction		4		
1	Pan	el Over	view	6		
	1.1	1 Structure				
	1.2	Mater	ials	6		
	1.3	Memb	pers	7		
2	Adult Case-Mix Adjustment					
	2.1 Summary of Presentation					
		2.1.1	Goals of Case-Mix Model Refinements			
		2.1.2	Statutory Requirement for Case-Mix Adjustment			
		2.1.3	Current ESRD PPS Case-Mix Adjustment			
		2.1.4	Stakeholder Comments on Current Case-Mix Adjustment			
		2.1.5	Alternative Method for Single-Equation Model			
		2.1.6	Alternative Case-Mix Adjusters			
		2.1.7	Summary of Refined Model Improvements over Current Model			
	2.2	Summ	nary of Discussion			
	2.3	Key F	indings	17		
3	Pedi	iatric C	ase-Mix Adjustment	18		
	3.1		nary of Presentation			
		3.1.1	Medicare Pediatric Dialysis Coverage	18		
		3.1.2	Pediatric Dialysis Overview			
		3.1.3	Current Case Mix Adjustment Model	19		
		3.1.4	Stakeholder Concerns			
		3.1.5	Options to Better Capture Pediatric Dialysis Costs	20		
	3.2	Summ	nary of Discussion			
	3.3	.3 Key Findings				
4	Low-Volume Payment Adjustment					
	4.1		nary of Presentation			
		4.1.1	Current LVPA and Rural Adjuster Policy	24		
		4.1.2	Current LVPA Shortcomings and Premise of Alternative Methodology			
		4.1.3	Alternative LVPA Methodology	25		
		4.1.4	Applying the New Methodology	26		
	4.2	Summ	nary of Discussion	28		
	4.3	Key F	indings	29		
5	Acu	te Kidr	ney Injury (AKI) Payment System (PS)	30		
	5.1		nary of Presentation			
		5.1.1	Goals of Dialysis for AKI Patients and AKI Policy	30		
		5.1.2	Descriptive Statistics for AKI-D Patients	30		
		5.1.3	Outcomes and Utilization for AKI-D Patients	31		
		5.1.4	Costs of Furnishing Dialysis to AKI-D Patients	31		
		5.1.5	Dialysis Modality and Changes Observed in 2020			
	5.2	Summ	nary of Discussion	33		
	5.3 Key Findings			34		
6	Cost	t Repor	t Revisions	35		

7 Summary of Panel Response		mary o	of Panel Response	43
		-	indings	
	6.2	Sumn	nary of Discussion	41
		6.1.5	Cost Report Revisions for Pediatric Dialysis	40
			Costs	37
		6.1.4	Revising the Cost Report to Obtain More Accurate Assessment of Compo	onent
		6.1.3	Obtaining Total Cost and Cost per Treatment	36
			Costs	36
		6.1.2	Duration of Treatment Provides Framework for Allocating Composite Ra	ate
		6.1.1	Component Costs of Dialysis Treatment	35
6.1		1 Summary of Presentation		35

INTRODUCTION

This report summarizes the third annual Technical Expert Panel (TEP) convened by Acumen, LLC, in December 2020, to discuss refinements to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS), including new methodologies for the outlier payment and the low-volume payment adjustment (LVPA). The first TEP explored the components of the existing ESRD PPS, identified limitations of the current payment model, and presented alternative approaches with the goal of achieving a more refined case-mix adjusted payment system. The second TEP elaborated on this theme, focusing on alternative approaches to measuring the cost of a dialysis session that would better reflect treatment-level variations in cost. Other topics covered during the second TEP included the Transitional Drug Add-on Payment Adjustment (TDAPA) and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). Following the 2018 TEP, CMS issued a Request for Information (RFI) in the CY 2020 Notice of Proposed Rulemaking (NPRM) seeking broader stakeholder input on data collection strategies to support these payment model refinements. A summary of the input received is included in the CY 2020 Notice of Final Rulemaking (NFRM).

The overall goal of this project is to recommend to CMS options for a new payment model for the ESRD PPS—one that improves its overall accuracy and statistical stability. Currently the ESRD PPS relies on two regression equations to approximate variation in costs of treatment: the first uses facility-level data and the second uses patient- (or treatment)-level data. Facility-level data lack information about cost variation across treatments. This is not an optimal approach either statistically or from the point of view of transparency. It involves using facility-level data to estimate patient-level variation in costs. Stakeholders have consistently requested a single-equation model constructed at the patient level to reduce its complexity and to better align payment with costs.

Based on input received from the previous ESRD PPS TEPs and the RFI, the third TEP offered a forum for the presentation and discussion of new methodological approaches for the case-mix model, the LVPA, and the pediatric dialysis payment structure. The results of the first three years of integration into the ESRD PPS of dialysis treatments for beneficiaries with acute kidney injury (AKI) were also presented. Finally, suggestions were made for revisions to the ESRD PPS cost report to improve accuracy and better support the payment model.

¹ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf.

https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-december.pdf.

³ https://www.federalregister.gov/documents/2019/11/08/2019-24063/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis

This report begins with an overview of the 2020 TEP, including its structure, objectives, and introduction of panelists and Acumen staff. A uniform format was used to present each session; that format is recreated in this report: (i) the topic was introduced and its relevance to the current ESRD PPS was described; (ii) previously received stakeholder concerns about the topic were summarized; (iii) alternative methodological approaches that address concerns were presented; (iv) discussion was opened to obtain input on the topic from TEP members; and (v) key findings from the session were identified and summarized. Finally, an open discussion was held following the completion of the last topical session. The report concludes with the next steps for investigating potential refinements to the ESRD PPS.

During the first topical session, a new methodological approach for case-mix adjustment and strategies for the selection of case-mix adjusters were presented. This was followed by a session focused on the costs of pediatric dialysis and methods to incorporate cost factors specific to the pediatric setting into the above model. During the third session a completely new approach for determining eligibility for the LVPA was presented. During the fourth session, Acumen reported results from first three years of incorporation of dialysis treatment for patients with AKI into the ESRD PPS. The fifth and final topical session focused on recommended revisions to the facility cost report that were necessary to support the new case-mix payment model described in the first topical session. The final session included an open discussion and review of the day's topical presentations.

1 PANEL OVERVIEW

This section presents an overview of the 2020 ESRD PPS TEP. Section 1.1 describes the structure of the TEP. Section 1.2 describes the materials provided to panelists, and Section 1.3 contains a list of TEP panelists and brief descriptions of their backgrounds.

1.1 Structure

This report summarizes the proceedings of this TEP, held remotely via videoconferencing on December 10 and 11, 2020. The TEP was organized into five topical sessions, each of which focused on an aspect of the ESRD PPS for which refinements or enhancements are being considered. This TEP builds on discussions held during the previous ESRD PPS TEPs, held in December 2018 and 2019. During this TEP Acumen presented innovative methodological approaches that addressed stakeholder concerns about shortcomings in the current payment model.

The TEP included a brief introductory session followed by the five topic-driven sessions. Panelists were invited to participate in discussion during each session. During the seventh and final session, both panelists and observers were invited to participate in an open-ended discussion about the issues that arose over the course of the day.

1.2 Materials

Prior to the TEP, Acumen provided panelists with the following materials: the agenda for the day, the presentation slides, the TEP charter stating the goals and duties of the panel, a list of TEP members, and a logistics document. The agenda can be seen in Table 1.

Table 1. TEP Agenda

Session	Торіс
1	Introductions and Goals for this TEP
2	Adult Case-Mix Adjustment
3	Pediatric Case-Mix Adjustment
4	Low-Volume Payment Adjustment (LVPA)
5	Acute Kidney Injury Payment System (AKI PS)
6	Cost Report Revisions
7	Open Discussion

1.3 Members

This year's ESRD PPS TEP included 19 panelists, representing dialysis providers, independent researchers, patient advocates, and representatives from professional associations and industry groups.

Table 2. TEP Members

Name	Professional Role	Organizational Affiliation
Brendan Bowman, MD	Associate Professor, Division of Nephrology	University of Virginia
Eileen Brewer, MD	Medical Director, Renal Transplant Program	Texas Children's Hospital
Johnie Flotte, RN	Vice President of Clinical Services	US Renal Care
Joseph Flynn, MD, MS	Chief, Division of Nephrology	Seattle Children's Hospital
Derek Forfang	Kidney Patient Advocate and Public Policy Committee Chair	National Kidney Foundation
J. Michael Guffey	Treasurer	Dialysis Patient Citizens
Alice Hellebrand, MSN, RN, CNN	Chief Nursing Officer	Dialyze Direct
Andrew Howard, MD, FACP	Nephrologist	Forum of ESRD Networks
Jeffrey Hymes, MD	Senior Vice President, Clinical and Scientific Affairs	Fresenius Medical Care
Mahesh Krishnan, MD, MPH, MBA, FASN	Group Vice President, R&D	DaVita
Keith Lester, MA	Senior Vice President, Home Therapies/Optimal Life	Satellite Healthcare
Chris Lovell, RN, MSN, CNN	Director of Medical Informatics and Systems	Dialysis Clinics, Inc.
Gayle Nemecek, MBA, RN, BSN, CNN	Chief Operating Officer	Centers for Dialysis Care
Alicia Neu, MD	Medical Director, Pediatric Dialysis and Kidney Transplantation	Johns Hopkins University Children's Center
Rebecca Schmidt, DO	Clinical Nephrologist and Professor of Medicine	West Virginia University School of Medicine
Suzanne Watnick, MD	Chief Medical Officer	Northwest Kidney Centers
Julie A. Williams, BSA	President	National Renal Administrators Association
Jay B. Wish, MD	Professor of Clinical Medicine	Indiana University School of Medicine
LeAnne Zumwalt, CPA	Group Vice President, Government Affairs and Purchasing	DaVita

2 ADULT CASE-MIX ADJUSTMENT

The purpose of this first topical session was to present a new methodology for case-mix adjustment for the ESRD PPS and the results from implementing that method using existing data. The method leverages the use of a new data element that accounts for much of the patient-level cost of a dialysis session. Feedback on this new approach was elicited from the panel. The panel also discussed strategies for identifying new case-mix adjusters. The session included:

- Review of structure of the current payment equation(s)
- Presentation of refined case-mix adjustment model
- Presentation of strategies for selecting case-mix adjusters
- Discussion of potential data sources for case-mix adjusters

2.1 Summary of Presentation

The new approach to case mix adjustment presented during this session takes into account input received from the 2018 and 2019 ESRD PPS TEPs and from broader outreach to stakeholders thereafter.⁴

2.1.1 Goals of Case-Mix Model Refinements

This session explored potential refinements to the adult ESRD PPS case-mix adjustment with the following goals: (i) protect access to care for the most costly beneficiaries by ensuring PPS payment reflects facilities' costs, (ii) incorporate stakeholder input from TEP panelists and public comments on previous rules, (iii) better account for variation in per-treatment dialysis costs, (iv) improve statistical coherency, and (v) reflect recent data on variation in costs of treatment. Moreover, it is a foundational goal of this project that a new case-mix adjustment model for the ESRD PPS be understandable to providers, in terms of the factors and methods it employs.

2.1.2 Statutory Requirement for Case-Mix Adjustment

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 requires that the ESRD PPS include facility-level and patient-level adjustments to the base rate associated with resource utilization and the cost of providing dialysis treatment. The goal of case-mix adjustment is to ensure that payment for a dialysis treatment reflects expected and observed resource use. Payment adjustment protects access to care for the most costly beneficiaries by mitigating financial disincentives to providing that care.

⁴ The Summary Reports for previous TEPs are published on the CMS website. Please see the <u>December 2018 ESRD PPS TEP Summary Report</u> and the <u>December 2019 ESRD PPS TEP Summary Report</u>.

2.1.3 Current ESRD PPS Case-Mix Adjustment

The current case-mix model was introduced in the CY 2016 Final Rule and includes both facility- and patient-level adjustments. Facility-level adjustments include regional differences in wage rates using an area wage index developed from Core-Based Statistical Areas (CBSAs), a rural adjustment for facilities located outside of urban CBSAs, and a low-volume payment adjustment for facilities furnishing fewer than a designated threshold number of treatments and that meet certain other requirements. Patient-level case-mix adjusters include selected characteristics that have been associated with use of resources. These currently include: age, body surface area (BSA), body mass index (BMI), dialysis onset status, and four comorbidities (pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome). A different set of case-mix adjusters are applied to the pediatric population (see Section 3).

Currently, these adjusters are calculated using two equations: one for facility-level variables and one for patient-level variables. Final case-mix adjusters for adults are the weighted average of estimated coefficients from these two equations, where the weights are the fraction of costs that are derived from the use of composite rate (CR) versus formerly separately billable (FSB) items and services.

The CR refers to the bundle of dialysis-related services for which CMS paid a flat rate prior to the implementation of the ESRD PPS in 2011. The CR includes capital, labor, and administrative costs, as well as drugs, laboratory tests, and supplies necessary to administer the dialysis treatment. Because payment for these items is bundled, claims data do not contain detail on the use of these items and services. Therefore, limited information on variation in costs at the patient or treatment level is available. Instead, aggregated CR costs for each facility are obtained from annually submitted facility cost reports. CMS calculates the CR cost per treatment from these aggregated CR costs, with variation seen only across facilities. The facility-level regression then estimates the effects that facility characteristics (from annual cost reports) and patient characteristics (from claims) have on CR cost variation.

FSB items and services were added to the bundle in 2011, and include erythropoietin stimulating agents (ESAs) and other medications for anemias and mineral metabolism. Unlike CR items and services, FSB items and services are outlier-eligible and, as a result, their use is itemized for individual patients on 72x claims. Therefore, CMS can obtain patient-level variation in the use of FSB items and services. The patient-level regression estimates the effect that patient-level covariates (comorbidities and other risk factors) have on FSB cost variation. FSB costs can also be mapped to facility-level characteristics using cost report data.

The weighted case-mix factors from the facility- and patient-level equations are used to construct multipliers on the base rate to determine payments for patient types. Currently, the

statistical models and weighted averages for the case-mix adjustment are calculated using 2012 and 2013 claims and cost report data.

2.1.4 Stakeholder Comments on Current Case-Mix Adjustment

Stakeholders have expressed concerns about the current two-equation case-mix adjustment model. Specific to the two-equation methodology, commenters note that it is difficult to infer patient-level adjustments from facility-level data, and many commenters have doubts about the magnitude and significance of the age, BMI, and BSA coefficients. Additionally, they question the validity of taking the weighted average of estimates across the two equations without accounting for the joint distribution of CR and FSB costs.

Stakeholders also point to the logistical challenges of obtaining accurate data on the comorbidities that adjust payment in the existing model, as they are not routinely diagnosed or reported in the 72x claims, and the diagnoses contained in medical records may not be readily available to dialysis facilities. Furthermore, stakeholders warn that the operational costs of obtaining these data may exceed the value of any corresponding payment adjustment.

2.1.5 Alternative Method for Single-Equation Model

One option to improve the current case-mix adjustment model and meet the goals in Section 2.1.1 is the adoption of a single-equation model. This approach can simplify the case-mix adjustment and is aimed at permitting straightforward measurements of the effects of case mix on cost, as well as permitting control for facility-level characteristics and confounders, such as volume of services, wages for direct patient care, or hospital setting.

Because CR items are reported only at the facility level on cost reports, identifying patient-level variation in CR costs for use in a single-equation model is challenging; costs are stratified by modality, but granularity is limited. FSB costs, however, are reported at the patient level on 72x claims. Additionally, while patients' case-mix adjusters are supposed to be reported on 72x claims, these data may be incomplete, as facilities are not always able to obtain timely data from other health records on their patients' comorbidities. Facilities also perform multiple types of treatment (i.e., in-center hemodialysis [HD], home HD, and peritoneal dialysis [PD], and self-dialysis training), which makes assigning costs and the measurement of overall modality-independent treatment volume difficult.

In the single-equation case-mix adjustment model proposed for discussion during the TEP, an observation is defined as a beneficiary-facility-month unit of measurement – effectively the claim level.⁵ The cost for each observation (beneficiary-facility-month) is the sum of the following:

10 Acumen, LLC | ESRD PPS TEP Summary Report

_

⁵ In rare cases where a beneficiary has multiple claims at a facility in a given month, these claims are combined.

- (1) FSB costs calculated from claims charges and facility-level cost-to-charge ratios (CCRs)
- (2) CR costs for each beneficiary-facility-month calculated by allocating annual facility costs (less FSB costs) to the beneficiary-facility-month level using time on machine (duration of all treatments)⁶

Thus, the "single" equation is a regression of beneficiary-facility-month costs (sum of the above) on case-mix adjusters and facility characteristics.

The single-equation model addresses key stakeholder concerns with the current twoequation methodology. Estimating coefficients using a single equation directly adjusts payments for patient-case mix, without any weighting. This brings the ESRD PPS case-mix adjustment in line with the case-mix models for other Medicare payment settings, including Home Health, Inpatient Rehabilitation Facility, Skilled Nursing Facility, and Inpatient Psychiatric Facility.

Specifically, the use of treatment duration in the single-equation method addresses the fundamental challenge of obtaining patient-level variation in CR costs, when these costs are only reported at the facility level on cost reports. Notably, longer dialysis treatments have higher resource use on average, for a number of reasons. The longer a dialysis treatment, the more capital and labor resources are dedicated to the treatment as a proportion of the facility's total capital and labor resource use. Additionally, longer treatments generally require the use of more supplies (e.g., dialysate). When all else is equal, a longer dialysis session will have higher CR costs.

This is not to suggest that all variation in the cost of a dialysis treatment is related to treatment duration. In fact, CR costs can be split into three categories:

- (1) Costs that do not vary (or vary marginally) across treatments, such as administrative
- (2) Costs that vary across treatments but are unrelated to treatment duration
- (3) Costs that vary across treatments relative to treatment duration

The refined case-mix adjustment approach uses treatment duration to apportion variation in this third category of costs, and this TEP also solicited feedback from the panel on ways to better collect costs associated with the first and second categories.

The single-equation model uses cost reports to derive cost per minute for different types of patients, which is combined with data on treatment duration to infer a portion of differences in CR cost across beneficiary-facility-months. As noted in previous TEPs, treatment duration for these analyses is obtained from CROWNWeb clinical data, as duration is currently not reported

⁶ For some modalities and settings, however, time on machine is not available (or applicable) and is imputed.

on claims.⁷ Additionally, the model presented during this TEP specifically focuses on three modalities (in-center HD, home HD, and home PD) that represent 99.5% of all 72x treatments reported in claims.

Specifically, the single-equation methodology obtains, for each facility, total dialysis minutes for in-center HD and home HD and imputes total dialysis minutes for home PD. Minutes for in-center HD and home HD are calculated from 72x claim treatment counts and HD minutes from CROWNWeb, and minutes for home PD are imputed from 72x claim treatment counts and the national average HD minutes per treatment. Thus, a facility's total dialysis minutes is the sum of minutes across the three modalities. Next, CR cost is calculated for each beneficiary-facility-month with in-center HD, home HD, or home PD. This is calculated by dividing the facility-level total CR cost by the facility's total dialysis minutes to get the facility's CR cost per minute and then multiplying this by the total dialysis minutes for the beneficiary-facility-month. Beneficiary-facility-month FSB costs are calculated using FSB charges on claims and CCRs specific to FSB categories. Finally, the treatment-level total cost is the sum of the beneficiary-facility-month CR and FSB costs divided by the beneficiary-facility-month total treatment counts. The goal of the single-equation case-mix adjustment model then is to identify the magnitude of the factors that best reflect variation in this measure of total cost per treatment.

It is important to emphasize that treatment duration reported on claims would not directly affect payments. Dialysis treatment duration would be used solely to apportion CR costs, reported in aggregate at the facility level, to the patient level for use as the dependent variable in estimation of a refined model. In other words, dialysis session run time is not a case-mix adjuster, and treatment duration as reported in claims during any given payment year would have no direct effect on the ESRD PPS payments received by facilities in that payment year.

Outputs from the refined single-equation model (using treatment duration to apportion CR costs) show that median cost per treatment varies by patient group and modality. For example, the median cost per treatment for in-center HD decreases as beneficiaries get older, but increases with age for home HD and home PD.

The refined single-equation model also updates the way facility control variables are incorporated in the case-mix adjustment. The current model uses categorical variables for facility volume ranges and a categorical variable for LVPA. However, the refined model discussed during the TEP uses the log and log-squared of facility total treatment duration, continuous variables, which have a number of advantages over the current methodology. Namely, the case-

12 Acumen, LLC | ESRD PPS TEP Summary Report

⁷ Notably, CMS submitted a Change Request following the 2019 TEP to add a value code to the 72x claims for cumulative duration of dialysis (in minutes) covering all treatments on a claim. A new value code for the line item was granted by the National Uniform Billing Committee (NUBC) on April 15, 2020. Subsequently, the requirement for reporting duration of treatment on the claim was withdrawn until further notice. Please refer to slides 31 and 32 of the December 2020 ESRD PPS Slide Deck for more information on identifying duration for each treatment.

mix adjustment no longer relies on arbitrary, predetermined volume intervals. This approach allows for the determination of a minimum efficient scale for use in setting the LVPA threshold and similarly can be used to estimate how much facilities' average per-treatment costs fall as facility treatment volume increases. As expected, larger facility total treatment duration across all treatments is correlated with lower per-treatment costs.

Additionally, the refined single-equation model directly incorporates the hospital wage index into the estimation as a control variable rather than imposing its effect via a preset formula. In other words, the model directly estimates the effect of the wage index on a facility's costs.

Including these new facility control variables for facility total treatment duration and hospital wage index improves the model's fit with minimal change to the case-mix coefficients.

2.1.6 Alternative Case-Mix Adjusters

Stakeholders have long argued for changes to the ESRD PPS case-mix adjusters, citing duplicative or counteracting adjusters and emphasizing the difficulty of obtaining necessary diagnostic information for reporting comorbidities. To address these concerns, a refined casemix adjustment model would optimally include a parsimonious set of case-mix adjusters that accounts for a significant portion of the variation in total costs, with each case-mix adjuster subject to the following selection criteria:

- (1) Facilities are likely aware if a beneficiary has the comorbidity/condition
- (2) There is an intuitive clinical and observable effect on dialysis treatment costs
- (3) The adjuster cannot be easily manipulated by facilities. Specifically, two considerations are important for ensuring this:
 - (a) The case-mix adjuster is not too ambiguous to define and measure, and
 - (b) It does not overlap with treatment decisions⁸

Case-mix adjusters can be obtained from a variety of potential data sources, specifically 72x claims, Medicare claims from other (non-ESRD) care settings, and the ESRD Medical Evidence Report (CMS 2728 form). Each of these data sources has its advantages and drawbacks. 72x claims data are updated regularly by facilities and easily accessible. However, current 72x reporting is incomplete with regard to comorbidities (likely because there is currently no direct benefit to providers from reporting these data), which leads to incorrect estimations of case-mix adjusters. Additionally, more complete reporting on 72x claims may

⁸ For example, if a facility gives an injectable vitamin D analogue, a diagnosis of vitamin D deficiency or secondary hyperparathyroidism may not be an appropriate case-mix adjuster, since this could be claimed every time the medicine is administered.

⁹ See slide 46 in the December 2020 ESRD PPS TEP Slide Deck.

increase provider burden, and although reporting behavior may improve with the implementation of a new case-mix adjustment model, this is not guaranteed.

More complete information on beneficiaries' comorbidities and conditions can be obtained from non-ESRD Medicare claims, reducing the burden on dialysis facilities to diagnose and report this information. However, dialysis providers do not always have access to data from other Medicare settings, and this could delay providers' knowledge of the exact payment amounts for their claims. During the TEP, Acumen presented a method that could be used to derive a set of key conditions from Medicare claims. For each provider-beneficiary-month, Acumen constructs Clinical Classifications Software Refined (CCSR) categories based on diagnosis codes from all Medicare claims from six months prior and flags CCSR categories that have high frequency, or are associated with higher cost per treatment. Next, Acumen conducts a clinical review of the full CCSR list and selects conditions that are likely related to high cost and are reasonably trackable by dialysis providers (this results in a selection of 163 CCSR conditions). Finally, Acumen clinicians classify selected CCSR categories into broader condition groups (29 groups). Acumen then assesses these 29 condition groups according to the selection criteria listed at the beginning of this subsection and whether the condition group is significantly correlated with increased total costs, which identifies six condition groups (clinical judgment as to why these conditions correlate with higher costs are listed as sub-bullets):

- (1) Coagulopathy
 - (a) Increased CR costs through direct patient care labor
 - (b) Increased CR costs through drugs and supplies when filters clog more regularly
- (2) Disorder of red blood cell production and hematologic malignancy
 - (a) Increased FSB costs
- (3) Heart failure
 - (a) Increased CR costs through direct patient labor (patients often require longer, gentler treatments)
 - (b) Increased CR capital costs per treatment due to missed treatments
 - (c) Increased CR costs through drugs for blood pressure support
- (4) HIV
 - (a) Increased CR capital costs due to missed treatments
 - (b) Potential increased FSB costs and likely increased CR labor and supply costs due to staff taking additional infection control precautions
- (5) Peptic ulcer disease and gastrointestinal bleed
 - (a) Increased FSB costs

- (b) Increased CR supply costs, since filters are more likely to clot when facilities avoid heparin
- (6) Pericardial disease
 - (a) Increased CR labor costs
 - (b) Increased CR supply costs, including dialysate

Acumen does not propose that these six condition groups be added as case-mix adjusters. These selection criteria are an example of how additional adjusters could be selected, and what the selection process would look like using Medicare claims as a data source.

Finally, a refined case-mix adjustment model could identify case-mix adjusters using comorbidities on the CMS 2728 form, which includes detailed information on selected comorbidities and other patient characteristics present at the initiation of dialysis treatment and which are likely relevant to dialysis treatment costs. These include items and conditions that may not appear in claims and would be unlikely to change over time (e.g., ambulatory status, institutionalization, requiring assistance with daily activities). The 2728 form is completed only once. Barring future policy changes that would require regular updates to the 2728 form, this approach would not generate additional provider burden. The major drawback to use of this data source is that because the 2728 form is filled out only at dialysis initiation, the data may become outdated. Moreover, existing studies have questioned the accuracy of 2728 form data. ¹⁰ It has been recommended that the 2728 form be standardized and simplified to improve accuracy. If this were to take place along with periodic reassessments, the 2728 form could be a reliable source of comorbidity data with minimal burden to providers as compared to other options.

2.1.7 Summary of Refined Model Improvements over Current Model

Compared to the current two-equation methodology, the refined single-equation case-mix adjustment allows for a more intuitive interpretation of a single case-mix adjuster by directly adjusting payments for patient case mix without any weighting. Additionally, in the single-equation model, case-mix adjusters are derived relative to variation in total cost of care, which reflects a beneficiary's use of facility resources relative to the facility's other beneficiaries. The design of the refined single-equation methodology considers the impact of increased provider burden resulting from new data reporting by attempting to limit the degree of new reporting. Facilities would only need to report on the claims (i) total machine-recorded treatment minutes and (ii) codes for new comorbidities instead of the current comorbidities. Finally, the magnitude of the effects of the case-mix adjusters in the example above is significantly attenuated relative to the current ESRD PPS adjusters. For example, a budget-neutral implementation of such a

¹⁰ Tucker, B. M., & Freedman, B. I. (2018). Need to Reclassify Etiologies of ESRD on the CMS 2728 Medical Evidence Report. *Clinical journal of the American Society of Nephrology: CJASN*, *13*(3), 477–479. https://doi.org/10.2215/CJN.08310817.

system would result in a significant increase in the base rate (5-10%) to offset lower average variation in payments resulting from the case-mix adjusters.

2.2 Summary of Discussion

Panelists confirmed Acumen's categorization of the two types of variation in patients' CR costs: costs that vary with treatment duration and those that do not. However, panelists emphasized that treatment duration often does not correlate directly with other treatment-related factors that affect total treatment costs, especially labor costs. As an example, panelists described situations where non-ambulatory patients required staff assistance and additional labor time that was completely unrelated to duration of treatment. Panelists also noted that dialysis center staff often call patients before they arrive for pre-screening, which increases labor costs. ¹¹ Moreover, the panel emphasized that there is significant variation in staff time required before and after the actual treatment that would not be captured in the refined single-equation model. Panelists also differentiated between prescribed and actual treatment duration. They explained that facilities assign staff based on prescribed treatment time, even when that does not match actual treatment duration.

Panelists preferred the concept of a single-equation case-mix adjustment model to the current two-equation model. However, some panelists opposed using treatment duration in the refined model and emphasized the technical difficulty of the approach. Several panelists maintained that treatment duration was not the most important factor driving variation in the cost of treatments. The panel also question whether treatment duration is compatible across dialysis modalities, asserting that duration for home modalities is not comparable to duration for incenter modalities. One panelist noted that some home PD machines automatically collect treatment duration, but this panelist also emphasized that collecting treatment duration for home PD at scale would introduce additional provider burden at many facilities. The panel expressed concern with the added provider burden associated with reporting in-center HD treatment duration, especially for facilities without automated treatment duration that would have to manually record these data.

The panel affirmed Acumen's three criteria for selecting alternative case-mix adjusters and suggested that a fourth criterion be added related to whether the case-mix adjuster is observed in some minimum volume of a facility's patients. Panelists suggested multiple conditions that could be used as potential case-mix adjusters. One panelist noted that patients with mental disorders have significantly increased dialysis costs. Another stated that patients with hospitalizations, ER visits, and missed treatments before their dialysis session are likely to

¹¹ The panelist noted that while this aligns with current COVID-19 protocols, dialysis facilities also engage in prescreening for non-COVID-related concerns such as tuberculosis.

have higher costs. One panelist suggested that BSA can be used as a proxy for treatment duration. The panelist noted that using BSA to apportion CR costs instead of treatment duration would incur no additional burden on providers, since BSA is already reported on 72x claims, and encouraged Acumen to investigate this approach. ¹² Additionally, one panelist worried that an increased focus on grouping patients to facilitate the case-mix adjustment conflicts with an individualized care approach to dialysis treatment.

With regard to potential data sources for the alternative case-mix adjusters, the panel strongly supported using all Medicare claims (including non-72x settings) to obtain comorbidity data for ESRD beneficiaries. Panelists noted that this could reduce burden on dialysis facilities because they would no longer be required to report patients' conditions that had already been reported in other claims settings. However, the panel opposed using data from the CMS 2728 form, noting that because these data are collected at dialysis onset, they quickly become outdated and inaccurate.

2.3 Key Findings

- Panelists agreed that a single-equation refined case-mix adjustment model is more intuitive than the current two-equation model, but did not rule out a two-equation approach if a single-equation model results in increased provider burden
- Panelists emphasized that duration of treatment does not include staffing time related to variation in CR cost before and after the treatment
- Panelists opposed apportioning costs using treatment duration, asserting that this
 approach cannot be applied consistently across modalities and would increase provider
 reporting burden
- Panelists confirmed Acumen's criteria for selecting alternative case-mix adjusters and suggested also considering whether the adjuster is observed in a minimum volume of a facility's beneficiaries
- Panelists strongly supported using non-72x Medicare claims to collect data for potential alternative case-mix adjusters but opposed using data from the CMS 2728 form

 $^{^{12}}$ After the TEP, Acumen ran a set of regressions of treatment duration on BSA and found that BSA was not an adequate replacement for treatment duration. The regressions iterated between linear-linear, linear-log, and log-log specifications. The sets also included/excluded BMI as an additional control. The highest R^2 that was achieved was 0.1936 for a linear-linear specification of duration regressed on BSA and BMI. The low R^2 suggests that BSA is not an appropriate proxy for duration.

3 PEDIATRIC CASE-MIX ADJUSTMENT

In conjunction with its development of the case-mix model for adult dialysis patients, Acumen described new methods for adjusting the pediatric dialysis payment to better match costs for this highly vulnerable subset of patients. During this session, Acumen used existing cost and utilization data to determine a potential pediatric payment adjustment and to identify changes to cost reporting needed to better reflect the costs of pediatric dialysis. The session included the following topics:

- Identify unique costs associated with pediatric dialysis
- Present existing data describing pediatric dialysis utilization and costs
- Describe limitations to accurate reporting of pediatric dialysis costs
- Describe options for adjusting these costs in a refined ESRD payment model

3.1 Summary of Presentation

3.1.1 Medicare Pediatric Dialysis Coverage

To be eligible for Medicare coverage of pediatric dialysis, a patient must meet certain eligibility criteria. First, the child's legal guardian(s) must have earned at least six credits within the last three years by working and paying Social Security taxes, or be eligible for Social Security or Railroad Retirement Board benefits. The child (defined as a person under age 22 years, or age 22-26 years and meeting other requirements) must need regular dialysis because their kidneys have failed, or have had a failed kidney transplant, to qualify.

3.1.2 Pediatric Dialysis Overview

Compared to the Medicare adult dialysis population, the pediatric population is notably small, comprising approximately 0.14% of the total ESRD population in 2019. Consequently, there are only a small number of dedicated pediatric dialysis facilities, where "pediatric facilities" are defined as those providing at least 100 pediatric dialysis treatments in 2019. These facilities are mostly urban, and tend to be based in a children's hospital or major medical center. Pediatric facilities are also either very small (furnishing less than 4,000 treatments per year) or very large (furnishing at least 10,000 treatments per year). Also, facilities providing an appreciable amount of pediatric dialysis have higher labor expenditures than those that do not. The overall median person-hours per treatment in 2019 were one hour higher than those for adult dialysis patients, and registered nurses (RNs)/licensed practical nurses (LPNs) contributed roughly double the person-hours toward a pediatric dialysis treatment, compared to adult dialysis.

To examine pediatric dialysis further, the pediatric dialysis patient population was split into two age groups: patients younger than age 13 years and those ages 13-17 years. Pediatric

patients younger than age 13 are more likely to dialyze using home PD, when compared to patients ages 13-17 and adults. Use of in-center HD increases as patients get older, and this was the most frequently used modality for adults. Lastly, weekly treatment frequency tends to be very similar between both populations. Differences in treatment frequency mainly lie in the 99th percentile of pediatric patients less than 13 years of age, who receive an average of five in-center HD dialysis sessions per week, a frequency rarely seen in the adult population.

3.1.3 Current Case Mix Adjustment Model

The ESRD PPS estimates pediatric case-mix adjusters using the following equation:

$$MultEB = P*C*WCR+WSB*MultSB$$

Where:

- *MultEB* = Extended bundle payment multiplier for pediatric dialysis per treatment cost
- P = Pediatric to adult ratio of total treatment cost (FSB+CR)
- C =National Average Payment Multiplier for Adults
- WCR/WSB = Ratio of Composite Rate to Separately Billable pediatric costs
- MultSB = Estimated effects of age and dialysis modality

The calculation begins with a patient-level model for formerly separately billable (FSB) costs to obtain the estimated effects on per-treatment cost of age and dialysis modality. A ratio of total composite rate (CR) and FSB (SB) pediatric costs to adult costs is calculated, as well as the average payment multiplier for adults and the fractions of total pediatric costs that are CR versus FSB. The combination of these factors yields the final pediatric case-mix adjustment.

The main challenge for estimating the total cost of treatment for pediatric dialysis is the small number of patients, which reduces the precision of statistical models. Another difficulty is disentangling CR costs for adult versus pediatric patients from the hospital-based facility cost report data, as these cost reports do not distinguish between adult and pediatric costs.

3.1.4 Stakeholder Concerns

Stakeholder comments regarding the payment model for pediatric dialysis mostly have focused on the high total cost of care for pediatric patients. Many noted that costs unique to pediatric dialysis, such as child life specialists, developmental and behavioral psychologists, pediatric dieticians, and social workers, are not adequately captured in current cost reports or claims, and therefore are not accounted for in pediatric adjustments. Stakeholders also have noted that although pediatric patients disproportionately receive treatment in hospital-based facilities, the hospital cost report (CMS Form 2552-10) does not distinguish between pediatric and adult dialysis costs.

3.1.5 Options to Better Capture Pediatric Dialysis Costs

In response to stakeholder comments and concerns, three non-mutually exclusive options to more accurately estimate pediatric dialysis costs under a revised payment model are considered: (i) the addition of pediatric-specific case-mix adjustment multipliers; (ii) the creation of a separate payment bundle for pediatric ESRD treatment costs; and (iii) revisions to current data collection practices. These three options are explained in greater detail below.

Pediatric-Specific Case-Mix Adjustment Multipliers

Using an approach analogous to the one presented in Session 2, the total cost per treatment for pediatric patients is estimated. The results are depicted using two alternative age groupings: the current age groupings (<13 years and 13-17 years) used by the ESRD PPS and the American Society of Pediatric Nephrology (ASPN) recommended age groupings: age <2, 2-4, 5-10, 11-17, and 18-24 years (which includes the transition to adult dialysis treatment). The median total cost per treatment for those younger than 13 years is \$390.10. This number declines steadily as patients get older. Stratification of age groups, however, results in total cost per treatment resembling an inverted "U"-shaped distribution, peaking for those aged 5-10 years.

To illustrate how the refined one-equation model would incorporate the pediatric population, the model was applied using each of the two age groupings. The refined methodology shows an increased effect of age on costs, with multipliers of 1.61 and 1.74 for age <13 years and ages 13-17 years, respectively, compared to the reference adult population. When further stratified into the ASPN age categories, the multipliers have a similar inverted "U"-shaped distribution, as was seen in the median total cost per treatment.

It is apparent from these results that pediatric dialysis costs decrease with age. However, since duration of treatment increases with age and size (BMI and BSA), these two factors may cancel the effects of each, making appropriate payment adjustment difficult for older pediatric patients. Therefore, duration of treatment may not be an appropriate input to the one-equation model regression when applied to the pediatric population.

To correct for this potential shortcoming, the median total cost per treatment was calculated, as well as the regression results using the national average HD treatment duration for all pediatric treatments. Using this method, the relationship between total cost per treatment and age comes closer to expected patterns noted by stakeholders. This difference results in modest increases in total cost per treatment and their respective regression coefficients, and the relationships between cost and age remain the same.

Refining the pediatric multiplier does not introduce significant provider burden, as reporting practices for providers would not change substantially. However, because duration of

treatment is not as applicable to the pediatric population compared to adults, this method may not adequately capture all costs.

Creation of a Pediatric Bundle or Separate Pediatric ESRD PPS

Stakeholders have suggested that the variables affecting pediatric dialysis costs are sufficiently different from those associated with adult dialysis costs, and that a separate payment system may be warranted. The creation of a Pediatric Bundle or Separate Pediatric ESRD PPS has the potential to more accurately estimate pediatric costs, as the model would be tailored to pediatric dialysis. Specialized labor, equipment, and supplies would be better accounted for under this system, and the model would address comorbidities specific to pediatrics and not currently incorporated into the PPS (seizures, growth failure, cognitive abnormalities, etc.).

Although this method may improve cost estimates for the pediatric population, the time required for implementation would be substantial. This is because the creation of a new bundle/ payment system would require an act of Congress, and because an extensive amount of new data collection would precede the implementation of the model, which may also present a burden to providers.

Revisions to Current Data Collection to Better Identify Pediatric Dialysis Costs

Several modifications to the cost reports were presented that would better capture resources utilized in the pediatric dialysis setting. ¹³ These include adding lines itemizing pediatric-specific labor categories and pediatric-specific supplies, clarifying cost report instructions as they pertain to pediatric dialysis, and better aligning the freestanding facility cost report with the hospital cost report. Although these changes have the advantage of being highly feasible to implement, uptake may take additional time, as pediatric facility accounting and billing staff are not generally familiar with Medicare cost reports. Furthermore, changes to the freestanding facility cost report would be of limited value, since pediatric dialysis primarily takes place in hospital-based facilities.

3.2 Summary of Discussion

Panelists agreed that accounting and billing departments at children's hospitals are not well equipped to accurately complete Medicare cost reports and suggested that this may be due both to their general lack of familiarity with Medicare (one panelist notes that only 30% of pediatric patients are Medicare beneficiaries) and the cost report's current structure.

One panelist cautioned that because most pediatric dialysis is delivered in the hospital setting, if the revised hospital cost report does not include the modifications recommended for the freestanding facility cost report, pediatric expertise for dieticians, social workers, child life

¹³ Suggested changes to the cost report are discussed in greater detail in Section 6 of this report.

specialists, and behavioral specialists may remain overlooked. Despite this, panelists expressed the desire to move forward with Acumen's suggested cost report modifications to improve pediatric payment.

Panelists generally favored the addition of pediatric case-mix adjustment multipliers. One panelist noted that prior to the current case-mix adjustment, the multiplier applied to pediatric facilities was based on actual costs incurred during treatment that were more accurate than the costs being reported currently. The case-mix adjustment multipliers presented during the TEP were similar to the multipliers from the prior payment method, which the panelist found encouraging.

However, there is shared concern that there will continue to be underpayment for pediatric dialysis patients. One panelist noted that time on dialysis may not accurately reflect all costs, and may be especially misleading for those under 2 years of age. For this patient population, expenditures on some fixed costs (e.g., dialysate) will decrease, but staffing costs would be considerably higher, as they require one-on-one nursing and child life specialists and are more difficult to initiate on dialysis. Therefore, panelists expressed the concern that Acumen's alternative multipliers (based on duration of treatment) would not accurately reflect costs. Another panelist noted that certain state laws with personnel requirements for pediatric dialysis can also increase costs.

Panelists conceded that although a new bundle would be the most comprehensive in terms of considering all pediatric dialysis costs, they preferred moving forward with the cost report and case-mix multiplier modifications, due to the burden of implementing a new bundle.

One panelist noted that a time and motion study attempted by their dialysis organization failed, as there was a high degree of variation among facilities. Another panelist described their facility's success in securing additional funding for their pediatric dialysis unit as a result of a time and motion study.

3.3 Key Findings

- Panelists maintained that pediatric facilities are not well equipped to fill out cost reports but still expressed desire for the freestanding and hospital cost reports to be better aligned to get closer to accurate payment for pediatric dialysis
- Panelists agreed on the utility and effectiveness of time and motion studies but noted that they are impractical for observing short-term change
- Panelists were in favor of moving forward with changes to the pediatric risk adjustment model but noted several ways in which this methodology may not accurately reflect costs:

- O Staffing costs for patients under two years of age is a significant expense that would not be captured with treatment duration, impacting the accuracy of pediatric multipliers within the one-equation model
- Costs may be different due to state-specific legislation on staffing requirements for pediatric dialysis treatments

4 LOW-VOLUME PAYMENT ADJUSTMENT

During this session, Acumen presented an alternative Low-Volume Payment Adjustment (LVPA) and Rural Adjustment methodology to maintain and improve access to dialysis for beneficiaries in regions with limited dialysis options. This session covered the following topics:

- Review existing LVPA and Rural Adjustments
- Introduce motivation for geographically based LVPA framework
- Review alternative LVPA methodology
- Gather TEP feedback on the alternative approach

4.1 Summary of Presentation

4.1.1 Current LVPA and Rural Adjuster Policy

The LVPA and Rural Adjustment are facility-level adjustments, which were created to incentivize dialysis facilities to locate in areas with low demand for dialysis services, and to preserve beneficiary access to care.

The LVPA became effective on January 1, 2011. Section 1881(b)(14)(D)(iii) of the Social Security Act requires a payment adjustment to the ESRD PPS that reflects the extent to which renal dialysis costs incurred by low-volume facilities exceed the costs incurred by other facilities. The Code of Federal Regulations defines a low-volume facility as meeting two criteria: one pertaining to treatment threshold and one to ownership status. Section 413.232(b)(1) specifies that low-volume facilities must have furnished less than 4,000 treatments in each of the three cost reporting years preceding the current payment year (based on three as-filed or final settled 12-consecutive-month cost reports, whichever is most recent). Section 413.232(b)(2) specifies that the low-volume facility has not opened, closed, or received a new provider number due to a change in ownership in the three cost reporting years preceding the payment year (based on as-filed or final settled 12-consecutive-month cost reports, whichever is most recent).

Currently, the LVPA provides a 23.9% payment adjustment to all treatments. The rural adjustment provides a 0.8% increase in payment for all facilities located in rural Core-Based Statistical Areas.

4.1.2 Current LVPA Shortcomings and Premise of Alternative Methodology

Stakeholders have noted that the current LVPA logic does not consider whether LVPA-eligible facilities are in close proximity to other dialysis facilities owned by different organizations, creating the possibility for duplicate LVPA payments in a single area and for small inefficient providers to receive the adjustment. Additionally, the policy may not sufficiently incentivize placement of facilities in underserved areas, as LVPA-deserving facilities must operate for three years before becoming eligible for the adjustment. Stakeholders also have

expressed concern about the current LVPA's treatment threshold. They noted that the treatment threshold creates the potential for gaming, as facilities that provide slightly more than 4,000 treatments may be induced to reduce their treatment count to remain eligible, thereby increasing their overall revenue by 23.9%. Others maintained that the adjustment likely does not reflect actual treatment costs for facilities operating at the margins of this threshold, as there are no tiered adjustments for facilities that provide treatments that number slightly above or below the threshold.

Ideally, the LVPA adjustment should provide sufficient incentive to encourage facilities to operate in geographically isolated areas, which are critical to provide access to isolated communities. With these policy objectives in mind, a new approach to the LVPA methodology was presented that directly addresses each of the stakeholder concerns described above. The new methodology is geographically based on census tracts and provides the payment adjustment to an entire closely defined geographic area with low dialysis demand, instead of awarding this designation to individual facilities. This approach reorients the LVPA to support facilities essential to preserving access to care in geographically isolated areas, where demand for dialysis is too low for it to be financially viable for providers without a payment adjustment.

The shift in focus to geographic areas removes any incentive for facilities to withhold treatment to remain LVPA eligible, as treatment count is not considered. Targeting is also improved under this methodology, as small facilities surrounded by other dialysis facilities under separate ownership would not receive the adjustment. Lastly, the alternative model can easily incorporate tiered thresholds to account for varying degrees of LVPA payments necessary to maintain or open facilities in underserved areas.

4.1.3 Alternative LVPA Methodology

The alternative LVPA methodology awards LVPA designation based on the latent need for dialysis services in a geographic area, rather than facility treatment counts. The alternative methodology is summarized in the following steps:

- (1) Divide the United States into geographic areas
- (2) Calculate the adjusted latent demand of each geographic area
- (3) Apply the LVPA threshold

These steps are described in greater detail below.

Divide the United States into geographic areas

The first step in the alternative methodology divides the United States into market areas/geographic divisions based on a reasonable assessment of ESRD beneficiaries' ability or willingness to travel. Counties were first considered to be the unit of geographic division, but census tracts were ultimately chosen because counties can vary greatly in size and population

among states. Census tract size is also inversely proportionate to population density, thus tracts have more equalized population in comparison to counties.

Calculate the adjusted latent demand of each geographic area

The next step is to divide US census tracts into four regions (North, South, Midwest, and West), and deciles by population density, yielding 40 categories of census tracts. Claims data is used to determine the driving time between each beneficiary's home address and the address at which they receive dialysis care. Then, a circle is drawn around each beneficiary home address, where the radius corresponds to a chosen threshold of driving time observed for each census tract category. The alternative methodology presented at the 2019 TEP used geodesic distance, but panelists noted that this metric does not account for natural or manmade boundaries (e.g., bodies of water or highway off-ramps) that exist between these points. Using driving time has the advantage of accounting for such deviations. Of note, driving time (and thus the radii of beneficiary circles) tends to be shorter in urban areas and longer in more rural areas.

The number of times that these driving circles overlap with a facility, multiplied by the average number of treatments for Medicare FFS ESRD beneficiaries, yields latent demand. However, the hypothetical facility captured in the beneficiary circle may not be the facility where the beneficiary receives care. Additionally, not all beneficiaries receiving treatment from the hypothetical provider will travel from inside the circles. Therefore, the latent demand will need to be adjusted using a statistical model to better approximate what a provider would observe in terms of demand if they were to locate in this region. A three-year rolling estimation of adjusted latent demand is used to provide stability to the system.

Apply the LVPA threshold

There are a variety of ways a threshold of adjusted latent demand, below which a census tract is deemed LVPA eligible, can be chosen. This can be determined based on cost analyses or budgetary considerations, or can be chosen to maintain the same number of LVPA facilities or to maintain current standards. Different adjusted latent demand thresholds, and thus different levels of payment enhancement, can be employed in this step to better align resource use with payment for each facility.

4.1.4 Applying the New Methodology

Estimation of the three-year predicted demand for all US census tracts shows that tracts with high predicted demand are mostly located in the East and in populated urban areas. Current LVPA facilities that would no longer receive the LVPA under the alternate method are concentrated in these areas, whereas facilities that would gain the LVPA are largely located outside urban areas, mostly in the Midwest and far West of the country.

Use of the alternative methodology also improves the targeting of isolated facilities. Facilities eligible for the LVPA under the alternative method have an average of 1.6 facilities located within their respective driving circles, compared to an average of three neighboring facilities for those that would lose designation. LVPA facilities under the alternate method are also more isolated in terms of surrounding ESRD beneficiaries; over a three-year period, facilities gaining the adjustment have an average of 850 patient-months within their respective circles, while those that would lose the designation have an average of 2,500 patient-months within their standard travel distance.

Using the new methodology, some facilities will gain LVPA eligibility by virtue of being located in geographically isolated areas, despite the large treatment counts these facilities furnish. Facilities that would no longer be eligible for the LVPA had an average of 2,905 treatments per year in 2016, compared to the average 5,931 treatments per year for facilities gaining the adjustment. These facilities are typically responsible for furnishing all dialysis treatments across a large geographic area, and beneficiaries likely must travel long distances to receive treatment. Awarding LVPA to these tracts, and incentivizing placement of new facilities in these areas, alleviates this burden on beneficiaries and improves access to care in rural areas.

There are several limitations to the new method. First, mode of transportation may not always be driving in a private car. Acumen investigated whether these "driving" circles should be smaller in cases where transportation is more likely to be by public transportation or walking and found these differences to be marginal. A gaming possibility would arise if providers move into LVPA-eligible tracts to receive the adjustment. While this behavior may be read as gaming, it is the intent of the new methodology to promote access of care in isolated areas. Acumen also noted that the alternative LVPA methodology provides the adjustment to several urban tracts, where loss of providers may make access difficult. Acumen considered the possibility that the alternative methodology could result in inefficiently duplicative facilities in low population census tracts, but this level of competition would nullify the adjustment for all providers involved, making this scenario unlikely.

The alternative methodology is simpler from an administrative standpoint compared to the existing method. The current method includes verification of the volume standards, an attestation process, which can provide a disincentive for some providers to complete LVPA attestation. The alternative method simply generates a list of LVPA-eligible geographic tracts, and any and all facilities located within those tracts are then LVPA eligible, with no further action needed by facilities.

4.2 Summary of Discussion

Panelists were generally amenable to the use of the new LVPA methodology. They appreciated the consideration of terrain and geographic barriers and their potential effect on dialysis access. However, they had a number of concerns about the implications the alternative system may have for facilities that would lose the adjustment. Panelists noted that it could be difficult for surrounding providers to absorb incoming patients in the event of a sudden closure, and suggested that facilities that lose eligibility be phased out of LVPA payments gradually. Panelists also noted that gradual transition plans exist for the Wage Index, for which facilities are given two- to three-year notice before significant changes are implemented, to ensure continuity of care for patients. Panelists cautioned that the loss of the adjustment may impact large dialysis organizations and small independent providers differently.

One panelist noted that as urban facilities lose the LVPA adjustment, it may be difficult for newly designated LVPA facilities to attract staff willing to drive considerable distances to rural areas.

Panelists also noted that some states have Certificate of Need processes that govern the acquisition of major medical equipment, to ensure that facility resources align with community need. Therefore, these dialysis facilities may only be awarded a small number of dialysis machines by their state, limiting the number of treatments they can provide. They commented that these facilities tend to be located in newly developed communities, and may not be viable in the absence of the LVPA, while the dialysis population grows.

One panelist argued that the use of a statistical model to calculate adjusted latent demand lacked transparency, and suggested that Acumen use latent demand to set LVPA thresholds, assuming the difference between these two metrics is negligible.

There was also considerable discussion about preservation of access to care were the alternative method to be implemented, specifically for beneficiaries in urban areas that are more reliant on public transportation. Panelists noted the possibility that these underserved beneficiaries may have access to a current LVPA facility, but bus or train routes may not operate in areas that would be provided the LVPA under the alternative method.

Additionally, panelists favored a tiered approach for LVPA designation, as it would lessen the potential for gaming and better estimates actual costs incurred by facilities. Panelists noted that a tiered approach would also allow for a smoother transition into the alternative methodology, as facilities would be allowed to adapt to changes in treatment size and payment gradually. One panelist suggested using duration of treatment to create a scaled adjustment. Several panelists suggested that Acumen consider the Medicare Payment Advisory Commission's recommendations related to the LVPA.

Most panelists felt that maintaining the rural adjustment while implementing the alternative method would be duplicative. However, one panelist suggested that the rural adjustment be maintained and potentially combined into the alternative methodology.

Lastly, panelists noted that Medicare is not the only payer for dialysis services, and suggested that Acumen consider whether other payers should be considered when making an LVPA designation based on latent demand for treatment. Panelists also suggested that Acumen expand the analyses to include Medicare Advantage beneficiaries.

4.3 Key Findings

- Panelists generally supported the alternative methodology but shared several suggestions to improve the alternative LVPA
- Panelists strongly suggested that LVPA designation be withdrawn gradually for facilities no longer eligible under the alternative method
- Panelists expressed concern regarding social risk and emphasized that any alternative LVPA methodology must not adversely impact economically disadvantaged communities
- Panelists preferred a tiered approach to the LVPA
- Panelists suggested that Medicare Advantage beneficiaries be considered in the alternative methodology for future analyses

5 ACUTE KIDNEY INJURY (AKI) PAYMENT SYSTEM (PS)

This session reviews cost and utilization of AKI-related dialysis services since the policy change of 2017, which incorporated payment for dialysis treatment for these patients into the ESRD PPS, assesses the accuracy of reported data, and discusses the effectiveness of the AKI PS in capturing dialysis costs for this population. Included are the following topics:

- Describe payment for outpatient dialysis for patients with AKI (AKI-D) through the AKI PS
- Review utilization and cost of AKI-D treatment
- Solicit input from TEP regarding how reported costs align with realized costs of treatment for AKI-D patients

5.1 Summary of Presentation

Acumen described dialysis-related costs, resource utilization, and characteristics of the AKI-D population beginning January 1, 2017, when their outpatient dialysis treatment first became eligible under the 72x claims system. To allow for delays in implementing the AKI-D benefit across facilities, the analyses only included CY 2018 claims data and beyond.

5.1.1 Goals of Dialysis for AKI Patients and AKI Policy

The primary goal of dialysis for AKI patients is to promote the recovery of kidney function and prevent transition to ESRD. In addition to the benefits of greater health for patients resulting from recovery, recovery also reduces Medicare expenditures and taxpayer burden. Dialysis for AKI patients also aims to stabilize patient health and promote patient well-being, allowing patients to undergo treatment for coexisting medical conditions.

Dialysis treatments furnished to AKI patients in outpatient dialysis facilities are paid by Medicare under the ESRD PPS according to the following formula:

Payment = ESRD PPS Base Rate * [Labor Share * Hospital Wage Index + (1 - Labor Share)]

Payments for AKI treatments do not include ESRD adjustments/add-ons for case-mix, low-volume status, rural status, outlier, TDAPA, TPNIES, and self-dialysis training. For reference, the ESRD PPS base rate established in the CY 2021 Final Rule is \$253.13.

5.1.2 Descriptive Statistics for AKI-D Patients

The number of new monthly AKI-D beneficiaries identified on 72x claims has increased slightly from January 2018 to May 2020. The number of new AKI-D beneficiaries ranged from 1,000 to approximately 1,300 per month from January 2018 to May 2020.

Analysis of 2019 claims data reveals that certain demographic characteristics differ between AKI-D beneficiaries, incident ESRD beneficiaries, and prevalent ESRD beneficiaries. Unlike ESRD beneficiaries, patients with AKI do not automatically qualify for Medicare coverage, so AKI-D patients observed in 72x claims are at least 65 years old or are disabled. To make the two ESRD populations more comparable to the AKI-D population, the analysis restricts to aged (≥65 years old) beneficiaries. Specifically, incident ESRD beneficiaries are those who had their first incident ESRD claim anytime in 2019, while one-year prevalent ESRD beneficiaries are those who reached their one-year mark of receiving prevalent ESRD dialysis anytime in 2019. After accounting for the age restrictions, the average age across the three populations is similar, at roughly 75 years. Compared to the ESRD patient population, AKI-D patients are more likely to be white than of other race/ethnicity, and less likely to be dually eligible. The three populations have similar gender distribution and rates of rurality.

5.1.3 Outcomes and Utilization for AKI-D Patients

Using a Kaplan-Meier curve focusing on the 180 days after starting outpatient dialysis treatment for AKI (for patients who started treatment for AKI between January 2019 and October 2019), probabilities for the presence of AKI-D, death, developing ESRD, and no subsequent dialysis claims observed are produced. By the 90-day mark after starting dialysis for AKI in the outpatient dialysis setting, approximately 25% of AKI-D patients seem to recover, meaning that no subsequent AKI-D or ESRD claims are observed for them, and no indication of death is observed. At this 90-day mark, approximately 40% of AKI-D beneficiaries have developed ESRD.

In terms of treatment frequency, AKI-D patients have similar treatment frequencies to those observed for incident ESRD and one-year prevalent ESRD beneficiaries, when comparing the weekly treatment frequencies for the first, second, and third months after the reference date for each population (i.e., start of AKI-D, start of incident ESRD, or the date at which an ESRD beneficiary reached prevalent status in 2019). Although Medicare does not limit the number of paid treatments for AKI, as is done for ESRD treatments, the treatment patterns for AKI-D and ESRD do not noticeably differ from each other, as the average number of treatments per week for each population are all in the range of 2.68 to 2.85.

5.1.4 Costs of Furnishing Dialysis to AKI-D Patients

Freestanding facility cost reports were updated to include AKI on February 20, 2018, allowing treatment costs for AKI-D patients to be calculated separately from treatment costs of ESRD patients. Hospital-based cost reports do not allow for separation of AKI-D and ESRD treatment costs. On freestanding facility cost reports, all component categories of costs (capital, labor, administrative, drugs, labs, and supplies) are itemized on Worksheet B/B-1 and stratified

by modality to AKI-Hemodialysis (HD) and AKI-Intermittent Peritoneal Dialysis (IPD). Treatment counts for AKI-HD and AKI-IPD are reported separately on Worksheet C.

Cost report data from 2019 reveal the average cost per treatment for AKI-D patients is \$29 greater than that of ESRD (\$296 compared to \$267), approximately 10 percent higher than the average ESRD PPS treatment cost. Higher average costs for AKI-D generally persist across the facility types and locations, including rural status, for-profit status, census region, facility size (in terms of annual number of treatments), and ownership type. Average treatment costs for smaller facilities (<4,000 treatments) are particularly high among both populations, \$468 for AKI-D and \$414 for ESRD.

Comparing the average costs of the previously mentioned six cost component categories (capital, labor, administrative, drugs, labs, and supplies), AKI-D treatments have higher labor and capital costs than ESRD treatments. Administrative costs are similar across the two populations, and average supply costs are slightly lower for AKI-D (\$23) compared to ESRD (\$29). Drugs, which are the only category for which composite rate (CR) and separately billable (SB) costs can be differentiated, have similar costs across the two populations.

Costs for SB items, which are drugs, labs, and supplies, can also be calculated using 72x claims rather than cost reports. These costs are obtained by multiplying utilization units on 72x claims by the prices for each SB item separately. Compared to the costs calculated from cost reports, the average cost of drugs per treatment for AKI-D treatments is noticeably lower when multiplying units on 72x claims by the prices for each SB item, \$8.20 compared to \$28 on cost reports. The average cost of SB supplies per treatment is also noticeably lower compared to costs calculated on cost reports for both AKI-D and ESRD patients.

5.1.5 Dialysis Modality and Changes Observed in 2020

Since Medicare does not pay for home dialysis treatments for AKI-D patients, in-center HD is the only modality observed for AKI-D treatments. Stakeholders have advocated for flexibility in coverage, recommending that home dialysis for AKI-D patients be covered under Medicare, particularly during the 2020 COVID-19 public health emergency (PHE).

Due to the PHE, Medicare has temporarily allowed dialysis facilities to travel to nursing homes and furnish 72x dialysis to their beneficiaries there, with the treatments still being classified as in-center HD. These treatments are indicated by either the DR (disaster related) condition code or CR (catastrophe/disaster related) modifier. Acumen's analysis of claims data reveals that the number of 72x AKI-D claims slightly increased starting in March 2020, with approximately 2% of AKI-D claims in May 2020 having either a DR condition code or CR modifier.

Focusing on weekly treatment frequencies for the AKI-D patients who received 72x dialysis in nursing homes, there are no noticeable changes in treatment frequencies for patients receiving dialysis in nursing homes compared to those in dialysis facilities, although the patient population with a DR condition code or CR modifier is small. The data reveal that changing the setting of dialysis did not seem to alter the pattern of care the AKI-D patients were receiving.

5.2 Summary of Discussion

Panelists agreed that some AKI-D patients could benefit from different treatment regimens. In particular, they noted that more frequent, gentler dialysis would be a viable option for some patients, possibly preventing hypotension. Given that many patients receive acute PD treatments in the hospital upon developing AKI, panelists expressed support for allowing AKI-D patients to continue receiving acute PD once they are discharged from the hospital. One panelist noted that their hospital tries to get AKI-D patients accustomed to a more standard treatment regimen such as three treatments per week before discharging them to a dialysis facility. Another panelist expressed support for the implementation of transitional care units, suggesting these would help patients new to dialysis adjust to treatment and the lifestyle changes that accompany it. Panelists also advocated for allowing AKI-D patients to be treated at home, especially in light of the COVID-19 PHE.

Members of the panel commented on the similar treatment frequencies observed for AKI-D and ESRD patients, stating that the payment system is currently constructed to facilitate the standard treatment plan for AKI-D patients. Panelists stressed that the payment system should be flexible in terms of number of treatments for AKI patients, so that those who need more frequent treatments are not impeded from receiving them.

Panelists expressed support for the CMS guidance temporarily allowing dialysis facilities to send dialysis facility staff to furnish 72x dialysis to their patients in nursing homes, from both a cost and patient health perspective. Particularly for the patients with multiple comorbidities, the full spectrum of care provided in the skilled nursing facility setting is appropriate.

Panelists commented on the costs per treatment observed for AKI-D patients, expressing that the higher observed costs compared to ESRD treatments aligns with their expectations. They noted that AKI patients receive more lab tests to monitor for signs of recovery, but typically are not prescribed calcimimetics or ESAs. Some panelists also noted that due to the very small AKI-D population size, reporting AKI-D costs and statistics on cost reports at a granular level would introduce an outsized reporting burden on the providers.

Overall, panelists concurred that the AKI PS is effective and benefits both patients and facilities. One panelist pointed out the AKI policy change also helps hospitals, as they can send

AKI patients requiring dialysis to dialysis facilities and consequently free up capacity at the hospital.

5.3 Key Findings

- Observed costs for treating AKI-D patients compared to ESRD patients align with panelists' expectations
- Panelists noted that some AKI patients would benefit from different treatment regimens, including more frequent, gentler dialysis and receiving treatment at home instead of incenter
- Panelists explained that the similar observed treatment frequencies for AKI-D patients and ESRD patients is a result of how the payment system is constructed
- Panelists expressed support for the CMS guidance temporarily allowing dialysis facilities to furnish dialysis to their patients in nursing homes and to bill to 72x claims

6 COST REPORT REVISIONS

The objective of this session was to provide recommendations for revisions to the ESRD PPS independent facility cost report and to obtain feedback from panelists on implementing those changes. The suggested revisions would support data input needs for the refined case-mix adjustment model described in Session 2 (adults) and Session 3 (pediatrics). The session included the following topics:

- Description of how current cost report data can be used to obtain per-treatment total costs
- Presentation of recommended cost report changes
- Illustration of how the recommended changes facilitate the development of a refined payment model
- Description of additional revisions/additions to the cost report to support more accurate reporting of costs unique to pediatric dialysis

6.1 Summary of Presentation

Acumen began this session with a review of the components of dialysis treatment costs and the difficulty of determining how these costs vary at the patient or treatment level because they are not itemized on claims. Acumen also reviewed the current methodology for computing cost per beneficiary-month. A new method for this calculation was recommended along with Acumen's rationale for the recommended cost report revisions. The revisions include changes to several composite rate cost components including (1) capital costs related to dialysis machines and other equipment used to provide the dialysis treatment, (2) labor categories used for direct patient care and management and administrative staff positions, and (3) differentiating separately billable from composite rate supplies. Moreover, the suggested changes incorporate the differentiation of costs associated with home dialysis treatment from in-center treatment. Finally, Acumen suggested several revisions related to the reporting of pediatric dialysis treatment costs.

6.1.1 Component Costs of Dialysis Treatment

Six component costs of dialysis treatment are recorded in the cost report: capital, direct patient care labor, administrative, drugs, laboratory tests, and supplies. They are described in Table 3 below.

Table 3. Components of Composite Rate Dialysis Treatment Costs

Capital	Buildings and fixtures, movable equipment, operation 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

Composite rate costs constitute 89% of total treatment costs, while formerly separately billable costs, mostly drug costs, but also including some lab tests and a small portion of supplies, comprise the remaining 11%. The bundle of essential services included in the composite rate are not itemized on the 72x claim. These costs can only be determined from the cost report. Differentiating how these costs vary at the patient level is essential to the efforts to develop a more refined payment model.

6.1.2 Duration of Treatment Provides Framework for Allocating Composite Rate Costs

Patient-level differences in composite rate costs within a facility can be attributed to differences in treatment duration and differences in costs unrelated to treatment duration. With all other factors being equal, a longer dialysis treatment session will result in higher composite rate costs than a shorter one. Using duration data, cost reports can be used to derive cost per minute of dialysis treatment session time for defined groups of patients, such as pediatric patients or patients with hepatitis B virus (HBV) infection who must be isolated. Cost report data can be combined with treatment times collected on claims to infer differences in composite rate costs across patient months. The cost report revisions recommended in this presentation will facilitate the disaggregation of composite rate costs related to differences in treatment time from costs unrelated to treatment time. These revisions to the cost report will entail minimum burden to the provider.

6.1.3 Obtaining Total Cost and Cost per Treatment

Applying the new framework for obtaining total cost per treatment based on duration of treatment, it is assumed that within each facility, all beneficiary-months have the same cost per minute (this would apply to in-center HD, home HD, and home PD costs). Across facilities, however, this amount may vary.

The method is applied as follows:

- For each provider:
 - o Obtain total dialysis minutes for in-center and home HD
 - From 72x claim treatment counts and HD minutes from CROWNWeb
 - Estimate total dialysis minutes for home PD
 - From 72x claim treatment counts and national average HD minutes per treatment
 - Derive total dialysis minutes across all three modalities
- For each provider-beneficiary-month with in-center HD, home HD, or home PD:
 - CR cost = provider-level total CR cost / provider's total dialysis minutes * total dialysis minutes for the provider-beneficiary-month
- Use formerly separately billable (FSB) charges on claims and cost-to-charge ratios specific to FSB categories to calculate FSB costs
- Add CR cost to FSB cost to obtain total cost for the provider-beneficiary-month

The provider-beneficiary-month cost per treatment equals the total cost divided by total treatment counts in the particular month.

6.1.4 Revising the Cost Report to Obtain More Accurate Assessment of Component Costs

To obtain more accurate per-minute per-treatment costs for each facility, Acumen is proposing that certain composite rate costs be reported with more precise detail and that the definition of cost components reported be clarified to ensure comparability across facilities (or across dialysis organizations). Whereas the starting assumption is that per-minute dialysis costs are the same for all treatments within a facility, more accurate stratification of costs by modality and patient type will allow for the relaxation of this assumptions, if costs are found to vary across modalities and/or patient type.

There are two basic goals for the cost report revisions recommended here: (1) to be better able to determine which component costs can be attributed to each dialysis modality and which costs are shared equally across modalities, and (2) to determine, within each modality, what fraction of costs vary with duration of treatment.

Currently, it appears that component costs are allocated evenly across modalities using crude accounting rules. Once the recommended revisions are implemented and more accurate cost data are collected, composite rate costs per minute will likely show some variation across modalities (within each facility). This new information will be sufficient for making a more accurate allocation of composite rate costs to the treatment (or beneficiary-provider-month) level.

Acumen suggests that four specific revisions be made to the freestanding facility cost reports. These include:

- Differentiating capital costs by modality and location for dialysis machines and related equipment
- Differentiating direct patient labor costs by modality and updating the labor categories to reflect current staffing patterns
- Better differentiating administrative and managerial costs, so that lower-cost administrative labor can be separated from higher-cost managerial positions
- Stratifying supply costs for composite rate and separately billable supplies

These are changes that reflect the costs that are most likely to vary with treatment duration and also correct for costs that are insufficiently differentiated on the current cost report.

Capital-Related Dialysis Machine Costs

Currently costs related to purchase or rental of dialysis machines are not differentiated by modality of use. Correcting this problem by requiring the reporting of such costs by modality (and location) will allow the precise computation of capital costs by modality and allow for variation to be seen in per-minute capital costs across modalities within the same facility.

The specific revisions for discussion are as follows:

- Item definition
 - o Itemize each machine and stratify by setting and modality
 - Home or in-center
 - Home HD, Home PD, In-center HD
 - o Include purchase, depreciation, and rental costs
- Location in cost report
 - o Expand Worksheet A, Line 6
 - Itemize on Worksheet A-1
 - Add specificity to instructions regarding what costs are to be itemized
- Format: Lines could take following form
 - o 0601: machine-related capital, rental, or maintenance in-center HD
 - o 0602: machine-related capital, rental, or maintenance in-home HD
 - o 0603: machine-related capital, rental, or maintenance in-home PD
- Metric: Dollars actually spent
 - o Do not use accounting rule to allocate costs across modalities

Examples of the revisions as they would actually appear in the cost report can be found on slide 154 in the 2020 ESRD PPS TEP Slide Deck.

Direct Patient Care Labor Costs

Currently the job categories for direct patient care labor, measured in full-time equivalents (FTEs), do not indicate the distribution of time spent by dialysis modality. To remedy that and provide a better estimate of cost by labor category, Acumen proposes to differentiate each modality on the lines dedicated to direct patient care labor and for FTEs for each labor category to be distributed accordingly on the form. This change is restricted to direct patient care labor, as administrative and management costs are not thought to vary by duration of treatment. In addition, Acumen recommends that staffing category designations be updated to reflect current staffing patterns and that the Bureau of Labor Statistics (BLS) occupational categories for outpatient care centers be used for this purpose, rather than the currently used inpatient hospital staff categories. With these changes in place, it will be possible to correlate (higher) labor costs with specific groups of patients.

Direct patient labor categories recommended for addition to the cost report include: pharmacists; nutritionists and dieticians (currently only dieticians are listed); intermediate-level providers (e.g., nurse practitioners and physician assistants); and RNs with varying credentials. A potential new layout for Worksheet S-1 in the cost report that includes these revisions can be found on slide 157 in the slide deck.

Management and Administrative Labor Costs

Existing job categories on the cost report do not differentiate between higher-cost management positions and lower-cost administrative and clerical functions. Acumen recommends selected changes to better estimate this component of composite rate costs, which are not thought to vary with duration of treatment. As with the direct patient labor job categories, Acumen recommends bringing these functions up to date with use of select BLS categories for outpatient care centers. The suggested job categories include:

- For management occupations: add business and financial roles
- For operations occupations: add office and administrative support workers
- For computer systems: add programmers and analysts

A potential new layout for Worksheet S-1 showing the placement of the recommended new managerial and administrative staff categories can be found on slide 160 in the slide deck.

Differentiating Separately Billable from Composite Rate Supplies

Supplies comprise approximately 10% of composite rate costs. Separately billable supplies are not differentiated from composite rate supplies on the current cost report. Many supplies, including dialysate, are directly related to the duration of the dialysis treatment. Drug

costs are already differentiated on the cost report, although drugs contribute only a small portion of composite rate costs. Acumen recommends that a separate column differentiating composite rate from separately billable supplies be added to Worksheet B/B-1, Column 7. An example of the formatting for this revision can be found on slide 162 in the slide deck. Acumen also recommends that the list of dialyzers, currently reported on Worksheet S-1, be updated and moved to Worksheet B/B-1 as a separate line item.

6.1.5 Cost Report Revisions for Pediatric Dialysis

Pediatric composite rate costs are not differentiated from adult costs on hospital cost reports. Some pediatric costs are itemized on the existing freestanding facility cost report. Here we present Acumen's computational method used for comparing composite rate component costs for pediatric dialysis to those for adult dialysis by modality.

Using CY 2019 cost report data, Acumen computed total and component-specific cost per treatment for hemodialysis-equivalent treatments, stratified by modality (when possible from existing data). For each facility that reported both adult and pediatric treatments, the ratio of pediatric cost per treatment to adult cost per treatment was obtained. The results demonstrate that there is variation in costs across components for pediatric and adult treatments. Overall, the ratio of pediatric to adult total cost per treatment was 1.58, indicating the cost of a pediatric dialysis treatment was almost 60% higher than the mean cost of an adult treatment. When broken down by cost component, administrative costs and supply costs were found to be significantly higher for pediatric treatments. This cost differential was especially notable with regard to supplies. The pediatric to adult per-treatment cost ratios were 1.70 and 7.30 for administrative costs and supply costs, respectively.

Further investigation revealed that some facilities that treat both adult and pediatric patients do not differentiate costs between the two patient populations in their cost report accounting practices. Facilities in which pediatric cost per treatment was found to differ by less than 2% from adult cost per treatment were determined to not differentiate between adult and pediatric costs.

The results show that overall, across all treatment modalities, 13% of facilities that treat both pediatric and adult dialysis patients are not differentiating costs between the two age groups. Twenty-nine percent do not distinguish between adult and pediatric costs with regard to in-center HD and home PD, while 25% do not do so with regard to home HD costs. When broken down by component costs, a very high proportion of facilities that serve both adult and pediatric patients do not differentiate costs for drugs, laboratory tests, or supplies.

As a result of these findings and taking into consideration the recommendations of stakeholders, several changes are being recommended to the cost report. Two categories of cost

report changes are noted: (1) those that differentiate pediatric from adult composite rate costs and (2) those that allow for further differentiation of composite rate costs within a facility's pediatric patient population. The revisions being recommended for immediate consideration by CMS include the addition of select direct patient care labor categories to Worksheet S-1 and further specification of pediatric supplies on Worksheet B/B-1.

Specifically, it is recommended that the following staff categories be added to Worksheet S-1, Lines 21-31 (Renal Dialysis Facility-Number of Employees [FTE]): pediatric dialysis nurses and nurse practitioners by specialty; pediatric social workers, pediatric dietitians; child life specialists; teachers; pediatric dialysis unit coordinators; and bio-technicians and engineers. It is also recommended that additional columns be added to this section of the cost report to differentiate pediatric home dialysis and in-center dialysis. These recommended revisions to Worksheet S-1 can be viewed on slide 169 in the slide deck.

With regard to pediatric supplies and equipment, stakeholders have indicated that there must be clear differentiation of pediatric supplies (which vary greatly in number and size) from those used in adults. They would like to see specific categories of supplies itemized in the cost report. These include: crit lines for blood volume monitoring, dialyzers, catheter kits, fistula needles, saline flushes, monitors for vitals and blood pressure cuffs, and items used to occupy children during their treatment.

These revisions would have the greatest impact on the hospital cost report, which currently does not differentiate pediatric from adult dialysis patients. Approximately two-thirds of pediatric dialysis treatments take place in the hospital or medical center setting.

6.2 Summary of Discussion

Panelists posed numerous questions regarding the suggested cost report revisions. Panelists also invoked residual concerns about collecting data on duration of treatment, as presented in Session 2. With regard to the cost report, panelists had the following reservations:

- Adding the level of granularity being requested to cost reporting would take time, as
 facilities would need to change their internal reporting practices to make sure data are
 available
 - o For example, currently supply costs are not broken down by those that are separately billable versus those that are not (and are composite rate)
 - o It would be difficult, if not impossible, to make this change by 2022
- It was suggested that a different nomenclature be used to designate the type of medical or other biotechnicians involved in direct patient care
- Some panelists felt that it would be difficult, if not impossible, to allocate staff labor time by treatment modality

- It was noted that a substantial proportion of professional staff (e.g., social workers) are contractors and that it would be difficult to allocate their time across modalities
- Some panelists felt that allocating staff costs by FTEs is misleading, as adding a shift is very costly. Panelists suggested using a different metric to measure staff labor costs
- Other panelists commented that it would be difficult to break out depreciation and other costs of capital-related dialysis equipment because most equipment was leased
- There was concern that reporting this level of detail on composite-level costs would be tantamount to "unbundling the bundle"
- There was doubt expressed about the effort it would take to break out pediatric costs in the detail described given that pediatric patients represent a small percentage of total treatments
- There were calls for results of the national cost report audit to be released

Panelists suggested that input was needed from facility accounting and/or billing staff. In particular, it was noted that children's hospital governance often distances pediatric dialysis experts from hospital administrative personnel who are charged with completing the cost report. This is a hindrance to accurate reporting. There was general agreement, however, from the pediatric stakeholders present that more granular detail on pediatric costs would allow for more accurate reporting.

6.3 Key Findings

- More detailed reporting on component costs of the dialysis treatment is needed to be able to map duration of treatment data to the use of resources, including staff time, supplies, etc.
- Panelists were hesitant to endorse more detailed reporting and expressed doubt about providers' ability to break down costs by modality
- There was general agreement about the need for more detailed reporting of pediatric costs

7 SUMMARY OF PANEL RESPONSE

Acumen presented a complex array of new methodologies for refining the ESRD PPS payment model. The purpose of these efforts is to both simplify and improve the statistical validity of the regression model used to estimate cost of care and cost per treatment for dialysis patients. The current model uses two equations and requires patient-level differences in cost to be extrapolated from facility-level cost report data. While the panel generally endorsed the effort to move from a two-equation to a one-equation model, some objected to the use of duration of treatment as the framework around which the model would be built, stating that additional factors other than treatment time are also drivers of increased cost. Panelists are supportive of efforts to refine the use of case-mix adjusters in the new model. They also agreed that the model needed modification to better account for the costs of pediatric dialysis. With regard to the LVPA, panelists appreciated that the new geographically based method was a logical approach to consider but expressed concern that it was conceptually hard to understand. They also were concerned that loss of LVPA status could affect treatment access in certain urban, hard to reach areas. While panelists agreed that changes were needed to improve the cost reports, the level of detail required by the changes Acumen recommended were generally viewed as too burdensome by the panelists. Finally, panelists were appreciative of the report summarizing the first years of 72x utilization and cost data on the AKI-D patient population.