

Measure Information Form

General Characteristics

<b>Measure ID:</b>	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
<b>Measure Name:</b>	ESRD- HD Adequacy CPM II: Method of Measurement of Delivered Hemodialysis Dose.
<b>Measure Description:</b>	Percentage of all adult ( $\geq 18$ years old) in-center HD patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.

**CMS contact:**

Thomas Dudley, MS, RN

**Consumer Care Need**

- Living With Illness

**Quality Domain**

- Effectiveness

**Type of Measure**

- Process

**Body System:**

Kidney/urinary tract  
ESRD

Variable Characteristics

**Measure Care Setting**

- Ambulatory Care
- Dialysis Facility

**Unit of Measurement**

- Facility
- Other:  
Stratified by ESRD Network

**Consensus Endorsement Status**

- NQF (National Quality Forum)

**Consensus Endorsement Process Status**

- Endorsed  
**Endorsed Status Date**  
November 15, 2007

## Technical Specifications

### Target Population

#### Age

##### Lower limit

- 18

##### Lower Span

-Years

#### Gender

- Both Males and Females

#### Anchor Date

NA

#### Effective Date

- 4/1/08- Please see Phase III ESRD Clinical Performance Measures (link below):

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDPhaseIIICPM04012008Final.pdf>

#### Effective date basis

NA

#### Payer Source

- Medicare

#### Measure result reported as

- Positive

#### Current Alignment with CMS

NA

#### CHI Compliant

- Yes

#### Method of Data collection

- Electronic supplemented by medical record review

#### Numerator statement

Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified

#### Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

#### Numerator Time Window

Three month time period. Data collected for this ESRD CPM is for the three month time period (Oct-Dec) for the in-center hemodialysis patients. However, facilities implementing this measure may choose any time period.

#### Denominator statement

All adult ( $\geq 18$  years old) in-center HD patients in the sample for analyses.

**Data source**

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

**Denominator Time Window**

Three months

**Exclusion Criteria**

None

**Data source**

NA

**Exclusion Criteria Time Window**

NA

**History****Measure Status**

- Implemented/approved by CMS

**Measure Developer**

- CMS  
Contractor: Arbor Research/UM-KECC

**Intellectual property status**

- Public Domain

**Measure Source**

- Adapted - No changes were made to the original measure

**CMS Final Approval Date**

- 4/1/08

**CMS Implementation Use**

- ESRD Disease Management
- ESRD Network Program
- Other  
Quality Improvement and Public Reporting

**Attachments****The Measure Justification is a required attachment**

Depending on the measure contract (development/maintenance/reevaluation) and, if the measure is risk adjusted, some of the listed Measures Management System forms may be required:

- Risk Adjustment
- Ad Hoc Measure Reevaluation
- Measure Maintenance Reevaluation
- Comprehensive Measure Reevaluation

Other attachments

Comments:

## Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	ESRD- HD Adequacy CPM II: Method of Measurement of Delivered Hemodialysis Dose.
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	February 1, 2009
Date of Last Review	November 15, 2007

### Section I: Importance/Relevance

***Epidemiological relevance, Financial relevance, Policy relevance:***

***Epidemiological relevance***

At the end of 2003 there were 298,101 patients treated with hemodialysis in the US, which accounts for 92% of all dialysis patients. During that year 93,276 patients started ESRD therapy with hemodialysis (USRDS 2005 ADR).

At the end of 2004 there were 321,539 patients being dialyzed of which 104,056 were new (incident) ESRD patients.

***Financial relevance***

At the end of 2003, total Medicare costs for the ESRD program were \$18.1 billion, an increase of 7.2 percent over costs in 2002. A portion of this increase is due to a 4% increase in the number of hemodialysis patients in from 2002 to 2003. The majority of this cost is for hemodialysis patients accounting for nearly 63,000 per person per year for Medicare (USRDS 2005 ADR)

At the end of 2004, total Medicare costs for the ESRD program were \$20 billion. This represents approximately 8% of the total Medicare annual budget.

***Policy relevance***

In 1998, CMS developed ESRD Clinical Performance Measures (CPMs) based on the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines, in response to the Balanced Budget Act of 1997. Sixteen CPMs were developed to measure and report the quality of dialysis services provided under Medicare, three of them in the areas of adequacy of hemodialysis and others dealing with peritoneal dialysis, anemia management, and vascular access management. Section 4558 (b) of the Balanced Budget Act (BBA) requires CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, CMS decided to fund the development of CPMs based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines. KDOQI Guidelines have recently been updated for hemodialysis adequacy.

## Section 2: Scientific Soundness

### Explicit evidence base:

Complete one literature citation for each guideline or study on which the measure is based, stating level of evidence and rating scheme used. A suggested format is below; another format may be used.

#### Literature citation for clinical guideline

Author Last Name/Organization: National Kidney Foundation (NKF)  
Author First Name:  
Title of Chapter or Article: NKF-K/DOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2006.  
Title of Book or Journal: American Journal of Kidney Disease  
Publication Date: July 2006  
Journal Volume and Number: 48 (1 Suppl 1)  
Pages: S17  
Web link: [http://www.kidney.org/Professionals/kdoqi/guideline\\_upHD\\_PD\\_VA/index.htm](http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm)  
Level of Evidence and Rating Scheme: A

#### Literature citation for supporting evidence/study

Author Last Name/Organization: Daugirdas JT  
Author First Name:  
Title of Chapter or Article: Second generation logarithmic estimates of single-pool variable volume Kt/V: An analysis of error.  
Title of Book or Journal: Journal of the American Society of Nephrology  
Publication Date: 1993  
Journal Volume and Number: 4  
Pages: 1205-1213  
Web link: [www.jasn.org](http://www.jasn.org)  
Level of Evidence and Rating Scheme: A

Author Last Name/Organization: Depner TA  
Author First Name:  
Title of Chapter or Article: Equations for normalized protein catabolic rate based on two-point modeling of Hemodialysis urea kinetics.  
Title of Book or Journal: Journal of the American Society of Nephrology  
Publication Date: 1996  
Journal Volume and Number: 7  
Pages: 780-785  
Web link: [www.jasn.org](http://www.jasn.org)  
Level of Evidence and Rating Scheme: A

## **Other aspects of scientific soundness:**

### ***Reliability, Validity, and Adequacy of risk adjustment:***

Please see below link for the Reliability Report

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf>

*Appendix B*

***Please see the following reports on the validity of the CPM data.***

*Appendix D* - "Relationship Between CPM's and Outcomes Among Patients Receiving Long-Term Hemodialysis

*Appendix E* – "Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Centers for Medicare & Medicaid Services and The Renal Network Inc.

### ***Adequacy of risk adjustment***

Risk adjustment is not applicable for this measure.

## **Section 3: Usability/Actionability**

***Provides actionable decision support, Message is clear to recipient, Operational relevance***

*Please see below link for the Annual Report.*

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006AnnualReport.pdf>

*Appendix C*

## **Section 4: Feasibility**

***Specifications are well-defined, Reasonable burden of data collection, Minimum distortion***

Administrative and Medical Record data is used.

There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.

### ***Approximate time for data collection,***

FOR ALL MEASURES TOTAL IN THE ESRD DIALYSIS FACILITY MEASURES SET: Approximately 30 minutes for data abstraction, less if the patient's medical record has not been sent to offsite storage. This is the time estimate if all of the data elements are manually abstracted. However, for those facilities that are owned by Large Dialysis Organizations (LDO's), a majority of the data elements are submitted electronically from the LDO's corporate database to CMS. Only a few if any elements are abstracted manually by facility staff, so their time for data abstraction is reduced considerably.

CMS is in the process of implementing a web-based data collection system called **CrownWeb** for the measures; however, at this time CMS has not assessed the cost and administrative burden of using CrownWeb by dialysis facilities. CrownWeb is scheduled to be implemented early 2009.

## Comprehensive Reevaluation

<i>Measure ID</i>	<b>(Auto-generated when entered into QMIS)</b>
<b>Measure Set:</b>	Hemodialysis Adequacy
<b>Measure Name</b> <i>(should be brief, concise):</i>	ESRD- HD Adequacy CPM II: Method of Measurement of Delivered Hemodialysis Dose.
<b>Measure Description:</b>	Percentage of all adult (>= 18 years old) in-center HD patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.
<b>CMS GTL/PO:</b>	Thomas Dudley, MS, RN

### Version Changes

**Summarize what has changed in this version?**

No changes

**Date of review** (NQF approval date(s))

November 15, 2007

**I. Summary of Current Performance Data Analysis on Each Measure—(measure data as submitted to NQF).**

74% of patients had their delivered spKt/V calculated using either UKM or the Daugirdas II formula  
Please see page 14 of the 2007 CPM Annual Report for trends in this measure.

**II. Summary of Analysis of the Comments and Questions Received Going into the TEP and during the NQF comment period:**

- A. Importance
- B. Scientific Acceptability
- C. Feasibility
- D. Usability

The workgroup recommended and the committee agreed that home Hemodialysis patients should be included in measures of dialysis adequacy; that six months was too long of an exclusion period; and that for combined outcome/process measures, the outcome component must be scored and reported and plan of care further specified. The workgroup recommended and the committee agreed that a plan for inadequate hemodialysis should address at least the dialysis prescription, vascular access, and justification of a lower Kt/V based on residual renal function.

The committee also discussed that if a measure contained a process component for a plan of care for patients who do not achieve the outcome value, exclusions were not needed. Measures were recommended only on the condition that the measures were revised to address these issues.

### **III. Environmental scan to identify relevant scientific or other information published since the last time the measure was evaluated.**

Document all relevant publications found, with a clear indication of:

- A. The type of information
- B. The level of evidence
- C. The relevant Web address (if the article is accessible via the Web)
- D. A brief synopsis of the information and its relevance to the Comprehensive Reevaluation
  - Example #1 (for new guidelines): “ACC HF guidelines now consider ARBs to be equivalent to ACEIs.”
  - Example #2 (for a study on antibiotics): “Study shows increase in inappropriate use of antibiotics in ER patients since measure was implemented.”

#### **List of Publications is as follows:**

1. Fernandez EA, Valtuille R, Presedo JM, Willshaw P., Comparison of different methods for hemodialysis evaluation by means of ROC curves: from artificial intelligence to current methods. *Clinical Nephrology*. 2005 Sep; 64(3):205-13.
2. Stuart L. Goldstein, Andrew Brem, Bradley A. Warady, Barbara Fivush, Diane Frankenfield, Comparison of single-pool and equilibrated Kt/V values for pediatric hemodialysis prescription management: analysis from the Centers for Medicare & Medicaid Services Clinical Performance Measures Project, *Pediatric Nephrology* (2006) 21: 1161–1166
3. Tanja Hojs-Fabjan and Radovan Hojs, Polyneuropathy in hemodialysis patients: The most sensitive electrophysiological parameters and dialysis adequacy *Wien Klin Wochenschr* (2006) 118 [Suppl 2]: 29–34
4. Korohoda P, Pietrzyk JA, Miklaszewska M, Komorowska M, Rumian R, Drozd D, Krawentek L, Zachwieja K., Does daily hemodialysis influence urea kinetic modeling (UKM) coefficients?--Preliminary report], *Przegl Lek*. 2006; 63 Suppl 3:194-7.
5. John K. Leypoldt, Bertrand L. Jaber and Deborah L. Zimmerman, Predicting Treatment Dose for Novel Therapies Using Urea Standard Kt/V, *Seminars in Dialysis-Vol 17, No 2 (March–April) 2004* pp. 142–145
6. Sridhar Nagaraja Rao, Hurst, Carolyn, Hayes, Patrick, Tandem Dialyzers With Two Monitors to Meet Target KT/V, *Dialysis & Kinetics ASAIO Journal* 2005
7. Robert A. Wolfe, Tempie E. Hulbert-Shearon, Valarie B. Ashby, Sangeetha Mahadevan, and Friedrich K. Port, Improvements in Dialysis Patient Mortality Are Associated With Improvements in Urea Reduction Ratio and Hematocrit, 1999 to 2002, *American Journal of Kidney Diseases*, Vol 45, No 1 (January), 2005: pp 127–135

### Literature citation for clinical guideline

Author Last Name/Organization: National Kidney Foundation (NKF)  
Author First Name:  
Title of Chapter or Article: NKF-K/DOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2006.  
Title of Book or Journal: American Journal of Kidney Disease  
Publication Date: July 2006  
Journal Volume and Number: 48 (1 Suppl 1)  
Pages: S17  
Web link: [http://www.kidney.org/Professionals/kdoqi/guideline\\_upHD\\_PD\\_VA/index.htm](http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm)  
Level of Evidence and Rating Scheme: A

### Literature citation for supporting evidence/study

Author Last Name/Organization: Daugirdas JT  
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Title of Book or Journal: Journal of the American Society of Nephrology  
Publication Date: 1993  
Journal Volume and Number: 4  
Pages: 1205-1213  
Web link: [www.jasn.org](http://www.jasn.org)  
Level of Evidence and Rating Scheme: A

Author Last Name/Organization: Depner TA  
Author First Name:  
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Title of Book or Journal: Journal of the American Society of Nephrology  
Publication Date: 1996  
Journal Volume and Number: 7  
Pages: 780-785  
Web link: [www.jasn.org](http://www.jasn.org)  
**Level of Evidence and Rating Scheme: A**

**IV. A technical expert panel was convened:**  Yes  No

If yes, date(s) of the meeting(s):

**Clinical-TEP:** September 18-19, 2006

**Data-TEP:** October 11-12, 2006

Briefly summarize the TEP recommendations here.

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDTEPFinalReport05212008.pdf>

### **C-TEP: (Overview of recommendations)**

*Current CPM II*

#### **Method of Measurement of delivered HD Dose**

The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modelling (UKM) or the Daugirdas II formula for spKt/V.

**Numerator:**

Number of patients in the denominator for whom delivered HD dose was calculated using formal UKM or Daugirdas II during study period

**Denominator:**

All adult (>18 years old) HD patients in the sample for analysis

*Proposed Revised CPMII*

**The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modelling (UKM) or the Daugirdas II formula for spKt/V.**

**Numerator:**

Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified

**Denominator:**

All HD patients in the sample for analysis

**Exclusions:**

None

**Recommended Revisions to the Current CPMs from C-TEP**

**CPM II: Method of Measurement of HD Dose**

- Include all patients in the calculation of this CPM and not limit it only to adult patients.
- This measure should include patients on hemodialysis *31 days or longer*

**D-TEP :**

*CPM II:* Method of measurement of the delivered hemodialysis dose.

Current CPM II: The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula for spKt/v.

Comments:

**There were no proposed changes to this CPM. The consensus of the D-TEP was to accept the C-TEP's recommendation.**

**V. If any of the codes used in the technical specifications have changed since the last measure update or comprehensive reevaluation, specify the change(s) with an explanation of its impact on the measure.**

NA

**VI. If material<sup>1</sup> changes to the measure have occurred — i.e., wording, data elements, time periods, abstraction instructions, etc. – document them here. If material changes were made to the measure, was the measure tested?**

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<sup>1</sup> A **material change** is one that changes the intended meaning of the measure or the strength of the measure in terms of measure evaluation criteria. NQF's process for an ad hoc expedited review will be triggered at any point when the measure developer make material changes to the measure construct (including the numerator, denominator, and exclusions) or measure logic. The timing of the ad hoc review will depend on whether there is an accompanying safety concern. If changes to the measure are deemed appropriate:

- Would a change in the measure result in statistical discontinuity from the current measurement baseline?
- Would a change in the measure significantly impact current processes and the burden for data collection, analysis, and reporting?
- Would the proposed change unintentionally result in the modification of a current clinical or administrative practice?

Yes     No

Measure Contractor Recommended Disposition				
Measure contractor recommended disposition of the measure	<input type="checkbox"/> Retain			
				Effective Date of Action
	<input checked="" type="checkbox"/> Revise (as described above)			
	<input type="checkbox"/> Replace			
	<input type="checkbox"/> Rotate			
<input type="checkbox"/> Retire				
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date	<input type="checkbox"/> Other:
Recommended by	Name: Date:			

CMS Role	
CMS decision for measure disposition	<input type="checkbox"/> Retain
	Effective Date of Action
	<input type="checkbox"/> Revise
	<input type="checkbox"/> Replace
<input type="checkbox"/> Approved as recommended.	<input type="checkbox"/> Rotate
	<input type="checkbox"/> Retire
Comments about decision	
Approved by	Name: Date: