



NATIONAL QUALITY FORUM

**National Voluntary
Consensus Standards
for End Stage
Renal Disease Care**

A
CONSENSUS
REPORT

NATIONAL QUALITY FORUM

Foreword

Nearly half a million American lives have been altered by a diagnosis of end stage renal disease (ESRD), a serious condition that is almost always fatal unless treated with dialysis or transplantation. ESRD is the only disease-specific condition that is explicitly guaranteed Medicare coverage, with Medicare costs for the condition totaling approximately \$20 billion in 2004. Because the overwhelming majority of ESRD care in the United States is supported by Medicare, the Centers for Medicare & Medicaid Services (CMS), together with many other healthcare stakeholders, has been concerned about the improvement of the quality of ESRD care since the CMS ESRD program's inception in 1972.

This report presents 25 standardized performance measures for ESRD care in the areas of anemia; dialysis adequacy; mineral metabolism; vascular access; influenza immunization; mortality; and patient education, perception of care, and quality of life.

These measures will facilitate efforts to improve the quality of care delivered to ESRD patients in all care settings, including dialysis facilities, in-home settings, physician offices, and hospitals, and they can be used by consumers, providers, federal and private purchasers, and researchers, among others. They have been carefully vetted through the National Quality Forum's (NQF's) Consensus Development Process, bestowing on them special legal status as voluntary consensus standards.

We thank CMS for its support of this project. We also thank NQF Members and the ESRD Care Steering Committee and Steering Committee Workgroups for their stewardship of this work and for their dedication to improving the quality of ESRD care.



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National Voluntary Consensus Standards for End Stage Renal Disease Care

Table of Contents

Executive Summary.....	v
Introduction.....	1
National Voluntary Consensus Standards for End Stage Renal Disease Care.....	2
Identifying the Set.....	3
Purpose.....	3
Framework for Quality Measurement.....	3
Scope.....	4
Priority Areas for Measurement and Reporting.....	4
Identification of Candidate Consensus Standards.....	4
Selection Criteria.....	4
Box A. Criteria for Evaluation and Selection.....	5
National Voluntary Consensus Standards for ESRD Care.....	7
Table 1. National Voluntary Consensus Standards for End Stage Renal Disease Care.....	7
Research Recommendations.....	12
Research Recommendation 1: General.....	12
Research Recommendation 2: Topics Related to the Consensus Standards Reviewed.....	12
Research Recommendation 3: Gaps in Quality Measures for ESRD Care.....	13
Relationship to Other NQF-Endorsed Consensus Standards.....	13
Acknowledgment.....	14

(continued)

Appendix A – Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care	A-1
Appendix B – Steering Committee, Steering Committee Workgroups, and Project Staff	B-1
Appendix C – Commentary	C-1
Appendix D – Selected References	D-1
Appendix E – Consensus Development Process: Summary	E-1

NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for End Stage Renal Disease Care

Executive Summary

End stage renal disease (ESRD)—which occurs when the kidneys are no longer able to function at a level necessary for daily life—is a serious condition that affects the lives of nearly half a million Americans. Almost always fatal unless treated with dialysis or transplantation, ESRD is the only disease-specific condition for which Medicare explicitly guarantees coverage, even to those patients under the age of 65. The annual cost to Medicare is approximately \$20 billion.

The quality of care provided to ESRD patients is of concern to many healthcare stakeholders, particularly consumers and the federal government, which, through Medicare, pays for the overwhelming majority of ESRD care in the United States. Medicare has been interested in improving the quality of ESRD care since the inception of its ESRD program in 1972.

This report is the result of a National Quality Forum (NQF) project to identify, evaluate, and endorse the “best-in-class” performance measures for the reporting of ESRD care quality. The 25 measures and recommendations identified in this report were vetted through NQF’s Consensus Development Process, comporting with the National Technology Transfer and Advancement Act, and thus bestowing upon them and their specifications the special legal status as voluntary consensus standards. NQF-endorsed[®] consensus standards are the standards of choice of federal purchasers, quality oversight organizations, and others.

These consensus standards represent an initial set of quality measures for ESRD care and are suitable for public reporting. They can be used by dialysis facilities and

by the variety of personnel who provide care in that setting, individual physicians, and consumers and purchasers.

National Voluntary Consensus Standards for End Stage Renal Disease Care

- **Anemia**

- Assessment of iron stores

- Monitoring hemoglobin levels below target minimum

- **Dialysis Adequacy (hemodialysis and peritoneal)**

- Hemodialysis adequacy Clinical Performance Measure I: hemodialysis adequacy—monthly measurement of delivered dose

- Hemodialysis adequacy Clinical Performance Measure II: method of measurement of delivered hemodialysis dose

- Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose

- Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose

- Hemodialysis adequacy/plan of care

- Peritoneal dialysis adequacy—measurement of total solute clearance at regular intervals

- Peritoneal dialysis adequacy—calculate weekly KT/Vurea in the standard way

- Peritoneal dialysis adequacy—delivered dose of peritoneal dialysis above minimum

- Peritoneal dialysis adequacy/plan of care

- **Mineral Metabolism**

- Measurement of serum calcium concentration

- Measurement of serum phosphorus concentration

- **Vascular Access**

- Hemodialysis vascular access—minimizing use of catheters as chronic dialysis access

- Hemodialysis vascular access—maximizing placement of arterial venous fistula

- Vascular access: functional AV fistula access or seen by vascular surgeon for placement

- Vascular access: catheter vascular access and seen by vascular surgeon for evaluation for permanent access

- Hemodialysis vascular access—decisionmaking by surgeon to maximize placement of autogenous arterial venous fistula

- **Influenza Vaccination**

- Influenza immunization

- Influenza vaccination in the ESRD population—facilities

- **Mortality**

- Dialysis facility risk-adjusted standardized mortality ratio

- **Patient Education, Perception of Care, Quality of Life**

- Patient education awareness—facilities

- Patient education awareness—physician

- Assessment of Health-Related Quality of Life (Physical & Mental Functioning)

- CAHPS® In-Center Hemodialysis Survey

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National Voluntary Consensus Standards for End Stage Renal Disease Care

Introduction

End stage renal disease (ESRD) – which occurs when the kidneys are no longer able to function at a level necessary for daily life – is a serious condition that alters the lives of nearly half a million Americans. Almost always fatal unless treated with dialysis or transplantation, ESRD is the only disease-specific condition for which Medicare explicitly guarantees coverage even to those patients under the age of 65.¹

As of December 31, 2004, there were 472,099 patients suffering from ESRD in the United States, with 335,963 of these patients receiving dialysis therapy.² The annual adjusted mortality rate of prevalent ESRD patients receiving dialysis was 207 per 1,000 patient years, and the adjusted average number of hospitalizations per year for dialysis patients was 2.02, with an average total of 14.5 days per year. Total Medicare costs for ESRD were approximately \$20 billion in 2004.³

The quality of care provided to ESRD patients is of concern to many healthcare stakeholders, particularly consumers and the federal government, which, through Medicare, pays for the overwhelming majority of ESRD care in the United States. Medicare has been interested in improving the quality of ESRD care since the inception of its ESRD

¹The Social Security Act was amended in 1972 to extend Medicare coverage to patients with ESRD who require dialysis or kidney transplantation to survive.

²U.S. Renal Data System, *USRDS 2006 Annual Data Report: Atlas of End-Stage Renal Disease in the United States*. Bethesda, MD: NIDDKD; 2006. Mortality data–Table H.4; hospital data - Tables G.2 and G.7. Available at www.usrds.org. Last accessed March 2007.

³Ibid.

program in 1972. The Balanced Budget Act of 1997 required the Centers for Medicare & Medicaid Services (CMS) to develop and implement a method to measure and report the quality of renal dialysis services provided under Medicare, and CMS funded the development of Clinical Performance Measures based on the National Kidney Foundation's Dialysis Outcomes Quality Initiative Clinical Practice Guidelines. In January 2001, CMS launched the Dialysis Facility Compare public reporting tool to provide information on 9 facility characteristics and 3 quality measures for more than 3,500 U.S. dialysis facilities.⁴ Accordingly, ESRD is an appropriate condition for measurement and public reporting of nationally vetted, stakeholder-endorsed standards.

National Voluntary Consensus Standards for End Stage Renal Disease Care

This report presents a set of 25 national voluntary consensus standards endorsed by the National Quality Forum (NQF) for ESRD care in the following topic areas:

- anemia;
- dialysis adequacy (hemodialysis and peritoneal);
- mineral metabolism;
- vascular access;
- influenza immunization;
- mortality; and
- patient education, perception of care, and quality of life.

These consensus standards, which represent an initial set of quality measures for ESRD care, were endorsed under the NQF Consensus Development Process (Appendix E) and can be used by dialysis facilities and the variety of personnel who provide care in that setting, individual physicians, and consumers and purchasers. Gaps in performance measures in ESRD care are identified in the recommendations provided later in this report.

⁴See www.medicare.gov.

Identifying the Set

An NQF Steering Committee (Appendix B) established the initial approach to evaluating potential consensus standards. This approach included defining a specific purpose and scope for the performance measures and screening candidate measures through the application of standardized NQF-endorsed[®] measure evaluation criteria (Box A). For this project, *end stage renal disease* is defined as a complete or near complete failure of the kidneys to function to excrete wastes, concentrate urine, and regulate electrolytes.⁵

The purpose, framework, and scope for the measure set help identify what should be measured regarding ESRD care as well as allow for the identification of gaps in the measure set and areas for future development. The endorsed measure set does not address all of the indicated areas for quality measurement because of limitations in available measures, and the gaps are addressed in the research recommendations.

Purpose

This project was undertaken at the behest of CMS with the guiding objective of producing “a set of consensus standards relevant to the care of patients with ESRD who require dialysis or kidney transplantation for the purposes of public reporting and quality improvement.” With this in mind, this set of voluntary consensus standards for ESRD care can be used to:

- evaluate the performance of ESRD care in the United States as it relates to the aims for healthcare quality (safety, effectiveness, patient-centeredness, timeliness, efficiency, equity);
- improve ESRD care (e.g., patient safety, healthcare outcomes, patient satisfaction);
- serve as a mechanism for public accountability, including the selection and incentive-based rewarding of high-performing providers by supplying stakeholders with information that will enable them to better understand the quality of ESRD care;
- identify priority areas for needed research related to ESRD care performance; and
- facilitate the benchmarking and sharing of best practices among ESRD care providers.

Framework for Quality Measurement

The ESRD measures can be categorized by:

- type of measure (structure, process, outcome);
- renal replacement therapy options (hemodialysis, peritoneal dialysis, kidney transplant, no treatment);
- stage of treatment (initiation and ongoing); and
- the healthcare aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.

⁵National Library of Medicine. MedlinePlus. See www.nlm.nih.gov/medlineplus/ency/article/000500.htm.

Scope

The ESRD performance measure set should encompass measures that:

- are fully open source;⁶
- are structure, process, outcome, or patient experience measures;
- apply to renal replacement therapy—kidney dialysis (hemodialysis and peritoneal dialysis) and/or kidney transplantation;
- apply to new ESRD patients (incident) and/or ongoing ESRD patients (prevalent);
- apply to physicians, facilities, and/or other levels of aggregation (e.g., system, health plan);
- apply to all settings where ESRD care is provided (e.g., dialysis facilities, in-home dialysis, physician offices, hospitals); and
- reflect those aspects of care over which healthcare providers have control or influence, but not necessarily total control.

Priority Areas for Measurement and Reporting

Priorities for the ESRD care performance measure set include the following:

- measures that address the aims of safety, effectiveness, patient-centeredness, and timeliness, and, if possible, efficiency and equity;
- measures that are in common, widespread use and/or that are required for other purposes;

- at least some measures that apply to all ESRD care providers;
- at least some cross-cutting measures that apply to all ESRD patients;
- measures that can be stratified by race/ethnicity to identify disparities in care;
- measures that can be used at varying levels of aggregation (rather than separate measures for each level)—that is, patient based versus provider based; and
- measures that address process and outcome components separately (either separate measures or the ability to disaggregate combination measures).

Identification of Candidate Consensus Standards

Candidate consensus standards were identified through several complementary strategies. Measures were solicited through NQF's "Call for Measures" process. Steering Committee members also suggested measures for consideration.

Selection Criteria

The endorsed consensus standards are intended for use at various levels of analysis, including at dialysis facilities and by individual practitioners. However, they also are appropriate for physician groups and larger healthcare systems.

In addition to the framework, scope, priorities, and evaluation criteria, the following principles also guided the selection of consensus standards:

⁶On January 29, 2003, the NQF Board of Directors adopted a policy that NQF will endorse only fully open source measures.

- The focus of the measures is primarily accountability as a driver of quality improvement.
- In the interest of standardization and minimizing the burden of data collection, only one out of a group of duplicative measures with similar numerator and denominator specifications should be recommended as a consensus standard.
- To facilitate comparisons and aggregation at various levels, measures should be harmonized to the extent possible. The first level of harmonization involves having identical definitions of terms, numerator statements, denominator statements, and exclusions.
- Ideally, if applicable for different settings, a measure should apply to all levels of analysis with potential differences in data collection indicated by setting. If different measures are developed by setting, they should have the same definition of terms, denominator population and exclusions, risk adjustment or stratification method, numerator statement, time window, and, when possible, data collection method. Sometimes identical measures are not necessary for different settings, and the measures for different settings should be complementary and compatible.

Box A—Criteria for Evaluation and Selection⁷

Proposed measures were evaluated for their suitability based on four sets of standardized criteria (e.g., importance, scientific acceptability, usability, and feasibility). Not all acceptable measures will be strong—or equally strong—among each of the four sets of criteria, or strong among each of their related criteria. Rather, a candidate measure was assessed regarding the extent to which it meets any of the desired criteria within each set:

1. **Importance.** This set addresses the extent to which a measure reflects a variation in quality, low levels of overall performance, and the extent to which it captures key aspects of the flow of care.
 - a. The measure addresses one or more key leverage points for improving quality.
 - b. Considerable variation in the quality of care exists.
 - c. Performance in the area (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.
2. **Scientific acceptability.** A measure is scientifically sound if it produces consistent and credible results when implemented.
 - a. The measure is well defined and precisely specified. Measures must be specified sufficiently to be distinguishable from other measures, and they must be implemented consistently across institutions. Measure specifications should provide detail about cohort definition, as well as the denominator and numerator for rate-based measures and categories for range-based measures.
 - b. The measure is reliable, producing the same results a high proportion of the time when assessed in the same population.

⁷NQF, *A National Framework for Healthcare Quality Measurement and Reporting: A Consensus Report*, Washington, DC: NQF; 2002; NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.

Box A—Criteria for Evaluation and Selection (continued)

- c. The measure is valid, accurately representing the concept being evaluated.
 - d. The measure is precise, adequately discriminating between real differences in provider performance.
 - e. The measure is adaptable to patient preferences and a variety of contexts of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choices, including refusal of treatment and clinical exceptions.
 - f. An adequate and specified risk-adjustment strategy exists, where applicable.
 - g. Patient outcomes or consistent evidence is available linking the structure and process measures to patient outcomes.
- 3. Usability.** Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decisionmaking.
- a. The measure can be used by the stakeholder to make decisions.
 - b. The differences in performance levels are statistically meaningful.
 - c. The differences in performance are practically and clinically meaningful.
 - d. Risk stratification, risk adjustment, and other forms of recommended analyses can be applied appropriately.
 - e. Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available when needed to make decisions).
 - f. Information produced by the measure can/will be used by at least one healthcare stakeholder audience (e.g., public/consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
 - g. Information about specific conditions for which the measure is appropriate has been given.
 - h. Methods for aggregating the measure with other, related measures (e.g., to create a composite measure) are defined, if those related measures are determined to be more understandable and more useful in decisionmaking. Risks of such aggregation, including misrepresentation, have been evaluated.
- 4. Feasibility.** Feasibility is generally based on the way in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.
- a. The point of data collection is tied to care delivery, when feasible.
 - b. The timing and frequency of measure collection are specified.
 - c. The benefit of measurement is evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
 - d. An auditing strategy is designed and can be implemented.
 - e. Confidentiality concerns are addressed.

National Voluntary Consensus Standards for ESRD Care

The national voluntary consensus standards for ESRD care encompass 25 measures that will facilitate efforts to improve the quality of care delivered to ESRD patients. Table 1 presents brief descriptions of each recommended

measure. The recommended measures are applicable for non-hospitalized ESRD patients on maintenance dialysis. Measures that have not been tested are endorsed for a limited time and are so designated.⁸ Because consensus standards must be precisely specified to meet the goal of standardization, detailed specifications are provided in Appendix A.

Table 1—National Voluntary Consensus Standards for End Stage Renal Disease Care

MEASURE NAME	MEASURE DESCRIPTION	IP OWNER ^a
Anemia		
0252* Assessment of iron stores Level: facility	Percentage of all adult (≥18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHr) are measured at least once in a three-month period for in-center hemodialysis patients, and at least twice during a six-month period for peritoneal dialysis patients and home hemodialysis patients.	CMS
0370 Monitoring hemoglobin levels below target minimum Level: facility Time-limited endorsement ^b	Percentage of all adult (≥18 years old) hemodialysis or peritoneal dialysis patients with ESRD ≥3 months and who had Hb values reported for at least 2 of the 3 study months, who have a mean Hb <10.0 g/dL for a 3 month study period, irrespective of ESA use.	CMS

(more)

*NQF measure number.

^a IP owner – Intellectual Property IP owner. For the most current specifications and supporting information, please refer to the IP owner.

IP OWNERS

AHRQ - Agency for Healthcare Research and Quality (www.ahrq.gov)

CMS - Centers for Medicare & Medicaid Services (www.cms.hhs.gov)

KCQA - Kidney Care Quality Alliance (www.kidneycarepartners.org)

RAND - (www.rand.org; <http://gim.med.ucla.edu/kdqol>)

RPA/PCPI - Renal Physicians Association (www.renalmd.org)/Physician Consortium for Performance Improvement (www.physicianconsortium.org)

SVS - Society for Vascular Surgery (www.svs.vascularweb.org)

^b Measures that require testing may receive time-limited endorsement during which testing must be completed and results submitted to the Consensus Standards Approval Committee for a determination of whether to continue endorsement.

⁸ In May 2007, the NQF Board of Directors approved the concept of a time-limited endorsement for consensus standards that meet the NQF-endorsed evaluation criteria, with the exception of not having been adequately tested.

Table 1—National Voluntary Consensus Standards for End Stage Renal Disease Care

MEASURE NAME	MEASURE DESCRIPTION	IP OWNER ^a
Hemodialysis Adequacy		
0247 Hemodialysis adequacy Clinical Performance Measure I: hemodialysis adequacy—monthly measurement of delivered dose Level: facility	Percentage of all adult (≥ 18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.	CMS
0248 Hemodialysis adequacy Clinical Performance Measure II: method of measurement of delivered hemodialysis dose Level: facility	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.	CMS
0249 Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose Level: facility Sunset when new measure (0250) implemented	Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the study period.	CMS
0250 Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose Level: facility Time-limited endorsement	Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m ² , whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the study period.	CMS
0323 Hemodialysis adequacy/plan of care Level: individual clinician Time-limited endorsement	Percentage of patient calendar months during the 12 month reporting period in which patients aged 18 years and older with a diagnosis of ESRD and receiving hemodialysis have a Kt/V ≥ 1.2 OR patients have a Kt/V < 1.2 with a documented plan of care.	RPA/PCPI

(more)

Table 1—National Voluntary Consensus Standards for End Stage Renal Disease Care

MEASURE NAME	MEASURE DESCRIPTION	IP OWNER ^a
Peritoneal Dialysis Adequacy		
0253 Peritoneal dialysis adequacy—measurement of total solute clearance at regular intervals Level: facility	Percentage of all adult (≥18 years old) peritoneal dialysis patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period.	CMS
0254 Peritoneal dialysis adequacy—calculate weekly KT/Vurea in the standard way Level: facility	Percentage of all adult (≥18 years old) peritoneal dialysis patients who have: <ul style="list-style-type: none"> ■ Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance ■ Residual renal function (unless negligible [<100 mL urine in 24 hours]) is assessed by measuring the renal component of Kt/Vurea and estimating the patient’s glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance ■ Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method or the Haycock method of using actual body weight, during the four month study period. 	CMS
0318 Peritoneal dialysis adequacy—delivered dose of peritoneal dialysis above minimum Level: facility	Percentage of all adult (≥18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	CMS
0321 Peritoneal dialysis adequacy/plan of care Level: individual clinician Time-limited endorsement	Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V ≥1.7 AND patients who have a Kt/V <1.7 with a documented plan of care 3 times a year (every 4 months) during the 12 month reporting period.	RPA/PCPI
Mineral Metabolism		
0261 Measurement of serum calcium concentration Level: facility	Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month.	CMS
0255 Measurement of serum phosphorus concentration Level: facility	Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.	CMS

(more)

Table 1—National Voluntary Consensus Standards for End Stage Renal Disease Care

MEASURE NAME	MEASURE DESCRIPTION	IP OWNER ^a
Vascular Access		
0256 Hemodialysis vascular access—minimizing use of catheters as chronic dialysis access Level: facility	Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.	CMS
0257 Hemodialysis vascular access—maximizing placement of arterial venous fistula Level: facility	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles.	CMS
0251 Vascular access: functional AV fistula access or seen by vascular surgeon for placement Level: individual clinician Time-limited endorsement	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year who have a functional autogenous AV fistula (defined as two needles used) or do not have such a fistula but have been seen by a vascular surgeon for evaluation for permanent access at least once during the reporting year.	KCQA
0262 Vascular access: catheter vascular access and seen by vascular surgeon for evaluation for permanent access Level: individual clinician Time-limited endorsement	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year with a catheter after 90 days on dialysis who are seen by a vascular surgeon for evaluation for permanent access at least once during the 12 month reporting period.	KCQA
0259 Hemodialysis vascular access—decision-making by surgeon to maximize placement of autogenous arterial venous fistula Level: individual clinician Time-limited endorsement	Percentage of patients with advanced chronic disease (CKD4 or 5) or end stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).	SVS

(more)

Table 1—National Voluntary Consensus Standards for End Stage Renal Disease Care

MEASURE NAME	MEASURE DESCRIPTION	IP OWNER ^a
Influenza Immunization		
0227 Influenza immunization Level: individual clinician Time-limited endorsement	Percentage of patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis who received the influenza immunization during the flu season (September through February).	RPA/PCPI
0226 Influenza vaccination in the ESRD population—facilities Level: facility Time-limited endorsement	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis and peritoneal dialysis during the flu season (October 1 - March 31) who receive an influenza vaccination during the October 1 - March 31 reporting period.	KCQA
Mortality		
0369 Dialysis facility risk-adjusted standardized mortality ratio Level: facility	Risk-adjusted standardized mortality ratio for dialysis facility patients.	CMS
Patient Education, Perception of Care, Quality of Life		
0324 Patient education awareness—facilities Level: facility Time-limited endorsement	Percentage of all ESRD patients 18 years and older with documentation regarding a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no treatment). Measured once a year.	KCQA
0320 Patient education awareness—physician Level: individual clinician Time-limited endorsement	Percentage of all ESRD patients 18 years and older with documentation regarding a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no treatment). Measured once a year.	KCQA
0260 Assessment of Health-Related Quality of Life (Physical & Mental Functioning) Level: facility	Percentage of dialysis patients who receive a quality of life assessment using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once per year.	RAND
0258 CAHPS In-Center Hemodialysis Survey Level: facility	57-question survey that assesses patients' experience with In-Center Hemodialysis on 3 domains (Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, and Providing Information to Patients) and provides an overall rating.	AHRQ

Research Recommendations

Recommendations for further research and development of measures were identified to accompany the set of consensus standards.

Research Recommendation 1: General

NQF recommends that additional research be conducted in the following areas:

- inherent patient characteristics that affect achievement of intermediate outcomes for hemoglobin and dialysis adequacy that should be considered for risk adjustment or stratification of scores on outcome measures;
- the relationship between (and implications of) guideline “target values” and achieved values in intermediate outcome performance measures;
- comparability of measure scores across different data collection methods/sources;
- development of “improvement” measures rather than meeting one absolute value for facility-specific measures as a method to reduce the risk for selecting certain patient groups (e.g., improvement in Kt/V from one time point to another rather than $Kt/V \geq 1.2$);
- data items for electronic health records;
- acceptable reliability and validity testing and results;
- efficient data retrieval and audit systems; and
- measure implementation, analysis, and reporting methods.

Research Recommendation 2: Topics Related to the Consensus Standards Reviewed

Research topics related to the ESRD endorsed consensus standards are as follows:

- the optimal value for hemoglobin and the range for which it is possible to maintain the hemoglobin with ESA therapy without exceeding a hemoglobin value of 12;
- ESA safety for ESRD patients with cancer (dosing guidelines needed when both conditions exist simultaneously);
- optimal values of calcium and phosphorus based on randomized trials;
- the effect of improvement in mineral metabolism biomarkers as demonstrated by intervention trials on morbidity and mortality;
- improved risk adjustment of mortality measures;
- the interpretation and effective use of KDQOL-36 scores;
- the association between patient KDQOL-36 scores and social worker staffing ratios;
- the KDQOL-36 scores of in-center hemodialysis versus peritoneal and home hemodialysis patients;
- the applicability of measures to patients less than 18 years of age;
- a better understanding of mortality risks for hemoglobin values >12 and <11 ;
- a two- to three-year time interval for the mortality measure;
- the survival benefit of intravenous iron in dialysis patients;

- a more comprehensive patient education measure that includes self-care and minimum standards for what qualifies as patient education;
 - a quality-of-life outcome measure based on the KDQOL-36 with appropriate risk adjustment;
 - CAHPS used for in-center dialysis patients for home hemodialysis and peritoneal dialysis patients;
 - the impact of the frequency of dialysis treatment on patient outcomes; and
 - the impact of the length and frequency of dialysis treatment on blood pressure control.
- the cost of care and efficiency (and ability to compare by treatment modality);
 - hemodialysis catheter-related infection rates (and ability to compare by treatment modality);
 - hospitalization care coordination—communication between hospital provider and dialysis center;
 - end-of-life care;
 - nursing-specific measures;
 - medication safety;
 - parathyroid hormone testing and optimal values;
 - access to different therapy modalities (home hemodialysis, peritoneal dialysis, in-center hemodialysis); and
 - appropriate peritoneal access for dialysis.

Research Recommendation 3: Gaps in Quality Measures for ESRD Care

It is recommended that gaps in quality measures for ESRD care be explored, including:

- the evaluation of the applicability of NQF-endorsed measures for diabetes, hypertension, coronary artery disease, infections, and perioperative surgical management to ESRD patients and the development of measures as needed;
- the care of patients younger than 18 years of age;
- kidney transplant care;
- access to transplantation (referral, waitlist, and deceased and living donor transplant);

Relationship to Other NQF- Endorsed Consensus Standards

This report does not represent the entire scope of NQF work relevant to the quality of ESRD care. NQF has completed or is currently working on separate projects relevant to various healthcare settings, patient safety issues, and patient conditions, including ESRD. In the “Ambulatory Care” project, NQF has endorsed consensus standards for diabetes⁹ and hypertension¹⁰ that may be relevant to patients with

⁹NQF, *National Voluntary Consensus Standards for Ambulatory Care – Part 1: A Consensus Report*, Washington, DC: NQF; 2008.

¹⁰Ibid.

ESRD. *National Priorities for Healthcare Quality Measurement and Reporting*¹¹ identifies priorities applicable to ESRD care, including those related to kidney disease, the reduction of disparities, and care coordination and communication.

The 2006 update of *Serious Reportable Events in Healthcare* identifies 28 serious adverse events (e.g., patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than intended) that should be reported by all healthcare facilities.¹² Similarly, the 2006 update of *Safe Practices for Better Healthcare* describes 30 safe practices,¹³ such as Standardize the Methods for Packaging, Labeling, and Storing Medications, that should be universally used in applicable

settings to reduce the risk of harm resulting from processes, systems, or environments of care.

The full constellation of NQF-endorsed voluntary consensus standards, including those detailed in this report, together comprise a growing number of stakeholder-vetted standards that directly and indirectly reflect the importance of measuring and improving quality of care in the ESRD setting. Organizations that adopt these consensus standards will promote the development of safer and higher-quality care for patients throughout the nation.

Acknowledgment

This work was conducted under a contract from CMS.

¹¹NQF, *National Priorities for Healthcare Quality Measurement and Reporting: A Consensus Report*, Washington, DC: NQF; 2004.

¹²NQF, *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report*, Washington, DC: NQF; 2007.

¹³NQF, *Safe Practices for Better Healthcare – 2006 Update: A Consensus Report*, Washington, DC: NQF; 2007.

NATIONAL QUALITY FORUM

Appendix A

Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care

The following table presents the detailed specifications for the National Quality Forum (NQF)-endorsed[®] *National Voluntary Consensus Standards for End Stage Renal Disease Care*. All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process) and is current as of September 2008.

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care

ANEMIA					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0252 Assessment of iron stores Level: facility	CMS	Number of dialysis patients in the denominator for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHr) are measured at least once in a three-month period for in-center hemodialysis patients, and at least twice during a six-month period for peritoneal dialysis patients and home hemodialysis patients.	All adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb < 11.0 g/dL in at least one month of the study period. The study period consists of 3 consecutive months for in-center hemodialysis patients, and 6 consecutive months for peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for this calculation.	Acute HD, transient dialysis patients (seen at the specific center for less than 30 days), and kidney transplant patients are excluded from the calculation of this CPM.	Medical record; data collection instrument; administrative claims data.
370 Monitoring hemoglobin levels below target minimum Level: facility Time-limited endorsement	CMS	Adult hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have a mean Hb < 10.0 g/dL for a 3 month study period, irrespective of ESA use. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for the calculation.	All adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients with ESRD ≥ 3 months and who had Hb values reported for at least 2 of the 3 study months.	Patients on dialysis < 3 months at the start of study period, acute HD, transient dialysis patients, home hemodialysis patients, and kidney transplant patients are excluded from the calculation of this CPM.	Medical record; data collection instrument; administrative claims data. <i>(more)</i>

^a IP owner – Intellectual Property owner. For the most current specifications and supporting information, please refer to the IP owner.

IP Owners

AHRQ - Agency for Healthcare Research and Quality (www.ahrq.gov)
 CMS - Centers for Medicare & Medicaid Services (www.cms.hhs.gov)
 KCOA - Kidney Care Quality Alliance (www.kidneycarepartners.org)
 RAND - (www.rand.org); <http://gtm.med.ucla.edu/kdqol>)
 RPA/PCPI - Renal Physicians Association (www.renalmd.org)/Physician Consortium for Performance Improvement (www.physicianconsortium.org)
 SVS - Society for Vascular Surgery (www.svs.vascularweb.org)

Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement[®] (the Consortium), are intended to facilitate quality improvement activities by physicians.

These Measures are intended to assist physicians in enhancing quality of care. Measures are designed for use by any physician who manages the care of a patient for a specific condition or for prevention. These performance Measures are not clinical guidelines and do not establish a standard of medical care. The Consortium has not tested its Measures for all potential applications. The Consortium encourages the testing and evaluation of its Measures. Measures are subject to review and may be revised or rescinded at any time by the Consortium. The Measures may not be altered without the prior written approval of the Consortium. Measures developed by the Consortium, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and American Medical Association, on behalf of the Consortium. Neither the Consortium nor its members shall be responsible for any use of these Measures.

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THE SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

HEMODIALYSIS ADEQUACY					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0247 Hemodialysis adequacy Clinical Performance Measure I: hemodialysis adequacy—monthly measurement of delivered dose Level: facility	CMS	Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.	All adult (≥18 years old) HD patients in the sample for analyses.	None.	Medical record; data collection instrument; administrative claims data.
0248 Hemodialysis adequacy Clinical Performance Measure II: method of measurement of delivered hemodialysis dose Level: facility	CMS	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.	All adult (≥18 years old) in-center HD patients in the sample for analyses.	None.	Medical record; data collection instrument; administrative claims data.
0249 Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose Level: facility Sunset when new measure (0250) is implemented	CMS	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$.	All adult (≥18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly.	Patients on HD less than 6 months.	Medical record; data collection instrument; administrative claims data. <i>(more)</i>

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

HEMODIALYSIS ADEQUACY (continued)					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0250 Hemodialysis adequacy Clinical Performance Measure III: hemodialysis adequacy—minimum delivered hemodialysis dose Level: facility Time-limited endorsement	CMS	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$.	All adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose $RRF < 2$ ml/min/1.73m ² (if measured in the last three months).	Patients on HD less than 90 days. Patients with $RRF > 2$ ml/min/1.73m ² (measured in the last three months).	Medical record; data collection instrument; administrative claims data.
0323 Hemodialysis adequacy/plan of care Level: individual clinician Time-limited endorsement	RPA/PCPI ^f	Number of patient calendar months during which patients have a $Kt/V \geq 1.2$ OR patients have a $Kt/V < 1.2$ with a documented plan of care.* *A documented plan of care may include checking for adequacy of the AV access, increasing the blood flow, increasing the dialyzer size, increasing the time of dialysis sessions, adjusting dialysis prescription, or documenting residual renal function. INSTRUCTIONS: Report Numerator Component #1 (outcome) AND Report Numerator Component #2 (process) AND Report Total Score for Measure. Electronic Collection Electronic data collection requires users to identify the eligible population (denominator) and numerator using electronic data (also referred to as “administrative data”). Users report a rate based on all patients in a given practice for whom	Patient calendar months for all patients aged 18 years and older with a diagnosis of ESRD and receiving hemodialysis. Electronic Collection Electronic data collection requires users to identify the eligible population (denominator) and numerator using electronic data (also referred to as “administrative data”). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria. G codes and patient demographics (age, etc.) are used to determine patients that are included in the measure. ICD 9 code for ESRD diagnosis: 585.6 (end stage renal disease) AND G-codes or CPT I codes for ESRD patients receiving hemodialysis required to identify patients for denominator inclusion:	None.	Administrative claims data; CPT II/G Coding; medical record; electronic health record; pharmacy data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

HEMODIALYSIS ADEQUACY (continued)					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
<p>0323 Hemodialysis adequacy/plan of care</p> <p>Level: individual clinician</p> <p>Time-limited endorsement <i>continued</i></p>		<p>data are available and who meet the eligible population/denominator criteria.</p> <p>CPT Category II codes are used to report the numerator of the measure.</p> <p>1. If reporting CPT Category II codes, submit the listed G code and the appropriate CPT Category II code. CPT Category II codes are used to report the numerator of the measure.</p> <p>Identify patients documented to have a $Kt/V > 1.2$:</p> <ul style="list-style-type: none"> ■ CPT II code: 3083F $Kt/V \geq 1.2$ and < 1.7 (Clearance of urea [Kt]/volume [V]) <p><i>OR</i></p> <ul style="list-style-type: none"> ■ CPT II code: 3084F $Kt/V \geq 1.7$ (Clearance of urea [Kt]/volume [V]) <p>Identify patients who have a $Kt/V < 1.2$ with a documented plan of care:</p> <ul style="list-style-type: none"> ■ CPT II code: 3082F $Kt/V < 1.2$ (Clearance of urea [Kt]/volume [V]) <p><i>AND</i></p> <ul style="list-style-type: none"> ■ CPT II code: 0505F Hemodialysis plan of care documented. <p>Manual Abstraction</p> <p>Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection.</p> <p>Hybrid</p> <p>Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p>	<ul style="list-style-type: none"> ■ G-codes: for hemodialysis: G0314, G0315, G0316, G0317, G0318, G0319 ■ CPT I codes for hemodialysis: 90935, 90937. <p>Manual Abstraction</p> <p>Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection.</p> <p>The denominator (patients for inclusion): A sample should be determined using the most accurate data available in the settings in which the measure will be implemented. Sample sizes may be defined by different implementers.</p> <p>Hybrid</p> <p>Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p> <p>EHR</p> <p>Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. EHR users may opt to use the codes listed in the electronic data collection methodology to identify the calendar months for all patients aged 18 years and older with a diagnosis of ESRD and receiving hemodialysis.</p>		(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

HEMODIALYSIS ADEQUACY (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0323 Hemodialysis adequacy/plan of care Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>EHR Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. EHR users may opt to use the codes listed in the electronic data collection methodology to identify the number of calendar months during which patients have a $Kt/V \geq 1.2$ AND the number of patient calendar months during which patients have a $Kt/V < 1.2$ with a documented plan of care.</p>			

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PERITONEAL DIALYSIS ADEQUACY

Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0253 Peritoneal dialysis adequacy— measurement of total solute clearance at regular intervals Level: facility	CMS	Patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period.	All adult (≥ 18 years old) peritoneal dialysis patients.	None.	Medical record; data collection instrument; administrative claims data.
0254 Peritoneal dialysis adequacy— calculate weekly KT/Vurea in the standard way Level: facility	CMS	Patients with: <ul style="list-style-type: none"> ■ Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance ■ Residual renal function (unless negligible [< 100 mL urine in 24 hours]) is assessed by measuring the renal component of Kt/Vurea and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance ■ Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method or the Haycock method of using actual body weight, during the four month study period. 	All adult (≥ 18 years old) peritoneal dialysis patients.	None.	Medical record; data collection instrument; administrative claims data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PERITONEAL DIALYSIS ADEQUACY (continued)					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0318 Peritoneal dialysis adequacy—delivered dose of peritoneal dialysis above minimum Level: facility	CMS	The delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	All adult (≥18 years old) peritoneal dialysis patients who have been on peritoneal dialysis for at least 90 days.	None.	Medical record; data collection instrument; administrative claims data.
0321 Peritoneal dialysis adequacy/plan of care Level: individual clinician Time-limited endorsement	RPA/PCPI ^b	Patients who have a $Kt/V \geq 1.7$ AND patients who have a $Kt/V < 1.7$ with a documented plan of care* at least 3 times a year (every 4 months) during the 12 month reporting period. *A documented plan of care may include assessing for non-adherence with the peritoneal prescription, sampling, and collection; assessing for error in the peritoneal dialysis prescription and/or inadequate monitoring of the delivered dose; performing peritoneal equilibrium testing; assessing for inadequate patient education; increasing the exchange volume; increasing the number of exchanges per 24 hours; assessing for modality (CAPD or CCPD). INSTRUCTIONS: Report Numerator Component #1 (outcome) AND Report Numerator Component #2 (process) AND Report Total Score for Measure.	All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis. Electronic Collection Electronic data collection requires users to identify the eligible population (denominator) and numerator using electronic data (also referred to as “administrative data”). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria. ICD code for ESRD diagnosis: 585.6 (end stage renal disease) AND G codes and patient demographics (age, etc.) are used to determine patients that are included in the measure. G-codes or CPT I codes for ESRD patients receiving peritoneal dialysis required to identify patients for denominator inclusion: <ul style="list-style-type: none"> ■ G-codes: for peritoneal dialysis: G0322, G0323, G0326, G0327 ■ CPT I codes for peritoneal dialysis: 90945, 90947. Manual Abstraction Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection.	None.	Administrative claims data; CPT II/G Coding; medical record; electronic health record; pharmacy data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PERITONEAL DIALYSIS ADEQUACY (continued)					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
<p>0321 Peritoneal dialysis adequacy/plan of care Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>CPT Category II codes are used to report the numerator of the measure.</p> <p>1. If reporting CPT Category II codes, submit the listed G code and the appropriate CPT Category II code.</p> <p>Identify patients documented to have a $Kt/V > 1.7$:</p> <ul style="list-style-type: none"> ■ CPT II code: 3084F $Kt/V > 1.7$ (Clearance of urea [Kt]/volume [V]). <p>Identify patients who have a $Kt/V < 1.7$ with a documented plan of care:</p> <ul style="list-style-type: none"> ■ CPT II code: 3083F $Kt/V \geq 1.2$ and < 1.7 (Clearance of urea [Kt]/volume [V]) <p>OR</p> <ul style="list-style-type: none"> ■ CPT II code: 3082F $Kt/V < 1.2$ (Clearance of urea [Kt]/volume [V]) <p>AND</p> <ul style="list-style-type: none"> ■ CPT II code: 0507F Peritoneal dialysis plan of care documented. <p>Manual Abstraction Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection.</p> <p>Hybrid Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p>	<p>The denominator (patients for inclusion): A sample should be determined using the most accurate data available in the settings in which the measure will be implemented. Sample sizes may be defined by different implementers.</p> <p>Hybrid Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p> <p>EHR Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. EHR users may opt to use the codes listed in the electronic data collection methodology to identify all patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis.</p>		

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PERITONEAL DIALYSIS ADEQUACY (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0321 Peritoneal dialysis adequacy/plan of care Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>EHR Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. EHR users may opt to use the codes listed in the electronic data collection methodology to identify patients who have a $Kt/V > 1.7$ AND patients who have a $Kt/V < 1.7$ with a documented plan of care at least three times during the 12 month reporting period.</p>			

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

MINERAL METABOLISM					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0261 Measurement of serum calcium concentration Level: facility	CMS	Number of adult (≥ 18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month.	All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.	Transient dialysis patients (in unit <30 days), pediatric patients and kidney transplant recipients with a functioning graft.	Medical record; data collection instrument; administrative claims data.
0255 Measurement of serum phosphorus concentration Level: facility	CMS	Number of adult (≥ 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month.	All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.	Transient dialysis patients (in unit <30 days), pediatric patients and kidney transplant recipients with a functioning graft.	Medical record; data collection instrument; administrative claims data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

VASCULAR ACCESS

Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0256 Hemodialysis vascular access—minimizing use of catheters as chronic dialysis access Level: facility	CMS	Patients who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session during the study period.	Patients on maintenance hemodialysis during the last HD treatment of study period.	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.	Medical record; data collection instrument; administrative claims data.
0257 Hemodialysis vascular access—maximizing placement of arterial venous fistula (AVF) Level: facility	CMS	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month.	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis.	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.	Medical record; data collection instrument; administrative claims data.
0251 Vascular access: functional AV fistula access or seen by vascular surgeon for placement Level: individual clinician Time-limited endorsement	KCOA	Number of patients from the denominator who have functional (defined as two needles used) autogenous AV fistula or do not have such a fistula but have been seen by a vascular surgeon or other surgeon qualified in the area of vascular access for a functional (defined as two needles used) autogenous AV fistula at least once during the reporting year. Each of the subgroups (the outcomes subgroup and the process subgroup) of the numerator will be reported separately from the total numerator described above as well. CPT II code: 4052F (hemodialysis via AV fistula).	All ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year and on dialysis >90 days. ICD codes for ESRD diagnosis: 585.6 (end stage renal disease). This measure includes both in-center and home hemodialysis patients.	None.	Medical record; administrative claims data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

VASCULAR ACCESS (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0251 Vascular access: functional AV fistula access or seen by vascular surgeon for placement Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>Medical Record Collection Seen by a vascular surgeon or other surgeon qualified in the area of vascular access includes patients who have been assessed by a vascular access surgeon or other surgeon qualified in the area of vascular access at least once during the reporting year and have not received a functional (defined as two needles used) autogenous AV fistula during the reporting period. With respect to evidence of “being seen by a vascular access surgeon or other surgeon qualified in the area of vascular access” during the reporting period, documentation in the medical record must include: 1) a note or letter from a vascular access surgeon or other surgeon qualified in the area of vascular access summarizing the date on which the assessment took place and the results of it; or 2) a note, which may be prepared by the nephrologist, indicating the patient does not have a functional (defined as two needles used) autogenous AV fistula and that there was an assessment by a vascular access surgeon or other surgeon qualified in the area of vascular access along with the reason why there was not placement. An electronic collection option will be added when a CPT II code for “seen by a vascular access surgeon or other surgeon qualified in the area of vascular access” is available.</p>			

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

VASCULAR ACCESS (continued)

Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
<p>0262 Vascular access: catheter vascular access and seen by vascular surgeon for evaluation for permanent access Level: individual clinician Time-limited endorsement</p>	KCOA	<p>Number of patients from the denominator who are seen by a vascular surgeon or other surgeon qualified in the area of vascular access for evaluation for permanent vascular access at least once during the 12 month reporting period.</p> <p>Medical Record Collection Seen by a vascular surgeon or other surgeon qualified in the area of vascular access includes:</p> <ol style="list-style-type: none"> 1) patients with a catheter after 90 days on dialysis and who have been assessed for a permanent access by a vascular access surgeon or other surgeon qualified in the area of vascular access at least once during the reporting year and have received a permanent access during the reporting period 2) patients with a catheter after 90 days on dialysis and who have been assessed for a permanent access by a vascular access surgeon or other surgeon qualified in the area of vascular access at least once during the reporting year and have not received a permanent access during the reporting period. <p>With respect to evidence of “being seen by a vascular access surgeon or other surgeon qualified in the area of vascular access” during the reporting period, documentation in the medical record must include:</p> <ol style="list-style-type: none"> 1) a note or letter from a vascular access surgeon or other surgeon qualified in the area of vascular access summarizing the date on which the assessment took place and the results of it; or 	<p>All ESRD patients aged 18 years and older with a diagnosis of ESRD with a catheter after 90 days on dialysis.</p> <p>ICD codes for ESRD diagnosis: 585.6 (end stage renal disease).</p> <p>This measure includes both in-center and home hemodialysis patients.</p>	<p>Patients enrolled in hospice.</p>	<p>Medical record; administrative claims data.</p>

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

VASCULAR ACCESS (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0262 Vascular access: catheter vascular access and seen by vascular surgeon for evaluation for permanent access Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>2) a notation indicating that a patient has had the placement of a permanent access; or 3) a note, which may be prepared by the nephrologist, indicating the date on which the procedure was performed and that there was an assessment by a vascular access surgeon or other surgeon qualified in the area of vascular access along with the results of that consultation; or 4) a note, which may be prepared by the nephrologist, indicating the patient does not have a functional (defined as two needles used) autogenous AV fistula and that there was an assessment by a vascular access surgeon or other surgeon qualified in the area of vascular access along with the reason why there was not placement. An electronic collection option will be added when a CPT II code for “seen by a vascular access surgeon or other surgeon qualified in the area of vascular access” is available.</p>			
<p>0259 Hemodialysis vascular access—decisionmaking by surgeon to maximize placement of autogenous arterial venous fistula Level: individual clinician Time-limited endorsement</p>	SVS	<p>CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula <i>OR</i> Fistula not Performed for Medical Reasons <i>OR</i> Fistula not Performed for Patient Reasons. NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.</p>	<p>Patients with CKD4, CKD5 or End stage renal disease who undergo open surgical placement of permanent hemodialysis access. ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830.</p>		<p>Administrative claims data; CPT II/G Coding; medical record.</p>

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

VASCULAR ACCESS (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0259 Hemodialysis vascular access— decisionmaking by surgeon to maximize placement of autogenous arterial venous fistula Level: individual clinician Time-limited endorsement <i>continued</i></p>		<p>G8081: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula</p> <p><i>OR</i></p> <p>Fistula not Performed for Medical Reasons: Append modifier (1P) to G8081 to report documented circumstances that appropriately exclude patients from an autogenous fistula. A typical medical exclusion would include clinician documented that CKD4, CKD5 or ESRD patient requiring hemodialysis vascular access was not eligible for autogenous AV fistula based on results of vein mapping</p> <p><i>OR</i></p> <p>Fistula not Performed for Patient Reasons: Append modifier (2P) to G8081 to report documented circumstances that exclude patients for patient related reasons. For instance, clinician documented that CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access refused autogenous AV fistula following recommendation for same by provider. Autogenous is defined as the patient's own native tissue. Fistula is defined as a surgical connection established between an artery and a vein. Data to be analyzed annually.</p>			

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

INFLUENZA VACCINATION

Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0227 Influenza immunization Level: individual clinician Time-limited endorsement	RPA/PCPI ^b	Patients who received the influenza immunization during the flu season (September through February). Electronic Collection Electronic data collection requires users to identify the eligible population (denominator) and numerator using electronic data (also referred to as “administrative data”). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria. CPT Category II codes are used to report the numerator of the measure. 1. If reporting CPT Category II codes, submit the listed G code, and the appropriate CPT Category II code. Identify patients documented to have received influenza immunization. ■ CPT I: 90656, 90658, 90660 OR ■ CPT II 4037F: Influenza immunization ordered or administered. Manual Abstraction Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection. Documentation in medical record that the influenza immunization was received during the flu season (September through February).	All patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis. Electronic Collection Electronic data collection requires users to identify the eligible population (denominator) and numerator using electronic data (also referred to as “administrative data”). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria. ICD code for ESRD diagnosis: S85.6 (end stage renal disease) AND G code and patient demographics (age, etc.) are used to determine patients that are included in the measure. G-codes for ESRD patients receiving hemodialysis or peritoneal dialysis required to identify patients for denominator inclusion: ■ G-codes: for hemodialysis: G0314, G0315, G0316, G0317, G0318, G0319, or for peritoneal dialysis: G0322, G0323, G0326, G0327 ■ CPT I codes: for hemodialysis: 90935, 90937, or for peritoneal dialysis: 90945, 90947. Manual Abstraction Manual abstraction of data elements from patient records (hard-copy charts) constitutes medical record data collection. The denominator (patients for inclusion): A sample should be determined using the most accurate data available in the settings in which the measure will be implemented. Sample sizes may be defined by different implementers.	Documentation of medical reason(s) for patient not receiving the influenza immunization. Documentation of patient reason(s) for patient not receiving the influenza immunization. Documentation of system reason(s) for patient not receiving the influenza immunization. Exclude patients for whom influenza immunization was not received by reason of appropriate denominator exclusion. If using electronic data, exclude patients using the following codes: Append a modifier (1P, 2P or 3P) to the CPT Category II code to report patients with documented circumstances that meet the denominator exclusion criteria. ■ 1P: Documentation of medical reason(s) for not receiving the influenza immunization ■ 2P: Documentation of patient reason(s) for not receiving the influenza immunization ■ 3P: Documentation of system reason(s) for not receiving the influenza immunization. If using the medical record or hybrid methodologies, exclude patients who have documentation in the medical record of:	Administrative claims data; CPT II/G Coding; medical record; electronic health record; pharmacy data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

INFLUENZA VACCINATION (continued)					
Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
0227 Influenza immunization Level: individual clinician Time-limited Endorsement <i>continued</i>		<p>Hybrid Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p> <p>EHR Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. SNOMED-CT 86198006 (influenza vaccination). EHR users may opt to use the codes listed in the electronic data collection methodology to identify patients documented to have received influenza immunization.</p>	<p>Hybrid Users should follow the requirements of electronic data collection, then supplement where needed with medical record abstraction of data elements to fulfill measure reporting requirements.</p> <p>EHR Electronic Health Record (EHR) users may opt to use this methodology or the electronic data collection methodology described previously. EHR users should collect data on 100% of their denominator population instead of a sample. EHR users may opt to use the codes listed in the electronic data collection methodology to identify all patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis.</p>	<ul style="list-style-type: none"> ■ Documentation of medical reason(s) for not receiving the influenza immunization ■ Documentation of patient reason(s) for not receiving the influenza immunization ■ Documentation of system reason(s) for not receiving the influenza immunization. <p>If using the EHR methodology, exclude patients using the codes listed in the electronic data collection methodology or who have documentation in the medical record of the appropriate denominator exclusions.</p> <p>Codes for the denominator exclusions: ICD-9 V15.03, 995.68 (allergy to eggs) OR 995.21, 995.27, 995.3, 995.4, 999.5 (allergy or other adverse reaction) AND E949.6 SNOMED-CT 91930004 (allergy to flu vaccine), 420113004 (adverse reaction to flu vaccine), 390796006 (contraindication to flu vaccine) OR 315640000 (flu vaccine declined).</p>	(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

INFLUENZA VACCINATION (continued)

Measure	IP Owner ^a	Numerator	Denominator	Exclusions	Data Source
<p>0226 Influenza vaccination in the ESRD population—facilities Level: facility Time-limited endorsement</p>	<p>KCOA</p>	<p>Number of patients from the denominator who receive an influenza vaccination during the flu season (October 1 – March 31). CPT codes: 90656 (Influenza virus vaccine, split virus, preservative free, when administered to 3 years and older, for intramuscular use), 90658 (Influenza virus vaccine, split virus, when administered to 3 years of age and older, for intramuscular use).</p>	<p>All ESRD patients aged 18 years and older receiving hemodialysis and or peritoneal dialysis during the flu season (October 1 – March 31). ICD Codes for ESRD diagnosis: 585.6 (End stage renal disease).</p>	<p>None.</p>	<p>Medical record; administrative claims data.</p>

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

MORTALITY

Measure	IP Owner ^a	Numerator	Denominator	Exclusions/Adjustment	Data Source
<p>0369 Dialysis facility risk-adjusted standardized mortality ratio Level: facility</p>	<p>CMS</p>	<p>Number of deaths among eligible patients at the facility during the 4-year time period.</p>	<p>Number of deaths that would be expected among eligible dialysis patients at the facility during the 4-year time period, given the patient mix at the facility.</p> <p>Denominator Data Collection For each patient, the dialysis provider was identified using a combination of the Medicare paid dialysis claims, the Medical Evidence Form, and data from the Standard Information Management System (SIMS) maintained by the ESRD Networks. Treatment facility histories were determined for each patient starting at day 91 of ESRD. Patients are assigned to a facility only once they have been treated there for 60 days. Similarly, patients remain assigned to a facility for 60 days after transfer out of the facility. The continued tabulation of the time at risk for 60 days after transfer out of the facility ensures that the sequelae of treatment at a facility are attributed to that facility, even if the patient is transferred to another facility, such as a hospital-based facility, after the patient's condition worsens. In particular, patients are placed in their initial facility on day 91 of ESRD if they have been treated for at least 60 days at the facility. If on day 91, the patient has been treated at the facility for less than 60 days, the patient is not placed in any facility until they reach day 60 of treatment at a facility. Paid dialysis claims and SIMS data are used to determine that a patient has transferred to another facility. Patient outcomes are attributed to the original facility for 60 days after transfer out. On day 61 after transfer</p>	<p>Deaths from street drugs or accidents unrelated to treatment are excluded from the calculation (corresponding time at risk is not excluded).</p> <p>Risk Adjustment The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.</p> <p>The Standardized Mortality Ratio measure appears in the Dialysis Facility Report, Sections III and IV of the Guide to the Dialysis Facility Reports (1) and the document Technical Notes (2) on the Standardized Mortality Ratio contain information about the calculation of the SMR (including the risk adjustment methodology). These are available at the University of Michigan KECC website for the Dialysis Facility Reports at http://www.sph.umich.edu/kecc/usr/usr.htm.</p> <p>1) http://www.sph.umich.edu/kecc/usr/facguide.pdf and 2) http://www.sph.umich.edu/kecc/usr/smrdoc.pdf.</p>	<p>Administrative claims data.</p>

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

MORTALITY (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions/Adjustment	Data Source
<p>0369 Dialysis facility risk-adjusted standardized mortality ratio Level: facility <i>continued</i></p>			<p>out of a facility, the patient will be placed in the new facility if they have been treated there for 60 days. If the patient has not been treated for 60 days at the new facility (for instance, if there were 2 switches within 60 days of each other), the patient is not placed in any facility until they reach day 60 of treatment at a facility. Patients who receive a transplant are removed from the facility on the day of transplant. Patients who withdraw from dialysis or recover renal function remain assigned to the facility of treatment for 60 days after withdrawal or recovery. Patients are considered lost to follow-up and are removed from the analyses for a facility 1 year after the last evidence of dialysis treatment. In other words, if there is a 1 year period where there are no paid dialysis claims and no SIMS information indicating that a patient is receiving dialysis treatment, the patient is considered lost to follow-up and is not used in the analysis unless dialysis claims or other evidence of dialysis reappears.</p> <p>Deaths at Each Facility Only deaths during the time at risk described above are included for each facility. Deaths from street drugs or accidents unrelated to treatment are excluded from the calculation (corresponding time at risk is not excluded).</p> <p>Time at Risk For all patients, time at risk began at the start of the facility treatment period (as described above) and continued until the earliest occurrence of the following: transplant; date of death; end of facility</p>		

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

MORTALITY (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions/Adjustment	Data Source
<p>0369 Dialysis facility risk-adjusted standardized mortality ratio Level: facility <i>continued</i></p>			<p>treatment period; or December 31 of the year. A patient may have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility.</p> <p>Deaths Information on death is obtained from several sources, which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the four year period is calculated. This count does not include deaths from street drugs or accidents unrelated to treatment: Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded from the calculations.</p> <p>Expected Deaths The number of expected deaths for each patient is calculated as $-\ln(S_i(t_i))$, where $S_i(t)$ was the survival curve from a Cox model adjusted to the characteristics of patient i, and t_i was the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc, 2000; Andersen, 1993; Collett, 1994). The Cox model is</p>		(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

MORTALITY (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions/Adjustment	Data Source
<p>0369 Dialysis facility risk-adjusted standardized mortality ratio Level: facility <i>continued</i></p>			<p>adjusted for age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence. In cases where the comorbidities and BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race, sex, diabetes). We also control for age-adjusted population death rates by state and race, based on the U.S. population in 2001-2003 (National Center for Health Statistics, 2005). The number of expected deaths for the facility during the 4-year time period is the total expected for all eligible patients at the facility.</p>		(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PATIENT EDUCATION, PERCEPTION OF CARE, QUALITY OF LIFE					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0324 Patient education awareness—facilities Level: facility Time-limited endorsement</p>	KCOA	<p>Number of ESRD patients with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no renal replacement therapy) at least once during the 12 month reporting year.</p> <p>Medical Record Collection A discussion of renal replacement therapy modalities includes a conversation with patients about renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no renal replacement therapy).</p> <p>With respect to “discussion of renal replacement therapy modalities,” documentation must include:</p> <ol style="list-style-type: none"> 1) A note or letter from a nephrologist or other healthcare professional not employed by the facility summarizing the date on which the discussion occurred; or 2) A note, which may be prepared by the facility, indicating the date on which the discussion occurred. 	<p>All ESRD patients aged 18 years and older. ICD codes for ESRD diagnosis: 585.6 (End stage renal disease).</p>	<p>None.</p>	<p>Medical record; administrative claims data.</p>

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PATIENT EDUCATION, PERCEPTION OF CARE, QUALITY OF LIFE (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0320 Patient education awareness—physician Level: individual clinician Time-limited endorsement</p>	KCOA	<p>Number of ESRD patients with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no renal replacement therapy) at least once during the 12 month reporting year.</p> <p>Medical Record Collection A discussion of renal replacement therapy modalities includes a conversation with patients about renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no renal replacement therapy).</p> <p>With respect to “discussion of renal replacement therapy modalities,” documentation must include:</p> <ol style="list-style-type: none"> 1) A note or letter from a dialysis facility or healthcare professional summarizing the date on which the discussion occurred; or 2) A note, which may be prepared by a nephrologist or other healthcare provider, indicating the date on which the discussion occurred. 	<p>All patients aged 18 years and older with a diagnosis of ESRD receiving renal replacement therapy. ICD codes for ESRD diagnosis:585.6 (End stage renal disease).</p>	None.	Medical record; administrative claims data.

(more)

Appendix A—Specifications of the National Voluntary Consensus Standards for End Stage Renal Disease Care (continued)

PATIENT EDUCATION, PERCEPTION OF CARE, QUALITY OF LIFE (continued)					
Measure	IP Owner^a	Numerator	Denominator	Exclusions	Data Source
<p>0260 Assessment of Health-Related Quality of Life (Physical & Mental Functioning) Level: facility Also see 0258 below.</p>	RAND	Number of patients who complete a KDQOL-36 with or without assistance at least once per year.	Number of eligible prevalent dialysis patients (peritoneal dialysis, in-center hemodialysis, home hemodialysis) in the facility census during the year minus exclusions.	<p><age 18. Unable to complete due to cognitive impairment, dementia, or active psychosis. Non-English speaking/reading (no native language translation or interpreter available). Patients under the facility's care for <3 months. Patients who refuse to complete the questionnaire.</p>	Patient survey; medical record.
<p>0258 The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) In-Center Hemodialysis Survey Level: facility</p>	AHRQ	See Survey Specifications on the next page.			Patient survey.

(more)

0258 **The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) In-Center Hemodialysis Survey**

Source: Agency for Healthcare Research and Quality (AHRQ)

Date of Last Review/Update: October 2006

Proprietary Status: Public domain

Description: Self-reported survey that assesses the quality of care provided to in-center hemodialysis patients

MEASURE SPECIFICATIONS—SURVEY CHARACTERISTICS

Download Survey Tool and Instructions: www.cahps.ahrq.gov/cahpskit/ICH/ICHchooseQX.asp

Measure Developer/Instrument Website: www.cahps.ahrq.gov

Domains: Nephrologists' communication and caring (Q3-7 & Q9)

Quality of dialysis center care and operations (Q10-17, [Q21-removed], Q22, Q24-27, Q33, Q34, & Q43)

Providing information to patients (Q18, Q19, Q28-31, Q36, & Q38-40)

Number of Questions: 57 [with Q21 removed]

Survey Population: Adult hemodialysis patients (aged 18 years and older) who are currently dialyzing in-center and have at least three months of experience on hemodialysis at their current facility

Reporting: Global ratings and composites scores for the facility

Level of Analysis: Facility

MEASURE SPECIFICATIONS—SURVEY ADMINISTRATION

Sampling Specifications: Random sample of eligible patients. The developer recommends a sample of 200 for institutional comparisons.

Survey Administration: Mail with telephone follow-up for non-responders, telephone only. Developer does not recommend mail only.

Scoring Instructions: Provided for global rating and three domain-level composite scores. Scores are case mix adjusted for age, education and self-reported health status.

Reporting Instructions: Guidance on reporting is provided.

Kidney Disease and Quality of Life—KDQOL™-36

Source: RAND

Date of Last Review/Update: 2000

Proprietary Status: Copyrighted; publicly available

Description: Self-reported survey that assesses health-related quality of life (physical and mental functioning) of ESRD patients receiving dialysis

MEASURE SPECIFICATIONS—SURVEY CHARACTERISTICS

Download Survey Tool and Instructions: <http://gim.med.ucla.edu/kdqol/downloads/download.html> (available free, but must register)
KDQOL-36 survey, scoring adjusted by age, gender, and diabetes status, with interventions to improve scores and documentation for professionals at <http://www.lifeoptions.org/kdqol/>

Measure Developer/Instrument Web site: <http://gim.med.ucla.edu/kdqol/>

Domains: SF12 Physical Composite Summary and SF12 Mental Composite Summary (Items 1-12)
Burden of Kidney Disease (Items 13-16)
Symptoms/Problems (Items 17-28)
Effects of Kidney Disease (Items 29-36)

Number of Questions: 36

Survey Population: Currently dialyzing in-center and home hemodialysis and peritoneal dialysis patients (aged 18 years and older) minus exclusions: unable to complete due to cognitive impairment, dementia, or active psychosis; non-English speaking/reading (no native language translation or interpreter available); patients under the facility's care for <3 months; patients who refuse to complete the questionnaire

Reporting: Facility - percentage of eligible patients age 18 or older with annual survey

Level of Analysis: Survey scores—patient; Percentage of all eligible patients with an annual assessment—facility

MEASURE SPECIFICATIONS—SURVEY ADMINISTRATION

Sampling Specifications: Annually for all patients under a facility's care 3 months or longer; exclude patients unable to complete due to cognitive impairment, dementia, or active psychosis; non-English speaking/reading if no native language translation or interpreter is available; and patients who refuse to complete the questionnaire.

Survey Administration: The KDQOL-36 can be self-administered—or administered by another, or can be administered by telephone. There are multiple language translations, and family/volunteer/paid interpreters could help non-English speakers/readers.

Scoring Instructions: The KDQOL-36 scoring Excel template provides individual and summary scores for each patient, *and a facility mean score for each of the composite scores*. The scoring template is also publicly available.

Reporting Instructions: Percentage of patients with annual health-related quality of life assessment; at this time do not suggest comparing facility mean scores without risk adjustment.

NATIONAL QUALITY FORUM

Appendix B

Steering Committee, Steering Committee Workgroups, and Project Staff

Steering Committee

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Dialysis Adequacy

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Jay Barry Wish, MD (Co-Leader)
Peter Crooks, MD (Co-Chair)
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Vascular Access and Mineral Metabolism

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Peter Crooks, MD (Co-Chair)
Raymond Hakim, MD, PhD
Carol Motes Headley, DNSc, MSN, RN
James McCarthy, MD

Patient Education, Perception of Care, Mortality, and Influenza Immunization

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Dorian Schatell, MS (Patient Education and Perception of Care Leader)
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John Newmann, MPH, PhD
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NATIONAL QUALITY FORUM

Appendix C Commentary

Introduction

In February 2007, the National Quality Forum (NQF) initiated a project under a contract with the Centers for Medicare & Medicaid Services (CMS) to achieve consensus on a set of quality measures for end stage renal disease (ESRD) care. As with other NQF consensus projects, a Steering Committee (Appendix B) representing key health-care constituencies—including consumers, providers, purchasers, and research and quality improvement organizations—was convened. The Steering Committee members also served on smaller Workgroups (Appendix B) to assist NQF staff with measure evaluations, advise the Steering Committee on whether the measures met the evaluation criteria, and make recommendations to the Steering Committee. This commentary summarizes the proceedings of the Steering Committee and its Workgroups.

Approach to Measure Evaluation

Identifying Candidate Consensus Standards

Candidate consensus standards were identified through the following complementary strategies:

- solicitation of measures through a “Call for Measures” from March 13 to April 11, 2007. The “Call” was distributed through the following avenues:
 - posted on NQF’s website,
 - e-mailed to NQF Members,

- e-mailed to other organizations with a known interest in ESRD care, and
- e-mailed to NQF's public notification list; and
- solicitation of suggestions of candidate consensus standards from Steering Committee members.

A total of 52 measures were evaluated in 7 topic areas:

- anemia;
- dialysis adequacy (hemodialysis and peritoneal dialysis);
- mineral metabolism;
- vascular access;
- influenza immunization;
- mortality; and
- patient education, perception of care, and quality of life.

Purpose, Framework, Scope, and Priorities

The Steering Committee agreed upon the purpose, framework, scope, and priorities for the ESRD measures. The main debate involved whether measures relevant to the care of patients with chronic kidney disease (CKD) should be included in the measure set. Although the Committee agreed that some aspects of care provided to CKD patients can affect ESRD patient outcomes (e.g., placement of arteriovenous [AV] fistulas before dialysis begins), the Committee chose not to expand the scope because the "Call for Measures" was specific to ESRD care.

The Steering Committee recognized that management of underlying and concurrent conditions, such as diabetes

and hypertension, is integral to the provision of quality care for ESRD patients. However, no measures related to these conditions were submitted. Measures for care of such concurrent conditions are already endorsed by NQF; however, the Committee noted that those measures may not apply to the special circumstances of ESRD and that, in some cases, ESRD patients may be excluded. It was determined that it was beyond the scope of this project to review the existing NQF-endorsed[®] measures for these other conditions to evaluate their suitability for the ESRD population. This instead was addressed as a research need and as an area for future expansion of the ESRD care measure set.

The Steering Committee agreed that recommending multiple similar measures was counter to the concept of standardization and would create additional burden for those providers that are implementing consensus standards. Therefore, the Committee established additional considerations for selecting measures for the candidate consensus standards, as follows:

- for similar, duplicative measures, the best measure should be selected, and
- to the extent possible, measures that could be used at different levels of analysis and settings, such as at dialysis facilities and by nephrologists, should be selected instead of selecting separate measures for each setting.

Initial Review of Measures

The candidate consensus standards were unusual in their degree of duplication. For example, eight variations of measures on

hemoglobin levels were considered. The Workgroups' first task was to review measures for overlap, similarities, and inconsistencies. The Workgroups identified duplicate measures and issues that cut across multiple measures, and questions were sent to the measure developers, who were asked to:

- harmonize facility and clinician measures (i.e., identify one measure that could be applied to all levels of analysis);
- for duplicate measures, agree on measure specifications and measure/owner stewardship issues; and
- for combined outcome/process measures, separate the outcome and process measure components, or score and report the individual components.

Initially, the measure developers replied that they could not resolve any of the duplicative measure issues and did not change any measure specifications; therefore, the Committee proceeded with evaluating each measure as submitted.

Evaluation of Candidate Consensus Standards

The measures were evaluated using the NQF standard criteria of importance, scientific acceptability, usability, and feasibility.

The information submitted by the measure developers was summarized in a standard evaluation format so that the Committee could evaluate each measure against the NQF-endorsed criteria. Each measure was evaluated individually on each criterion and then compared with similar measures to identify the "best in

class." The Workgroups conducted the initial in-depth measure evaluations and constructed tables that included their conclusions about whether each criterion was met, a summary recommendation, and rankings of similar measures. These tables were distributed for the Workgroups' reports of their conclusions and recommendations, including their preference or ranking for duplicative measures, to the full Steering Committee. The Steering Committee deliberated on each measure and made a recommendation regarding its status as a potential voluntary consensus standard, as follows:

- recommend a measure as submitted;
- recommend a measure if specified conditions were met; or
- not recommend a measure.

In addition, because of the new option of offering time-limited endorsement for untested measures, the Committee could suggest time-limited endorsement in its recommendations.

Evaluation of Measures

Following is a summary of the Workgroups' and the Steering Committee's evaluation of the measures and their decisions regarding the recommendation of consensus standards. Issues that apply to multiple measures for the same topic area are discussed first and are followed by comments that pertain to specific measures. The measures that were recommended (and ultimately endorsed) are listed in Table 1 in the body of this report, and their

detailed specifications appear in Appendix A. The measures that were not recommended are listed at the end of this appendix.

The following issues were identified in multiple measures in most of the topic areas:

- Definitions of terms (e.g., definition of a transient patient, what constitutes an acceptable plan of care) should not be assumed to be commonly understood. Rather, they should be explicit.
- Home hemodialysis patients should be included in relevant measures.
- Measures designed for pay for reporting, such that the numerator specifications result in scores of 100 percent, are not appropriate for public accountability.
- Duplicative/similar measures undermine standardization and increase the burden to implementers.
- For combined outcome/process measures, computing and reporting only a total score is not acceptable for public accountability.
- All of the physician measures and some facility measures were submitted without any prior testing that demonstrated the scientific acceptability of the measure properties of the measures.

When these issues were encountered regarding a measure, that measure was not recommended, or it was recommended only with the condition that the issue would be remedied. Measures without any testing data were eligible for the new time-limited endorsement that is overseen by NQF's Consensus Standards Approval Committee (CSAC).

Duplicative Measures

The Steering Committee encouraged the measure developers to resolve the differences in measure specifications and ownership/stewardship for their duplicative measures with similar specifications. Ultimately, however, the measure developers reported that they were not able to resolve those issues. Therefore, the Committee was able to select only one of each group of duplicative measure. One exception was the agreement by the Kidney Care Quality Alliance (KCQA) and CMS on specifications for some facility measures; however, CMS retained sole ownership of its measures. Duplicative measures generally were equally important and had adequate clinical evidence. If there were no variations in the data source or scoring, the duplicative measures also were generally equally feasible and useable. Therefore, decisions about "best in class" were most often determined by the scientific acceptability of the measure properties as demonstrated by testing results or by the precision of the measure specifications. For example, if two measures were essentially the same, but one had been tested and found to demonstrate adequate reliability and/or validity, it would be considered superior to the untested measure.

Although the Committee sought measures that applied to all levels of analysis (including facilities and physicians), most of the measure developers had expertise and/or interest in only one level or setting. Therefore, similar measures were recommended for different levels of analysis.

Reporting of Combined Outcome/Process Measures

All of the physician measures for hemodialysis adequacy and vascular access submitted by the Renal Physicians Association/Physician Consortium for Performance Improvement (RPA/PCPI) and KCQA combined an outcome and a process into one measure. The measures were specified to compute a total score based on patients who achieved a specified outcome (e.g., hemoglobin level, dialysis adequacy, and vascular access with AV fistula) plus patients not achieving the specified outcome if there was a plan of care (or referral for vascular access). The Committee rejected this approach, because identical scores could represent very different rates of achieving the outcome and would not be useful for public accountability, particularly for consumers and purchasers. Some Committee members also noted that the plan-of-care component simply required that the physician use a CPT II code indicating that a plan of care was in place; there would be no validation of the adequacy of the plan.

In all cases, the Committee recommended a measure only if the outcome component was scored and reported separately and if the process component was more precisely specified. Some Committee members thought the plan of care component essentially would guarantee scores close to 100 percent and would therefore provide little differentiation among providers. Other members said that the process component was actionable and important to quality care. In response, some Committee members pointed out that all patients should (and

probably do) have a plan of care, and that the data collection method does not ensure that the plan of care is adequate or responsive to the reason for not achieving the outcome. Ultimately, the Committee agreed to recommend measures with both components, but only if the outcome was computed and reported separately.

Although the Committee agreed that the outcome component should be computed and reported, initially the Committee did not have a shared understanding of the additional numerator components that should be computed and reported. Three options were discussed among the Committee members for computing and reporting combined outcome/process measures:

■ Option #1

- Outcome (≥ 1.2): 60/100=60 percent
- Process (< 1.2 with plan): 35/100=35 percent
- Total (≥ 1.2 and < 1.2 w/plan): 95/100=95 percent
- If the above reported, also know that 5/100=5 percent < 1.2 and no plan

■ Option #2

- Outcome (≥ 1.2): 60/100=60 percent
- Total (≥ 1.2 and < 1.2 w/plan): 95/100=95 percent
- If the above reported, also know that 35 percent were < 1.2 w/plan and 5 percent were < 1.2 and no plan

■ Option #3

- Outcome (≥ 1.2): 60/100=60 percent
- Process (< 1.2 with plan): 35/100=35 percent
- If the above reported, also know that 5 percent were < 1.2 and no plan and 95 percent were ≥ 1.2 and < 1.2 w/plan

The Committee did not agree on the best approach beyond requiring that the outcome component be computed and reported separately and specifically asked for comments from NQF Members and the public on the various options. NQF received seven comments regarding the computing and reporting of combined outcome/process measures. Option 1 was suggested most frequently (outcome, process, total). Option 1 also encompasses both Option 2 and Option 3. The Steering Committee agreed to recommend that Option 1 (outcome, process, total) be used as the approach for computing and reporting combined outcome/process measures. This was conveyed to the measure developers who modified their measures accordingly. It refers to any measure that is a combined process/outcome measure. As noted, the options were illustrated using hemodialysis as an example.

Anemia: Hemoglobin

The Steering Committee was divided on whether to recommend any of the submitted hemoglobin measures. The primary area of controversy was the appropriate hemoglobin values that should be included in performance measures in light of the 2006 and early 2007 Food and Drug Administration (FDA) warnings that “erythropoiesis-stimulating agents (ESA) increased the risk of death and for serious cardiovascular events when administered to target a hemoglobin of >12 g/dL.”¹ The Workgroup recommended that ranges

in the submitted measures be changed from “11-12” to “10-12” and that submitted measures of “<11” or “>11” be changed to “<10.” The rationale was that it is biologically impossible to maintain hemoglobin values within a narrow range of 11-12, and with 12 being a bright line upper limit, the lower limit should be decreased. The Workgroup recommended that measures be paired: a range of 10-12 for ESA-treated patients and <10 for all patients as an indicator of patients in need of treatment.

The Steering Committee was divided, with half agreeing with the Workgroup recommendation and half favoring the values as originally submitted. As a result, no measure related to hemoglobin values was recommended.

During the discussion, Committee members noted that there are important distinctions between guidelines and performance measures, and between targets and achieved values. Individual patient circumstances can be accommodated by guidelines; and target values are appropriate goals, but they are not always achieved. Outcome measures cannot always account for special patient circumstances through exclusions or case-mix adjustments; however, 100 percent usually is not the benchmark as it is with precisely constructed process measures. It also was noted that substantial uncertainties exist in the evidence related to the mortality risk associated with hemoglobin levels >12 and <11.

¹Food and Drug Administration, Center for Drug Evaluation and Research, *FDA Information for Healthcare Professionals: Erythropoiesis Stimulating Agents (ESA)*; 2007. See www.fda.gov/cder/drug/InfoSheets/HCP/RHE2007HCP.htm.

The Committee did not disagree with the guideline to target hemoglobin values between 11 and 12. The issue, as some saw it, was with performance measures that did not adequately reflect the danger to patients with values >12 and the liability to providers if the FDA warning is exceeded. On the other hand, some Committee members acknowledged that the FDA warning would move the distribution of hemoglobin values downward, but that did not change the desired values. Patient representatives advocated that patients can feel the difference between hemoglobin values of 10 and 11 and would not want a measure that indicated 10 was sufficient.

The Anemia Workgroup also determined that measures based on hematocrit values instead of hemoglobin values were not consistent with current science and practice and that those measures also were duplicative of measures using hemoglobin values. In addition to the recommendation to modify ranges (on which the full Committee was divided), the Workgroup also recommended some other conditions for measures, if they were recommended, such as the following: define *transient patient*, clarify data collection for first or last value of the month, include home hemodialysis patients, and exclude patients with hematological causes of anemia. The Workgroup noted that the KCQA facility measure was essentially the same as the CMS facility measure, but measured hemoglobin ≥ 11 rather than < 11 . In light of the FDA

warning, a measure with no upper limit was not considered viable. The CMS physician measure was constructed such that most physicians would achieve 100 percent, so it would not be usable for public accountability.

Ultimately, the Committee did not recommend any hemoglobin measures with or without the Workgroup's recommended conditions and specifically asked for comments from NQF Members and the public on appropriate hemoglobin values for performance measures. Twelve comments were received on anemia hemoglobin measures: one recommended values of 10-12; one referred to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) update; one supported current CMS measures; three supported the RPA/PCPI measure (≥ 11); two supported values of 11-12; one said values should be consistent with FDA labeling; one suggested more research; one commented on the relationship with quality of life; and one supported values of ≥ 11 . The updated KDOQI guideline still recommends target hemoglobin values of 11-12 g/dL, but in those receiving ESA therapy the value should not exceed 13.² As of the end of the comment period, FDA had not issued a final determination regarding labeling following the September 11, 2007, Cardio-Renal Drugs Advisory Committee. In light of the continued uncertainty, the Steering Committee agreed not to recommend measures with specific

²KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. See www.kidney.org/professionals/kdoqi/guidelines_anemiaUP/guide1.htm.

hemoglobin values, but suggested that NQF should revisit hemoglobin measures after the FDA final action. The Committee also discussed how different types of measures might be more appropriate for anemia management than achieved hemoglobin values, such as ones focused on appropriate dosing to achieve targets.

On November 8, 2007, FDA issued its final label warning for ESA therapy and advised that for chronic renal failure patient dosing should be individualized to achieve and maintain hemoglobin levels within the range of 10-12 g/dL.³

Following the FDA notice of November 8, 2007, CMS notified NQF of its intention to modify its facility hemoglobin measures and submitted the following revised measures:

Monitoring hemoglobin levels below target minimum

Percentage of all adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients with ESRD ≥ 3 months and who had Hb values reported for at least 2 of the 3 study months, who have a mean Hb < 10.0 g/dL for a 3 month study period, irrespective of ESA use.

Hemoglobin range for ESA therapy

Percentage of adult hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have received ESA therapy at any time during a 3 month study period AND have achieved a mean hemoglobin of 10.0-12.0 g/dL for the 3 month study period.

The Steering Committee recommended only the measure of hemoglobin levels

< 10 g/dL for all patients for time-limited endorsement, which was subsequently endorsed. The Committee did not recommend the measure of hemoglobin in the range of 10-12 g/dL for ESA-treated patients, because the majority of the Committee agreed that the science was not clear on setting “achieved” values versus “target” values that were used in most studies. It noted that mortality is associated with large doses used in trying to achieve “targets” and may be related to some other factor besides the hemoglobin level achieved, and the measure does not take into account (adjust for) ESA responsiveness (e.g., patients who go over 12 with low doses of ESAs). The minority dissenting opinion was that the measure of hemoglobin range of 10-12 should be recommended because there is agreement that patients with hemoglobin < 10 should have action taken, it is consistent with the range established by FDA, and without it there is no measure related to an upper limit.

Anemia: Iron Levels

Three measures related to iron management—a process measure for testing, an outcome measure for maintenance of iron stores, and a process measure for prescribing intravenous iron therapy—were submitted. Only the process measure for testing was recommended, on the condition that home hemodialysis patients also be included. The other two measures were not recommended by the Workgroup because of the lack of consensus on the

³Information for Healthcare Professionals: Erythropoiesis Stimulating Agents (ESA). See www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm.

specified achieved values and safety concerns and lack of exclusions related to intravenous iron therapy. The Workgroup noted that the guideline targets were opinion based with acknowledged “serious limitations to the evidence” and did not believe the evidence was sufficient to put the guideline targets into performance measures. A Workgroup member noted that the primary goal of iron therapy is to lower the ESA dose and that iron therapy has not been tied to specific patient outcomes.

Dialysis Adequacy: Hemodialysis

Nine measures on hemodialysis adequacy were evaluated: six for facilities and three for physicians. However, the measures essentially represented one outcome, adequacy of dialysis, and two processes, monthly assessment of dialysis adequacy and assessment method used to determine dialysis adequacy using UKM or Daugirdas II methods. Some physician measures combined the outcome of dialysis adequacy with a plan of care. Some measures were based on outdated urea reduction ratio (URR) assessment instead of Kt/V^4 ; thus, the Committee did not recommend them. Other issues that were identified and that developers were asked to address before measures could be recommended for the set were excluding home hemodialysis patients, denominator exclusion of patients on hemodialysis less

than six months, and combining outcome and process in the physician measures.

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 for 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 noted that if a measure contained a process component for a plan of care for patients who do not achieve the outcome value, exclusions would not be needed. Measures were recommended only on the condition that they would be revised to address these issues.

In the case of the CMS facility outcome measure, CMS agreed to change the exclusion period to <90 days, but noted that patients with residual renal function of ≥ 2 ml/min/1.73m² should be excluded. The six-month exclusion period was used as a proxy to exclude patients with residual renal function. CMS thought that this was necessary because the distribution of patients on dialysis for 90 days to 6 months varies widely across facilities. The current data collection system does not capture

⁴ $(K_{\text{urea}} \times T_d) / V_{\text{urea}}$ (abbreviated as Kt/V), where K_{urea} is the effective (delivered) dialyzer urea clearance in milliliters per minute integrated over the entire dialysis, T_d is the time in minutes measured from beginning to end of dialysis, and V_{urea} is the patient's volume of urea distribution in milliliters. See www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/hd_guide2.htm.

residual renal function. CMS submitted a revised measure and also requested that the current measure be approved until residual renal function could be collected in the CROWN system beginning in 2009. The Steering Committee agreed to recommend both the current and revised facility outcome measures, as well as the two process measures for monthly adequacy assessments. A revised physician measure with specifications to score and report the outcome component also was recommended.

Regarding the RPA/PCPI measure, the Committee also recommended that the measure be specified to count patients rather than months to be consistent with other measures in the set, particularly the physician peritoneal dialysis adequacy measure. If the intent is for monthly measurement, then it should be consistent with the facility measure and measure the percent of patients. The RPA/PCPI responded that if the measure is used in the CMS Physician Quality Reporting Initiative (PQRI) program, only yearly reporting occurs (i.e., one score for the year), and percentage of calendar months would be more accurate in that case. The Committee accepted that rationale, but asked that the term *patient calendar months* be used.

Comments received during the review period focused on four topics: the need to explicitly state that home hemodialysis patients are included; the usage of different methods of measuring dialysis adequacy for home hemodialysis patients; the rationale for using calendar months for

the physician measure; and reconsideration of the facility URR measure. Home hemodialysis patients were not excluded from the recommended measures, but the comment was sent to the developers. The Steering Committee agreed that because the hemodialysis adequacy measure denominator specifies patients “dialyzing thrice weekly,” there was no need for a different method of measuring dialysis adequacy for home hemodialysis or for stratifying results.

The Steering Committee reaffirmed its prior conclusion that a measure of URR was outdated and that the recommended measure of Kt/V is superior. It was recommended that CMS transition Dialysis Facility Compare to the recommended measure when the data become available.

Dialysis Adequacy: Peritoneal Dialysis

Six measures on peritoneal dialysis adequacy were evaluated: four for facilities and two for physicians. However, the measures essentially represented one outcome, adequacy of dialysis, and two processes, assessment of dialysis adequacy every four months and assessment method used to determine dialysis adequacy, including residual renal function and total body water. Some issues that were identified and that developers were asked to address were the need to include residual kidney function in the outcome measure and combining outcome and plan of care in the physician measures and the CMS facility outcome measure. The Workgroup recommended and the Committee agreed that residual renal function should be

included in measures of peritoneal dialysis adequacy and that for combined outcome/process measures, the outcome component must be scored and reported and the plan of care further specified.

The Workgroup recommended and the Committee agreed that a plan for inadequate peritoneal dialysis should address at least the dialysis prescription, modality (continuous ambulatory peritoneal dialysis versus continuous cycling peritoneal dialysis), and the performance of peritoneal equilibration test. Measures were recommended only on the condition that they would be revised to address these issues. CMS decided to remove the prescription change process component in its facility outcome measure so that it becomes an outcome measure only. The Steering Committee agreed to recommend the facility outcome measure, as well as the two process measures for adequacy assessments. A revised physician measure with specifications to score and report the outcome component also was recommended.

The comments received focused on three topics: suggesting testing less often than three times per year; suggesting an exclusion for patients with peritonitis; and clarifying the frequency of “weekly” Kt/V. Current guidelines recommend testing every four months. The Steering Committee agreed that peritonitis does not need to be an exclusion, but that the test should not be performed at the time of active peritonitis. This should not be a problem if the measure specifications allow for a test any time during the four-month period. The Committee recognized that “weekly”

Kt/V does not mean weekly testing and suggested that the developer clarify this in the specifications.

Mineral Metabolism

Four facility measures on mineral metabolism were submitted—two outcome measures for calcium and phosphorus serum concentration and two process measures for assessing calcium and phosphorus serum concentration.

The Committee recommended the process measures because of the importance of identifying and managing abnormalities of serum calcium and phosphorus. The recommendations were conditional regarding the inclusion of all dialysis patients, including home hemodialysis patients.

Although the actual serum calcium and phosphorus levels (intermediate outcome) are most important and there is greater variability in achieving the guideline levels, the Workgroup advised that the guideline target values were an opinion-based guideline and that there is some controversy about the ideal range. A Committee member suggested focusing on poor control (e.g., calcium >10.2 or phosphorus <5.5), but ultimately the outcome measures were not recommended. Additionally, it was noted that serum calcium requires a correction based on serum albumin and that there are two ways to measure albumin (there is no national standard). The Workgroup and the Committee agreed that the evidence was not sufficient to include specified values in outcome performance measures at this time.

The comments received during the review period focused on questioning the value of the process measures; explicitly including home hemodialysis patients; and discussing the need for a parathyroid hormone measure. Comments about the specifications were sent to the developer; however, the Committee agreed that the measures should go forward for consideration. Although the Committee agreed there was a need for a measure related to parathyroid hormone, no measures had been submitted or identified for consideration.

Vascular Access

Eleven vascular access measures were submitted, representing five unique concepts: patients on hemodialysis >90 days with a catheter; hemodialysis patients with an AV fistula; monitoring of AV fistula or graft for stenosis; performing surveillance tests on AV grafts; and placement of AV fistulas by vascular surgeons. The physician measures combined the vascular access outcome with a process component of referral to a vascular surgeon.

Some issues that were identified and that developers were asked to address prior to measures being recommended for the set included the following: specifying “autogenous” AV fistula; changing “referred” to “seen” by a vascular surgeon; removing reference to “permanent” catheters; and scoring and reporting the outcome component of combined outcome/process measures.

The Workgroup recommended that referral be explicitly defined. One option

was to define *referred* as making the appointment; however, the Steering Committee decided that being seen by a surgeon was too important to not ensure that the patient was actually seen. The Committee also agreed that catheters should not be described as “permanent.” *Permanent* could be interpreted in various ways such as referring to a timeframe or a tunneled catheter, or that no other viable options for vascular access exist. Furthermore, any catheter puts patients at risk, and patients who need ongoing dialysis should receive AV fistulas.

The Committee discussed why the vascular surgeon measure focused on first-time vascular access placement and agreed that this was the most important and the most straightforward way to measure at this time. The Committee also thought that the measure should not address stage 3 CKD and recommended that this be removed.

The Workgroup recommended the measure on monitoring an AV fistula for stenosis, but not the measure on performing surveillance tests on AV grafts. However, the Steering Committee did not recommend either of the monitoring measures. One concern was that monitoring and surveillance were not adequately defined. In addition, members noted that the use of routine duplex ultrasound was not warranted; that Medicare does not pay for routine surveillance tests; and that stenosis cannot be detected by physical exam (monitoring). Ultimately, the Committee did not recommend either measure.

Comments received during the review period focused on explicitly including home hemodialysis patients; defining a functioning fistula; clarifying that the measure for surgical placement is specific for surgeons; including specific coding or data collection instructions for “seen by a vascular surgeon” in the physician measures; and reconsidering the RPA/PCPI measures for vascular access. The Steering Committee agreed with the definition of using two needles and that alternative definitions of a functioning fistula would be difficult to measure; the other comments were sent to the measure developers. It was noted that there is no current CPT II code for “seen by a vascular surgeon;” however, there is a code for “referred to a vascular surgeon” as specified in the RPA/PCPI measures. The Committee already had deliberated extensively on this issue and decided in favor of measures that require “seen by a vascular surgeon.” Even though a CPT II code may not currently exist for “seen by a vascular surgeon,” the measure can be specified. It was suggested that the diabetes eye exam measure be used as an example. The measure developer was asked to revise the specifications because CPT II codes do not currently exist, and the developer was given the diabetes eye exam measure as an example.

Influenza Vaccination

The Steering Committee recommended a facility measure and a physician influenza measure on the condition that they be based on a flu season rather than on the calendar year. The Committee suggested

the period of October 1 to March 31 as a definition for the flu season. The facility measure was consistent with the Committee’s suggested flu season period and that of the CMS nursing home influenza measure, while the physician measure time window was consistent with that of other physician measures (September through February). The Steering Committee requested comments on the specification of the period during which the measures should be calculated. During the comment period, several suggestions were received on specifying the flu season that were consistent with the two recommended measures as originally presented. The Committee agreed that, rather than wait for harmonization of all influenza immunization measures, the flu season specifications would go forward without making any changes to the flu season period. A subsequent NQF project on influenza and pneumococcal immunizations included a review of endorsed measures including these ESRD influenza immunization measures. Modifications were recommended to the ESRD immunization measures consistent with standard specifications, which were endorsed. The measure developers were notified that the measures would need to be revised when they came up for review under time-limited endorsement.

Mortality

The Workgroup recommended approval of both submitted mortality measures, preferring the standard mortality measure because the more conservative measure

provided little differentiation. With the conservative measure, 2 percent of facilities were classified as better than expected and 4 percent as worse than expected; with the standard measure, 13 percent were classified as better than expected and 14 percent as worse than expected.

Some Workgroup members were concerned with potential misclassifications using the standard method. Other members noted that because the conservative measure provided little differentiation among providers, it was less useful. Another concern was the adequacy of the risk adjustment—particularly that new conditions may not be detected. Some Committee members raised the concern that the standard measure could lead facilities to “cherry-pick” less risky healthier patients; others did not think that was any more of a concern for a mortality measure than for other outcome measures. Ultimately, the Steering Committee recommended only the conservative mortality measure for inclusion in the ESRD set. A comment regarding the transfer assignment period received during the review period was sent to the measure developer.

Although the mortality measure was supported by the membership vote, the CSAC did not approve the mortality measure for endorsement. The CSAC noted that the measure specifications included cut points and levels of statistical significance used for reporting and that other NQF-endorsed mortality measures are specified differently. The CSAC noted that reporting methods should not be embedded in the measure specifications. CMS agreed

with the CSAC recommendation and resubmitted the risk-adjusted mortality measure without the reporting parameters. The revised measure was presented to the membership for voting and subsequently endorsed.

Patient Education

Identical measures were submitted for facilities and physicians. The Committee agreed that what is known as modality education is important before beginning renal replacement therapy and should include all options, including the option of no treatment. The Committee initially discussed focusing on incident ESRD patients to determine whether patients had received modality education prior to renal replacement therapy. It was agreed that although that would be informative, it should not be used as an accountability measure because ESRD providers cannot be held accountable for what occurred before beginning ESRD therapy. The Committee recommended both the facility and the physician measures on the condition that the measures focus on prevalent ESRD patients, with an annual timeframe, and include all modality options.

Comments received during the review period addressed terminology and coding or data collection instructions and were sent to the developer. The Steering Committee suggested removing “quality of life” from the measure title and changing “no treatment” to “no renal replacement therapy.”

Patient Perception of Care

The Committee agreed that it was desirable to include a patient perception of care measure in the set. The Committee recommended the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program on the condition that the developer clarify the scoring, frequency of administration, items with facility-level reliability estimates below 0.70, and the justification for the large composite “Dialysis Facility Care and Operations” composed of 17 items. The measure developer responded that CAHPS should be conducted annually, removed one item with low “r,” and explained that the other items with a low “r” did well on other criteria such as item-total correlations and that statistical analysis did not support any of a variety of breakdowns of the large composite on facility care and operations.

According to the CAHPS team, seemingly unrelated content was indistinguishable statistically because all of these items were features of the thrice-weekly, regular dialysis center visit. Given the frequent and routine nature of these visits, patients experience all the different aspects talked about in the questions as part of one whole. By contrast, items in the “Nephrologists Communication and Caring” and “Providing Information to Patients” composites refer to events that are much less frequent than the daily visit or to events that differ in context. The Committee accepted this explanation and recommended the measure.

Quality of Life

The Committee agreed that quality of life is an important outcome for ESRD patients. The process measures for “offering” either a patient satisfaction or quality tool were not considered adequate and were not recommended. The Committee gave two reasons: “offering” is too weak, and satisfaction and quality of life are two distinct constructs that should not be combined.

The Committee initially tabled action on the Kidney Disease Quality of Life (KDQOL) instrument that was submitted until the developer offered a provider-level measure. The measure developer had not recommended aggregating patient scores for a facility score until risk adjustment can be applied, but it did provide a process measure of conducting a quality-of-life assessment using the KDQOL-36 on an annual basis. The Steering Committee recommended that it be included in the set. The KDQOL-36 has been tested with demonstrated reliability and validity. The submitted process measure is a straightforward rate of annual assessment using the KDQOL-36. During the review period, many comments were received in support of the quality-of-life measure.

Voting Period Comments and CSAC Action

Most comments received from Members during the voting phase were similar to those made during the initial comment period. Additional comments included the following: performance of individual clinicians should not be measured; the ICD-9 code 585.5, Chronic Kidney Disease,

Stage V (excludes stage V requiring dialysis), should be added to some of the measures; and hemodialysis adequacy should be adjusted for hemodialysis more than three times per week. Each of these comments was made only by individual voters, and changes to the candidate consensus standards were not suggested. The reasons for no changes were that the measure set was intended for both facilities and individual clinicians; the set focuses on ESRD, not its precursor, CKD; and the hemodialysis adequacy measures were specified for those dialyzing three times per week.

The CSAC recommended that the testing plan for the vascular surgeon measure include detailed analysis of the reasons for not placing a fistula. The CSAC recommended that the measure developers consider applying the measures to patients younger than 18 years of age, unless the evidence clearly excludes the younger patients. The CSAC discussed the limitations of measures that simply require documentation that education has been provided. Although the CSAC recommended the endorsement of the two patient education measures, it indicated the need for NQF to signal that measures focused on documentation should be replaced with other means of assessing whether patient education has occurred (e.g., through a patient survey).

Measures Considered by the Steering Committee But Not Recommended for Inclusion in the Set of Voluntary Consensus Standards

Anemia

Hemoglobin range for ESA Therapy; CMS; Level: Facility

Percentage of adult hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have received ESA therapy at any time during a 3 month study period AND have achieved a mean hemoglobin of 11.0-12.0 g/dL (revised measure: 10.0-12.0 g/dL) for the 3 month study period.

Anemia Management—Facilities; KCOA; Level: Facility

Percentage of all ESRD patients receiving hemodialysis or peritoneal dialysis whose Hgb ≥ 11 .

Facility Anemia Measurement (percentage of ESA-treated dialysis patients at the facility with an average hematocrit lower than 33 in the calendar year); CMS; Level: Facility

Percentage of eligible ESA-treated dialysis patients at the facility during the calendar year with an average hematocrit < 33 .

Facility Anemia Management (percentage of ESA-treated patients at the facility with an average hematocrit between 33 and 36 in the calendar year); CMS; Level: Facility

Percentage of eligible ESA-treated dialysis patients at the facility during the calendar year with an average hematocrit between 33-36.

Plan of Care for Anemia; RPA/PCPI;
Level: Individual Clinician

Percentage of calendar months during the 12 month reporting period in which patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis have a Hgb ≥ 11 AND calendar months in which patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis have a Hgb < 11 with a documented plan of care.

Anemia Management—Physician; KCQA;
Level: Individual Clinician

Percentage of all ESRD patients receiving hemodialysis or peritoneal dialysis whose Hgb ≥ 11 AND number of patients whose Hgb < 11 with a documented plan of care.

Hematocrit Level in End Stage Renal Disease (ESRD) Patients; CMS; Level: Individual Clinician

Percentage of patients aged 18 years and older with a diagnosis of end stage renal disease undergoing hemodialysis with a documented hematocrit value ≥ 33 (or a hemoglobin value ≥ 11).

Maintenance of Iron Stores; CMS; Level: Facility

Percentage of all adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb < 11.0 g/dL in at least one month of the study period who have at least one serum ferritin ≥ 200 ng/mL (≥ 100 ng/mL for peritoneal dialysis) AND either one transferrin saturation $\geq 20\%$ or one CHr ≥ 29 pg, during a three-month study period for hemodialysis patients (six-month study period for peritoneal dialysis patients).

Administration of Supplemental Iron; CMS; Level: Facility

Percentage of all adult (≥ 18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb < 11.0 g/dL in at least one month of the study period, AND with at least one of the following during any month of the study period: transferrin saturation $< 20\%$, CHr < 29 pg, or serum ferritin concentration < 200 ng/mL (< 100 ng/mL for PD patients) who are prescribed intravenous iron at any time during the study period (3 month study period for hemodialysis patients and 6 month study period for peritoneal dialysis patients).

Hemodialysis Adequacy

Adequacy of Dialysis—Facilities; KCQA; Level: Facility

Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more, dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) < 2 ml/min/1.73m² whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 (excluding RRF). Reported monthly.

Facility Adequacy of Dialysis (percentage of the facility's hemodialysis patients with a urea reduction ratio [URR] of 65% or greater in the calendar year); CMS; Level: Facility

Percentage of hemodialysis patients at the facility during the calendar year with a median URR value of 65% or higher.

Adequacy of Dialysis—Physicians; KCQA; Level: Individual Clinician

Percentage of all adult ESRD patients receiving hemodialysis dialysis for >90 days who have a Kt/V ≥ 1.2 (including residual function) AND patients who have a Kt/V < 1.2 with a documented plan of care. Reported three times a year. Reporting is the number of patients measured once during the past 4 months.

Dialysis Dose in End Stage Renal Disease (ESRD) Patients; CMS; Level: Individual Clinician

Percentage of patients aged 18 years and older with a diagnosis of end stage renal disease undergoing hemodialysis with a documented URR value $\geq 65\%$ (or a Kt/V ≥ 1.2).

Peritoneal Dialysis Adequacy

Adequacy of Dialysis—Facilities; KCQA; Level: Facility

Percentage of all ESRD patients receiving peritoneal dialysis whose Kt/V level is \geq a threshold of 1.7. Reporting will be the number of patients measured once during the past 4 months (3 times a year).

Adequacy of Dialysis—Physician; KCQA; Level: Individual Clinician

Percentage of all adult ESRD patients receiving peritoneal dialysis for >90 days whose Kt/V level is \geq a threshold of 1.7 AND patients whose Kt/V level is < 1.7 and have a documented plan of care. Reporting is the number of patients measured once during the past 4 months (3 times a year).

Mineral Metabolism

Evaluation of Serum Calcium Concentration; CMS; Level: Facility

Percentage of all adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis with appropriately adjusted serum calcium concentration between 8.4 and 10.2 mg/dL.

Evaluation of Serum Phosphorus Concentration; CMS; Level: Facility

Percentage of all adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis with serum phosphorous concentration between 3.5 and 5.5 mg/dL.

Vascular Access

Vascular Access—Facilities; KCQA; Level: Facility

Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year with a permanent catheter after 90 days on dialysis [who are] referred for evaluation for permanent access.

Vascular Access—Facilities; KCQA; Level: Facility

Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year who have a functioning AV fistula or are referred for permanent access at least once during the reporting year.

Vascular Access—Patients Receiving Hemodialysis; RPA/PCPI; Level: Individual Clinician

Percentage of patients aged 18 years and older with a diagnosis of ESRD and receiving hemodialysis who have a functioning AV fistula or are referred for an AV fistula/ permanent vascular access at least once during the 12 month reporting period.

Vascular Access—Patients Receiving Dialysis with Permanent Catheter; RPA/PCPI; Level: Individual Clinician

Percentage of patients aged 18 years and older with a diagnosis of ESRD with a permanent catheter after 90 days on dialysis who are referred for evaluation for permanent vascular access at least once during the 12 month reporting period.

Monitoring for Vascular Access Dysfunction; CMS; Level: Facility

Percentage of patients with AV graft or AV fistula at the last HD treatment of study period whose AV fistula or AV graft was routinely monitored for the presence of stenosis until the last treatment of the study period.

Monitoring for Vascular Access Dysfunction; CMS; Level: Facility

Percentage of patients with AV graft at the last HD treatment of study period who undergo specific surveillance tests, according to defined frequencies, until the last HD treatment of study period.

Influenza Vaccination

Influenza Vaccination in the ESRD Population—Physician; KCQA; Level: Individual Clinician

Percentage of all ESRD patients aged 18 years and older receiving hemodialysis and peritoneal dialysis during the 12 month reporting year who receive an influenza vaccination during the 12 month reporting year.

Mortality

Facility Patient Survival Classification (based on Standardized Mortality Ratio), Standard Method; CMS; Level: Facility

Facility classified as better or worse than expected based on SMR being <0.8 or >1.2 and significantly different than 1.0. (Facilities with SMRs between 0.8 and 1.2 or with SMRs not significantly different than 1.0 are classified as “as expected.”)

Patient Education, Perception of Care, Quality of Life

Quality of Life and Patient Satisfaction—Facilities; KCQA; Level: Facility

Percentage of all ESRD patients aged 18 years and older receiving hemodialysis or peritoneal dialysis during the reporting period who were offered a patient satisfaction/quality of life tool to complete.

Quality of Life and Patient Satisfaction—Physician; KCQA; Level: Individual Clinician

Percentage of all ESRD patients aged 18 years and older receiving hemodialysis or peritoneal dialysis during the reporting period who were offered a patient satisfaction/quality of life tool to complete.

NATIONAL QUALITY FORUM

Appendix D

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NATIONAL QUALITY FORUM

Appendix E

Consensus Development Process: Summary

The National Quality Forum (NQF) is a unique, multistakeholder organization dedicated to improving healthcare quality through performance measurement and public reporting. NQF's Consensus Development Process (CDP) is the formal process through which it achieves consensus on the standards it endorses, including performance measures and other standards to improve healthcare quality.

Through this multistep process, NQF brings together diverse healthcare stakeholders who are represented in eight Member Councils: Consumer Council; Purchaser Council; Health Professional Council; Provider Organization Council; Supplier and Industry Council; Quality Measurement, Research, and Improvement Council; Health Plan Council; and Public/Community Health Agencies Council.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www.qualityforum.org.

NQF's CDP process begins with the formation of a Steering Committee that guides the project and that includes critical expertise and represents a balance of perspectives on the matter(s) under consideration. The purpose of the Steering Committee is to develop and carry out, in conjunction with NQF staff and technical advisors, as needed, a work plan that will result in a recommended product for endorsement by NQF membership, the Consensus Standards Approval

Committee (CSAC), and the NQF Board of Directors. Priority will be given to nominations for Steering Committees members that are made by NQF Members.

The next step involves a "Call for Measures." NQF invites the owners or stewards of performance measures or other types of candidate standards to submit their measures for consideration. Organizations do not need to be NQF Members to participate. Once NQF issues a "Call for Measures," organizations have 30 days to submit the requisite information. Organizations are asked to adhere to NQF Measure Submission Guidelines and must agree to provide free, public access to measures, including technical specifications, if they are endorsed by NQF.

The proposed consensus standards are distributed for review and comment by NQF Members and non-members. After NQF review and comment of the candidate consensus standards, member organizations are provided with a revised draft, on which they generally have 30 days to vote. Each organization has one vote.

Next, the candidate consensus standards and the voting results are submitted to the CSAC to consider in making its decision. Although the CSAC makes most of the

final decisions regarding approval, on occasion, it may defer decisionmaking and request additional consensus building, and Member Council chairs are given an opportunity to provide input. As is the case with the Board of Directors, consumers and those who purchase services on their behalf constitute a simple majority on the CSAC.

After approval by the CSAC and ratification by the Board of Directors, NQF Members and non-members are provided 30 days to file an appeal. All appeals are reviewed by the CSAC and are forwarded with its recommendation to the Board of Directors for final consideration.

Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF CDP, version 1.8, was in effect. The complete process can be found at www.qualityforum.org.

THE NATIONAL QUALITY FORUM (NQF) is a private, nonprofit, open membership, public benefit corporation whose mission is to improve the American healthcare system so that it can be counted on to provide safe, timely, compassionate, and accountable care using the best current knowledge. Established in 1999, NQF is a unique public-private partnership having broad participation from all parts of the healthcare industry. As a voluntary consensus standards setting organization, NQF seeks to develop a common vision for healthcare quality improvement, create a foundation for standardized healthcare performance data collection and reporting, and identify a national strategy for healthcare quality improvement. NQF provides an equitable mechanism for addressing the disparate priorities of healthcare's many stakeholders.

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