



ACUMEN

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

Date of TEP: December 6, 2018

Date of Report: June 2019

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INTRODUCTION

This report summarizes the technical expert panel (TEP) convened by Acumen, LLC to discuss options for improving data collection on composite rate (CR) items and services provided by the End Stage Renal Disease (ESRD) Prospective Payment System (PPS). CR items and services comprise the essential components of dialysis treatment, including all drugs, laboratory tests and supplies necessary to administer the treatment. The TEP also explored the selection of new risk adjusters for the ESRD PPS payment model. This TEP was convened by Acumen to fulfill its contract with the Centers for Medicare and Medicaid Services (CMS) to identify options for a refined case-mix adjusted payment model.

Medicare coverage for ESRD dialysis treatment began in 1972. Initially, Medicare employed the same fee-for-service (FFS) payment system to pay for ESRD dialysis treatment as was used by the broader Medicare program. After finding that the FFS payment model resulted in rapid escalation in spending, CMS implemented payment reforms. Most notable were the introduction of the fixed composite rate system in 1983 and the ESRD PPS in 2011. The CR includes the costs of capital (dialysis machine use and maintenance), administrative services (legal, record keeping, etc.), direct patient labor, and the drugs, laboratory tests, and supplies essential for providing a dialysis treatment. In 2011, an expanded CR bundle was defined to include drugs, labs, and supplies that were formerly separately billable (FSB) under the 1983 system, including erythropoietin stimulating agents (ESAs) and other medications for anemias and mineral metabolism. The goal of the ESRD PPS is to pay providers based on average treatment costs, with less costly patients subsidizing the costs of higher cost patients.

In order to facilitate reimbursement, FSB items are itemized on Medicare claims, however CR items and services are not. Therefore, it is not possible to determine how use of these items and services vary across patients or across treatments. CR costs can only be estimated, roughly, from annual cost reports, which aggregate costs at the facility level.¹ As a result, two equations are required to calculate the base rate for payment: one at the facility level for CR costs and one at the patient or treatment level for FSB costs. Without data on the variation in the use of these services at the patient or treatment level, it is not possible to make accurate assessments of their true costs for the purpose of case-mix adjustment.

Acumen is conducting research to support improvements to the payment model for the ESRD PPS. The first phase of this process was the convening of a TEP to obtain input from stakeholders, including clinical experts and facility managers, on improving data collection

¹ Medicare Claims Processing Manual. Chapter 8 – Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. (Rev. 4202, 01-18-19). Page 7/143.

practices to better elucidate the use and cost of CR services. This TEP was part of Acumen's broader effort to refine the ESRD payment model to more accurately reflect actual use and cost of dialysis-related services. Acumen presented the TEP with several options for optimizing data collection on CR services. Each option was specifically formulated to minimize reporting burden on the providers. Acumen will use the feedback on these options and input on alternative approaches, as provided by the panelists, to further develop practical approaches for more accurate data collection.

The report begins by outlining the objectives and composition of the TEP panel. It presents the results of data analysis that Acumen conducted in preparation for the panel, including information obtained during a series of pre-TEP interviews with dialysis providers. The report includes summaries of the discussions that followed each presentation, highlighting panelist responses to the options for data collection as presented by Acumen, as well as alternatives offered by the panelists themselves. The highlighted panelist responses and alternatives offered are not meant to represent a consensus view shared by all TEP panelists but rather to consolidate related suggestions made by one or more panelist. Finally, the report concludes by identifying next steps toward improving data collection and refining the payment model.

1 PANEL OVERVIEW

This section presents an overview of the ESRD PPS TEP that focused on options for improving data collection on CR costs and selected risk adjusters for a refined case-mix adjustment model. Section 2.1 summarizes the objectives of the TEP. Section 2.2 describes the structure of the TEP. Section 2.3 describes the materials provided to panelists, and Section 2.4 contains a list of TEP panelists and brief descriptions of their backgrounds.

1.1 Structure

This report summarizes the proceedings of this TEP, held on December 6, 2018, from 9:00 a.m. to 5:30 p.m. at the Acumen Washington D.C. office. The TEP was organized into a series of sessions related to the components of CR costs and presented options for improving the accuracy of reporting those costs.

The TEP included a brief introductory session followed by four topic-driven sessions, each one focusing on the improved collection of cost data for CR items and services covered under the ESRD PPS bundled payment. An additional session identified patient characteristics to be considered for inclusion in a revised case-mix adjustment model. During the 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.

Table 1. TEP Agenda

Session	Topic
1	Introductions and Purpose of the TEP
2	Current Measurement of ESRD PPS Costs
3	Costs Associated with Length of Dialysis Treatment
4	Variation in Costs Associated with Complex Patients
5	Facility-Level Drivers of Cost
6	Additional Patient Attributes Necessary for Developing a Revised ESRD Payment Model
7	Open Discussion

The overarching purpose of this TEP was to identify CR items and services that are potentially appropriate for either itemized data collection on claims or improved reporting on

cost reports. More accurate reporting on the use of CR items and services is needed to better align the case-mix adjustment model for the ESRD PPS with actual variation in treatment costs. Acumen presented the panelists with selected options to accomplish this purpose and solicited responses from the panelists with regard to the feasibility and acceptability of each option. While no formal recommendations were made, bulleted highlights of those discussions are presented at the end of each session. The highlighted points are not meant to represent a consensus view shared by all TEP panelists but rather to consolidate related suggestions made by one or more panelist.

1.2 Materials

Prior to the TEP, Acumen provided panelists with the following materials: the agenda for the day, the presentation slides, a supplemental packet of background materials, 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, above.

1.3 Members

The TEP was comprised of 15 members, representing a cross section of dialysis providers, independent researchers, and representatives from professional associations and industry groups. The TEP also included a patient advocate.

Table 2. TEP Members

Name	Professional Role	Organizational Affiliation
Helen Currier, MA, RN, CNN, CENP	Director, Renal & Pheresis Services	Texas Children's Hospital
Johnie Flotte, RN	Vice President of Clinical Services	US Renal Care
J. Michael Guffey	Treasurer	Dialysis Patient Citizens
John Hartman, MD	CEO	Visonex
Alice Hellebrand, MSN, RN, CNN	Senior Vice President	American Nephrology Nurses Association
. Andrew Howard, MD, FACP	Ad-Hoc Member	Forum of ESRD Networks
Mahesh Krishan, MD, MPH, MBA, FASN	Group Vice President, R&D	DaVita
Chris Lovell, RN, MSN, CNN	Director of Medical Informatics and Systems	DCI
Klemens Meyer, MD	Dialysis Facility Medical Director	Tufts Medical Center
Rebecca J. Schmidt, DO, FACP, FASN	Professor of Medicine, Dialysis Medical Director	West Virginia University School of Medicine
Siddharth Shah, MD, FACP, FASN	Associate Professor of Medicine	UPenn School of Medicine
Elsa Spicochi, RN, MHA	Clinical Informatics Manager	Northwest Kidney Centers
Suzanne Watnick, MD	Chief Medical Officer	Northwest Kidney Centers
Daniel Weiner, MD, MS	Associate Professor of Medicine	DCI, Boston
Julie A. Williams, BSA	President	National Renal Administrators Association
Jay B. Wish, MD	Professor of Clinical Medicine	Indiana University School of Medicine

2 COMPONENTS OF DIALYSIS TREATMENT COSTS AND LIMITATIONS OF CURRENT DATA COLLECTION

The objective of this session was to identify the main components of dialysis treatment costs and current limitations in their measurement. Panelists discussed the following topics:

- Description of the existing ESRD PPS
- Composition of dialysis treatment costs
- Limitations of existing data on CR costs

2.1 Summary of Presentation

Payment is intended to cover all costs directly related to a maintenance dialysis treatment for a patient with ESRD.^{2 3} Total treatment costs can be divided into CR costs and FSB costs. CR costs are those associated with the essential items and services administered during a routine dialysis treatment session. CR items and services, which have been part of the ESRD bundle since 1983, can be categorized into six mutually exclusive cost components: capital, labor, administration, drugs, laboratory tests, and supplies. FSB items include injectable drugs (principally ESAs) and their oral equivalents, laboratory tests, and supplies that were incorporated into the bundle in 2011 when the ESRD PPS was implemented. Individual CR items and services are not itemized on the Medicare 72x claim, whereas FSB items and services are itemized. Therefore, the actual treatment- or patient-level cost of CR items and services has to be extrapolated from the cost report, which aggregates costs at the facility level.

The current case-mix adjustment uses two equations. This is necessary to account for costs that are available at the patient level (principally FSB costs) and those available only at the facility level (CR costs obtained from cost reports). The current payment adjusters are derived using weighted averages of the coefficients from the facility-level and patient-level equations.

Acumen's analysis of 2016 cost report data reveals that CR costs now comprise approximately 90% of total treatment costs, as shown in Table 3 below.⁴ Nevertheless, under current reporting practices, it is impossible to determine with precision CR costs per treatment or how those costs vary across patients (or by patient characteristics). The remaining sessions of

² Outpatient dialysis services payment system. Payment basics. MedPAC. October 2016. The following link will take you to the [MedPAC report](#).

³ Dialysis treatment for patients diagnosed with Acute Kidney Injury (AKI) is included in the ESRD PPS bundled payment, however these represent a different population of patients and payment for items and services provided for their care is subject to different rules and regulations.

⁴ Drugs covered under the Transitional Drug Add-on Payment Adjustment (TDAPA) are not included in this analysis as the TDAPA program was not implemented until January 1, 2018.

this TEP explored options for capturing these component costs so as to improve the precision of the payment model.

Table 3. Average Total CR and FSB Treatment Costs

Cost Category from Cost Reports	Freestanding and Hospital-Based Facilities (5,277)	
	Average Facility Cost per Treatment	Percent of Total Per-Treatment Costs
Total Treatment Cost	\$287.15	100.00%
Total CR Costs	\$255.71	89.05%
Total FSB Costs	\$31.44	10.95%

One potential approach for obtaining treatment-level variation in the use of CR services would be to improve the accuracy of charges, as reported on claims. Acumen assessed 2016 claims data to determine the current variation in charges, as reported for each treatment session, and found that for any given revenue center code (combination of dialysis modality and location), only a small number of distinct charges were reported by any given facility. Approximately 95% of facilities reported four or fewer distinct values for charges for hemodialysis over the course of a year. This indicates that it is difficult or impractical for providers to allocate component costs for each treatment. Therefore, Acumen concluded that charges were not a good proxy for estimating patient- or treatment-level variation in the use and cost of CR services.

2.2 Discussion Questions

- Do the six cost components include all aspects of dialysis treatment costs covered by Medicare?
- Within each component, are there significant costs that are currently missing from cost reports?
- Given the relatively small contribution of drugs, labs, and supplies to CR costs, should any further discussion of CR costs focus on capital, labor and administrative components?
- Why is there such limited variation in reported charges?
 - Would it be useful to focus on improving reporting of these charges instead of collecting new information on cost reports or claims?
 - Why is there such limited reporting of costs for items and services included in the Consolidated Billing List (CBL)?
 - Are there subsets of CR items and services that could be successfully reported on claims?

2.3 Panelist Discussion

Panelist comments were largely focused on two issues: 1) FSB cost estimates and 2) component costs of CR items and services. Initially, panelists expressed surprise at the relatively low estimates of per treatment FSB costs, especially when compared to CR costs. Panelists noted that while the use of ESAs had decreased, prices for these drugs have increased, leading them to believe that these FSB drug costs accounted for a larger share of total cost. The Acumen team acknowledged that because of reliance on cost reports to obtain the cost of CR drugs, the data used might not fully reflect the true costs per treatment. In a post-TEP review of external sources, Acumen found close correspondence in the estimation of dialysis component costs between its own results and those obtained by the National Renal Administrators Association (NRAA) report on the use Medicare Cost Report data.⁵ Both studies used Medicare Cost Report data (FY 2016 for the NRAA studies and CY 2015-2017 for the Acumen study) and similar methodologies. Table 4 presents the results from both studies showing the relative contribution of FSB and CR costs to total average dialysis costs. In both cases, the shortcomings of cost report data are acknowledged, including ambiguity in the cost report instructions. Acumen applied strict inclusion criteria for its analysis, limiting to facilities reporting positive treatment counts monthly during the analytic time period. The data for the total FSB amounts were obtained from cost reports. These data also show that FSB costs have been declining proportional to CR costs since 2011.

Table 4. Total Average Dialysis Costs: Comparison of Two Studies

Cost Category from Cost Reports	Acumen's TEP Analysis	NRAA Report
Total Treatment Cost	\$287.15	\$276.85
Total CR Cost	\$255.71	\$247.06
Total FSB Cost	\$31.44	\$29.79

While panelists largely agreed that *labor, capital and administration* were the components that comprised the majority of CR costs, they noted that patient and administrative services have changed over the years in ways that are not captured by cost reports. For example, patients with complex clinical profiles require the services of a broader array of providers than are currently reflected in the cost report (e.g., child life specialists for pediatric patients), and incident patients making the transition into dialysis treatment and sicker patients require more skilled nursing services (i.e., more highly educated nurses), another source of cost variation not currently captured.⁶ They also noted that dialysis patients are presenting as sicker and with a more complex array of comorbidities than in the past.

⁵ The following page will take you to the [NRAA report](#).

⁶ It should be noted that the base rate currently is adjusted for both incident and pediatric patients.

Panelists noted that there were some component costs missing from the cost reports and recommended that the cost reports be revised to account for these services. CROWNWeb fees and other IT services were mentioned as examples.

In response to the question of why such little variation was seen in charges, as reported on claims, panelists reported that in some circumstances, only a limited number of charges were accepted by claims processors for non-Medicare payers, including payers for Medicare Advantage plans, and that if more items were listed, claims were more likely to be rejected by these payers. Panelists also suggested that itemizing charges separately for each dialysis treatment would present a burden on providers and might result in inconsistent reporting. They also noted that there was no incentive to itemize charges more accurately, as it would not directly affect payments. Panelists agreed, however, that charges, as currently reported, were not an accurate indicator of either labor intensity or the cost of providing services. Panelists repeatedly cautioned that there would likely be poor compliance if more stringent reporting requirements were put in place for allocating charges at the treatment level.

2.4 Key Findings

- Panelists were not previously aware of the decline in the proportion of total costs represented by FSB costs from approximately 40% at the beginning of the PPS in 2011 to its current level of approximately 10%.
- Panelists agreed that capital, labor, and administrative costs make up the majority of CR costs.
- Panelists observed that the level of complexity of dialysis patients has been increasing over time.
- Panelists noted some costs at the margins (e.g., IT costs) that are not reflected in cost reports.
- Panelists were averse to required reporting of individualized charges to reflect treatment-level variation in the items and services provided, unless this reporting was somehow linked to payment.

3 COSTS ASSOCIATED WITH LENGTH OF DIALYSIS TREATMENT

The objective of this session was to discuss the use of time on dialysis as a proxy for treatment costs. Panelists discussed the following topics:

- Use of dialysis session length to estimate certain CR costs
- Review of CROWNWeb time on dialysis data for reliability
- Practical implications of routinely reporting time on dialysis on claims

3.1 Summary of Presentation

The session began with a proposed paradigm in which patient-level differences in CR costs could be attributed to two discrete categories: differences due to dialysis treatment duration (measured in units of time) and differences unrelated to treatment duration. Currently, cost reports can be used to derive cost per unit of time for specific types of patients. If treatment duration was reported uniformly on claims, data from these two sources could be combined to infer differences in CR costs across patient-months that were due to differences in treatment duration. In this paradigm, treatment duration would not be used to directly adjust payment, rather it would be used to apportion CR costs to the individual treatment level for use in case-mix adjustment. The remainder of this session focused on options for capturing data on treatment duration.

Acumen provided examples of ways that extended treatment duration could affect cost components. These included increased utility costs, accelerated depreciation on equipment, and potentially lower counts of daily patients could increase per-treatment capital costs. Additional labor hours for patient care could increase per-treatment labor costs, and increased use of dialysate and water treatment supplies or equipment could increase per-treatment supply costs.

Acumen then presented as an example duration of dialysis session data already collected in CROWNWeb. The duration of a single treatment session is reported monthly into CROWNWeb for patients receiving in-facility hemodialysis (HD). This corresponds to the treatment session during which laboratory specimens are taken to measure a patient's blood urea nitrogen (BUN). Analysis of CROWNWeb data demonstrated that most facilities report clinically reasonable BUN laboratory test session HD time. Substantial across- and within-facility variation was observed in this treatment duration variable, especially for patients who would be expected to have extended dialysis treatment duration, including those with high BMI or BSA.

Acumen then demonstrated how time on dialysis data can be used to estimate patient- or treatment-level variation in the cost of a dialysis treatment. An imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb and facility cost-

per-minute data from cost reports to infer differences in CR costs across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating that there is significant within facility variation in dialysis treatment time. Significant variation in average imputed cost per HD sessions also was observed, with an across-facility interquartile range of \$62.62. Overall, it was found that CR costs increased with longer treatment times, and this pattern was consistent for the individual CR components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, with the exception of CR drugs.⁷

Acumen proposed two approaches to collect treatment duration data: 1) use the existing BUN laboratory test session time on dialysis in CROWNWeb, or 2) have facilities report treatment duration on Medicare claims. For the latter, treatment duration data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each dialysis treatment or by updating the definition of the existing revenue center code for dialysis treatments so that the units equal some interval of treatment time instead of the number of treatments. Facilities already report (to CMS) a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that facilities are able to collect treatment duration. Moreover, many facilities' EHR systems automatically collect this information for every dialysis treatment, minimizing any additional burden of reporting this metric on claims. Facilities will likely incur some upfront costs to update their information technology to allow for transfer of duration of treatment session data from the EHR to their claims processing infrastructure. Once this change is complete, however, no additional burden is expected.

3.2 Discussion Questions

Panelists were asked to consider the following questions:

- Which of the six CR cost components are most likely to vary with treatment duration?
- Should new information for these cost components be collected on cost reports, for use in better inferring the CR costs associated with treatment duration?
- What are the advantages and disadvantages of obtaining treatment duration information from BUN time on dialysis through CROWNWeb, versus collecting treatment duration through new fields on claims?
- What challenges would be encountered in reporting treatment duration on claims, using one of the options proposed?

⁷ Acumen, LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation. Slide #42. December 2018.

- Are there alternative proxies for resource utilization that can be reported at the patient/treatment level?

3.3 Summary of Discussion

Panelists provided feedback on the preferred method for collecting treatment duration data and articulated additional considerations for the methodologies proposed.

Many panelists reported that their facilities already collected duration of treatment data and agreed it would be feasible to report this metric on claims. This may be more difficult for smaller facilities that do not have EHR systems in place. Panelists uniformly agreed that CROWNWeb was not a reliable source for this metric. They noted a number of limitations inherent to CROWNWeb's data entry protocols and recommended reporting this metric directly on claims. They noted that CROWNWeb is designed as a quality monitoring system and restrained by business rules, which can delay or obstruct the timely submission of patient data. They reported that users of CROWNWeb frequently experience delays in access to the database after a change in facility ownership. They also noted that some patients, including those slated for kidney transplantation are sometimes removed from the CROWNWeb database. Panelists also noted that some facilities may have issues collecting these data, particularly smaller facilities without an EHR system.

Panelists suggested that if duration of treatment time was to be reported on the claim, that the unit of measurement should be actual minutes used and not 15-minute increments of time, as proposed in one example by Acumen. Panelists noted that actual run-times are sometimes different from the prescribed dialysis treatment. Since facilities are staffed based on prescribed treatment time, panelists felt this factor should be taken into account, especially when it is different from actual runtime. Panelists were concerned, however, that both prescribed and actual treatment time could be "gamed." They wanted to avoid dis-incentivizing longer treatments when they are medically necessary, and agreed that multiple data sources need to be used to validate data and prevent gaming.

Panelists pointed out possible confounders that could affect the distribution of time on dialysis and have an impact on costs. There was concern that nocturnal treatments could skew the distribution as these treatments have long dialysis treatment times and may not utilize staff resources as intensively as daytime treatments. Acumen investigated this concern in a post-TEP analysis and found that nocturnal dialysis represented a small fraction of total dialysis sessions. When the 0.65% of dialysis treatments that lasted longer than six hours were excluded from the analysis, the pattern of distribution of costs presented during Session 3 of the TEP remained the same. Factors associated with geographic location may also affect costs, such as the wage index used. Higher BMI and BSA are associated with longer treatment times, and average patient size

can also vary by geographic area. Vascular access type was another potential confounder, as it may affect both treatment time and costs independently.

Panelists did not wholly endorse the notion that variation in duration of dialysis treatment provides an adequate proxy for patient-level variation in treatment costs. Several panelists challenged the premise that, independent of other risk factors, dialyzing patients for a longer duration is more expensive than dialyzing for a shorter period. Conceding, however, to the logic of a direct association between duration and cost, panelists acknowledged that longer treatment translates to fewer patients being dialyzed during the course of any staff shift, thereby adding to per-session costs. Panelists maintained that the costs incurred by the most expensive patients may not be wholly captured by runtime, since intensity of care is not reflected in duration. Panelists also noted that while larger, healthier patients require a longer runtime, they do not necessarily use more resources (and similarly, that dialysis patients with the smallest body mass required both longer (and slower) dialysis and more frequent treatments).

Panelists were concerned that the distribution of component costs by treatment times may not be reflective of how costs are actually incurred at their facilities. Increased treatment time might result in higher labor costs if more highly skilled labor or extra shifts were required, but facilities could also avoid an increase in total labor costs across treatments if an increased efficiency in staffing occurs in response. Acumen noted that this example could still result in differences in the allocation of staff time across treatments in the same facility, even in the absence of an increase in total staff time, thus still resulting in an increase in labor costs for one treatment relative to another treatment. One panelist noted that time recorded on dialysis machines might be misleading in cases where patients have to periodically come off the dialysis machine to address other health issues. Therefore, the duration of treatment metric would need to be carefully defined. One panelist pointed out that variation in time could be based on systematic decisions by a facility to increase dialysis time, and not based on patient need. Variation in costs related to factors other than treatment duration was discussed in detail during Session 4.

Finally, one panelist questioned whether the additional administrative burden of reporting treatment duration would be worth the incremental improvement in the estimation of costs. However, this additional burden would be minimal with minor revisions to claims form. If the current line for a dialysis treatment is modified to indicate units of time, then there would be no net increase in reporting.

3.4 Key Findings

- Acumen proposed a method for apportioning CR costs to the treatment level using time on dialysis. This method does not use time on dialysis as a case-mix adjuster in the current or any future refined risk adjusted model.

- To record time on dialysis, panelists preferred that the data be collected on Medicare claims. They did not support using existing CROWNWeb data on treatment duration, as there were too many questions about its completeness and timeliness.
- Panelists concurred that if duration of dialysis treatment time is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments.
- Panelists cautioned that reporting time on dialysis on the claims would place additional burden on facilities.
- For facilities with EHRs, the burden associated with the collection of dialysis treatment time is expected to be small and temporary because the information is already collected. Collecting time on dialysis could be difficult to accomplish for facilities that do not use EHRs.
- Some panelists maintained that certain factors related to patient complexity – such as comorbidities and mental health status – that are associated with treatment costs are unrelated to treatment duration.
- In post-TEP analysis, Acumen found that excluding data on nocturnal dialysis sessions had minimal impact on treatment costs.
- Further analyses of the association between time on dialysis and cost will take into account geographic factors related to cost variation.

4 VARIATION IN COSTS ASSOCIATED WITH COMPLEX PATIENTS

The objective of this session was to describe and discuss data collection options for specific types of CR costs that vary independently from treatment duration. Panelists discussed the following topics:

- Information and insights from pre-TEP interviews on CR cost variation due to patient factors other than treatment duration
- Methodological approaches for collecting usable data on these CR costs
- Existing cost data and proposals for improved cost data collection

4.1 Summary of Presentation

Acumen began by summarizing information obtained from pre-TEP interviews with providers on the patient-level factors that drive CR cost variation. Acumen focused on costs that vary independently of treatment duration. Drivers of cost identified from the interviews include:

- Maintenance of isolation rooms and use of dedicated nurses to attend patients with active hepatitis B virus infection
- Treatment and care for incident dialysis patients (first 120 days)
- Treatment and care for patients with central venous catheter
- Pre- and post-dialysis session care for non-ambulatory patients
- Treatment and care for pediatric patients
- Treatment of patients exhibiting behavioral problems related to mental illness/drug dependency
- Treatment and care for home dialysis patients

Each of the above costs entails more intensive use of direct patient care labor. Some of these costs, such as lifts for non-ambulatory patients or isolation rooms, also involve capital expenses.

Acumen described two methodological approaches for collecting informative data on these CR costs. The first option would involve reporting costs associated with CR items and services on claim lines. However, a considerable challenge with this approach would be the difficulty of reporting labor time and related costs directly on claims. For this reason, this first option was not explored further. The second option would involve apportioning the costs associated with CR items and services across all patients of a certain type. The challenge with this approach would be that patients would have to be grouped into a set of mutually exclusive and exhaustive groups to facilitate meaningful cost apportionment. The remainder of the presentation explored this second option.

To facilitate discussion among the panelists, Acumen proposed a set of potential patient groupings and presented empirical results evaluating whether existing cost report data corroborate interview findings. The results of these empirical investigations are presented below.

- **Pediatric population (0.1%):** Cost report data indicate that a higher percentage of pediatric patients is associated with higher total and CR cost per treatment.
- **Adult incident population, i.e. first 120 days of chronic renal dialysis (5.0%):** Cost report data show an increased cost per treatment for incident patients across the distribution of provider-beneficiary months.
- **Adult maintenance home training (0.1%) and non-training population (10.4%):** Cost report data are insufficient to determine whether home HD is more costly than in-center. Assuming that facilities accurately allocate costs to home vs in-center in cost reporting, in-center HD appears more costly than home HD. If this assumption is relaxed, it is not clear if in-center HD or home HD is more costly.
- **Adult maintenance in-center dialysis treatment for patients with hepatitis B virus infection (0.9%):** Cost report data indicate that facilities that maintain isolation rooms or isolation areas have higher costs on average than those that do not. Isolation is required for treating patients with hepatitis B positivity, and these areas cannot be used for other purposes until all **patients with active hepatitis B infection** are discharged from the facility.

For the largest patient group, **adult, maintenance, in-center patients, who are not positive for hepatitis B virus (83.4%)**, Acumen considered three additional methods of disaggregation for improving the specificity of cost reporting.

- Stratification by distribution of current ESRD case-mix scores
- Stratification by distribution of beneficiaries with at least one select risk factor: catheter, substance abuse, or paraplegia/ quadriplegia
- Stratification by distribution of ESRD Hierarchical Condition Category (HCC) composite scores

Acumen examined the correlation between each of these risk factors and cost and found that each distribution had a positive association with cost per treatment.

4.2 Discussion Questions

Following the presentation on variation in costs associated with complex patients, the panelists were asked to consider the following questions:

- Is labor the dominant source of variation in treatment-level CR costs?
- Are there other dimensions of treatment for which CR costs vary independent of treatment duration?
- Are there discrete, high-cost CR items and services that vary at the patient level that could be feasibly itemized on claims?

- How, if at all, should the set of mutually exclusive, exhaustive patient groups be expanded/revised to incorporate patients with common patterns of resource use?
 - Specifically the largest group: maintenance/adult/in-center patients who are not positive for hepatitis B virus
- Are there barriers to implementing the proposed reporting solutions on cost reports?
- Are pediatric and home dialysis costs currently apportioned in a way that represents the true cost of treatment for every cost component?

4.3 Summary of Discussion

Panelists agreed that there is variation in the costs associated with treating complex patients that is difficult to capture in the current cost report. The panel had some concerns, however, with the proposed option of allocating labor time for specific patient groups, such as home dialysis patients. Finally, panelists offered suggestions for alternative approaches to measuring resource use associated with complex patients. Panelists emphasized throughout the TEP that the severity of illness of dialysis patients has been increasing over time. There is also an increased focus on the use of home dialysis modalities. Given the convergence of these two issues, it becomes increasingly important that facilities have a means to carefully screen and monitor those patients being encouraged to dialyze at home.

Panelists indicated that providers would face a considerable burden were they required to further itemize CR costs, and would find it especially difficult to capture costs associated with complex patients. The group noted that it is particularly challenging to assign costs or allocate FTEs to specific modalities or units, since staff are often shared across these divisions. Patients shifting between dialysis modalities, such as home versus in-center, also confound a simple solution for itemizing CR costs. This problem is exacerbated by the complex structure of the current cost report, and the lack of clear instructions, resulting in inconsistent reporting in various cost centers.

The panelists identified several patient types in addition to those presented by Acumen that they associated with increased resource use. These patient groups included patients with:

- Hemodynamic instability
- Dual eligibility for Medicare and Medicaid
- Depression
- Poor functional status
- No primary caregiver

- Institutionalized status / incarcerated or residence in a skilled nursing facility⁸

One panelist maintained that some of these complexities are subjective assessments that would be difficult to categorize on claims or cost reports. Other panelists contended that there is no standard approach, staffing mix, or set of extra services that could be applied to patients with particular sets of comorbidities. One reason for this is that treatment patterns and their associated costs often vary with state-level requirements.

Some members of the panel expressed skepticism that facilities would be able to allocate costs by any defined grouping of patients. The fundamental challenge being that dialysis facilities do not currently track staff time dedicated to each patient. Panelists agreed, however that the driving source of cost variation across complex patient types is labor costs. For example, complex patients often require more interventions, including calls to the patient, doctor, and hospital. They also require more staff time spent reconciling medications, more counseling sessions with the social worker and dietician, and more rescheduled treatments. Furthermore, staffing mix and total labor costs do not always change when overall complexity of the patient caseload changes. Staffing models are generally inflexible, thereby the cost of labor might remain the same regardless of case mix. Finally, panelists emphasized that resource-intensive patients comprise a small percentage of their total case load and that it would present undue burden to attribute unique costs for each patient type.

Some panelists proposed alternative approaches for quantifying resource use associated with complex patients. One panelist proposed drawing on lessons from the physician outpatient payment system and classifying patients' resource use by intensity of service provided or how much time was spent with the patient. Facilities could then assign costs associated with treating each patient level. Another panelist proposed recording total time patients spent in the facility and comparing this to the time spent on the dialysis machine. A large discrepancy between the total facility time and total session time would indicate additional resource use in the set-up and cleanup for the patient. Finally, one panelist proposed using technological solutions to track the amount of time staff spent dedicated to a given patient, either in person or on the phone.

4.4 Key Findings

- Panelists expressed support for improving consistency in cost reporting across facilities. They recommended clarifying cost report instructions to ensure comparable reporting across facilities.
- Panelists agreed that labor is the major source of patient-level cost variation, but expressed concern that allocating labor costs to the patient level or even the patient type would pose significant challenges.

⁸ Panelists noted that they were increasingly seeing patients coming from residences where bedbug infestation was endemic, and this growing problem taxed facility resources and increased costs.

- Panelists noted that certain high-cost items and services used to treat complex patients, such as isolation rooms or lifts, could be easily itemized on claims and reported in cost reports.
- Panelists proposed alternative approaches for quantifying resource use associated with complex patients, such as classifying resource use by intensity of care provided or tracking staff time across patients.

5 FACILITY-LEVEL DRIVERS OF COST

The objective of this session was to discuss improvements to data collection for costs common to all patients within a dialysis facility. Panelists discussed the following topics:

- Potential drivers of facility-level cost variation
- Differences in CR cost per treatment by facility characteristics
- Revisions to cost reports for improved data collection

5.1 Summary of Presentation

The previous two TEP sessions focused on costs that differ across patients within a given facility. This session opened discussion of costs that vary across facilities, when patient-level factors are held constant. This type of cost variation occurs primarily due to differences in facility size, treatment volume and frequency of missed treatments, geography, ownership structure, and other factors related to the type of care offered. The motivation for this session was to solicit panelist input on which facility-level factors they viewed as relevant to variation in treatment cost.

Chief among these factors is the relationship between treatment volume and cost. Currently, the ESRD PPS adjusts the base rate by 23.9% through the low-volume payment adjustment (LVPA) to account for the increased costs incurred by low-volume facilities. Cost report data clearly indicate a negative relationship between cost per treatment and treatment volume with lower volume facilities having higher FSB costs, as well as higher CR capital, administrative, drug, and lab costs. CMS also provides a 0.8% payment adjustment for facilities located in rural areas, although empirical evidence of a relationship between rural setting and cost is inconclusive. Acumen's analysis of 2016 cost report data reveals that non-rural facilities report slightly higher total costs, as well as marginally higher FSB drug and CR capital, drugs, lab, and supplies costs, and rural facilities report higher CR administrative and FSB drug costs.⁹ Some stakeholders have suggested there is redundancy between the LVPA and the rural adjustment. Others have maintained that the adjustments address separate issues and both should be retained.

A facility's realized treatment volume relative to its capacity can also affect cost. Underutilization could result from a high proportion of missed treatments, which are associated with higher cost per provided treatment. Acumen estimated a facility-level measure of utilization

⁹ Acumen, LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation. Slide #87. December 2018.

relative to capacity using the relationship between the number of dialysis sessions furnished and the number of outpatient stations and found that the lowest quintile of this utilization capacity metric is correlated with higher cost per treatment, particularly in urban, low-volume facilities.

Another factor associated with facility cost is geography, which results in variation in input prices and wages. The labor-related share of the ESRD PPS base rate adjusts for wage-level differences due to geographic location. Analysis of cost report data indicates that a higher wage index is directly correlated with higher treatment cost, motivating the need to have an accurate wage index. Stakeholders have expressed concern that the existing wage index inaccurately estimates facility wages, as it does not account for dialysis facilities' unique occupational mix. A hospital wage index is used, rather than one that better reflects the wages and occupational mix at outpatient care centers, which comprise most of the freestanding facilities.

In the cost report data, hospital-based facilities have the highest FSB and CR costs in all examined categories, including capital, labs, labor, and supplies. Regional chains report the second-highest costs after hospital-based facilities, although their costs are more similar to costs reported by independent facilities and Large Dialysis Organizations (LDOs).

The presentation concluded with additional factors associated with facility-level cost variation, including whether the facility administers a pediatric or home dialysis program. Both of which are associated with increased costs due to the unique needs and supplies associated with treating these patients.

5.2 Discussion Questions

After Acumen outlined these potential facility-level drivers of cost, panelists were asked to consider the following questions:

- Do existing CR cost data, as obtained from the cost report, reflect the expected patterns?
 - If not, what additional data should be collected to better capture CR costs?
- Do the facility adjusters used in the existing model adequately capture drivers of facility costs?
 - If not, how could these costs be adequately reported?
- What are costs incurred by pediatric dialysis units that do not vary at the patient-level?
- What types of costs do facilities providing home dialysis services incur that do not vary at the patient-level?
- How do variations in drivers of facility costs affect CR costs at the facility level?
- To what extent are these CR costs outside the facility's control?

- What are the challenges or barriers to reporting missed treatments on claims and/or cost reports?

5.3 Summary of Discussion

The panelists began by affirming that there are differences in cost at the facility level associated with the characteristics presented in this session. Then, the group discussed potential facility-level sources of variation in average treatment cost. Panelists emphasized economies of scale as a main driver of variation in facilities' average treatment cost and added that ownership type and treatment volume relative to capacity are associated with cost as well. Finally, those representing rural facilities maintained that they incur increased costs compared to non-rural facilities even after accounting for treatment volume, particularly for drugs and supplies. They also noted increased costs related to staff travel to remote facilities. Because of this, panelists did not consider the LVPA and rural adjuster redundant.

Panelists stated that LDOs accrue significant cost advantages through economies of scale, noting that these facilities have significant bargaining power with suppliers and pharmaceutical companies, resulting in lower average supply and drug costs. These economies of scale also apply to the costs of implementing employee benefit programs.

Panelists then affirmed that a portion of the cost differences between hospital-based and freestanding facilities observed in the cost report data stem from differences in organizational structure and operations across facility types rather than differences inherent to the two types of cost reports. One webinar observer commented that hospital-based facility costs are higher due to a higher proportion of Registered Nurses (RNs) on staff, compared to freestanding facilities, which employ a higher proportion of Licensed Vocational Nurses (LVNs) and medical technicians.

The panelists concurred that use of electronic health records (EHR) can impact cost. Panelists noted that lack of interoperability between electronic health records at freestanding dialysis facilities and hospitals can drive up average treatment cost at the facility level. Having to acquire patient records from other facilities, without the advantage of shared electronic records, requires staff time and effort, the costs of which are not broken out in cost reports.

The panelists indicated that treatment volume relative to capacity is associated with variation in facility-level costs and affirmed that decreases in treatment volume are often due to missed treatments. Panelists strongly agreed that missed treatments drive up facility costs, and one panelist stressed the importance of differentiating between planned and unplanned missed treatments. Unplanned missed treatments are more likely to be associated with complex patients who may have behavioral and mental health issues or lack sufficient social support. These unplanned missed treatments are costly to facilities because supplies and labor time are expended

setting up stations and facilities may not be able to dismiss staff on short notice. Facilities are better able to accommodate scheduling changes for planned missed treatments, such as when a patient is out of town, and mitigate increases in cost. However, both planned and unplanned missed treatments result in facility-level costs (e.g. capital costs) being distributed across fewer treatments. Another panelist noted that facilities cannot fill a missing patient's chair with a new patient for 30 days following the first missed treatment and not until the patient is discharged in CROWNWeb. This can result in up to one month of increased average treatment costs across the facility's remaining treatments. The group added that the cost variation associated with treatment volume relative to capacity is especially relevant for pediatric facilities. One panelist noted that pediatric facilities have an unstable volume of patients, and consequently pediatric units are frequently operating below treatment capacity.

Finally, panelists noted that the differences in facility-level costs between rural and urban facilities are significant and emphasized that the LVPA and rural adjuster are not redundant. For one, independent rural facilities pay higher rates for supplies and pharmaceuticals due to lower bargaining power and higher costs for suppliers to ship to isolated areas. Other factors that were thought to contribute to higher facility costs include nursing shortages, which affect specific geographic regions, and compensation for affiliated nurses, nutritionists, and physicians who must travel long distances to rural facilities or patients' homes. Home dialysis patients may not have proper water filtration to use in the dialysis machines, resulting in the added cost of providing treated water for in-home programs. Natural disasters were said to have a higher impact on rural areas, which may not have the resources to repair damaged buildings – either facilities or home dialysis beneficiaries' homes – or recover quickly from power outages.

5.4 Key Findings

- The panelists affirmed that there are differences in cost at the facility level associated with the characteristics presented in this session
- Larger facilities have significant cost advantages over smaller facilities due to economies of scale, including lower prices on pharmaceuticals and supplies
- Ownership type and EHR practices are also associated with variation in facility-level cost
- The Panelists emphasized that treatment volume relative to capacity has a significant financial impact on dialysis facilities; however, these costs currently are not reflected in cost reports
 - Panelists suggested that missed treatments be recorded on the cost report (enabling a capacity utilization measure to be computed)
 - Panelists also suggested distinguishing between more costly missed treatments and less costly planned absences, as the latter can be adjusted so that the facility chair is filled

- The panelists indicated that rural facilities have costs not incurred by non-rural facilities, even among facilities with similar treatment volume, and do not believe the LVPA and rural adjuster to be redundant

6 ADDITIONAL PATIENT ATTRIBUTES NECESSARY FOR DEVELOPING A REVISED ESRD PAYMENT MODEL

During this session, panelists focused on identifying additional patient characteristics to consider adding as explanatory or independent variables for a revised case-mix adjustment model. The Panelists discussed the following topics:

- Differentiating patient characteristics to add to the case-mix model from the patient- and facility-level costs that were discussed during TEP Sessions 3-5
- Identifying patient characteristics that are associated with higher treatment costs
- Identifying existing data sources for obtaining patient characteristics and assessing the need for new data collection

6.1 Summary of Presentation

While the previous sessions focused on improving the reporting of patient- and facility-level treatment costs for refining the left-hand side of the case-mix adjustment model equation, the goal of this session was to identify patient-level variables that could be assessed for inclusion as payment adjusters in the right-hand side of a revised case-mix adjustment model. Acumen clarified that future analyses would be required to determine the extent to which the patient-level variables identified during this session are associated with variation in treatment cost.

When discussing possible patient-level variables, Acumen emphasized that proposed patient characteristics must be (1) outside the influence of the facility's care, (2) necessary adjusters to ensure equitable access to care, and (3) able to be incorporated into a case-mix adjustment model. Acumen also suggested that potential increased reporting burden would be minimized by focusing on variables that can be identified from existing data sources, such as Medicare 72x claims, the Medicare Enrollment Database (EDB), and CROWNWeb.

In order to develop a comprehensive list of patient characteristics for potential inclusion in a revised case-mix model, Acumen acquired input from provider interviews, review of stakeholder comments and CMS responses during rulemaking, and Acumen's internal nephrology team. The patient characteristics identified were classified into four categories as detailed below in Table 5: demographic factors, environmental factors, comorbidities, and other clinical characteristics.

Table 5. Example Patient Characteristics in Existing Medicare Data¹⁰

Demographic Factors	
Age Race/Ethnicity	Sex
Environmental Factors	
Institutionalized Status	Socioeconomic Status
Comorbidities	
Chronic Comorbidities	Acute Comorbidities
Other Clinical Factors	
Body Mass Index (BMI) Body Surface Area (BSA) Dialysis Onset Vascular access type	Ambulatory Status Morbid Obesity Substance Abuse

A number of these variables are available from existing data sources. Sex is reported in the EDB, and a beneficiary’s institutionalized status can be identified using Minimum Data Set (MDS) assessments.¹¹ Additionally, data on dual eligibility, which can proxy for a dialysis patient’s socioeconomic status, are available in the Common Medicare Environment. BMI and catheterization can be obtained from the 72x claim access type modifier. The current ESRD PPS includes four comorbidity adjustments – two chronic and two acute – and along with other comorbidities, can be identified from diagnoses in Inpatient, Outpatient, and Carrier claims in a beneficiary’s clinical history. Acumen suggested the ESRD HCC model as a mechanism for providing a convenient grouping of these diagnoses to capture patient characteristics of interest, including cancer, HIV, dementia, substance abuse, and hepatitis B virus positivity.

6.2 Discussion Questions

- Are the patient characteristics identified above likely to affect total treatment costs?
 - Can comorbidities for ESRD beneficiaries be adequately identified from other types of claims?
 - Are the HCCs useful as indicators of these comorbidities?
 - What parameters should be used to investigate variation in treatment costs by specified patient characteristics when using data sources other than 72x claims?
 - Is new data collection necessary to capture data on these characteristics?

¹⁰ Bolded characteristics are used as payment adjusters in the current ESRD PPS.

¹¹ The term “sex” is used here to indicate biological differences between males and females. The term “gender”, which was used in the 2011 ESRD PPS Final Rule, is now more commonly used to denote the role of a male or a female in society.

- Are there patient characteristics not discussed here that should be included in exploratory analysis?
 - Can these characteristics be captured through existing data?
 - If not, what are potential sources for those data?

6.3 Summary of Discussion

The panelists supported efforts to improve reporting so that payments more accurately account for variation in cost across patients. They noted that in cases where a facility has a disproportionate share of high-resource beneficiaries, inadequate adjustment for patient-level variation in cost could result in the facility being systematically underpaid, consequently inhibiting access to care. The panelists agreed that the patient characteristics presented in Table 5 would affect total treatment costs. Panelists suggested that a number of other patient-level factors also be considered for inclusion in a refined case-mix adjustment model. These include:

- Comorbidities and other clinical factors
 - Type 1 diabetes
 - Hemodynamic instability
 - Depression
 - Isolation status as a proxy for active hepatitis B infection
 - Organ failure patients who are left ventricular assist device (LVAD) dependent or other circulatory support dependent or ventilator dependent or who have a tracheostomy
 - Previous failed transplant
 - Previous heart surgery (especially the first 30 days post-surgery)
 - More frequent dialysis sessions of shorter duration
 - Volume overload
 - Increased number of hospitalizations
 - Evidence of prior nephrology care
 - Patient without a primary care provider
 - Existence of care plan
- Other patient-level characteristics
 - Bedbug infestation at beneficiary's place of residence
 - Educational status
 - Non-English speaking status
 - Dual eligibility status

Following the identification of additional patient characteristics to consider for the case-mix model, panelists commented broadly on the quality of existing data sources and on providers' ability to report more detail on claims. Panelists questioned the use of cost report data for analytic purposes. They noted that cost reporting practices can vary considerably across facilities and that certain costs (e.g., direct patient care labor) cannot be easily apportioned to individual patients or patient groups. The group also suggested that the reporting of any additional patient-level characteristics be restricted to those that are familiar to facility staff and could easily be identified on the claim, such as whether a patient was treated in an isolation unit.

Panelists stressed that the benefits accrued from a more refined ESRD PPS case-mix model should be weighed against any additional provider burden that might result from changes to claims and cost reporting.

During the final discussion, the panelists noted that the severity of illness of dialysis patients has been increasing over time and that many facilities provide additional non-ESRD-related services to their patients, including care management and primary care. The panelists expressed interest in innovative models that could leverage dialysis facilities' frequent access to patients to better coordinate care across settings. Panelists specifically cited the ESRD Seamless Care Organizations (ESCOs) as an example of programs that reward dialysis facilities for coordinating care for ESRD beneficiaries.

6.4 Key Findings

- The panelists agreed that the patient characteristics presented by Acumen (see Table 5) are associated with variation in treatment cost.
- The panelists were hesitant to use cost report data to inform patient-level risk adjusters.
- The panelists emphasized that socioeconomic status and environmental factors are significant drivers of treatment cost.
- The panelists noted that any benefits from the case-mix adjustment model refinements would need to be weighed against any additional provider burden from the changes to claims and cost reporting.

7 NEXT STEPS

CMS is committed to refining the precision of the cost estimates that are used to construct the case mix model for the ESRD PPS. This TEP was convened as a first step in developing more effective data collection procedures for this purpose. During the TEP, ESRD PPS stakeholders were presented with several methods for improving the reporting of composite rate (CR) costs and asked to provide their feedback and to offer additional suggestions. The CR comprises the basic dialysis treatment received by all ESRD PPS beneficiaries. In order to more precisely estimate the average cost of a dialysis treatment, it is critical to know the variation in treatment level costs for each component of the CR. Acumen also invited the TEP to identify potential new risk adjusters for incorporation into a new model. This report is being issued to coincide with the release of the CY 2020 ESRD PPS NPRM in summer 2019.

CMS is seeking input on the topics covered during the TEP and material summarized in this report from the broader stakeholder community. The input sought could include comments on or elaborations of the options presented and discussed during the TEP, described above, as well as novel approaches for improving the reporting of patient-level and facility-level costs that are not described herein.

In particular, through the CY 2020 NPRM, CMS invites further comment on 1) incentivizing the itemization of CR drugs, labs and supplies (via their inclusion in the outlier eligible services list), and 2) reporting the length of each dialysis session directly on the claim. Comments are also welcomed pertaining to particular patient characteristics which contribute significantly to the cost of dialysis care. Suggestions for improving the quality of facility-level data as reflected in the cost report are similarly invited.

Stakeholder comments will aid CMS in decision making about potential changes to reporting and will influence decisions about topics of discussion in potential future ESRD PPS TEPs. CMS has not endorsed any method or option at this time.