



## Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

### Brief Measure Information

**NQF #: 2705**

**De.2. Measure Title:** Delivered Dose of Dialysis Above Minimum

**Co.1.1. Measure Steward:** Centers for Medicare & Medicaid Services

**De.3. Brief Description of Measure:** Percentage of patient months for adult ( $\geq 18$ ) and pediatric ( $< 18$ ) patients in which the delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified target during the reporting period.

**1b.1. Developer Rationale:** Published studies indicate there is an association between low spKt/V (HD) and increased mortality. Furthermore, the 2006 KDOQI Hemodialysis Adequacy Guidelines indicate 'minimally adequate dose of HD given 3 times per week to patients with  $K_r$  less than 2 mL/min/1.73 m<sup>2</sup> should be a spKt/V of 1.2 per dialysis. In considering target spKt/V, the pediatric HD population should receive at least a spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children.

Evaluation of PD adequacy every four months for adults is critical to ensure timely dose adjustment as needed, and adequate dialysis doses ( $K_t/V_{urea} > 1.7$  for adult patients and  $K_t/V_{urea} > 1.8$  for pediatric patients) have been linked to improved patient outcomes. Therefore, this measure is needed to ensure frequent adequacy measurement and adequate dialysis dosing. Studies have shown a  $K_t/V$  of 1.8/week or greater in adult PD patients was associated with better serum albumin levels[1] and improved survival [2]. The ADEMEX did not show clinical benefit with in weekly  $K_t/V$  doses exceeding 1.7/week in adult CAPD patients [1].

Pediatric PD adequacy targets should be no lower than existing adult PD adequacy targets since generally, pediatric patients' greater metabolic demands require higher adequacy targets in terms of small solute clearance. No equivalent large scale clinical trials have been conducted in the pediatric peritoneal dialysis population but smaller scale observational studies support the association between delivered peritoneal dialysis dose and patient outcomes including the potential for improved growth [3].

Rationale for  $K_t/V$  Combined Measures (including #2705)

CMS submitted four individual dialysis adequacy measures for NQF maintenance or new endorsement (#0249, #1423, #0318, #2706). 0249 and 0318 have been endorsed since 2008, 1423 since 2011, while 2706 is a new pediatric PD adequacy measure. In conjunction with these individual adult and pediatric measures, CMS also submitted three measures (#2703, #2704, #2705) that are comprised of the constituent individual HD and PD adult and pediatric measures, as described in the documentation and at the in-person Steering Committee meeting May 6 -7. These seven measures assess dialysis adequacy based on the respective  $K_t/V$  thresholds which are based on clinical guidelines, published research, and TEP recommendations as provided in the evidence submission:

- For hemodialysis patients, all ages (0249, 1423, 2703):  $spKt/V > 1.2$  (calculated from the last measurement of the month)
- For pediatric (age  $< 18$  years) peritoneal dialysis patients:  $K_t/V_{urea} > 1.8$  (dialytic + residual, measured within the past six months)
- For adult (age  $\geq 18$  years) peritoneal dialysis patients:  $K_t/V_{urea} > 1.7$  (dialytic + residual, measured within the past four months)

The primary rationale for the combined measures is to make more facilities eligible for public reporting of these metrics by meeting the  $>11$  eligible patients restriction. For public reporting on Dialysis Facility Compare (DFC) and the ESRD Quality Incentive Program (QIP), a facility has to treat at least 11 qualifying patients for each measure in order to receive a score on that measure. The 11 patient requirement is anchored in HHS policy, related to small cell sizes to protect identification of patients and release of protected health information. An additional reason is the need for sufficient data to achieve reliability of a measure calculation for  $<11$  patients. We recognize there is no published evidence describing use of the combined subpopulation and modality measures.

However, each component measure has strong evidence support from literature and each also reflects consensus guideline recommendations. Combining these established consensus measures to counter an unintended consequence of the application of federal protected health information regulations should not require additional scientific justification beyond what already exists.

In the case of dialysis adequacy, CMS found that a significant number of facilities that have <11 PD patients, or <11 pediatric patients would be included in the new combined measures but excluded from the individual measure, leading to the systematic exclusion of these facilities from assessment on these measures because of the reporting requirements.

To account for this, CMS proposed the three new measures that assess dialysis adequacy by modality that includes both adult and pediatric populations (#2703, #2704), and an overall measure of all adult and pediatric hemodialysis and peritoneal dialysis patients (#2705). CMS also seeks maintenance endorsement of the individual measures previously endorsed, based on the same level of evidence presented for those measures. It is CMS's intention to eventually retire the individual measures once the combined measures are endorsed and implemented.

1. Paniagua R, Amato D, Vonesh E, et al. "Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial." Journal of the American Society of Nephrology: JASN (2002) 13:1307-20. PMID: 11961019.
2. Lo WK, Lui SL, Chan TM, et al. "Minimal and optimal peritoneal Kt/V targets: Results of an anuric peritoneal dialysis patient's survival analysis." Kidney international (2005) 67:2032-8. PMID: 15840054.
3. Rees L, Feather S, Shroff R. "Peritoneal Dialysis Clinical Practice Guidelines for Children and Adolescents." British Association of Pediatric Nephrology (2008).

**S.4. Numerator Statement:** Number of patient months from the denominator in which the delivered dose of dialysis met the specified target. The targets are as follows:

Hemodialysis (adult and pediatric):  $\text{spKt/V} \geq 1.2$  (calculated from the last measurement of the month using UKM or Daugirdas II)

Peritoneal dialysis (pediatric <18 years):  $\text{weekly Kt/Vurea} \geq 1.8$  (dialytic + residual, measured within the past 6 months)

Peritoneal dialysis (adult  $\geq 18$  years):  $\text{weekly Kt/Vurea} \geq 1.7$  (dialytic + residual, measured within the past 4 months)

**S.7. Denominator Statement:** To be included in the denominator for a particular month, patients need to meet the following requirements:

1) Hemodialysis patients: Patients must be on hemodialysis for the entire month, must have had ESRD for greater than 90 days at the beginning of the month, must be dialyzing thrice weekly, and must be assigned to the facility for the entire month.

In addition, pediatric patients must be dialyzing in-center.

2) Peritoneal dialysis patients: Patients must be on peritoneal dialysis for the entire month, and have had ESRD for greater than 90 days at the beginning of the month. In addition, patients must be assigned to the facility for the entire month.

**S.10. Denominator Exclusions:** Exclusions that are implicit in the denominator definition include

- 1) Adult and pediatric hemodialysis patients not on thrice weekly dialysis
- 2) Pediatric home hemodialysis patients
- 3) All patients who have had ESRD for <91 days at the beginning of the month
- 4) All patients who were not assigned to the facility for the entire month

There are no other exclusions for this measure.

**De.1. Measure Type:** Outcome

**S.23. Data Source:** Administrative claims, Electronic Clinical Data

**S.26. Level of Analysis:** Facility

**IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:**

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

**De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?**

## 1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. **Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.**

### 1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form 2705Evidence\_revised.docx

#### 1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

#### 1b.1. Briefly explain the rationale for this measure (e.g., the benefits or improvements in quality envisioned by use of this measure)

Published studies indicate there is an association between low spKt/V (HD) and increased mortality. Furthermore, the 2006 KDOQI Hemodialysis Adequacy Guidelines indicate 'minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73 m<sup>2</sup> should be a spKt/V of 1.2 per dialysis. In considering target spKt/V, the pediatric HD population should receive at least a spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children.

Evaluation of PD adequacy every four months for adults is critical to ensure timely dose adjustment as needed, and adequate dialysis doses (Kt/Vurea > 1.7 for adult patients and Kt/Vurea > 1.8 for pediatric patients) have been linked to improved patient outcomes. Therefore, this measure is needed to ensure frequent adequacy measurement and adequate dialysis dosing. Studies have shown a Kt/V of 1.8/week or greater in adult PD patients was associated with better serum albumin levels[1] and improved survival [2]. The ADEMEX did not show clinical benefit with in weekly Kt/V doses exceeding 1.7/week in adult CAPD patients [1].

Pediatric PD adequacy targets should be no lower than existing adult PD adequacy targets since generally, pediatric patients' greater metabolic demands require higher adequacy targets in terms of small solute clearance. No equivalent large scale clinical trials have been conducted in the pediatric peritoneal dialysis population but smaller scale observational studies support the association between delivered peritoneal dialysis dose and patient outcomes including the potential for improved growth [3].

#### Rationale for Kt/V Combined Measures (including #2705)

CMS submitted four individual dialysis adequacy measures for NQF maintenance or new endorsement (#0249, #1423, #0318, #2706). 0249 and 0318 have been endorsed since 2008, 1423 since 2011, while 2706 is a new pediatric PD adequacy measure. In conjunction with these individual adult and pediatric measures, CMS also submitted three measures (#2703, #2704, #2705) that are comprised of the constituent individual HD and PD adult and pediatric measures, as described in the documentation and at the in-person Steering Committee meeting May 6 -7. These seven measures assess dialysis adequacy based on the respective Kt/V thresholds which are based on clinical guidelines, published research, and TEP recommendations as provided in the evidence submission:

- For hemodialysis patients, all ages (0249, 1423, 2703): spKt/V > 1.2 (calculated from the last measurement of the month)
- For pediatric (age < 18 years) peritoneal dialysis patients: Kt/Vurea > 1.8 (dialytic + residual, measured within the past six months)
- For adult (age >= 18 years) peritoneal dialysis patients: Kt/Vurea > 1.7 (dialytic + residual, measured within the past four months)

The primary rationale for the combined measures is to make more facilities eligible for public reporting of these metrics by meeting the >11 eligible patients restriction. For public reporting on Dialysis Facility Compare (DFC) and the ESRD Quality Incentive Program

(QIP), a facility has to treat at least 11 qualifying patients for each measure in order to receive a score on that measure. The 11 patient requirement is anchored in HHS policy, related to small cell sizes to protect identification of patients and release of protected health information. An additional reason is the need for sufficient data to achieve reliability of a measure calculation for <11 patients. We recognize there is no published evidence describing use of the combined subpopulation and modality measures. However, each component measure has strong evidence support from literature and each also reflects consensus guideline recommendations. Combining these established consensus measures to counter an unintended consequence of the application of federal protected health information regulations should not require additional scientific justification beyond what already exists.

In the case of dialysis adequacy, CMS found that a significant number of facilities that have <11 PD patients, or <11 pediatric patients would be included in the new combined measures but excluded from the individual measure, leading to the systematic exclusion of these facilities from assessment on these measures because of the reporting requirements.

To account for this, CMS proposed the three new measures that assess dialysis adequacy by modality that includes both adult and pediatric populations (#2703, #2704), and an overall measure of all adult and pediatric hemodialysis and peritoneal dialysis patients (#2705). CMS also seeks maintenance endorsement of the individual measures previously endorsed, based on the same level of evidence presented for those measures. It is CMS's intention to eventually retire the individual measures once the combined measures are endorsed and implemented.

1. Paniagua R, Amato D, Vonesh E, et al. "Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial." *Journal of the American Society of Nephrology: JASN* (2002) 13:1307-20. PMID: 11961019.
2. Lo WK, Lui SL, Chan TM, et al. "Minimal and optimal peritoneal Kt/V targets: Results of an anuric peritoneal dialysis patient's survival analysis." *Kidney international* (2005) 67:2032-8. PMID: 15840054.
3. Rees L, Feather S, Shroff R. "Peritoneal Dialysis Clinical Practice Guidelines for Children and Adolescents." *British Association of Pediatric Nephrology* (2008).

**1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.** *(This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

Based on January 2013 – December 2013 CROWNWeb and Medicare claims data there were 5818 facilities with at least eleven eligible patients. The mean performance score was 91.1%, with a standard deviation of 9.5%. Distribution: Min=1.2%, Max=100.0%. These results indicate that on average, facilities are meeting the Kt/Vurea targets in 90% of their patients. A description of the data is included in questions 1.1-1.7 under "Scientific Acceptability".

**1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.**

N/A

**1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.** *(This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

Disparity analyses were performed among the entire eligible adult and pediatric population (n=413,239) to examine the difference in performance scores by sex, race, ethnicity, and age.

In particular, for each facility, the percent of patient-months by demographic group (sex, race, ethnicity, age) was calculated. Then, the facilities were divided into quintiles (Q1-Q5) based on the percentage of patient-months in the particular demographic category (i.e., a facility with percentage of females similar to the national median will be included in quintile 3). The top 20% of facilities in terms of rank, based on the percentages of females, were classified as Q5, while the bottom 20% of facilities were classified as Q1. Average (mean) performance for the measure was calculated for each quintile, and the means were examined for trend across quintiles (Q1-Q5). The Cochran-Armitage test for trend was performed to assess disparities in performance scores. All the results for

each group across quintiles were statistically significant ( $p < 0.0001$ ), which imply that there are statistically significant changes in performance scores depending on facility level quintile by population group for sex, race, ethnicity, and age. While these differences appear to be statistically significant, we did not determine that they are clinically significant. In the absence of biological effects explaining these differences, risk adjustment for these factors would potentially mask disparities in care.

The mean performance scores for percent of patient-months with a Kt/v measurement in each quintile, by demographic group, are presented below. Males, non-Black, non-White, non-Hispanic, Age 18-64, are the respective reference categories.

Facility Level Quintiles by Population Group (Quintile 1-5):

Females (Q1=90.9%, Q2=91.1%, Q3=91.2%, Q4=91.1%, Q5=91.0%,  $P < 0.0001$ )

Black (Q1=91.9%, Q2=90.9%, Q3=90.6%, Q4=90.5%, Q5=91.5%,  $P < 0.0001$ )

White (Q1=91.0%, Q2=90.6%, Q3=90.7%, Q4=90.9%, Q5=92.2%,  $P < 0.0001$ )

Hispanic (Q1=91.8%, Q2=91.4%, Q3=91.2%, Q4=90.2%, Q5=90.7%,  $P < 0.0001$ )

Age 65+ (Q1=88.0%, Q2=90.7%, Q3=91.4%, Q4=92.3%, Q5=93.0%,  $P < 0.0001$ )

Note: \*Statistics for Age<18 group are not shown because most facilities have 0 pediatric patients

**1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.**

N/A

**1c. High Priority** (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

**1c.1. Demonstrated high priority aspect of healthcare**

Affects large numbers, High resource use

**1c.2. If Other:**

**1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare.**

List citations in 1c.4.

Hemodialysis:

The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes [1,2]. In addition, at least one prior study demonstrates that a change in dialysis dose is associated with a change in patient outcome [3]. Furthermore, studies demonstrate an association between dialysis adequacy as measured by Kt/V and outcomes [4,5,6].

No equivalent large scale clinical trials have been conducted in the pediatric population but smaller scale observational studies support the association between delivered dialysis dose and patient outcomes [10] including the potential for improved growth with intensive hemodialysis regimens [11].

Since endorsement of this measure, published literature suggests there is insufficient evidence that compares methods of dialysis adequacy measurement, particularly measures that demonstrate superiority of alternative measures over spKt/V. It should also be noted that there have been no changes in the KDOQI Clinical Practice Guideline for Methods for Measuring and Expressing Hemodialysis Dose (CPG 2). Indeed, as stated in the KDOQI 2006 update, 'The delivered Kt/V determined by single-pool urea kinetic modeling continues to be preferred as the most precise and accurate measure of dialysis.' (p.12, KDOQI 2006 Update).

Currently, frequent hemodialysis (more than thrice weekly) is still rare, with approximately 1% of dialysis patients receiving this modality. As this population grows and the evidence base for alternative adequacy measurement methods grows, the use of stdKt/V, in particular should be evaluated by a Clinical Technical Expert Panel (CTEP), including a target measure because of the potential for a growing percentage of patients being dialyzed more than thrice weekly and where spKt/V is not comparable across treatment schedules.

Additional considerations for future expert review of the use of spKt/V measure relates to women and smaller patients. Recent studies that examine dialysis dosing in women and smaller patients should be considered [7,8]. In addition, because prior studies that evaluate the impact of hemodialysis dose on mortality have used spKt/V as the measure of hemodialysis adequacy, alternative methods of adequacy measurement should also be considered. Finally, recent clinical studies suggest the benefit of using online measurement methods for assessing ionic clearance, and these tools should be considered in the future [9].

#### Peritoneal dialysis:

On December 31, 2012, nearly 402,514 ESRD patients were receiving hemodialysis therapy, 40,605 were being treated with peritoneal dialysis. (USRDS 2014 ADR). KDOQI and European guidelines have set minimum standards for periodic assessment of peritoneal dialysis adequacy (KDOQI 2006; EBPG 2005; Lo 2006). Both peritoneal clearance and residual renal function (RRF) need to be assessed. Both guidelines and studies have emphasized the importance of total clearance. The one-year adjusted all-cause hospitalization rates from 2002–2006 to 2007–2011 in all children on renal replacement therapy rose 9.4 percent from 1,413 to 1,546 admissions per 1,000 patient years. In evaluating each modality the one-year adjusted all-cause hospitalization rates rose as follows: hemodialysis by 17.2 percent, peritoneal dialysis by 7.8 percent, and transplant by 9.4 percent between 2002–2006 and 2007–2011. In examining the rates of hospitalization by age, we find that the hospitalization rates were highest in those aged 0-4 years during both time periods. Despite significantly higher rates of hospitalization, children 0-4 years of age were the only age group that showed an improvement in hospitalization rates from 2002-2006 to 2007-2011 (USRDS 2014). Improved quality of dialysis care in this fragile patient group may help improve hospitalization rates, especially since no quality measures currently exist for pediatric PD patients. In the adult population, outcome studies have shown an association between dose of peritoneal dialysis and clinical outcomes (Lo 2006, Paniagua 2002).

#### **1c.4. Citations for data demonstrating high priority provided in 1a.3**

##### Hemodialysis:

1. Lowrie EG, et al. Effect of the hemodialysis prescription of patient morbidity: report from the National Cooperative Dialysis Study. *N Engl J Med* 305:1176–1181, 1981.
2. Owen WF Jr, et al. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. *N Engl J Med* 329:1001–1006, 1993.
3. Wolfe RA, Hulbert-Shearon TE, Ashby VB, Mahavadevan S, Port FK: Improvements in dialysis patient mortality are associated with Urea Reduction Ratio and Hematocrit, 1999 to 2002. *Am J Kidney Dis* 45(1):127-135, 2005.
4. Wolfe RA, Ashby VB, Daugirdas JT, Agodoa LY, Jones CA, Port FK: Body size, dose of hemodialysis, and mortality. *Am J Kidney Dis* 35:80-88, 2000.
5. Port FK, Ashby VB, Dhingra RK, Roys EC, Wolfe RA: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. *J Am Soc Nephrol* 13:1061-1066, 2002.
6. Port FK, Wolfe RA, Hulbert-Shearon TE, McCullough KP, Ashby VB, Held PJ: High dialysis dose is associated with lower mortality among women but not among men. *Am J Kidney Dis* 43:1014-1023, 2004.
7. Daugirdas JT, Greene T, Chertow GM, et al. Can Rescaling Dose of Dialysis to Body Surface Area in the HEMO Study Explain the Different Responses to Dose in Women versus Men? *Clin J Am Soc Nephrol*. 2010 Sep;5(9):1628-36.
8. Daugirdas JT, Hanna MG, Becker-Cohen R, et al. Dose of dialysis based on body surface area is markedly less in younger children than in older adolescents. *Clin J Am Soc Nephrol*. 2010 May;5(5):821-7.
9. Lowrie EG, Li Z, Ofsthun NJ, et al. Evaluating a new method to judge dialysis treatment using online measurements of ionic clearance. *Kidney Int*. 2006 Jul;70(1):211-7.
10. Gorman G, et al. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. *Am Journal Kidney Dis*; 47: 285-93, 2006.
11. Fischbach M, et al. Intensified and daily hemodialysis in children might improve statural growth. *Pediatr Nephrol* 21:1746–1752, 2006.

##### Peritoneal dialysis:

1. U.S. Renal Data System, USRDS 2014 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.
2. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. *Am J Kidney Dis* 48:S1-S322, 2006 (suppl 1).
3. European Best Practice Guidelines for Peritoneal Dialysis. Adequacy of peritoneal dialysis. *Nephrol Dial Transplant* 2005; 20 [Suppl 9]: ix24–ix27
4. Lo WK, Bargman JM, Burkart J, et al. Guideline on targets for solute and fluid removal in adult patients on chronic peritoneal



dialysis. Perit Dial Int 2006;26:520–522.

5. Paniagua R, Amato D, Vonesh E, et al. “Effects of increased peritoneal clearances on mortality rates in peritoneal dialysis: ADEMEX, a prospective, randomized, controlled trial.” Journal of the American Society of Nephrology: JASN (2002) 13:1307-20. PMID: 11961019

**1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)**

N/A

## 2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

**De.5. Subject/Topic Area** (check all the areas that apply):

Renal, Renal : End Stage Renal Disease (ESRD)

**De.6. Cross Cutting Areas** (check all the areas that apply):

**S.1. Measure-specific Web Page** (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

**S.2a. If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

**Attachment:**

**S.2b. Data Dictionary, Code Table, or Value Sets** (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

**Attachment:**

**S.3. For endorsement maintenance**, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

N/A

**S.4. Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Number of patient months from the denominator in which the delivered dose of dialysis met the specified target. The targets are as follows:

Hemodialysis (adult and pediatric): spKt/V  $\geq$  1.2 (calculated from the last measurement of the month using UKM or Daugirdas II)

Peritoneal dialysis (pediatric <18 years): weekly Kt/Vurea  $\geq$  1.8 (dialytic + residual, measured within the past 6 months)

Peritoneal dialysis (adult  $\geq$  18 years): weekly Kt/Vurea  $\geq$  1.7 (dialytic + residual, measured within the past 4 months)

**S.5. Time Period for Data** (What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)

The entire calendar month

**S.6. Numerator Details** (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Months where the Kt/V value met the specified target are counted in the numerator. Eligible Kt/V values are:

Hemodialysis (adult and pediatric):  $\text{spKt/V} \geq 1.2$

Adult peritoneal dialysis patients: weekly Kt/Vurea  $\geq 1.7$  (dialytic + residual)

Pediatric peritoneal dialysis patients: weekly Kt/Vurea  $\geq 1.8$  (dialytic + residual)

For adult and pediatric hemodialysis patients, the last spKt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month.

For adult peritoneal dialysis patients, if no weekly Kt/Vurea value is reported for a given patient in a reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 3 months is applied to the calculation for that reporting month.

For pediatric peritoneal dialysis patients, if no weekly Kt/Vurea value is reported for a given patient in a reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 5 months is applied to the calculation for that reporting month.

Missing, expired, and not performed are not counted as achieving the minimum Kt/V threshold.

**S.7. Denominator Statement** (Brief, narrative description of the target population being measured)

To be included in the denominator for a particular month, patients need to meet the following requirements:

1) Hemodialysis patients: Patients must be on hemodialysis for the entire month, must have had ESRD for greater than 90 days at the beginning of the month, must be dialyzing thrice weekly, and must be assigned to the facility for the entire month.

In addition, pediatric patients must be dialyzing in-center.

2) Peritoneal dialysis patients: Patients must be on peritoneal dialysis for the entire month, and have had ESRD for greater than 90 days at the beginning of the month. In addition, patients must be assigned to the facility for the entire month.

**S.8. Target Population Category** (Check all the populations for which the measure is specified and tested if any):

Populations at Risk

**S.9. Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN) and the Social Security Death Master File.

To be included in the denominator for a particular month, patients need to meet the following requirements:



1) Hemodialysis patients: Patients must be on hemodialysis for the entire month, must have had ESRD for greater than 90 days at the beginning of the month, must be dialyzing thrice weekly, and must be assigned to the facility for the entire month.

In addition, pediatric patients must be dialyzing in-center.

2) Peritoneal dialysis patients: Patients must be on peritoneal dialysis for the entire month, and have had ESRD for greater than 90 days at the beginning of the month. In addition, patients must be assigned to the facility for the entire month.

**S.10. Denominator Exclusions** (Brief narrative description of exclusions from the target population)

Exclusions that are implicit in the denominator definition include

- 1) Adult and pediatric hemodialysis patients not on thrice weekly dialysis
- 2) Pediatric home hemodialysis patients
- 3) All patients who have had ESRD for <91 days at the beginning of the month
- 4) All patients who were not assigned to the facility for the entire month

There are no other exclusions for this measure.

**S.11. Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

N/A

**S.12. Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)

N/A

**S.13. Risk Adjustment Type** (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)

No risk adjustment or risk stratification

If other:

**S.14. Identify the statistical risk model method and variables** (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)

N/A

**S.15. Detailed risk model specifications** (must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)

Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.

**S.15a. Detailed risk model specifications** (if not provided in excel or csv file at S.2b)

N/A

**S.16. Type of score:**

Rate/proportion

If other:

**S.17. Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Higher score

**S.18. Calculation Algorithm/Measure Logic** *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*

Patient months included in the denominator:

Adult hemodialysis:

- Patient modality is indicated as hemodialysis during the entire month (in-center or home)
- Patient is on thrice weekly dialysis during the month
- Patient age as of the beginning of the reporting month is at least 18 years
- Patient has had ESRD for greater than 90 days at the beginning of the month
- Patient has been assigned to the facility for the entire month

Pediatric hemodialysis:

- Patient modality is indicated as hemodialysis during the entire month (in-center)
- Patient is on thrice weekly dialysis during the month
- Patient age as of the beginning of the reporting month is less than 18 years
- Patient has had ESRD for greater than 90 days at the beginning of the month
- Patient has been assigned to the facility for the entire month

Adult peritoneal dialysis:

- Patient modality is indicated as peritoneal dialysis during the entire month
- Patient age as of the beginning of the reporting month is at least 18 years
- Patient has had ESRD for greater than 90 days at the beginning of the month
- Patient has been assigned to the facility for the entire month

Pediatric peritoneal dialysis:

- Patient modality is indicated as peritoneal dialysis during the entire month
- Patient age as of the beginning of the reporting month is less than 18 years
- Patient has had ESRD for greater than 90 days at the beginning of the month
- Patient has been assigned to the facility for the entire month

Numerator: For the reporting month, patient months from the denominator are also included in the numerator if they meet the following criteria:

Adult and pediatric hemodialysis patients:  $\text{spKt/V} \geq 1.2$  (using either Daugirdas II or UKM).

Adult peritoneal patients: weekly Kt/vurea  $\geq 1.7$  (dialytic + residual, calculated within the past 4 months)

For adult peritoneal dialysis patients, if no weekly Kt/Vurea value is reported for a given patient in a reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 3 months is applied to the calculation for that reporting month.

Pediatric peritoneal dialysis patients: weekly Kt/vurea  $\geq 1.8$  (dialytic + residual, calculated within the past 6 months)

For pediatric peritoneal dialysis patients, if no weekly Kt/Vurea value is reported for a given patient in a reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 5 months is applied to the calculation for that reporting month.

For all patients, the last Kt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month.

**S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment** *(You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No diagram provided

**S.20. Sampling** *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF a PRO-PM, identify whether (and how) proxy responses are allowed.

N/A

**S.21. Survey/Patient-reported data** (If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)

IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

N/A

**S.22. Missing data** (specify how missing data are handled, e.g., imputation, delete case.)

Required for Composites and PRO-PMs.

Patients with missing Kt/V values are not excluded from the measure. Therefore, patients for whom a Kt/V value is missing for the month are still included in the denominator. This is designed to ensure that facilities will still be evaluated for the measure.

**S.23. Data Source** (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.24.

Administrative claims, Electronic Clinical Data

**S.24. Data Source or Collection Instrument** (Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)

IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.

For the analyses supporting this submission, the measure is calculated using CROWNWeb as the primary data source. If a patient's data are missing in CROWNWeb, Medicare claims are used

**S.25. Data Source or Collection Instrument** (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No data collection instrument provided

**S.26. Level of Analysis** (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

Facility

**S.27. Care Setting** (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Dialysis Facility

If other:

**S.28. COMPOSITE Performance Measure** - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

N/A

**2a. Reliability** – See attached Measure Testing Submission Form

**2b. Validity** – See attached Measure Testing Submission Form

2705Testing\_revised.docx

### 3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

#### 3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

##### 3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

#### 3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

**3b.1. To what extent are the specified data elements available electronically in defined fields?** (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)

ALL data elements are in defined fields in a combination of electronic sources

**3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.**

**3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.**

Attachment:

### 3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

**3c.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.**

**IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.**

N/A

**3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).**

N/A

## 4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

### 4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

#### 4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Planned	Current Use (for current use provide URL)
Public Reporting	
Payment Program	

**4a.1. For each CURRENT use, checked above, provide:**

- Name of program and sponsor
- Purpose

- Geographic area and number and percentage of accountable entities and patients included

N/A

**4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

The measure is a combination of the individual adult and pediatric HD and PD Kt/V measures; 3 of these measures are NQF endorsed and have been publically reported or are proposed for public reporting.

**4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

CMS will ultimately decide if/when this measure is reported.

#### 4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

**4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)**

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

N/A

**4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.**

N/A

#### 4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

**4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.**

N/A

### 5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

#### 5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

##### 5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0249 : Delivered Dose of Hemodialysis Above Minimum

0318 : Delivered Dose of Peritoneal Dialysis Above Minimum

0321 : Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute  
0323 : Adult Kidney Disease: Hemodialysis Adequacy: Solute  
1423 : Minimum spKt/V for Pediatric Hemodialysis Patients

**5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.**

Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V - CMS

**5a. Harmonization**

The measure specifications are harmonized with related measures;

**OR**

The differences in specifications are justified

**5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**

**Are the measure specifications completely harmonized?**

No

**5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.**

Yes, the measure is harmonized with 0249, 0318, 1423, and the pediatric PD Kt/V measures. They all have the corresponding thresholds (numerator) and corresponding denominator populations. In the last maintenance cycle in 2011, 0318 was harmonized with 0321. Since then 0318 has been revised. The measure is not harmonized with 0321 and 0323 as this proposed measure does not count missing values in the numerator, in order to prevent gaming of the measure.

**5b. Competing Measures**

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

**OR**

Multiple measures are justified.

**5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):**

**Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)**

It is anticipated that this proposed measure will allow for assessment of a larger population given that it applies to both adult and pediatric patients, and both HD and PD modality. Missing values are not counted in the numerator, in order to prevent gaming of the measure.

**Appendix**

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

No appendix Attachment:

**Contact Information**

**Co.1 Measure Steward (Intellectual Property Owner):** Centers for Medicare & Medicaid Services

**Co.2 Point of Contact:** Helen, Dollar-Maples, [Helen.Dollar-Maples@cms.hhs.gov](mailto:Helen.Dollar-Maples@cms.hhs.gov), 410-786-7214-

**Co.3 Measure Developer if different from Measure Steward:** University of Michigan Kidney Epidemiology and Cost Center

**Co.4 Point of Contact:** Casey, Parrotte, [parrotte@med.umich.edu](mailto:parrotte@med.umich.edu)

**Additional Information**

**Ad.1 Workgroup/Expert Panel involved in measure development**

**Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role**



in measure development.

**Measure Developer/Steward Updates and Ongoing Maintenance**

**Ad.2** Year the measure was first released: 2015

**Ad.3** Month and Year of most recent revision: 02, 2015

**Ad.4** What is your frequency for review/update of this measure?

**Ad.5** When is the next scheduled review/update for this measure? 02, 2016

**Ad.6** Copyright statement:

**Ad.7** Disclaimers:

**Ad.8** Additional Information/Comments: July 2015:

Based on the discussion that took place at the NQF Steering Committee meeting, CMS has made the following revisions to the measure submission:

- This measure includes evaluation of the pediatric hemodialysis population. The specifications pertaining to measuring Kt/V in the hemodialysis pediatric population were revised in response to concerns from the NQF Steering Committee regarding the appropriateness of single pool Kt/V for measuring Kt/V in patients who are dialyzing 3 or 4 times per week. See detail under release notes for NQF 1423. Additionally it is also made more explicit that the adult component is also limited to patients on 3 times per week dialysis.
- The upper threshold for Kt/V values has been removed from the specifications.
- The specifications were edited to provide more clear descriptions of the numerator, denominator, exclusions, and calculation algorithm with respect to the constituent base measures included in this combined measure (NQF 0249, NQF 0318, NQF 1423, and NQF 2706 pertaining to the adult hemodialysis, adult peritoneal dialysis, pediatric hemodialysis, and pediatric peritoneal dialysis populations). These calculation clarifications are not material changes with respect to the documentation that the committee reviewed in May.
- The evidence form was revised to include the abstracts for the evidence listed in 1a.8.2.