End Stage Renal Disease Prospective Payment System

Technical Expert Panel

Summary Report

Date of TEP: December 5, 2019
Date of Report: May 2020

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INTRODUCTION

This report summarizes the second Technical Expert Panel (TEP) convened by Acumen, LLC, in December 2019, to discuss refinements to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS). The first TEP explored the components of the existing ESRD PPS, identified limitations of the current model and presented alternative approaches with the goal of achieving a more refined case-mix adjusted payment system. A summary of the first TEP can be found here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf. The second TEP elaborated on this theme, focusing on alternative approaches to measuring the cost of a dialysis session, to better reflect treatment-level variations in cost. New methodologies to strengthen other aspects of the payment system were proposed and discussed as well.

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. Stakeholders have consistently requested a single equation model constructed at the patient level to reduce the complexity of the current model and to better align payment with costs. Several options for collecting patient-level data were presented to the panelists at the first TEP to consider, each of which would result in more accurate cost data to improve the alignment of payment and treatment cost variation. Input from the first TEP and from subsequent Stakeholders' comments informed the options presented during the second TEP. Results of Acumen's development of two of these options were featured as the leading topic for this TEP.

This report begins with an overview of the 2019 TEP, including its structure, objectives, materials distributed to the panelists, and members. Each session of the TEP followed a uniform format, which is reflected in this report: 1) the topic was introduced and its relevance to the current ESRD PPS was described; 2) previously received stakeholder concerns about the topic were summarized; 3) alternative methodological approaches that address concerns were presented; 4) feedback was obtained from TEP members; and 5) key findings from the session were identified and summarized. Each session afforded panelists the opportunity to ask questions and engage in discussion about the session topics and these discussions are summarized at the end of each section of the report. The report concludes with the next steps for investigating potential refinements to the ESRD PPS.

During the first topical session, Acumen presented analyses of two alternative approaches to measuring variation in the cost of a dialysis session for use in a one-equation model for case-mix adjustment: 1) more specific reporting of charges and 2) reporting of the duration in time of each dialysis treatment. Each would require a change in claims reporting and either one would suffice to provide sufficient treatment-level data for a one-equation model.

Subsequent sessions covered the following topics:

- A new approach for constructing a dialysis facility wage index that is more reflective of prevailing wages in similar facilities and geographic areas;
- A novel method for determining facility eligibility for the low-volume payment adjustment;
- Transition of drugs from the Transitional Drug Add-on Payment Adjustment (TDAPA) status into the ESRD PPS bundled payment;
- An alternative approach to calculating the outlier adjustment to meet the 1% target;
- Criteria for establishing eligibility for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies; and
- Capturing the costs of home dialysis treatment.

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 2019 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 on December 5, 2019, from 8:15 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 composite rate (CR) costs and presented options for improving the accuracy of reporting those costs.

The TEP included a brief introductory session followed by seven topic-driven sessions, each one focusing on a different component of the ESRD PPS. 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.

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.

Table 1. TEP Agenda

Session	Topic
1	Introductions and Goals for this TEP
2	Measurement of Costs for Determining Case-Mix Adjustment
3	Wage Index
4	Low Volume Payment Adjustment and Rural Adjustment
5	Transitional Drug Add-on Payment Adjustment
6	Outlier Determination
7	Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies
8	Home Dialysis
9	Open Discussion

1.3 Members

The TEP comprised 15 members, representing dialysis providers, independent researchers, patient advocates, and representatives from professional associations and industry groups.

Table 2. TEP Members

Name	Professional Role	Organizational Affiliation
Eileen Brewer, MD	Medical Director, Renal Transplant Program	Texas Children's Hospital
Mark Desmarais	Partner	The Moran Company
Johnie Flotte, RN	Vice President of Clinical Services	US Renal Care
Derek Forfang	Kidney Patient Advocate and Public Policy Committee Chair	National Kidney Foundation
J. Michael Guffey	Treasurer	Dialysis Patient Citizens
John Hartman, MD	CEO	Visonex
Alice Hellebrand, MSN, RN, CNN	Chief Nursing Officer	Dialyze Direct
Andrew Howard, MD, FACP	Nephrologist	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.
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 MEASUREMENT OF COSTS FOR DETERMINING CASE-MIX ADJUSTMENT

This session examined alternative approaches to measuring variation in the cost of a dialysis session, for use in a "one-equation" model for ESRD PPS case-mix adjustment. The session included the following topics:

- Description of the current "two-equation" model used for case-mix adjustment
- Summary of stakeholder feedback on the current model
- Presentation of two alternative approaches for collecting data on dialysis treatment costs to facilitate the creation of a one-equation model
- Presentation of suggested changes to the cost reports and to claims to support additional refinements to the case-mix adjustment

2.1 Summary of Presentation

The following background information provides the context for this session's presentation on the ESRD PPS case-mix adjustment model.

2.1.1 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 resource use. Payment adjustment protects access to care for the most costly beneficiaries by mitigating financial disincentives to providing that care.

2.1.2 Current ESRD PPS Case-mix Adjustment

Acumen began by describing current adjustments to the model, introduced in the CY 2016 Final Rule. 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 characteristics presumed to be associated with use of resources. These currently include: age categories, body surface area (BSA), low body mass index (BMI), dialysis onset status, and selected comorbidities (pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied to the pediatric population.

These adjusters are calculated using two equations: one for facility-level variables and one for patient-level variables. Discrepancies in the availability of cost data from the facility and

patient-level data sources make a one-equation cost model difficult to implement and necessitate separate facility-level and patient-level equations.

The Composite Rate (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 aggregated CR costs, with variation occurring at the facility level. 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.

Formerly Separately Billable (FSB) items and services were added to the bundle in 2011, and include erythropoietin stimulating agents (ESAs) and other medications, for example, that treat 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 detect 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.

Results from these two regressions are weighted and combined to estimate the impact of the case-mix factors on cost and to construct payment 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.

The case-mix adjustment model is adapted for pediatric dialysis treatments. The central challenge for estimating the 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. To calculate case-mix adjusters for pediatric patients, CMS identifies the FSB costs per treatment for each pediatric patient from the 72x claims and estimates the effects of age and dialysis modality (hemodialysis or peritoneal dialysis) on total costs. Similarly to the case-mix adjustment for adult patients, the current pediatric adjusters were calculated using 2012-2013 claims and cost report data and were implemented in the CY 2016 ESRD PPS Final Rule.

2.1.3 Stakeholder Comments on Current Case-mix Adjustment

Acumen next summarized Stakeholder comments on the current case-mix adjustment model. Stakeholders have expressed concerns about the current two-equation, case-mix adjustment model. First, they have questioned using a facility's average cost per patient (derived from cost report data) to make patient-level adjustments to the base rate. Additionally, they have questioned the validity of using the weighted average from two separate equations derived from two levels of data with potentially different underlying distributions.

Stakeholders have also questioned the validity of the current set of case-mix adjusters. Some have argued for not using any patient-level adjusters, stating none have proven to be definitively associated with increased dialysis costs. Other commenters have recommended reducing the number of adjusters. Still others have noted that the BMI and BSA adjusters are highly correlated, and that since only the BSA variable is significantly associated with costs, that only BSA should be used.

Stakeholders have noted that the use of comorbidities as case-mix adjusters is problematic. Dialysis providers generally do not have direct access to patient medical records from other healthcare providers; therefore, the comorbidity information they do have and are able to report may be incomplete. Providers have found it difficult to obtain comorbidity data from hospitals and outpatient providers, making its acquisition time consuming and burdensome. This further discourages complete reporting.

Finally, stakeholders have expressed concern that costs unique to pediatric dialysis are not adequately captured in current cost reports or claims. They have suggested that an alternative reimbursement model be considered for this patient population.

2.1.4 Alternative Approaches for Case-mix Adjustment

Next, Acumen presented two alternative approaches for case-mix adjustment to the panelists and solicited feedback. Stakeholder comments suggest a sustained interest in refining the current case-mix adjustment by developing a single statistical model to estimate the effect of case-mix adjusters on total cost per treatment. This could be accomplished by estimating total cost per treatment as the dependent variable in a single regression model. This equation would estimate the effects of patient-level and facility-level adjusters on the CR and FSB items and services. Estimated coefficients for each factor would be directly used to adjust the base rate without the need to weight estimated effects across multiple models. The challenge in implementing such a model is obtaining sufficient patient (or treatment) level data on the variation in CR costs. As previously mentioned, data on FSB items and services are available at the treatment level from claims, while CR costs are only available at the facility level from cost reports. Therefore, CR costs are difficult to assign to individual patients. This is particularly the case for costs related to the use of capital equipment. During the December 2019 ESRD PPS

Technical Expert Panel (TEP), panelists were introduced to two alternative approaches to measuring patient-level variation in these costs, which is not currently captured.

Acumen presented two different approaches to creating a one-equation model. Both approaches would entail more detailed, patient-level reporting on claims; however only one additional data element would be required for each alternative. While the specific details of these two approaches differ, the basic principles are analogous to other CMS payment systems, including the Home Health PPS, the Inpatient Rehabilitation Facility PPS, the Skilled Nursing Facility PPS, and the Inpatient Psychiatric Facility PPS. As such, either of the two approaches described below, if implemented, would align the ESRD PPS with other CMS payment systems.

Approach 1: Dialysis Session Charges

The first approach would utilize dialysis session charges from claims. For each dialysis session line that is billed on claims, there is a field that records charges for that session. Those charges should reflect the use of CR items and services for that session. Because charges, as currently reported, often overestimate costs, charges must be converted into costs. To do this, Acumen computed a facility-level cost-to-charge ratio (CCR) for the different CR components (e.g. capital, labor, supplies, laboratory tests, etc.). Specifically, Acumen obtained the total cost for each of these components from facility cost reports and divided them by the total charges from the corresponding dialysis session lines on 72x claims. The result is a facility-level CCR for each of the CR components by treatment modality. To obtain CR costs that vary on the patient (or treatment) level, Acumen multiplied total charges for each facility-beneficiary-month by the facility-level CCR for the given dialysis modality. In this way cost reports and claims data are used to derive cost per treatment. It should be noted that charges on claims are used in this way by several other Medicare prospective payment systems.

After converting costs obtained in this manner to in-center HD equivalent treatments, Acumen found substantial dialysis cost variation by modality. Home HD and peritoneal dialysis (PD) were found to have lower reported CR costs than in-center HD, and treatment costs for home training sessions (for both HD and PD) were found to be higher than in-center HD.

Overall, the case-mix adjusters generated using Approach 1 are smaller in magnitude than the current ESRD PPS case-mix adjusters.[1] To illustrate, using case-mix adjusters included in the current model, the multipliers for each of three comorbidities decrease from 4-9% when going from the current model to the one that is generated with Approach 1 (gastrointestinal tract bleeding 1.08 to 1.04; hemolytic anemia 1.19 to 1.10; and myelodysplastic syndrome 1.10 to 1.05). However, there was no such decline in multiplier value for pericarditis which remained at

[1] This is the case for Approach 2 as well, for which the multipliers for the current comorbidities decline even further than they do for Approach 1, and the multipliers for other case mix factors, such as age group, dialysis onset status and BSA also show marked decline.

1.04. Similarly, while age >= 80 years has a 10% increase in cost per treatment using the current equation, the effect of this age variable decreases to unity under the multipliers generated by Approach 1, using currently available data. This may be due to limited variation in reported charges for patients within a facility or even across facilities. In 2017, roughly 90 percent of dialysis providers reported only 1-4 unique charges for dialysis sessions, irrespective of modality. The small effect of the adjusters might also be due to limited variation in treatment cost for these conditions, but without adequate information about differences in per treatment costs by type of patient or modality, the association of cost with any patient-level attribute cannot be determined.

Approach 1 thus would require more accurate reporting of charges that better reflect across-treatment variation in costs. One option for accomplishing this that limits provider administrative burden would be to quantify charges for a limited set of treatment categories (for example, combining modality with selected high-cost patient characteristics). One such set might include: home PD or HD, self-dialysis training session, in-center HD, in-center HD requiring a mobility assist device, in-center HD in a patient with labile blood pressures. Dialysis providers could then bill the charge associated with the treatment category.

Additionally, revising the cost reports so they more specifically identify the cost of each CR component would improve the accuracy of estimating facility-level costs. Clear differentiation of CR from FSB costs for laboratory services and supplies is needed. Similarly, reporting of capital costs for dialysis-related equipment needs to clearly differentiate in-facility from in-home dialysis equipment costs (e.g., dialysis machines and water treatment equipment). Finally, the cost reports need to be updated to reflect the direct patient labor categories currently employed by dialysis facilities.

Approach 2: Dialysis Treatment Duration

The second approach would obtain patient-level variation in CR costs by using dialysis treatment times to apportion CR costs to treatments. The underlying assumption of this approach is that labor costs, supply costs, and capital depreciation costs constitute a substantial portion of CR costs and that variation in these costs depends largely on treatment time. It follows that longer dialysis treatments, on average, will have higher per treatment costs than shorter treatments.

Costs per treatment under Approach 2 would follow a similar methodology to Approach 1, with the main difference being the way costs are apportioned to each dialysis treatment. Specifically, after total facility-level costs by modality are computed using the cost reports, the total treatment time across all beneficiaries for each facility would be totaled. Dividing these two quantities yields an average CR cost per minute for each dialysis modality, which can be aggregated to the facility-beneficiary-month level by determining the total number of treatment

minutes. Patient-level variation in CR costs is then attributable to variation in treatment times. Approach 2 requires the accurate reporting on claims of total dialysis minutes for each in-facility hemodialysis (HD) treatment.[2] For home HD, home PD, and in-facility PD, CR cost per treatment would be obtained from the cost report data, since the reporting of treatment duration is more problematic for those modalities. These would be scaled to be equivalent to weekly in-facility hemodialysis treatments. As with Approach 1, Approach 2 also would benefit from more accurate reporting on composite rate costs from cost reports for each modality and for each component cost, most especially the costs for dialysis machines and water treatment equipment, as well as accurate differentiation of labor costs associated with each modality. For example, if there are certain labor costs associated with onset patients, those costs should be reflected in cost reports. Those additional labor costs would be combined with treatment time to calculate patient-level CR cost per treatment.

Formerly Separately Billable Items and Case-mix Adjustment Factors

Both approaches treat FSB items and services in the same way they are treated in the current two-equation model. Since these costs are already itemized on the 72x claims, CCRs for each category of FSB items are used to calculate FSB cost per treatment. Both approaches would combine the FSB cost per treatment with the CR cost per treatment to obtain the total (CR + FSB) cost per treatment to be used in the one-equation model. This total cost per treatment will become the dependent variable in a single equation regression model for the ESRD PPS.

Selected patient characteristics and comorbidities can be used as case-mix adjustment factors for the model. Overall, the beneficiary characteristics currently used as case-mix adjusters have smaller effects on average cost per treatment, using either of the two approaches, relative to the current case-mix adjustment model. While the multipliers for most adjusters are equivalent or lower using either of the two alternative approaches as compared to the current two-equation model, Approach 2 appears to exhibit larger beneficiary characteristic variation than Approach 1. The differences in the multipliers between Approach 1 and Approach 2 derive from the differences in variation observed from charges on claims (Approach 1) and treatment times (Approach 2).

For both approaches, the effects of age are less than they are in the current system and the onset of dialysis effects are relatively low. The effects of both BSA and BMI decline under both approaches as compared to current multipliers.

Application of New Approaches to Pediatric Dialysis

[2] In discussions with CMS that took place subsequent to this TEP, it was suggested that a monthly aggregate number representing total treatment time in minutes over the course of one month for each patient would be a more feasible option for reporting on claims

Additional refinements would be needed to account for costs incurred by pediatric dialysis facilities. The two approaches described above could be adapted for pediatric dialysis patients, but challenges would remain. One such challenge is the small number of pediatric dialysis patients, which makes it difficult to generate robust statistical models. Another difficulty is disentangling CR costs for pediatric patients from those of adult patients, given that most pediatric dialysis treatments occur in hospital-based facilities, and pediatric dialysis costs are not adequately differentiated from adult dialysis costs in hospital cost reports.

To illustrate how a one-equation model could be adapted to incorporate the pediatric population, new pediatric-specific variables were created and applied to Approach 1. Explanatory variables (case-mix adjusters) in the adult model were assigned a zero value for pediatric patients and four pediatric-specific variables were created: Age < 13 years, Age 13 to 17 years, interaction term for PD treatment and age < 13 years, interaction term for PD treatment and age 13 – 17 years. For adult patients, a zero value was assigned for each of the pediatric-specific variables. When the full model was run, each of the two pediatric age variables were shown to have a significant increased effect on costs with multipliers of 1.87 and 1.67 for age <13 years and age 13 to 17 years, respectively, while the interaction terms for age group and PD modality were found to have a decreasing effect on costs with multipliers of 0.65 and 0.75 for age <13 years and age 13 to 17 years, respectively, compared to the reference adult population.

Reporting of Improved Charges or Treatment Times Not Used to Compute Payment

It is important to note that variation in CR costs as computed with either of these approaches would not be used directly to calculate payment and would not influence the payment multipliers. Specifically, patient variation in CR costs would be used to improve precision of the patient-level case-mix adjusters. With respect to Approach 2, dialysis session run time would be used solely to apportion CR costs to the patient level for use as the *dependent variable* in a one-equation regression model. Dialysis session run time would not be included as a case-mix adjuster. Consequently, treatment time 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. This caveat also applies to more precise reporting of charges under Approach 1. Improved reporting of charges in claims would not directly affect ESRD PPS payments in any given year.

Looked at from another view, and assuming that BSA is highly correlated with dialysis treatment duration, it follows that an increase in treatment time, were it collected, would on average increase the BSA multiplier. If treatment time is not collected, then BSA will appear to have less of an effect on costs, and facilities treating patients with higher BSAs will get paid less than they should.

2.2 Discussion

Panelists were encouraged to think about each of the preliminary approaches described and offer their thoughts on the feasibility of implementing each one, especially in regard to the changes in data reporting required by each approach. Panelists expressed a generalized concern that the proposed changes would be used to redistribute financial resources rather than provide an increase in the base rate. Panelists generally favored Approach 2, reporting of dialysis treatment time over Approach 1, improving reporting of charges. Some noted that dialysis run time is already recorded by many facilities, reducing the burden of collecting this information. Similarly, Approach 1 would require significant changes to facilities' data collection and reporting practices, as the charges currently reported on claims do not necessarily reflect resource use. When Acumen suggested that with the addition of special codes, charges could better reflect costs associated reflect a given patient's comorbidities, panelists responded that obtaining information on comorbidities is often challenging, and patient records are often difficult to acquire from hospital or outpatient medical records. Panelists also reported that some secondary payers will only accept claims billed with specific dialysis session charges, limiting the charges facilities can report. Panelists also noted that unlike other Medicare prospective payment systems, the ESRD PPS utilizes essentially one DRG and that may make it difficult for facilities to report more variation in charges for that essential service.

On the subject of patient-level case-mix adjusters, panelists urged the use of only a minimal set. BSA was assumed to have a high correlation with treatment duration and while panelists generally supported the continued use of BSA, they encouraged that BMI and the four currently used comorbidities be dropped from the model.

While the panelists preferred Approach 2, they had two major concerns. First, panelists stated that patients may be skeptical of a case-mix adjustment that incorporates time on dialysis. They explained that patients sometimes question whether facilities are recommending longer dialysis sessions not because of clinical benefit, but because they will receive a larger payment. At the same time, some panelists stated that they favored Approach 2 precisely because it appears to encourage longer treatment, which they believe is becoming standard of care in other parts of the world. Acumen acknowledged these concerns and emphasized that any effort to move forward with Approach 2 would require actively communicating to both patients and providers that dialysis run time will not have any direct impact on the payment associated with a given patient.

Second, some panelists noted that dialysis session run time is not the only measure of time associated with resource use. Total time in facility also varies across patients and is associated with different costs than run time. For example, non-ambulatory patients, on average, require more staff time immediately before and after treatments. Panelists emphasized that

patients with left ventricular assist devices, tracheostomies and other special needs all require additional nursing time independent of run times.

TEP members also expressed the opinion that unlike in-facility HD treatments, CR costs for home HD and PD are not directly related to treatment time, since labor is not a substantive cost center for home modalities. Acumen clarified that for home HD, home peritoneal dialysis (PD), and in-facility PD, the calculation of CR cost per treatment would be derived from the facility-level average CR cost per treatment. Panelists and Acumen agreed that there are difficulties in obtaining accurate treatment times from home dialysis treatments.

Finally, panelists cautioned that any attempt to collect total time patients spend in a facility, in addition to dialysis run time, would entail additional administrative burden, since a staff member would need to actively track when patients arrive at and leave the facility. It would also likely result in inaccuracies as it is not uncommon for patients to have to wait for transportation, adding to their total in-facility time, but not necessarily to time encumbered by staff.

In comments pertaining to pediatric dialysis, panelists noted that approximately 25% of pediatric dialysis patients are Medicare beneficiaries, while 40% are Medicaid, leading them to question the applicability of methods used in other Medicare payment systems to the pediatric dialysis setting. Since most pediatric dialysis is delivered in the hospital setting and the hospital cost report does not include the level of granularity that is being recommended for the free-standing facility cost report, such items as the specialized labor categories utilized by pediatric dialysis programs (e.g., child life specialists, school teachers, developmental specialists, etc.) may continue to be overlooked. There was overall concern by pediatric dialysis stakeholders that there will continue to be underpayment for this category of patients.

2.3 Key Findings

- Panelists strongly opined that the current base rate is insufficient to reimburse dialysis facilities for their costs
- Panelists were uniformly in support of a simplified case-mix adjustment for the ESRD PPS, including the removal of unnecessary adjusters
- Panelists favored Approach 2, which incorporates dialysis treatment duration, over Approach 1, which utilizes dialysis session charges on claims
- Some panelists noted that both approaches would lead to significantly larger pediatric multipliers, however, there were no objections to this cost differential
- Panelists were concerned that other measures of resource use tied to cost of composite rate services might be overlooked with the adoption of either of these approaches

- Acumen will explore various options for collecting dialysis treatment duration data which minimize impact on providers

3 WAGE INDEX

The objective of this session was to examine issues with the current ESRD PPS wage index and discuss options for creating a wage index more specific to dialysis facilities. The session included the following topics:

- Description of the current ESRD PPS wage index
- Summary of stakeholder comments on the current ESRD PPS wage index
- Presentation of an alternative construction of the wage index more specific to dialysis facilities
- Implications of the alternative wage index

3.1 Summary of Presentation

3.1.1 Current ESRD PPS Wage Index

Acumen began by describing the current ESRD PPS wage index, which is used to adjust two components of the ESRD PPS: the labor-related share of the base rate, and the training add-on payment. The wage index is used to adjust for geographic differences in wages. The ESRD PPS currently uses the pre-floor, pre-reclassified wage index from the Inpatient Prospective Payment System (IPPS), which is constructed using wage and employment data from hospital cost reports (Form CMS 2552-10). All else being equal, ESRD PPS payments are higher for facilities in areas with higher wage indices.

3.1.2 Stakeholders' Concerns with Current Wage Index

Stakeholders' comments on the current wage index focused on two issues. First, stakeholders voiced concerns with the data lag in constructing the wage index. The IPPS wage index is currently computed using data from four fiscal years prior, which stakeholders claim results in underestimation of wages because lagged data do not capture prevailing wages in the relevant sectors, current state and municipality minimum wage increases, and overall economic growth.

Second, stakeholders raised concerns about the likely differences in occupational mix and consequent labor costs between outpatient dialysis facilities and hospitals subject to the IPPS. Construction of the IPPS wage index includes wage data for occupations most often employed in the inpatient setting, which may be seldom or never utilized by dialysis facilities. In addition, the occupational mix survey used in the IPPS includes categories for a limited number of occupations, including Registered Nurse (RN), Licensed Practical Nurse, Nurse Aides, Medical Aides, and All Other. The All Other category includes occupations not typically seen in dialysis facilities, including non-physician anesthetists, teaching physicians, interns & residents, and home office personnel. Other occupations, including social workers, dieticians and others

typically employed in the dialysis facility setting are not included in the IPPS occupational mix survey. Acumen compared the occupational mix and average hourly wages between IPPS hospitals and dialysis facilities. For IPPS hospitals, occupational mix and wages were calculated using publicly available files from the CMS website that provided results from the occupational mix survey.[3] For dialysis facilities, occupational mix was calculated using independent facility cost reports (Form CMS-265-11) from 2016, and wages were calculated using data from public Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES). Dialysis facilities and IPPS hospitals have differing occupational mix and pay scales within comparable occupations. For example, RNs represent approximately 27% of staff positions at dialysis facilities compared to approximately 32% at IPPS hospitals. The hourly wage for RNs in dialysis facilities is markedly lower at approximately $49 per hour as compared to the average hourly wage for RNs at IPPS Hospitals which averaged $63.00, based on 2019 BLS OES data. Similar relationships apply across occupational categories.

3.1.3 Alternative Approach to Constructing Wage Index

Acumen presented an alternative approach to constructing the wage index that combines two sources of existing data and promises to more closely reflect the occupational mix in dialysis facilities. The approach was presented to initiate conversation of the wage index and is not a formal proposal. This approach would utilize publicly available wage data that are current, avoiding the data lag associated with the current wage index. The two data sources include independent dialysis facility cost reports and publicly available Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) survey data. Specifically, the approach would use occupational mix data from freestanding dialysis facilities in combination with geographically specific wage data from the BLS OES to obtain occupation-specific wages in each county. The OES program conducts a semiannual survey to produce estimates of employment and wages for a number of occupations, and each release of data by OES incorporates data from the last six semiannual surveys. For example, the May 2017 OES wage estimates are based on six semiannual surveys, spanning from November 2014 to May 2017. This alternative approach is more specific to dialysis facilities and utilizes more recent wage data than the IPPS wage index. It does not place any additional administrative burden on facilities.

The proposed alternative methodology for calculating the wage index for dialysis facilities was illustrated in the TEP slide deck.

[3] FY_2019_S3_and_OccMix_Final_Rule_PUF_07182018 downloaded from: https://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.

3.1.4 Implications of Alternative Wage Index

In a simulation using the alternative methodology, Acumen found that a majority of counties would experience a significant change in wage index values, with 60 percent of counties experiencing either an increase of more than 4 percent or a decline of more than 5 percent. Nevertheless, a majority of counties remain in the same quintile of wage indices as with the current approach.

Acumen also examined the impact of the alternative wage index on providers based on facility characteristics. Application of the proposed methodology would result in an average 2.7 percent increase in the wage index across all facilities, as compared to the current wage index. Rural facilities on average experience a relatively large increase in the wage index under the alternative approach, a 7.2 percent increase relative to the current wage index. Smaller facilities (based on annual treatment volume) experience a relatively larger increase in the wage index compared to larger facilities, although larger facilities also would experience an increase overall compared to the current wage index. Across other facility characteristics such as ownership type, the distribution of wage index changes from the current to the alternative approach is generally similar. Payments under the alternative approach generally mirror the above average wage index changes across facility characteristics.

3.2 Summary of Discussion

Panelists supported the addition of new labor categories to the cost report. One panelist suggested that changes to labor categories on the cost report should correspond with occupations reported in the BLS OES, if an alternative approach similar to the one presented by Acumen were to be adopted. Another member of the panel noted that labor costs associated with training should be captured, given that employees frequently move between different healthcare settings, requiring training and retraining. One panelist expressed support for adding specialists who treat pediatric patients as discrete labor categories on the cost report. This panelist noted that within the pediatric dialysis community there has been ongoing discussion about the need to modify the cost reports to better capture costs unique to pediatric dialysis. Another panelist suggested using labor costs as reported in costs reports to construct wage indices, rather than pulling wages from BLS OES data. Acumen noted that while this would be feasible, it raises questions about the consistency and reliability of current cost report data. Facilities might interpret the labor categories differently depending on their reading of cost report instructions. Another panelist suggested that construction of a new wage index should not require the differentiation of labor time by modality, as this would increase administrative burden.

Panelists inquired about the use of public BLS OES data and the level of detail captured in such data. One panelist asked if the publicly available BLS OES data that was used in the presentation of results using Acumen's alternative approach differentiated RNs by healthcare

setting, such as RNs in outpatient dialysis as compared to hospitals or other outpatient settings. Acumen noted that the publicly available data is aggregated and collected at the metropolitan statistical area (MSA) level, so the results presented capture variation in wages at the MSA level, but do not capture variation within occupations by healthcare setting. Confidential BLS data would provide greater disaggregation of wages and it would be possible to capture wages for dialysis facility registered nurses within small geographic areas. Another panelist noted that facilities in which the employees are unionized have higher wages, and expressed doubt that this would be captured by the geographic divisions in the BLS OES data. The panelist noted that unions tend to be more dominant in metropolitan areas, but rural hospitals could also have unions. Another panelist noted that the alternative approach accounts for the differences in wages between union and non-union facilities, as the approach uses county-level wages and would capture the effect of higher wages resulting from unionized staff.

One panelist noted that some states have requirements regarding staffing ratios and asked if this would be accounted for in the alternative approach. For example, some states cannot use licensed practical nurses (LPNs), and others can only use a certain level of patient care technician. Acumen noted that step 3 of the alternative approach weights the wages by the national occupational mix, using FTEs from cost reports, but does not directly incorporate required staffing ratios.

Another panelist observed that parts of California would experience a significant decrease in the wage index under the alternative approach, claiming this is counterintuitive since it is difficult to find qualified staff in California. Yet another panelist countered with the opinion that the alternative approach, which is more specific to dialysis facilities, demonstrates that most of California has a higher current wage index than is appropriate. Some panelists expressed concern that using the BLS data would result in lower wage indexes for certain geographic areas where wages are noted to be high, such as California. However, Acumen noted that changes in the wage index resulting from use of BLS data in combination with occupational mix and FTE data from the cost reports would result in a more accurate approximation of real wages paid to staff in free-standing dialysis facilities.

One panelist reported that hospitals in small, rural CBSAs sometimes request to be reclassified in order to receive a slightly higher wage index. The panelist asked if this should be considered when constructing new wage indices. Acumen noted that the ESRD PPS currently uses the IPPS pre-reclassified IPPS wage index but would consider options using the post-reclassification wage index.

One panelist asked if the alternative wage index would be budget neutral. Acumen answered that theoretically there would be budget neutrality factor but emphasized that the alternative approach is strictly a thought process and not being proposed.

In summary, panelists generally supported the use of more recent BLS data than is currently used in for the dialysis facility wage index, however they had a number of questions about the details of this approach and its ramifications for specific types of facilities and facilities located in certain geographical areas.

3.3 Key Findings

- Panelists supported better targeting of dialysis facilities when constructing a wage index
- Panelists support additional labor categories and more detailed breakdowns of existing labor categories on the cost report
- Panelists questioned the granularity of public BLS OES data, but concerns could be largely addressed with access to confidential BLS OES data

4 LOW VOLUME PAYMENT ADJUSTMENT AND RURAL ADJUSTMENT

The purpose of this session was to present an alternative methodology for determining eligibility for the Low Volume Payment Adjustment (LVPA). The presentation included:

- Review of the mandate for the LVPA
- Review of the methodology used for the existing LVPA and rural adjustments
- Review of stakeholder comments on existing policy
- Description of an alternative methodological approach to determining LVPA eligibility
- Description of preliminary results obtained from employing this methodology

4.1 Summary of Presentation

4.1.1 Current LVPA and Rural Adjuster Policy

Acumen began the session by presenting background material on both adjustments to provide context. The LVPA and rural adjustments are facility-level adjustments created in order to ensure beneficiary access to care. Currently, the LVPA is 23.9% of the baseline payment. The current methodology by which the LVPA is determined is described below. The rural adjustment is a 0.8 percent increase in payment for all facilities located in rural Core Based Statistical Areas.

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 cost 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 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).

The LVPA was effective January 1, 2011. It was refined in 2016 to update the payment adjustment and reduce opportunities for gaming.

4.1.2 Stakeholder Input on Current LVPA

Acumen's review of CY 2020 public comments found that stakeholder concern regarding LVPA policy is centered on inaccurate targeting of LVPA facilities. Stakeholders note that in the current rule, it is possible for LVPA to be awarded to facilities that are small (in terms of

treatment volume) but surrounded by a large number of ESRD patients and larger, more efficient facilities. Therefore, it is possible that the LVPA supports facilities that are both inefficient and non-essential to ensuring beneficiary access to care. Stakeholders also note that the 4,000-treatment threshold may incentivize facilities to provide less than 4,000 treatments per year in order to remain LVPA-eligible. Lastly, stakeholders held contrasting views on the relationship between the LVPA and Rural Adjuster. Some suggest that the rural adjustment accounts for costs not covered by current LVPA. Others suggest that the LVPA and rural adjuster are duplicative, as there is possible overlap between places where it is not financially feasible to operate large, efficient facilities, and places where population is low. Given these concerns, there has been a call to consider alternative approaches to the LVPA that would reduce burden, remove negative incentives, and better target facilities that are critical for beneficiary access.

4.1.3 Novel Approach: Basic Premise/Assumptions

Acumen noted that the ideal LVPA policy would provide incentives for facilities to locate in places where it would not be otherwise economically feasible to locate a facility in absence of the adjustment, and where locating the facility improves patient access to care. With this objective in mind, Acumen presented an alternative approach to the LVPA that directly addresses each of the shortcomings described above. The basic premise of the alternative LVPA methodology is to shift the focus from LVPA-designated facilities to LVPA-designated geographic areas. Identifying geographic areas where there are potential barriers to access and providing the LVPA to all dialysis facilities located in such places holds several advantages. Firstly, gaming incentives are eliminated (such as those that encourage facilities to hold their patient caseload below the 4,000 treatments threshold) as this method removes incentives relative to output. LVPA also becomes administratively simpler, as designation will include all facilities in designated geographic areas. This novel approach reorients the LVPA to support facilities that provide access for beneficiaries in geographically isolated areas, where demand for dialysis is too low for a provider to be financially viable without a payment adjustment. The overarching policy goals of this alternative approach to the LVPA are to encourage: 1) currently operating facilities to continue to provide access to care and 2) entry of facilities into areas at risk for limited access to care due to prohibitively low demand for dialysis treatment and high marginal treatment costs. A secondary goal is to reduce provider burden associated with the current attestation process.

4.1.4 Alternative Methodology to Designate LVPA Eligible Facilities

The alternative methodology designates LVPA eligibility based on the predicted demand for dialysis services in a specified geographic area, rather than on facility treatment counts. This new methodological approach is summarized in the following steps:

- Divide the United States into market areas based on willingness to travel to a dialysis facility
- Calculate the expected demand for dialysis in each area
- Determine a threshold number of treatments below which an area is eligible for the LVPA
- Consider the use of tiers to avoid a cliff effect

The execution of these steps is described in detail below.

(1) Stratify the United States into market areas or geographic divisions based on a reasonable assessment of ESRD beneficiaries' willingness to travel. Census tracts were chosen as the spatial unit because of their relatively uniform size based on population, in comparison to counties or zip codes, which can vary greatly in terms of both population size and physical area.

   (a) Using all census tracts in the US, divide into four regions (North, South, Midwest, West) and deciles by population density, yielding 40 categories of census tract

   (b) Using claims data, note the distance between beneficiary home address and address of facility at which beneficiary receives dialysis care. In – facility and home dialysis distances calculated separately

   (c) Create a distribution of these travel distances for all ESRD beneficiaries within a census tract and choose a percentile of these travel distances to denote willingness to travel. Acumen selected the 75th percentile for demonstration

   (d) Draw a circle around the centroid of the census tract for the 75th percentile of travel distance in each census tract category. This circle denotes willingness to travel for ESRD beneficiaries in this region/population density combination.

(2) Calculate the latent demand of services for providers in each area and adjust it appropriately.

   (a) Count the number of ESRD beneficiaries inside this circle and multiply by the average number of treatments per year for ESRD beneficiaries. This is the latent demand for this hypothetical area.

   (b) Calculate Adjusted Latent Demand

      (i) Acumen explains that not all beneficiaries located in the circle are going to go to the hypothetical provider, and not all beneficiaries going to the provider are going to come from inside the circle.

      (ii) In order to account for this movement, the latent demand calculated in Step 2 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.

(3) Determine a threshold of adjusted latent demand, above which facilities in the census tracts would not receive LVPA Facilities located in census tracts below this threshold would receive LVPA.

(a) Consider the use of payment adjustment tiers to avoid a "cliff effect". Currently, the LVPA provides no payment enhancement for providers treating slightly more than four thousand and provides no additional enhancement for providers treating substantially fewer than four thousand treatments. Since there is little reason to believe that costs of provision have a similar cliff, and since the cliff is large, reimbursement likely does not track the actual costs of provision.

(b) Different treatment thresholds could qualify facilities for different levels of payment enhancement.

4.1.5 Alternative Approach to the LVPA: Results of Preliminary Analyses

Acumen applied the alternative methodology for the LVPA to existing treatment data (from the calendar year 2016). The results of these analyses are presented below.

For the purposes of illustration here, Acumen chose a threshold of 5,000 treatments. This number was chosen because (1) the freestanding facility cost-per-treatment differential stabilizes around a threshold of 5000, and (2) the number of providers that would receive the LVPA under alternative method closely matches the current number of providers receiving LVPA when the threshold is set at 5,000 (333 and 335, respectively for the alternative LVPA and the existing LVPA).

Use of the alternative methodology results in a greater proportion of rural facilities qualifying for the LVPA. Using the proposed methodology, 86 percent of LVPA eligible facilities are located in rural areas as compared to 51 percent under the current LVPA. Acumen noted that the alternative LVPA methodology might result in considerable overlap with the rural adjustment and retention of both should be reconsidered.

Facilities eligible for the LVPA under the alternative methodology would be located an average of 30 miles away from the next nearest provider. Currently the mean distance from an LVPA facility to the next closest provider is 4.7 miles. The new methodology would therefore incentivize provider relocation to isolated areas, improving and preserving access to care.

With use of the alternative methodology, a greater proportion of LVPA eligible facilities would be hospital based. Under the current LVPA, 36% of designated facilities are hospital based. This proportion would be increased by 21% under the alternative methodology. The proportion of LDOs designated with the LVPA would decrease with use of the alternative methodology.

Use of a tiered approach with the alternative methodology calibrates reimbursement more closely with actual cost per treatment for LVPA eligible facilities. In regression models, where cost per treatment is regressed on proposed LVPA tiers (with thresholds of less than 3,000 treatments, 3,000 to 4,000 treatments and 4,000 to 5,000 treatments), the use of multipliers

(ranging from 1.07 to 1.24, depending on the threshold and the number of tiers) equalizes payments, by increasing them proportionately to compensate for facilities' increased cost.

4.2 Summary of Discussion

Panelists remarked on the thoroughness of this new approach to the LVPA. Several expressed the opinion that this approach represented a significant improvement over the current system and would likely result in better access for patients. They had a number of concerns, however, about the implications of this new system for their facilities. Chief among them was the potential loss of LVPA status, the capital costs of start up for new facilities and the risk of losing LVPA status if census tract eligibility is recalculated too frequently. In response to this concern, Acumen suggested that this was a design parameter that CMS would have to carefully consider to provide facilities with assurance that the incentive will remain for an appropriate length of time, when facilities invest in a new LVPA eligible facility.

Panelists also expressed the concern that there might be, among the facilities that lose LVPA status, those located in urban areas that serve a high proportion of high-risk patients, including dual eligible beneficiaries and the uninsured, for whom the LVPA is necessary for their operations to continue. There was also some concern that smaller, independent rural providers might be on the losing end of this new approach.

Another concern pertained to the complexity of the methodology itself. Panelists expressed some discomfort with the use of data and methodologies that were not readily accessible to them or transparent. They suggested that it might be in their interest for the methodology to be vetted more publicly to identify potential design flaws. In addition, it was suggested that there should be some type of appeal process that accounts for the eventuality of facility closures. Panelists also suggested that it would be useful to repeat the calculations presented here using more recent Medicare cost data.

There was a considerable amount of discussion about the assumptions underlying "willingness to travel" to receive dialysis treatment. Panelists expressed some doubt that the distance beneficiaries currently travel accurately represents their willingness to travel. They were concerned that using this assumption to calculate distances in the alternative LVPA methodology may lead to the overestimation of values for this metric. Acumen responded that the 75th percentile of the average distance traveled within each of the 40 geographic division was used to address this concern. In this way, calculations did not assume that beneficiaries were willing to travel maximum distances for care. Panelists noted that being ill and economically disadvantaged may result in a shorter 'willingness to travel' distance than Acumen anticipates. Furthermore, panelists observed that terrain should also be considered while calculating reasonable travel distance, and that this may be particularly important in the Midwest. Panelists also inquired as to

whether a different metric for willingness to travel should be calculated for home dialysis patients, who occasionally do need to visit the dialysis facility for care. Acumen responded that the 75th percentiles for home and in-center patients were calculated separately, but that more sensitivity analysis regarding the choice of the 75th percentile of distance traveled was in order, especially with regards to home versus in-facility patients. Panelists were also concerned that individual patient hardships were not being considered in the design of the new LVPA and that such factors as availability of public transportation, family support and other social factors need to be considered.

4.3 Key Findings

- Overall panelists felt that the alternative methodology represented a better approach to the LVPA and was more likely to provide better access for patients
- Panelists expressed interest in the release of details about the methodology
- Panelists feel strongly that should this policy be implemented, there should be a way for facilities to apply to receive LVPA if they do not locate in an LVPA census tract.
- Panelists note that the concept of "willingness to travel" should be examined more closely

5 TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENT

The objective of this session was to examine mechanisms to use in the process of adding drugs from Transitional Drug Add-on Payment Adjustment (TDAPA) status into the ESRD PPS bundle. The session included the following topics:

- Description of the TDAPA policy
- Summary of stakeholder comments about moving from TDAPA status to the ESRD PPS bundle
- Presentation of options for incorporating costs for eligible drugs after TDAPA period expires

5.1 Summary of Presentation

In this section, current TDAPA policies are reviewed, stakeholder comments are summarized and two options are presented for incorporating calcimimetics into the ESRD PPS base rate after expiration of TDAPA eligibility.

5.1.1 TDAPA Policy

Acumen began by presenting an overview of current TDAPA policy, describing its purpose and recent policy changes. The TDAPA is designed to facilitate beneficiary access to new renal dialysis drugs until sufficient data are collected to price the drugs into the bundle. The TDAPA was implemented starting in CY 2018, at which time an oral calcimimetic and an injectable calcimimetic each became eligible for the add-on payment for two years. TDAPA payments are made based on Average Sales Price (ASP), as reported by the drug manufacturers.

The CY 2020 ESRD PPS Final Rule extended TDAPA coverage for calcimimetics through CY 2020, with transition into the ESRD PPS bundle planned for CY 2021. Given that calcimimetics are currently the only drugs eligible for TDAPA and sufficient data are available on their utilization and costs, this TEP session focused on calcimimetics cost and utilization as observed in 72x claims, and explored methods for adjusting the base rate to account for calcimimetic use.

5.1.2 Stakeholders Input on Incorporating Calcimimetics

Acumen then presented a summary of stakeholders' comments regarding the TDAPA and, in particular, calcimimetics. Stakeholders agreed that the use of new and innovative treatments should be incentivized by a payment add-on to the ESRD PPS bundle. They also believe that the base rate should be expanded to include the additional cost of calcimimetics once their TDAPA eligibility expires. Some stakeholders suggest extending TDAPA coverage past the third year (i.e., past 2020). Some stakeholders also note that current billing practices adopted by Medicare Advantage and other payers discourage use of drugs and other items without HCPCS

codes. As a result claims are sometimes denied when they contain billing codes for TDAPA that fall outside of the existing Part B processes.

5.1.3 Calcimimetics Utilization

Acumen's analysis of dialysis claims shows that approximately 25 percent of ESRD beneficiaries received calcimimetics since TDAPA implementation in January 2018, which is consistent with observations from stakeholders. The percentage of ESRD beneficiaries using cinacalcet (oral) ranged from 20 percent to 25 percent between January 2018 and June 2019, while the percentage of ESRD beneficiaries using etelcalcetide (IV) steadily rose from 1 percent to about 8 percent during that time.

5.1.4 Option 1: Incorporating Calcimimetics Across All Treatments

The first option for incorporating calcimimetic cost into the base rate would distribute calcimimetics payments evenly across all treatments. It would result in a flat increase to the base rate. It is consistent with the ESRD PPS model prior to case-mix adjustment, which provides a single payment for a bundle of services. This payment would agree with realized calcimimetic use for the roughly 25 percent of recipients using the drug, and would not vary when facilities used more or less than this average.

5.1.5 Option 2: Case-mix Adjustment to Predict Calcimimetic Use

Option 2 uses case-mix adjustment to target potential calcimimetic use. This option would incorporate calcimimetics into the base rate and then would adjust payments by incorporating case-mix adjusters for beneficiaries likely to receive calcimimetics (rather than distributing calcimimetics payments evenly across all beneficiaries without consideration of calcimimetic use as in Option 1). This method concentrates a larger portion of payments to beneficiaries more likely to receive calcimimetics. The case-mix adjuster(s) used to identify TDAPA beneficiaries might include diagnoses/conditions, or medications, or a combination of both, that correlate with calcimimetic use. Under this potential method, the proposed case-mix adjuster would be included in the case-mix model, either in the existing model or a revised one-equation model, and the resulting values from PPS Pricer would be used to adjust the base rate (i.e., as the multipliers work in the existing model).

In a simulation of how Option 2 would work, Acumen constructed a potential clinical predictor of calcimimetic use, comprising the presence of secondary hyperparathyroidism (DGN code N2581) and a prescription for a vitamin D analog in the prior two months. Looking at IP, OP, and PB claims for ESRD PPS beneficiaries, secondary hyperparathyroidism was present in 90.3% percent of patient-months in 2018. The presence of an NDC for a vitamin D analog prescription was present 67 percent of patient-months, while the HCPCS for a vitamin D analog prescription was present 45 percent of patient-months. This potential clinical predictor would

thus be largely driven by the presence of a vitamin D prescription, as secondary hyperparathyroidism itself is highly prevalent in the ESRD population.

Acumen investigated the relationship between the presence of the proposed clinical predictor and calcimimetic use for patient-months in 2018. For 80 percent of patient-months with calcimimetic use, the proposed predictor was positive. At the same time, the predictor was positive for a number of patient-months in which the beneficiary did not use calcimimetics. When considering both, the proposed predictor accurately identified whether a beneficiary used calcimimetics around 50 percent of the time. Ultimately, 66.5 percent of patient-months in 2018 had a positive proposed predictor, meaning that calcimimetics payments would essentially be distributed across these 66.5 percent of treatments, compared to distributing evenly across 100 percent of treatments under Option 1.

Acumen expanded its investigation of the reliability of the proposed predictor by estimating a model predicting a beneficiary's future use of calcimimetics, controlling for additional risk adjusters included in the current case-mix model, including age, low BMI, and onset status. With the inclusion of these other risk adjusters, the proposed prediction model resulted in a 75 percent alignment with realized calcimimetic use. The results also indicated that the presence of one or more of these risk factors is correlated with calcimimetic use, suggesting that use of the risk adjuster(s) correlated with calcimimetic use would distribute payments more equitably to these treatments.

Further examination of the potential impacts of Option 2 on payments focused on the prevalence of the proposed predictor across facilities. The patient predictor was present in 64 percent of patient-months across all facilities in 2018. However, there was a lower prevalence among smaller (less than 4,000 treatments in a year), independent, and hospital-based facilities, with 53 percent, 43 percent, and 38 percent, respectively. Therefore a payment based on a risk adjuster such as in this Option 2 would align with calcimimetic use (or non-calcimimetic use) for 65 percent of beneficiaries.

5.2 Summary of Discussion

Most panelists supported Option 1. They preferred an option that would result in a flat increase to the base rate. Small volume providers liked Option 1 because they felt it would allow them to provide consistent care to all their patients and would be less of a burden to implement. Some panelists were of the opinion, however, that the way that TDAPA drugs were incorporated into the base rate should be considered on a case-by-case basis and that data collected during the TDAPA period should be taken into account when determining how each new drug would be worked into the bundle. Panelists were hesitant to embrace a single solution for drugs that might be eligible for TDAPA in the future.

While some panelists expressed the opinion that either Option 1 or Option 2 could work appropriately, they seemed less certain of Option 2 for future drugs for which differential use in the ESRD PPS population cannot be predicted. In addition, they questioned the use of the proposed predictor under Option 2, particularly its margin of error when predicting calcimimetics use. One member of the panel noted that there would be a large number of beneficiaries taking calcimimetics for which the facility would not receive any incremental payment, pointing to results showing that approximately one in five months of calcimimetic use was not associated with a positive predictor. The panelist expressed interest in knowing whether the group of beneficiaries receiving calcimimetics but not triggering the positive predictor had certain common characteristics that could explain this. Another panelist remarked that there is great variation in prescription of vitamin D analogues, with some practitioners being very conservative in prescribing it.

A member of the panel noted that dialysis patients sometimes cycle on and off calcimimetics, so using a clinical predictor like the one proposed under Option 2 might not be effective. The panelist went on to note that if calcimimetics' correlation with the proposed predictor changes over time, payments could potentially decrease. This panelist compared this to Option 1, in which the payment increase to the base rate would be lower relative to costs for facilities using more calcimimetics, but it would be guaranteed. Another panelist agreed that Option 2 could limit payments to a subset of treatments, and stressed that all patients should be able to benefit from innovative therapies, as is the intended purpose of the TDAPA.

Some panelists raised concerns about the potential for gaming the proposed clinical predictor in Option 2. One member of the panel noted that simply placing a beneficiary on a low-level vitamin D analog could qualify them for higher reimbursement under Option 2. Another panelist emphasized that medications should be paid for only when the patient requires it, and in no other circumstance. At the same time, one panelist noted a vitamin D analog is a titratable drug and there would be health consequences for a patient if the patient was improperly prescribed a vitamin D analog, which would suggest that the predictor in Option 2 is not easily gameable. This panelist also said that parathyroid hormone (PTH) and/or calcium levels could be monitored to serve as additional clinical predictors of calcimimetic use, noting that calcimimetic use corresponds to specific PTH ranges.

Panelists supported reporting of calcimimetic costs on cost reports. One panelist noted that it would be particularly helpful for small, independent providers, as it is more difficult to track medication use with limited resources. This panelist also supported reporting costs associated with calcimimetics on the Provider Statistical & Reimbursement (PS&R) reports. Another panelist cautioned against reporting of revenue, stating that revenue and cost should be looked at in their totality, not item by item.

Panelists commented on observed calcimimetics utilization data. One panelist noted that the utilization of calcimimetics has been stable (i.e., at about 25 percent) for years. The panelist noted that calcimimetics costs, on the other hand, have been volatile, particularly due to the entry of generic calcimimetics. The panelist went on to say that some patients require calcimimetics to be administered through IV, rather than the more common oral administration, which could potentially be considered when determining how to incorporate calcimimetics into dialysis facility payments. Another panelist expressed skepticism that the utilization of calcimimetics has stabilized, pointing particularly to the increasing use of calcimimetics through IV administration.

One panelist cautioned against using data from non-72x claims when constructing a potential clinical predictor of calcimimetic use. The panelist questioned the accuracy of the data from other settings, and noted that timeliness would also be an issue, slowing down the processing of claims. Acumen noted the vast majority of data used to construct the proposed predictor in Option 2 came from 72x claims, so excluding non-72x claims would have essentially no effect on this specific predictor.

One panelist asked if Medicare Advantage plans would adhere to the same base rate that results from Options 1 or 2, but that question was ultimately beyond Acumen's scope. This panelist added that Option 1 is more appealing than Option 2 in the sense that it would allow for more consistent care and has a lower chance of having to go through extra authorizations.

Some panelists commented on a lack of reimbursement for oral calcimimetics given to beneficiaries, but ultimately not taken by beneficiaries due to expiration. One panelist noted that providers often lose money when providing oral calcimimetics to home dialysis beneficiaries, as the beneficiary often will not complete the dosing regimen before the calcimimetics have expired, while another panelist noted this occurs both in home and in center.

One panelist emphasized the need to treat future TDAPA drugs on a case-by-case basis when deciding how to price the drugs after TDAPA expiration. The panelist raised a concern in particular about how to price future drugs that have low utilization and are more expensive than calcimimetics after TDAPA expires.

5.3 Key Findings

- Overall, panelists supported the adoption of Option 1
- Many panelists did not support using the proposed clinical predictor of calcimimetics use under Option 2 to incorporate calcimimetics payments after TDAPA expiration for several reasons
- Concerns about Option 2 included potential for gaming, high margin of error, and less of a guarantee for payment than under Option 1, which would distribute calcimimetics

payments across all treatments equally, rather than attempting to target beneficiaries using calcimimetics

- Panelists supported detailed reporting of calcimimetics costs on cost reports

6 OUTLIER DETERMINATION

The objective of this session was to consider an alternative approach to the outlier adjustment to meet the 1 percent target. The following topics were addressed:

- Current approach to outlier payments
- Stakeholder concerns regarding the current outlier adjustment
- Alternative methodology to achieve the 1% outlier target
- Feedback on the proposed approach

6.1 Summary of Presentation

6.1.1 Current Outlier Policy

Acumen began by presenting a review of the equation used to generate ESRD PPS outlier amounts. The outlier pays 80 percent of treatment costs above a given outlier threshold. The current equation for calculating the outlier amount per treatment is:

$$ESRD\ PPS\ Outlier\ per\ treatment = 0.8 * [MAP_0 - (\text{MAP}_0(\text{hat}) + FDL)]$$

Where (MAP_0) is the per treatment outlier Medicare Allowable Payment (MAP) amount from claims, $\text{MAP}_0(\text{hat})$ is the case-mix adjusted predicted per treatment outlier MAP amount, and FDL is the Fixed Dollar Loss (FDL) amount. The expected MAP amount and FDL create a threshold where, if the MAP amount on the claim is above that threshold, then there will be an outlier payment equal to the 80 percent of the amount exceeding the threshold.

This methodology assumes constant utilization over time. The expected MAP amount and FDL are created using data from two years prior, so the aforementioned threshold in the 2018 rule would be set using 2016 utilization data. Using 2016 data, an adult FDL amount of $77.54 was added to the predicted MAP to determine the outlier threshold. In 2018, outlier payments comprised 0.5 percent of total ESRD PPS payments.

6.1.2 Stakeholders Input on Current Outlier Policy

The outlier was originally intended for a small number of beneficiaries with high utilization of erythropoietin stimulating agents (ESAs) at a time when these medications were highly utilized and expensive. Providers have noted that while ESA use and price has declined, underpayment of the outlier, as indicated above, results in significant losses. Some Stakeholders have strongly advocated that a new outlier threshold be established, using alternative modeling approaches that account for trends in separately billable spending over time.

6.1.3 Alternative Methodology

The underlying basis of the proposed methodology is to relax the assumption of constant utilization over time. This approach allows for the modeling of the MAP amounts as they change

over time. It also allows for the use of data from a greater number of years to inform trends. The examples presented below illustrate how the proposed methodology can be used to better achieve the 1 percent outlier target, using data from 2011 to 2016.

The proposed methodology begins by determining the average monthly MAP amount for each beneficiary. This value is obtained from claims by dividing the amount associated with value code 79 by the number of covered dialysis sessions. Then a provider-beneficiary-month level regression model is fit, using outlier-eligible MAP amount per session as the dependent variable and a function of time as independent variables to obtain time trends for the outlier eligible MAP amount per session. The presentation showed both the quarter of the year (where 2011 Q1 =1, 2011 Q2 = 2) and the log of the quarter (log (1) or log (2)). This trend is then used to deflate the imputed outlier-eligible amount calculated from 2016 claims in order to project 2018 values that are informed by the trend in prior years. Projected MAP amounts are then applied to the current FDL algorithm to derive FDLs for 2018 (using trended 2018 values for outlier eligible MAPs per session).

Acumen noted that projecting quarterly and log-quarterly trends led to decreased FDL amounts for both adult and pediatric dialysis. This, in turn increases the percent of outlier payments in 2018. Comparing the current methodology to the use of both quarterly and log-quarterly methods using 2011 to 2016 trend data, Acumen found that the use of the current method yields an outlier payment of 52 percent in 2018 compared to 92 percent and 62 percent, respectively, for the quarterly and log-quarterly methods.

Using the same simulation model with more recent data (2014 – 2016) yields a decreased FDL amount for adults, but an increased FDL amount for pediatric patients. Using more recent data also yields a percentage of outlier payments that exceeds 1% (1.06%), illustrating the importance of the duration of time used to derive the trend.

Acumen also estimated total ESRD PPS payments in 2018 under the updated methodologies and calculated a payment ratio of updated payments to historical payments, specifically using actual ESRD PPS payments made in 2018 under the current methodology. The payment ratio (revised/historical) in 2018 is evenly distributed across geographic and census regions, as well as facility type, regardless of the Trend Functional Form or Time Period considered.

6.2 Discussion

Panelists expressed support for any change to outlier calculations that result in total outlier payments closer to the target. Panelists then discussed specific details of claims and care that generate outlier payments. Panelists noted that outlier payments are heavily weighted by the number of treatments delivered each month. Panelists also expressed concern about patients

receiving soon-to-be bundled calcimimetics being most likely to become outlier patients once they are bundled. They noted that, in such a scenario, patients receiving calcimimetics are likely to be under reimbursed. Thus, any shortfalls in the proposed outlier methodology that affect the payout to facilities will disproportionately affect these patients.

6.3 Key Findings

- Panelists are open to these modifications to outlier calculation, noting considerations for the number of treatments per month and how these modifications will affect TDAPA patients
- Panelists remained concerned that reimbursement for patients receiving calcimimetics will not reflect true costs once calcimimetics become part of the bundle

7 TRANSITIONAL ADD-ON PAYMENT ADJUSTMENT FOR NEW AND INNOVATIVE EQUIPMENT AND SUPPLIES

The objective of this session was to discuss the new Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and to contextualize it within the framework of other similar policies being implemented by other Medicare payment systems. In particular the session focused on the definition of Substantial Clinical Improvement (SCI), as it applies to ESRD care and treatment. The session included the following topics:

- Overview of TPNIES Policy including Eligibility Criteria
- Description of Two Related Policies: IPPS New Technology Add-on Policy (NTAP) and OPPS Pass-through Payments for New Devices
- Eligibility Criteria for TPNIES
- Description of Substantial Clinical Improvement Criteria

7.1 Summary of Presentation

7.1.1 Overview of TPNIES Policy

Acumen first presented an overview of the TPNIES, which was established in the CY 2020 ESRD PPS Final Rule. It will provide a supplemental payment for the use of certain new and innovative technologies beginning in CY 2021. The TPNIES is designed to reimburse dialysis facilities for use of these items while sufficient MAC-priced data are being collected to eventually have an accurate price structure for those technologies. Payment for technologies receiving the TPNIES will be made at 65 percent of the price established by Medicare Administrative Contractors (MACs) and will be made for two calendar years. After the TPNIES expires for a specific technology, the technology will qualify as an outlier service and no change will be made to the base rate. Acumen noted that stakeholders support the TPNIES to spur innovation for new equipment and supplies while also expressing concern that capital-related assets are not eligible for reimbursement.

Eligibility for TPNIES includes the following criteria:

(1) CMS-designated renal dialysis service

(2) FDA marketing authorization granted on or after January 1, 2020 and by September 1 prior to the payment calendar year

(3) Commercially available by January 1 of the payment calendar year

(4) HCPCS application submitted by September 1 of the previous calendar year

(5) Meets substantial clinical improvement (SCI) criteria as specified in the IPPS NTAP

(6) Does not include capital-related assets

Applications for TPNIES for CY 2021 were due February 1, 2020. CMS will establish a workgroup to review TPNIES applications.

7.1.2 Overview of IPPS NTAP Policy and OPPS Pass-through Payments for New Devices

Acumen then presented an overview of two similar add-on payments currently in use by other Medicare payment systems: 1) the IPPS New Technology Add-on Payment (NTAP) and 2) the OPPS Transitional Pass-through Payments. The IPPS NTAP was first implemented in 2001 and was created to adjust for delays between the data years used for DRG rate setting and the introduction of new technologies. Until FY 2020, CMS paid the lesser of: (1) 50 percent of the cost of the new technology, or (2) 50 percent of the amount by which the costs of the technology exceed the standard DRG payment. Starting in FY 2020, CMS increased this amount to 65 percent, and for certain anti-microbials, CMS increased the rate to 75 percent of cost.

Another comparable payment program is the Transitional Pass-through Payments for new devices under the OPPS. Similar to the TPNIES and NTAP, devices must meet substantial clinical improvement (SCI) criteria and, if required, have received FDA approval, to qualify for pass-through payments. Once the device is no longer eligible for pass-through payment status, it is incorporated into its appropriate ambulatory payment classification (APC) rate.

7.1.3 Substantial Clinical Improvement (SCI) Criteria

In order to qualify for TPNIES, the new technology must meet specific criteria for offering substantial clinical improving to the ESRD patient population. The TPNIES SCI criteria are derivative of the criteria used in making IPPS NTAP determinations. The criteria are listed below:

(1) Offers a treatment option for patients unresponsive to or ineligible for existing treatments

(2) Offers the ability to diagnose a medical condition earlier than existing methods or in patients where the condition is currently undetectable

   (a) Also requires evidence that use of the technology to make a diagnosis affects the management of the patient

(3) Significantly improves clinical outcomes relative to existing technologies, including

   (a) Reduction in mortality or a clinically significant complication

   (b) Decreased rate in the use of at least one subsequent diagnostic or therapeutic intervention

   (c) Decreased number of future hospitalizations or physician visits

   (d) Reduced length of stay or recovery time

   (e) Improvement in one or more activities of daily living or quality of life

(f) Greater medication adherence or compliance

(4) Or the totality of the circumstances otherwise demonstrates that the new technology substantially improves the diagnosis or treatment of Medicare beneficiaries relative to existing technologies

CMS considers evidence from FDA approved clinical trials, peer-reviewed articles, expert opinion, and other data sources submitted by the applicant in determining TPNIES eligibility. Examples of successful and unsuccessful IPPS NTAP applications were discussed with the TEP to shed light on how the SCI determination process could work for TPNIES.

Acumen provided examples of specific therapies that met the SCI criteria for the IPPS NTAP in recent years. For consideration in FY 2019, NTAP applications were submitted for Kymriah (tisagenlecleucel) and Yescarta (axicabtagene ciloleucel), two CAR T-cell immunotherapies used for the treatment of aggressive non-Hodgkin's lymphoma. Manufacturers provided peer-reviewed research supporting their application for the NTAP, which, along with input from expert hematologist-oncologists, demonstrated that both therapies represented substantial clinical improvement over existing technologies, met the other NTAP criteria, and were thus deserving of the NTAP in FY 2019.

Acumen then provided an example of a therapy that did not meet SCI criteria for the NTAP in FY 2020. For NTAP status in FY 2020, TherOx, Inc. submitted an application for super saturated oxygen (SSO2) therapy, suggesting its use during catheterization procedures for people with ST-segment elevation myocardial infarction (STEMI), a type of AMI which carries a substantial risk of death and disability. TherOx claimed reduction in the size of infarctions, lower risk of heart failure and mortality, and improved quality of life as benefits of SSO2 therapy. However, much of the literature on the therapy was not recent, raising concern from CMS and reviewers that the standard of care for STEMI had evolved in the time since the studies were published. Some studies also had insufficient controls, casting doubt on claims of better outcomes. The application also lacked long-term data. Based on these shortcomings, CMS determined that SSO2 therapy did not meet SCI criteria (1) or (2) above, and the application was denied.

7.2 Summary of Discussion

Panelists expressed support for the overall goal of TPNIES to foster innovation, but raised concerns that certain aspects of the policy could decrease its overall effectiveness in promoting innovation. One panelist noted that an application process requiring significant administrative burden could discourage innovation, particularly from small manufacturers with few resources. Another panelist expressed concerns that the uncertainty of reimbursement following TPNIES expiration would also discourage manufacturers and providers from investing more resources in creating innovative and clinically beneficial devices.

Panelists emphasized the importance of quality of life improvements when determining TPNIES eligibility. One panelist noted that CMS should consider relief of patient burden, particularly in home settings, when reviewing SCI criteria. This panelist noted that there is great burden and high burnout rates among home dialysis patients and their families, leading to discontinuation of home treatment. Another panelist emphasized that quality of life measures should be developed with patient input, allowing for different definitions of improved quality of life.

Panelists argued that therapies and technologies that received FDA approval before January 1, 2020 should be considered eligible for TPNIES, noting that there are existing therapies that are innovative but have not been adopted widely due to their high costs. One panelist specifically mentioned ClearGuard caps as an example of an innovative supply that has yet to see wide use due to its high costs. Another panelist mentioned wet/blood detection as an example of an existing therapy that is innovative and clinically effective but would likely not be eligible for TPNIES; the panelist noted that this therapy has disposable and capital-related components, making it ineligible under the current criteria. Acumen noted that a specific goal of the TPNIES is to generate and facilitate new innovation, which is why the TPNIES criteria specify FDA approval no earlier than January 1, 2020.

One panelist noted that there are likely useful innovations that are not as technologically complex as the CAR T-cell therapies discussed in Acumen's presentation. Such items could be a better needle, a better cap, or something to prevent infection or bleeding.

One panelist noted that improved dialysis technology, specifically hemodiafiltration and use of ultrapure dialysate, already exists outside of the U.S., but manufacturers have not sought FDA approval or tried to provide these technologies within the U.S. because they would not be reimbursed sufficiently. Another panelist noted this particular example would be a capital-related asset, so it would not be eligible for TPNIES under the current eligibility criteria. The panelist acknowledged this point, and said this warrants a separate discussion on how to apportion capital-related costs on a per treatment basis.

Panelists expressed the need for further discussion regarding the inclusion of capital-related assets for TPNIES eligibility. Several specific examples of innovative technologies provided by panelists are capital-related or have capital-related components, noted in the relevant examples of this discussion section. One panelist posed the option of accounting for capital-related assets that are used once, as opposed to items that can be used or re-used among many patients, as a first step to eventually including such capital-related assets among those that qualify for TPNIES eligibility.

One panelist noted that new technologies and equipment are often tested and used by adults first and not approved for use in the pediatric population until much later, resulting in

disqualification for TPNIES eligibility by the time pediatric dialysis patients can benefit from the product.

One panelist asked about the pricing of a technology after its NTAP expires under the IPPS. The panelist wondered if there was an incremental payment increase in the relevant DRG rate for the technology in every case, or if there were instances in which the relevant DRG rate did not increase once the new technology was incorporated.

7.3 Key Findings

- Panelists were highly supportive of TPNIES, expressing their belief that it will encourage greater innovation in the field of dialysis care
- Panelists strongly encouraged CMS to include capital-related assets under TPNIES
- Panelists emphasized the need to consider impacts on quality of life when reviewing applications for meeting the substantial clinical improvement criteria
- Panelists maintained that innovative therapies and technologies, already being deployed outside of the U.S., should be considered for inclusion under TPNIES
    - Some manufacturers of therapies and devices used commonly outside of the U.S. have not applied for FDA approval in the U.S. due to a lack of sufficient reimbursement under the ESRD PPS
    - Other new and innovative ESRD-related therapies that were approved by the FDA prior to January 1, 2020, and would therefore not be eligible for TPNIES, should be considered for inclusion

8 HOME DIALYSIS

The objective of this session was to discuss improved methods of capturing the costs of home dialysis treatment. The topics covered included:

- Overview of current issues pertaining to home dialysis costs and payment in the ESRD PPS
- Summary of stakeholder input on the cost of home dialysis treatment in comparison to in-facility treatment
- Suggested revisions to the cost report that would improve the ability to differentiate home from in-facility dialysis costs

8.1 Summary of Presentation

8.1.1 Overview of Current Issues

Acumen began the session with a review of current topics related to home dialysis. Recent federal policy initiatives encourage the use of home dialysis for the ESRD population. On July 10, 2019, an Executive Order was issued launching the Advancing American Kidney Health Initiative. That initiative and CMMI's ESRD Treatment Choices model have as a shared objective the increase in use of home dialysis modalities to 80% of the ESRD patient population by 2025. A payment incentive will award facilities that meet interim goals beginning 2020.

Current data sources are insufficient to determine the actual costs of home dialysis. Dialysis facility cost reports do not adequately differentiate home dialysis costs from in-facility costs, making interpretation of the results difficult. In particular, there is insufficient data on labor costs and equipment costs related to home treatment to be able to accurately compare home dialysis costs to in-facility costs.

Representatives of dialysis facilities have asserted that home dialysis costs exceed those for in-facility treatments. Acumen's analysis of available home dialysis cost data (using information available from current cost reports and claims) have not validated this claim and suggests instead that home treatment costs may be lower than in-facility treatment. Since recent policy initiatives incentivize increased use of home dialysis by facilities, it is important to know true costs for each of the home dialysis modalities and sources of any cost differentials.

In the ESRD PPS, home and in-facility hemodialysis (HD) treatments are paid using the same base rate. This base rate is also applied to patients undergoing peritoneal (PD) dialysis, which is generally administered in the home. Because PD patients undergo dialysis five to seven times per week, as compared to three times per week for typical in-center hemodialysis, individual PD treatment sessions are paid at 3/7 of the hemodialysis rate. This equates average

weekly payments between the two modalities. There is a case-mix adjustment for pediatric patients.

While there is a payment adjustment for home dialysis training sessions, maintenance dialysis treatments rendered in the home setting are paid at the same rate as in-center treatments. The training add-on covers a maximum of 25 sessions of HD training and 15 sessions of PD training. Payment is based on an estimated 1.5 hours of nursing time per training session and an average hourly wage taken from national Bureau of Labor statistics data on wages for RNs. The wage data is adjusted for geographic differences using the wage index.

There has been only modest growth in the use of home dialysis modalities since the beginning of the ESRD PPS. Claims data indicated that use of home treatment (all modalities) has increased only from 9.3% in 2011 to 11.7% in 2018. Home dialysis treatment is not used equally among patients of differing demographic characteristics. Home dialysis patients tend to be younger than those receiving treatment in-facility. Among home dialysis patients a larger proportion are white, and a smaller proportion are black compared to in-facility patients. Slightly more home patients are rural residents compared to in-facility patients. Finally home dialysis patients are less likely to be dually eligible for Medicare and Medicaid as compared to in-facility dialysis patients.

8.1.2 Stakeholder Input on Home Dialysis Costs

Home dialysis providers and other stakeholders maintain that home dialysis costs differ significantly from in-facility treatment costs. Each home dialysis patient requires a separate dialysis machine that can only be used by one patient at a time. This stands in contrast to in-center dialysis, where a single machine is used by multiple patients.

Home dialysis requires highly skilled nursing support. In many cases, registered nurses are required to attend to home dialysis patients. RNs from dialysis facilities require additional training before being able to work in the home setting. Currently, costs of this training are not reimbursed.

Costs for home dialysis have continued to rise in recent years. Stakeholders attributed cost increases to higher costs for supplies, equipment and water treatment. They also cite limited competition among suppliers, as providers of supplies consolidate or leave the market.

Logistical challenges also prevent a higher rate of facility uptake of home treatment, limiting economies of scale. Limited resources at the facility level may force facilities to choose between offering a home dialysis program and other priorities, such as active oversight of the transplant wait list.

8.1.3 Results of Cost Data Analysis: Charges

Analysis of charge data from 72x claims suggests that per treatment costs are higher for in-facility hemodialysis (HD) than for in-home HD or peritoneal (PD) treatment. (While home hemodialysis (HD) is generally reported as being accomplished in 3 dialysis sessions per week, similarly to in-facility HD, and is paid accordingly, peritoneal dialysis (PD) is most often furnished daily, and payments are adjusted so that one PD session is reimbursed as the equivalent of 3/7 of an HD session.) However, home HD training, PD training and in-center PD treatment charge data indicate that each of these modalities is more costly than in-facility HD and home HD and PD treatment. In the cases of home HD training, PD training and in-facility PD treatment, there is also considerably more variation in charges than that reported for in-facility HD, home HD and home PD treatment.

8.1.4 Results of Cost Data Analysis: Cost Reports

Previous analysis of home dialysis costs using cost report data also yielded inconclusive results.[4] Facilities that made greater use of PD (mostly administered in the home setting) had lower per-treatment costs, while those with proportionately higher use of home HD had higher per treatment costs.

The inconsistency between stakeholder claims of higher home dialysis costs and results from analysis of existing cost report and claims data raise issues about the accuracy of those data sources in collecting true costs of home dialysis treatment.

The full spectrum of dialysis treatments is not reported in sufficient detail on the cost report to differentiate facilities' expenses for home dialysis treatment from in-facility treatment. This is especially true with regard to capital expenses for dialysis machines and other equipment used in the direct rendering of a dialysis treatment. It is also true with regard to labor costs. There is no means of differentiating the use of labor time by type of staff (e.g., RNs) for home treatment versus in-facility treatment.

Component costs are allocated among each modality using rules that may be outmoded and do not address key questions regarding the costs of home dialysis. For example, capital costs are allocated based on square footage and treatment counts and are not further adjusted for home dialysis treatments. Machine costs are based on fraction of time used and not relevant to the home setting without adjustment. Staff salaries and benefits are allocated based on hours of work. And drug, laboratory, and supply costs are based on acquisition costs. It is not clear whether facilities are uniform in allocating these costs across modality by treatment number or

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

whether the costs reported for each component reflect the true costs as expended for treatments rendered in each modality.

Current cost reports leave unanswered key questions about the relative costs of capital equipment as they apply to the home dialysis setting.

- What are the separate purchase or leasing prices paid for home dialysis machines? For machines used in-facility?
- Does depreciation differ between machines used in each type of setting?
- Do manufacturers provide an expected lifetime for each type of machine?
- Does the cost of ancillary equipment or supplies (i.e., supplies used to support the dialysis treatment) differ for in-home versus in-facility treatments?
- What equipment, if any, can be reused for other patients?
- How do home HD equipment costs vary from those for home PD?

Cost reports also do not adequately capture the costs of labor as they apply to the home dialysis setting. Unanswered questions include:

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

8.1.5 Suggested Changes to Cost Reports

Changes to cost reports and claims to better differentiate costs related to home dialysis have been recommended by Acumen. Implementing these changes would provide needed detail on the relative capital costs for home versus in-facility treatment.

With regard to the reporting of capital costs, Acumen recommended that the costs of dialysis machines and dialysis support equipment used in the home setting be clearly differentiated from those used in facility. Specifically, Acumen suggested that the number and type of machines be listed as they are used for each modality and that home use equipment be further differentiated between HD and PD. Furthermore, the costs of rented equipment should be

differentiated from purchases, and depreciation amounts should be tracked for each machine in each modality.

Selected changes to the cost reports (and cost report instructions) were recommended to better identify the costs of labor, drugs, and supply costs as they pertain to the home dialysis setting. These changes include:

- Provide explicit instructions regarding the hours of effort to include in the allocation of salaries to routine or maintenance home dialysis care. Use an alternative metric (e.g., number of nursing or medical technician visits) that is easier to track than hours. Delineate the number of visits made by staff of various occupations (e.g., RNs, medical technicians, etc.)
- Use a separate metric to allocate drug and supply costs for home dialysis use, if current charge information reflects supplier's pricing rather than true costs incurred by the facility
- Improve cost report instructions for reporting of in-facility back-up sessions for home dialysis patients

8.2 Summary of Discussion

Discussion began with some questions about the reporting of charges for home dialysis sessions. Panelists indicated that the way charges were recorded for home dialysis sessions were dependent on the MACs and how many such sessions they would reimburse. Some panelists maintained that MACs would not pay if more than three HD-equivalent sessions per week were reported, regardless of whether these were HD or PD sessions.[5] Panelists further contended that because of this practice, claims and cost reports do not reflect true costs for home dialysis treatment. Panelists also encouraged Acumen to look more closely at charges for training versus maintenance sessions in the home setting.

Some panelists maintained that the costs for capital equipment and for labor for home dialysis treatment were standardized by reporting requirements. Currently, the cost report instructions specify that facilities are to allocate these costs according to square footage, which panelists acknowledged may be an inappropriate metric for the home setting. They maintained that the home dialysis setting is best understood as a standalone unit for cost appropriating purposes. Panelists cautioned not to draw too many conclusions from currently available cost report data.

[5] Post TEP analysis revealed that most home HD patients have more than three weekly sessions billed.

Panelists also pointed out that while equipment for home PD patients is always rented, home HD machines are always purchased. Typically, the machines are depreciated over a seven-year period.

Another panelist opined that it is difficult for the industry to allocate costs by modality. This is because units of equipment and staff (specifically nurses) work across modalities, e.g., CAPD to CCPD.

Panelists generally agreed that home HD costs were far more expensive than home PD costs. Travel costs are seen as significant contributors to overall costs for home HD, while training costs were believed to be underestimated at 1.5 nursing hours per home training session. Supplies shipped to home dialysis patients often go unused, contributing to excessive costs.

High training costs for nurses who provide home dialysis support was cited as a driver of cost. Providers maintained that two to three months of dedicated training was required.

Panelists noted that another hidden driver of costs for facilities offering a home dialysis program is the need to maintain open chairs in the facility for home patients who cannot dialyze at home.

Some panelists mentioned hidden costs that were not captured currently in the cost report. These included services such as internet, shipping, and remote assist devices. Acumen suggested that these costs could be incorporated into various cost components on the cost report, with revisions to the instructions.

Panelists maintained that facilities lost money on home HD, but they continue to offer it because of physician and patient preferences.

8.3 Key Findings

- Panelists contended that charges on claims do not reflect the true costs of home dialysis, in large part due to not reporting all sessions since some MACs do not cover treatments in excess of three a week
- Panelists maintained that cost reports do not accurately reflect the costs of providing home dialysis
- Panelists emphasized that providing home HD is significantly more expensive than providing home PD, partly due to having to purchase equipment for home HD but renting equipment for home PD

9 NEXT STEPS

Acumen continues its efforts to evaluate and recommend to CMS options for refining the case-mix model for the ESRD PPS. This was the second TEP in a series focused on this topic. The presentation of two articulated methodologies to achieve a single, simplified case adjustment payment model was the highlighted feature of this TEP. The option preferred by the TEP, which involves collection of duration of treatment data for each dialysis session, will be further pursued and put forth to CMS as a suggested change to claims. Panelist input on the other topics covered during the TEP will also be incorporated into proposed methodological refinements. The Recommendations and Next Steps that will guide Acumen's work through 2020 include:

- Continuation of efforts to develop a simplified, single-equation case-mix adjustment payment model for the ESRD PPS, including accommodation for the costs unique to pediatric dialysis patients
- Refinement of the alternative methodology for the LVPA based on geographic regions with low demand for dialysis services to address panelists' concerns
- Evaluation of the potential incorporation of calcimimetic costs into the CY2021 ESRD PPS base rate will examine modifications to the current cost report to support detailed reporting of these costs
- Continued development of a new outlier methodology that addresses panelists' concerns regarding net outflow of ESRD PPS funds
- Consideration of specific quality of life measures to be added to TPNIES eligibility criteria
- Evaluation of options for potential inclusion of capital-related dialysis equipment in TPNIES
- Further development of recommended changes to claims and cost reports to better reflect the true costs of home dialysis treatment

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

Comments on this report may be sent to ESRD-PPS-TEP-Support@acumenllc.com. Please include the topic of your email in the subject line (e.g., elaboration of options presented and discussed during the TEP or novel approaches for improving the reporting of patient-level and facility-level costs). Acumen also welcomes input related to potential topics for future ESRD PPS TEPs. Stakeholder comments will aid CMS in making decisions about inputs to the developing model and potential changes to reporting. CMS has not endorsed any method or option at this time.