

Verbatim Comment Report for ESRD Hospital Readmissions and Anemia Management Measures

Prepared by: Arbor Research Collaborative for Health and the
University of Michigan Kidney Epidemiology and Cost Center
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Comments on Anemia of chronic kidney disease: ESA management to avoid transfusion

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	This is a complex measure, the implementation of which is hindered by limitations in claims data. Network 5's Medical Review Board believes that this measure would be obviated by reintroducing a Hgb floor measure.
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Marsha Kimmer RN, CDN marsha.kimmer@gmail.com
Type of organization	Individual
Date submitted	4/12/2013
Comment	All patients are managed with epo to avoid transfusions.
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled "Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion".
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Derrick Latos, MD Medical Director Wheeling Renal Care, LLC DLatos@wrc3.com Comment submitted on behalf of Wheeling Renal Care, LLC
Type of organization	Dialysis Facility
Date submitted	4/18/2013
Comment	See Appendix 21_WheelingRenalCare
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. We appreciate the comments identifying conditions associated with gastrointestinal bleeding as contributors to ESA resistance. We note the expanded Prospective Payment System recognizes this clinical effect by providing a payment multiplier when GI bleeding is present. Furthermore, dialysis provider practices, including but not limited to dose of intradialytic anticoagulation, dialysis adequacy and prescription of medications can potentially contribute to the incidence of GI bleeding in this patient population. Given the complex interplay between clinical practices, payment system reimbursement and anemia management, we feel that it is inappropriate to include comorbidity adjustment for comorbidities associated with GI bleeding at this time.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Daniel W. Coyne, MD Professor of Medicine, Renal Diseases Washington University School of Medicine Dcoyne@dom.wustl.edu
Type of organization	Academic
Date submitted	4/18/2013
Comment	See Appendix 1_D.Coyne
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We note that the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure. Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for</p>

	<p>patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.</p> <p>We agree with the concern about increasing the dosage too quickly, and have developed a measure that examines dosage and transfusion after two months of Hgb below 10 g/dL.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Rosetta Jackson, RN, MS, LHRM rojackrn@aol.com
Type of organization	Individual
Date submitted	4/18/2013
Comment	<p>Anemia is a normal occurring phenomena in CKD patients of all stages and ages. Critical management tools for ongoing investigation and innovation for improvement are imperative. Inadvertently mismanaged anemia in CKD and ESRD can equate to early mortality, morbidity and a substantial decrease in their overall quality of life. Iron supplemental treatments and ESAs seem to be only part of the task for improved outcomes in these patients. As a patient myself I have experienced the pros and the cons of anemia management and abrupt changes in EPO dosing due to the narrowing of hemoglobin parameters. The caution for EPO prescribed patient populations is partially due to the development of associated Black Box warnings, past accusations of misuse, as well as how it relates to budgetary discretions and payment scales in ESRD care. I think the key would be to highly acknowledge how patients differ in their response rates to ESA management, specifically within the whirlwind of starting and suddenly stopping ESA treatment for those patients who have frequent serum hemoglobin changes. While standardization and safety are the goals, I feel a standardized investigative process for those patients who are unstable or seem difficult to manage could be helpful in tracking causes or closing in on individualized ESA management needs. Some factors to re-visit periodically for investigative purposes might be patients stage of CKD, concluded cause of CKD, length of time on a dialysis treatment modality, baseline response to anemia therapies, any seizure threshold issues, co-morbidities, and history of reports from patients on how they are feeling when on or off ESAs. This might assist in future research to better answer why certain patients have more adequate response rates to ESA treatment than others and whether the parameters being used are appropriately consistent with the quality of care intended.</p>
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the</p>

	<p>absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We note that the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we arbitrarily chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. However, the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.

In regards to the comments about whether this measure is appropriate at the facility level, we acknowledge that several commenters expressed concerns that dialysis providers are frequently not the decision-maker regarding prescription and administration of blood transfusions. We agree that most transfusion events occur in the inpatient setting, suggesting that some or all of these transfusions are the result of a non-dialysis provider's determination that an individual patient requires blood transfusion. Furthermore, blood transfusion is often motivated by clinician response to acute intercurrent patient events, such as GI bleeding or trauma. We agree that dialysis facilities do not control many of these factors. However, our own research, recently confirmed by research performed by one national dialysis organization (Hirth 2012, Sibbel 2013) identifies a strong association between recent achieved hemoglobin and subsequent transfusion event. In risk-adjusted models (both patient and facility-level) achieved hemoglobin is the strongest predictor of subsequent transfusion. These observational analyses are consistent with observations of an earlier RCT (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin, particularly for study subjects that developed acute GI bleeding during participation in the trial.

Avoidance of clinically unnecessary blood transfusion is the responsibility of all clinical providers. Dialysis facilities receive payment for anemia management, and therefore, have responsibility for achieved hemoglobin. Achieved hemoglobin is perhaps the strongest clinical factor determining need for blood transfusion when acute, intercurrent illness develops. There is shared responsibility for achieved hemoglobin in dialysis patients that involves the facility and the treating nephrologist. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

In regards to the concerns about data availability, the measure is claims-based. Facilities are not required to report transfusion events as a result of this measure. We disagree with the statement that facilities do not have the ability to change anemia management practices in response to facility level data. We thank the commenter for pointing out an additional benefit of the proposed measure Implementation of transfusion-based measures (see also STRR) will provide valuable feedback for dialysis facilities and nephrologists as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.

Finally, with regards to concerns about individualized care, we agree that the care of each patient requires individualization of risk-benefit assessment and decision-making. This principle does not preclude evaluating facility-level decision making to identify facility-level factors that contribute to overall facility care. This measure is focused on the facility-level decisions, in order to identify systematic facility-level decisions regarding anemia management that may result in unnecessary blood

	<p>transfusions for the facility's patients. We recognize that individual patient comorbidity will influence facility-level results. The measure includes significant risk-adjustment provisions to protect those patients at high risk for ESA complications as well as to protect facilities against the effects of patient comorbidity on facility-level outcome.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	<p>Jason Spangler, MD, MPH Executive Director U.S. Health Policy and Reimbursement Amgen jspangle@amgen.com Comment submitted on behalf of Amgen</p>
Type of organization	Pharmaceutical
Date submitted	4/26/2013
Comment	See Appendix 3_Amgen
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We note that the doses for erythropoietin and darbepoetin were obtained from the FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. However, the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.

In regards to the comment about patients admitted to the hospital, this measure excludes patient months with <6 sessions, so most patients with prolonged hospitalizations are excluded from the measure calculation. In addition, the measure, as specified, only flags the event if the patient has a low hemoglobin on the same claim as the below threshold ESA dose. The hemoglobin reported on the claim is the last value from the month prior to the ESA dose being evaluated, not simultaneous. It is also important to note the per session adjustment for ESA dose included in the proposed measure specifications. Thus, reduced ESA exposure secondary to missed sessions is addressed by the proposed measure specifications. Lastly, the transfusion event is not counted in the facility's numerator unless all three conditions are met. The hemoglobin was < 10 in (month-1), the ESA dose was below threshold in (month 0) and the patient received a transfusion in (month 1). Thus, if hospitalization occurred in (month -1) and the post-hospitalization hemoglobin was <10 gm/dl, the facility's next month (month 0) ESA dosing would be evaluated. The example patient would only be counted if both the month 0 ESA dose was below threshold and the patient subsequently received a transfusion in (month+1).

The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Lori Hartwell Founder and President Renal Support Network Lori@RSNhope.org Comment submitted on behalf of Renal Support Network
Type of organization	Patient advocacy organization
Date submitted	4/30/2013
Comment	See Appendix 4_ RenalSupportNetwork
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We clarify that the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.

In regards to the comments about whether this measure is appropriate at the facility level, we acknowledge that several commenters expressed concerns that dialysis providers are frequently not the decision-maker regarding prescription and administration of blood transfusions. We agree that most transfusion events occur in the inpatient setting, suggesting that some or all of these transfusions are the result of a non-dialysis provider's determination that an individual patient requires blood transfusion. Furthermore, blood transfusion is often motivated by clinician response to acute intercurrent patient events, such as GI bleeding or trauma. We agree that dialysis facilities do not control many of these factors. However, our own research, recently confirmed by research performed by one national dialysis organization (Hirth 2012, Sibbel 2013) identifies a strong association between recent achieved hemoglobin and subsequent transfusion event. In risk-adjusted models (both patient and facility-level) achieved hemoglobin is the strongest predictor of subsequent transfusion. These observational analyses are consistent with observations of an earlier RCT (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin, particularly for study subjects that developed acute GI bleeding during participation in the trial.

Avoidance of clinically unnecessary blood transfusion is the responsibility of all clinical providers. Dialysis facilities receive payment for anemia management, and therefore, have responsibility for achieved hemoglobin. Achieved hemoglobin is perhaps the strongest clinical factor determining need for blood transfusion when acute, intercurrent illness develops. There is shared responsibility for achieved hemoglobin in dialysis patients that involves the facility and the treating nephrologist. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

In regards to the suggestion that public reporting of Hgb levels would result in the best data for developing future guidelines, we appreciate the comments that support reintroduction of this type of measure as an alternative means of guarding against unnecessary transfusions in this population. However, at this time, no assumptions have been made regarding which of the proposed anemia measures will be endorsed by NQF or implemented in any quality improvement programs. The proposed transfusion avoidance measure specifically measures facility processes of care related to anemia management, rather than intermediate outcomes of anemia management. As such, it may be complementary to an intermediate outcome measure. Each measure has a different profile related to potential unintended consequences as well.

	<p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Glenda Harbert, RN, CNN, CPHQ Executive Director ESRD Network of Texas Inc GHarbert@nw14.esrd.net Comment submitted on behalf of ESRD Network of Texas Inc
Type of organization	ESRD Network
Date submitted	4/30/2013
Comment	See Appendix 5_ESRDNetwork14
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. With regards to your concerns about individualized care, we agree that the care of each patient requires individualization of risk-benefit assessment and decision-making. This principle does not preclude evaluating facility-level decision making to identify facility-level factors that contribute to overall facility care. This measure is focused on the facility-level decisions, in order to identify systematic facility-level decisions regarding anemia management that may result in unnecessary blood transfusions for the facility's patients. We recognize that individual patient comorbidity will influence facility-level results. The measure includes significant risk-adjustment provisions to protect those patients at high risk for ESA complications as well as to protect facilities against the effects of patient comorbidity on facility-level outcome.</p> <p>In regards to the comments about whether this measure is appropriate at the facility level, we acknowledge that several commenters expressed concerns that dialysis providers are frequently not the decision-maker regarding prescription and administration of blood transfusions. We agree that most transfusion events occur in inpatients, suggesting that some or all of these transfusions are the result of a non-dialysis provider's determination that an individual patient requires blood transfusion. Furthermore, blood transfusion is often motivated by clinician response to acute intercurrent patient events, such as GI bleeding or trauma. We agree that dialysis facilities do not control many of these factors. However, our own research, recently confirmed by research performed by one national dialysis organization (Hirth 2012, Sibbel 2013)</p>

	<p>identifies a strong association between recent achieved hemoglobin and subsequent transfusion event. In risk-adjusted models (both patient and facility-level) achieved hemoglobin is the strongest predictor of subsequent transfusion. These observational analyses are consistent with observations of an earlier RCT (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin, particularly for study subjects that developed acute GI bleeding during participation in the trial.</p> <p>Avoidance of clinically unnecessary blood transfusion is the responsibility of all clinical providers. Dialysis facilities receive payment for anemia management, and therefore, have responsibility for achieved hemoglobin. Achieved hemoglobin is perhaps the strongest clinical factor determining need for blood transfusion when acute, intercurrent illness develops. There is shared responsibility for achieved hemoglobin in dialysis patients that involves the facility and the treating nephrologist. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication. Finally, in regards to the comment about re-establishment of a hemoglobin floor, we appreciate the comments that support reintroduction of a “bottom floor hemoglobin payment measure” as an alternative means of guarding against unnecessary transfusions in this population. However, at this time, we are making no assumptions regarding which of the proposed anemia measures will be endorsed by NQF or implemented in any quality improvement programs. The proposed transfusion avoidance measure specifically measures facility processes of care related to anemia management, rather than intermediate outcomes of anemia management. As such, it may be complementary to an intermediate outcome measure. Each measure has a different profile related to potential unintended consequences as well.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. However, the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

	<p>Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7_NationalForumofESRDNetworks
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Dori Schatell, MS Executive Director Medical Education Institute, Inc. schatell@meiresearch.org Comment submitted on behalf of Medical Education Institute, Inc.
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 8_ MedicalEducationInstitute
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about re-establishment of a hemoglobin floor, we appreciate the comments that support reintroduction of a “bottom floor hemoglobin payment measure” as an alternative means of guarding against unnecessary transfusions in this population. However, at this time no assumptions have been made regarding which of the proposed anemia measures will be endorsed by NQF or implemented in any quality improvement programs. The proposed transfusion avoidance measure specifically measures facility processes of care related to anemia management, rather than intermediate outcomes of anemia management. As such, it may be complementary to an intermediate outcome measure. Each measure has a different profile related to potential unintended consequences as well.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. However, the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.

In regards to the suggestion of iron treatment as an alternative anemia management tool, we agree. The measure does not address that aspect of anemia management. There is less concern regarding the risk for undertreatment of iron deficiency associated with the current bundled payment system, given the favorable cost-benefit ratio of iron therapy in anemia management. Recent analyses of anemia management trends (ASN poster presented on the ESRD PPS) demonstrate increasing IV iron use temporally associated with implementation of the expanded PPS bundle. In addition, iron therapy was discussed by the Anemia TEP. Given the limitations in accuracy of currently available laboratory measures of iron and the inherent limitations of these tests in identifying iron deficiency accurately, the TEP recommended against development of an iron management measure at this time.

To respond to the comment about exclusions, we appreciate the comments identifying conditions associated with gastrointestinal bleeding as contributors to ESA resistance. In fact, the expanded ESRD Prospective Payment System recognizes this clinical effect by providing a payment multiplier when GI bleeding is present. Furthermore, dialysis provider practices, including but not limited to dose of intradialytic anticoagulation, dialysis adequacy and prescription of medications can potentially contribute to the incidence of GI bleeding in this patient population. Given the complex interplay between clinical practices, payment system reimbursement and anemia management, we feel that it is inappropriate to include comorbidity adjustment for comorbidities associated with GI bleeding at this time. We disagree with the comment “cancers with little likely impact on hemoglobin concentration and transfusion requirements are included in the exclusion list.” All categories of cancer included in the models are significantly associated with transfusion risk based on our research.

In regards to the suggestion that public reporting of Hgb levels would result in the best data for developing future guidelines, we appreciate the comments that support reintroduction of this type of measure as an alternative means of guarding against unnecessary transfusions in this population. However, at this time, no assumptions have been made regarding which of the proposed anemia measures will be endorsed by NQF or implemented in any quality improvement programs. The proposed transfusion avoidance measure specifically measures facility processes of care related to anemia management, rather than intermediate outcomes of anemia management. As such, it may be complementary to an intermediate outcome measure. Each measure has a different profile related to potential unintended consequences as well.

In regards to the concern about the data and additional burden to facilities, we agree that determination of blood

transfusion from Medicare claims is a complex undertaking. In addition to other researchers, we have successfully performed research using claims-based blood transfusion metrics. In regards to the facility burden question, the measure, as written, does not require facility reporting of blood transfusion events. There is no additional reporting burden on dialysis facilities based on the proposed measure.

The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the suggestion of iron treatment as an alternative anemia management tool, we agree. The measure does not address that aspect of anemia management. There is less concern regarding the risk for undertreatment of iron deficiency associated with the current bundled payment system, given the favorable cost-benefit ratio of iron therapy in anemia management. Recent analyses of anemia management trends (ASN poster presented on the ESRD PPS) demonstrate increasing IV iron use temporally associated with implementation of the expanded PPS bundle. In addition, iron therapy was discussed by the Anemia TEP. Given the limitations in accuracy of currently available laboratory measures of iron and the inherent limitations of these tests in identifying iron deficiency accurately, the TEP recommended against development of an iron management measure at this time.</p> <p>With regards to the concerns about individualized care, we agree that the care of each patient requires individualization of risk-benefit assessment and decision-making. This principle does not preclude evaluating facility-level decision making to identify facility-level factors that contribute to overall facility care. This measure is focused on the facility-level decisions, in order to identify systematic facility-level decisions regarding anemia management that may result in unnecessary blood transfusions for the facility's patients. We recognize that individual patient comorbidity will influence facility-level results. The measure includes significant risk-adjustment provisions to protect those patients at high risk for ESA complications as</p>

	<p>well as to protect facilities against the effects of patient comorbidity on facility-level outcome.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We note that the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

	<p>Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.</p> <p>In regards to the concerns about exclusions in the measure, these two conditions -- patients receiving dialysis less than 90 days and patients receiving more than one type of ESA -- are part of the measure definition. Thank you for highlighting the need for clarification of these measure definitions in our descriptions. The analyses provided for the MJF were conducted with these exclusions in place.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about ESA dosage, we agree that the ESA threshold doses appear, on the surface to be arbitrary. We note that the doses for erythropoietin and darbepoetin were obtained from the same FDA package insert information that many of the commenters have referenced. According to the FDA, the recommended starting dose for CKD patients on dialysis with hemoglobin <10 is 50-100 units/kg/session. Furthermore, the FDA Package Insert recommends incremental dosing with 25% increases times 1-2. For the draft measure, we chose the lowest recommended initial dose and calculated an approximate weight adjusted dose after 2 dose increments of 25%, consistent with the FDA recommendations. The darbepoetin dose was similarly derived, but for simplicity of presentation was expressed as a mcg/week rather than a weight-based dose.</p> <p>Commenters are correct in asserting that this dose threshold is not necessarily the ESA dose needed to achieve an adequate erythropoietic response in all CKD dialysis patients. We note that the available data confirm that 40-50% of Medicare dialysis patients in 2011 were receiving doses at or above this threshold, supporting the threshold as being near the median dose defined as clinically useful by the dialysis community. Given the consistency with clinical practice and FDA package insert recommendations, we are comfortable that the dose threshold represents a reasonable value, particularly since this measure has been designed as a facility level measure. Dose individualization is not discouraged by this measure.</p>

	<p>Rather, after applying a risk adjustment strategy, those facilities that use less ESAs than recommended ESA dosing for patients with low achieved hemoglobin subsequently transfusions will be differentiated from dialysis facilities that are better able to avoid transfusion events.</p> <p>In regards to the concerns about exclusions in the measure, these two conditions -- patients receiving dialysis less than 90 days and patients receiving more than one type of ESA -- are part of the measure definition. Thank you for highlighting the need for clarification of these measure definitions in our descriptions. The analyses provided for the MJF were conducted with these exclusions in place.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>
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Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about re-establishment of a hemoglobin floor, we appreciate the comments that support reintroduction of a “bottom floor hemoglobin payment measure” as an alternative means of guarding against unnecessary transfusions in this population. However, at this time, no assumptions have been made regarding which of the proposed anemia measures will be endorsed by NQF or implemented in any quality improvement programs. The proposed transfusion avoidance measure specifically measures facility processes of care related to anemia management, rather than intermediate outcomes of anemia management. As such, it may be complementary to an intermediate outcome measure. Each measure has a different profile related to potential unintended consequences as well.</p> <p>The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.</p>

Measure/Measure set	Anemia of chronic kidney disease: ESA management to avoid transfusion
Commenter	<p>David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center</p>
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	<p>Thank you for your comment regarding this ESRD measure. We appreciate your input. In regards to the comment about whether this measure is appropriate at the facility level, we acknowledge that several commenters expressed concerns that dialysis providers are frequently not the decision-maker regarding prescription and administration of blood transfusions. We agree that most transfusion events occur in inpatients, suggesting that some or all of these transfusions are the result of a non-dialysis provider's determination that an individual patient requires blood transfusion. Furthermore, blood transfusion is often motivated by clinician response to acute intercurrent patient events, such as GI bleeding or trauma. We agree that dialysis facilities do not control many of these factors. However, our own research, recently confirmed by research performed by one national dialysis organization (Hirth 2012, Sibbel 2013) identifies a strong association between recent achieved hemoglobin and subsequent transfusion event. In risk-adjusted models (both patient and facility-level) achieved hemoglobin is the strongest predictor of subsequent transfusion. These observational analyses are consistent with observations of an earlier RCT (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin, particularly for study subjects that developed acute GI bleeding during participation in the trial.</p> <p>Avoidance of clinically unnecessary blood transfusion is the responsibility of all clinical providers. Dialysis facilities receive</p>

payment for anemia management, and therefore, have responsibility for achieved hemoglobin. Achieved hemoglobin is perhaps the strongest clinical factor determining need for blood transfusion when acute, intercurrent illness develops. There is shared responsibility for achieved hemoglobin in dialysis patients that involves the facility and the treating nephrologist. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

In regards to the concerns about data availability, we note that the measure is claims-based, and facilities are not required to report transfusion events as a result of this measure. We thank the commenter for highlighting this additional benefit of the proposed measure. We note that we disagree with the statement that facilities do not have the ability to change anemia management practices in response to facility level data. Implementation of transfusion-based measures (see also STTrR) will provide valuable feedback for dialysis facilities and nephrologists as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.

In regards to the concerns about ESA resistant patients, to some extent, use of exclusions helps mitigate issues raised in these comments. In addition, the decision to transfuse a patient with an acute condition, in part, relates to the hemoglobin concentration present at onset, which is affected by the facility's anemia management. Finally, other commenters have indicated that for the proposed anemia management measures, the vast majority of transfusions occur during acute care hospitalizations. Thus, the clinicians determining transfusion need are not likely to be influenced by a measure designed to evaluate transfusion events at the dialysis facility level, other than taking the patient's achieved hemoglobin into consideration when determining whether transfusion is indicated.

We agree with the commenter regarding specification of exclusions and risk adjustment.

The ESA management to avoid transfusion measure was intended to identify transfusion events that might be caused by inappropriate dosing of ESAs in the months immediately prior to the transfusion event month. Analysis has shown that the absolute number of identified patient months meeting the measure definition remains very low, suggesting that inappropriate low ESA dosing is not commonly associated with subsequent transfusion events. Alternatively, this claims-based metric may be insensitive in terms of identification of transfusions related to inadequate ESA dosing. Given the relatively low impact of this proposed measure implied by this analysis, CMS has decided to cease further development of this measure, but will consider the continued monitoring of this metric.

Comments on Anemia of chronic kidney disease: Hgb>12 g/dL

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	Network 5's Medical Review Board finds this measure acceptable.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Marsha Kimmer RN, CDN marsha.kimmer@gmail.com
Type of organization	Individual
Date submitted	4/12/2013
Comment	The patients should have their anemia managed by their physician, not CMS. Every patient's level should be individualized. I've never seen a dialysis pt have a stroke from a hgb >12 and I have been a dialysis RN for 26 years. However, I have seen plenty of cardiac arrests and chest pain and they usually have a low hgb.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about individualized care, CMS supports and encourages individualization of treatment that is provided by the physician, and recognizes that there is variation among patients as well as physician care. However, thresholds for performance measures are selected based on a more global scale. The measures are intended to guard against adverse outcomes associated with higher levels of hemoglobin for ESA-treated dialysis patients at the facility level. Significant differences in this risk-adjusted measure's outcome reflect facility-level differences in care. In addition, comparisons of facility level measures essentially allow comparison of an individual facility's outcomes to a clinical consensus standard, defined by the dialysis community.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled "Anemia management of chronic kidney disease: Hgb > 12 g/dL".
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Dennis J. Cotter President Medical Technology and Practice Patterns Institute, Inc. dcott@mtppi.org Comment submitted on behalf of Medical Technology and Practice Patterns Institute, Inc
Type of organization	Research organization
Date submitted	4/5/2013
Comment	Our recent completed project Anemia Management Strategies and Mortality in Complex Elderly Dialysis Patients supports the following anemia management goals: Anemia management of chronic kidney disease: Hgb > 12 g/dL. Further elaboration on our findings will be presented to CMS on April 22nd.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Rex L. Mahnensmith, MD rex.mahnensmith@yale.edu
Type of organization	Individual
Date submitted	4/22/2013
Comment	<p>1 - it is appropriate that a clinic NOT be penalized in any way if a patient has Hb > 12 AND has not received an ESA -- this prevails among some PKD patients and among some who have acquired cystic disease.</p> <p>2 - it is also appropriate and important that a clinic NOT be penalized in any way if a patient has a Hb > 12 AND received one dose of an ESA earlier in the month -- recognized, ESA put on hold -- yet Hb may not fall to a Hb < 12 ---- the doctor and the clinic is managing anemia perfectly to recognize a target 'overshoot' and STOP the ESA --- and this can happen among healthy ESRD patients easily --- the Hb may not decline rapidly ---- this context should NOT receive any penalty ---- but should be REWARDED</p>
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. The proposed measure includes a 3-month average hemoglobin > 12 g/dL as opposed to a single monthly hemoglobin in order to reflect the transient variations in achieved hemoglobin frequently seen in ESA-treated chronic dialysis patients. In addition, the data is only included in the average calculation if at least 2 out of the 3 months report an ESA. Therefore, if ESA is stopped after its first occurrence then the hemoglobin value over 12 g/dL for a following month is not included in the average calculation for the 3-month period (or excluded all together if ESA is used in 1 or less months during the 3-month period). Hence, appropriate anemia care is accounted for in the situations that have been highlighted. The calculation for this measure is similar to what is currently in use by the Dialysis Facility Compare.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about the use of a 3 month reporting period, the historical annual measure referred to by the comments is based on a TEP held in 2007. The TEP's recommendations were made before the shift in anemia management, such that the measures approved by NQF for CPMIII and used in DFR and DFC were appropriate for revision. The 2012 Anemia TEP reviewed those specifications, as well as all other approved anemia measure specifications and strongly recommended use of an alternative definition, reflected in the proposed measures. Additionally, the 3-month average calculation has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage in at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). This suggests that more intervention may be needed within a shorter time frame to address more frequent fluctuations in hemoglobin levels. The 3-month measure also has a larger variation across facilities, which suggests that there is still a gap in performance (2011 IQRs: 7% vs. 3.6% patients).</p> <p>With regards to the definition of the 3 month reporting period, A greater level of clarity will be considered in updates during the next round of measure specification forms. To be clear this is a regular 3-month average, and not a 3-month rolling average. We are not combining the 3-month averages over a year. Rather the performance period is 3 months and not 12 months, which has been a common metric used for reporting in the past (e.g DFR). The 3-month calculation follows</p>

	closely with more recent reports (e.g. DFC). A 3-month average may be reported up to 4 times during a year, but are independent calculations. A data point is “flagged” during a 3-month period if the 3-month average exceeds the threshold of 12 g/dL.
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Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Lori Hartwell Founder and President Renal Support Network Lori@RSNhope.org Comment submitted on behalf of Renal Support Network
Type of organization	Patient advocacy organization
Date submitted	4/30/2013
Comment	See Appendix 4_ RenalSupportNetwork
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. While it is true that the hemoglobin levels in US dialysis patients are declining, there is still a need to monitor high hemoglobin levels in ESA-treated patients. The 3-month measure has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage out of at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). The 3-month measure also shows variation across facilities, which suggests that there is still a gap in performance that has been identified (2011 IQRs: 7% vs. 3.6% patients). However, this proposed quality measure does not reflect any changes that have been developed for QIP at this time.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Glenda Harbert, RN, CNN, CPHQ Executive Director ESRD Network of Texas Inc GHarbert@nw14.esrd.net Comment submitted on behalf of ESRD Network of Texas Inc
Type of organization	ESRD Network
Date submitted	4/30/2013
Comment	See Appendix 5_ESRDNetwork14
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7_NationalForumofESRDNetworks
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about individualized care, CMS supports and encourages individualization of treatment that is provided by the physician, and recognizes that there is variation among patients as well as physician care. However, thresholds for performance measures are selected based on a more global scale. The measures are intended to guard against adverse outcomes associated with higher levels of hemoglobin for ESA-treated dialysis patients at the facility level. Significant differences in this risk-adjusted measure's outcome reflect facility-level differences in care. In addition, comparisons of facility level measures essentially allow comparison of an individual facility's outcomes to a clinical consensus standard, defined by the dialysis community.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Dori Schatell, MS Executive Director Medical Education Institute, Inc. schatell@meiresearch.org Comment submitted on behalf of Medical Education Institute, Inc.
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 8_ MedicalEducationInstitute
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. While it is true that the hemoglobin levels in US dialysis patients are declining, there is still a need to monitor high hemoglobin levels in ESA-treated patients. The 3-month measure has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage out of at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). The 3-month measure also shows variation across facilities, which suggests that there is still a gap in performance that has been identified (2011 IQRs: 7% vs. 3.6% patients). However, this proposed quality measure does not reflect any changes that have been developed for QIP at this time.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree that a single month measure is undesirable; correspondingly, we are using a 3-month average. This would be expected to produce provider-level results that are quite similar to a 3-month rolling average. Although both 3-month and 3-month-rolling averages essentially smooth the data, the 3-month rolling average has the certain disadvantages which make it less desirable in the context of a calendar-year specific facility evaluations. Furthermore, we feel the 3-month non-rolling average is a reasonable compromise as it more appropriately reflects better anemia care than a single monthly measure, but also captures more fluctuations in hemoglobin levels than a 12-month average. The calculation for this measure is similar to what is currently in use by the Dialysis Facility Compare (DFC).

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about the 3 month reporting period, the historical annual measure referred to by the comments is based on a TEP held in 2007. The TEP's recommendations were made before the cataclysmic shift in anemia management, such that the measures approved by NQF for CPMIII and used in DFR and DFC were appropriate for revision. The 2012 Anemia TEP reviewed those specifications, as well as all other approved anemia measure specifications and strongly recommended use of an alternative definition, reflected in the proposed measures. Additionally, the 3-month average calculation has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage in at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). This suggests that more intervention may be needed within a shorter time frame to address more frequent fluctuations in hemoglobin levels. The 3-month measure also has a larger variation across facilities, which suggests that there is still a gap in performance (2011 IQRs: 7% vs. 3.6% patients).</p> <p>With regards to the definition of the 3 month reporting period, A greater level of clarity will be considered in updates during the next round of measure specification forms. To be clear this is a regular 3-month average, and not a 3-month rolling average. We are not combining the 3-month averages over a year. Rather the performance period is 3 months and not 12 months, which has been a common metric used for reporting in the past (e.g DFR). The 3-month calculation follows closely with more recent reports (e.g. DFC). A 3-month average may be reported up to 4 times during a year, but are</p>

	independent calculations. A data point is “flagged” during a 3-month period if the 3-month average exceeds the threshold of 12 g/dL.
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Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	<p>Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council</p>
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about individualized care, CMS supports and encourages individualization of treatment that is provided by the physician, and recognizes that there is variation among patients as well as physician care. However, thresholds for performance measures are selected based on a more global scale. The measures are intended to guard against adverse outcomes associated with higher levels of hemoglobin for ESA-treated dialysis patients at the facility level. Significant differences in this risk-adjusted measure's outcome reflect facility-level differences in care. In addition, comparisons of facility level measures essentially allow comparison of an individual facility's outcomes to a clinical consensus standard, defined by the dialysis community.</p> <p>With regards to your concerns about the 3 month reporting period, the historical annual measure referred to by the comments is based on a TEP held in 2007. The TEP's recommendations were made before the shift in anemia management, such that the measures approved by NQF for CPMIII and used in DFR and DFC were appropriate for revision. The 2012 Anemia TEP reviewed those specifications, as well as all other approved anemia measure specifications and strongly recommended use of an alternative definition, reflected in the proposed measures. Additionally, the 3-month average calculation has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage in at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). This suggests that more intervention may be needed within a shorter time frame to address more frequent fluctuations in hemoglobin levels. The 3-month measure also has a larger variation across facilities,</p>

which suggests that there is still a gap in performance (2011 IQRs: 7% vs. 3.6% patients).

With regards to the definition of the 3 month reporting period, A greater level of clarity will be considered in updates during the next round of measure specification forms. To be clear this is a regular 3-month average, and not a 3-month rolling average. We are not combining the 3-month averages over a year. Rather the performance period is 3 months and not 12 months, which has been a common metric used for reporting in the past (e.g DFR). The 3-month calculation follows closely with more recent reports (e.g. DFC). A 3-month average may be reported up to 4 times during a year, but are independent calculations. A data point is “flagged” during a 3-month period if the 3-month average exceeds the threshold of 12 g/dL.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. While it is true that the hemoglobin levels in US dialysis patients are declining, there is still a need to monitor high hemoglobin levels in ESA-treated patients. The 3-month measure has been shown to capture more frequent occurrences of hemoglobin levels exceeding 12 g/dL with continued ESA usage out of at least 2 of the 3 months when compared to the 12-month measure used by the DFR (2011 medians: 6.5% vs. 1.1% patients). The 3-month measure also shows variation across facilities, which suggests that there is still a gap in performance that has been identified (2011 IQRs: 7% vs. 3.6% patients). However, this proposed quality measure does not reflect any changes that have been developed for QIP at this time.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb>12 g/dL
Commenter	Maria Regnier, RN, MSN, CNN Dialysis Director Sanford Health maria.regnier@sanfordhealth.org Comment submitted on behalf of Sanford Health
Type of organization	Dialysis organization
Date submitted	4/18/2013
Comment	See Appendix 16_SanfordHealth
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Comments on Anemia of chronic kidney disease: Hgb < 10 g/dL

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	The Network 5's Medical Review Board supports reintroducing a Hgb floor to minimize variation in treatment but recommends the measure be Hgb<9 g/dl which is consistent with the most recent KDIGO anemia guideline. A floor value is implicit in the use of ESA therapy and its reintroduction would contribute to transfusion avoidance.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled "Anemia of chronic kidney disease: Hgb < 10 g/dl". Thank you.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Derrick Latos, MD Medical Director Wheeling Renal Care, LLC DLatos@wrc3.com Comment submitted on behalf of Wheeling Renal Care, LLC
Type of organization	Dialysis Facility
Date submitted	4/18/2013
Comment	See Appendix 21_WheelingRenalCare
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We recognize that gastrointestinal blood loss often can require additional anemia management resources with higher ESA or iron doses. The Prospective Payment System (PPS) bundle for ESRD allows for incremental facility payment for gastrointestinal bleeding to offset these costs. Therefore, we are not excluding these conditions from the measure, but do understand that some patients will not be able to reach an achieved hemoglobin of > 10 g/dl or that it may not be appropriate to do so.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Daniel W. Coyne, MD Professor of Medicine, Renal Diseases Washington University School of Medicine Dcoyne@dom.wustl.edu
Type of organization	Academic
Date submitted	4/18/2013
Comment	See Appendix 1_D.Coyne
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We appreciate comments that highlight potential unintended consequences of a measure. However, this measure does not specify how facilities or providers should respond to hemoglobin levels < 10 g/dl.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Jerome A. Bailey Communications Director, American Association of Kidney Patients (AAKP) jbailey@aakp.org Commenting on behalf of AAKP
Type of organization	Patient organization
Date submitted	4/25/2013
Comment	The concern about hemoglobin falling too low is rational given the age of dialysis patients and the high evidence of cardiovascular including peripheral vascular and cerebrovascular disease in this population. In contradistinction to the NICE recommendations the KDIGO and the KHA-CARI guidelines suggest use of ESA to prevent the Hb falling below 9.5 g/dl to avoid the need for transfusions, etc. The latter two guidelines are riskier for patients, not necessarily because the guidelines are wrong, but because given the practice of medicine in dialysis units and particularly the usual once a month measurement Hb will often fall below 9.5 and even below 9 in a population of patients such that in a proportion of patients adverse effect might be more common. The NICE guidelines permit large safety margin and should be preferred.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. The decision to use 10 g/dL as the lower threshold for hemoglobin was made by the Technical Expert Panel (TEP) convened in 2012. The TEP considered the available guidelines when deciding on using the value of 10 g/dl as the lower threshold.

Measure/Measure set	Anemia of chronic kidney disease: Hgb<10 g/dL
Commenter	Dennis J. Cotter President Medical Technology and Practice Patterns Institute, Inc. dcott@mtppi.org Comment submitted on behalf of Medical Technology and Practice Patterns Institute, Inc
Type of organization	Research organization
Date submitted	4/5/2013
Comment	Our recent completed project Anemia Management Strategies and Mortality in Complex Elderly Dialysis Patients supports the following anemia management goals: Anemia management of chronic kidney disease: Hgb < 10 g/dL. Further elaboration on our findings will be presented to CMS on April 22nd.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb<10 g/dL
Commenter	<p>Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology</p>
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We appreciate your support of the 3 month average hemoglobin, which this measure uses for reporting. We recognize that some ESRD patients will have difficulty achieving a hemoglobin > 10 g/dl, or that achieving such a hemoglobin may not be appropriate, but defining the proportion of patients that meet this target is beyond the scope of the measure development process. This measure is designed to evaluate facility practice, and was not designed to preclude individualization in patient care.</p> <p>We agree that a one-month measure is undesirable; correspondingly, we are using a 3-month average. This would be expected to produce facility-level results that are quite similar to a 3-month rolling average. Although both 3-month and 3-month-rolling averages smooth data, the 3-month rolling average can be problematic in the context of calendar-year specific facility evaluations. We would also like to note that the 12-month calculation has been a common metric for reporting in the past (e.g. DFR). The calculation for this measure is similar to what is currently in use by the Dialysis Facility Compare. The four 3-month time periods will not be combined into a yearly measure. That is, each 3-month time period will be evaluated independently as to the proportion of patients with a Hgb < 10 g/dl.</p>

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree that thoughtful discussion with all stakeholders is critical in the measure development process as evidenced by convening technical expert panels, public comment periods, and other mechanisms to inform the process. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, we anticipate that future updates to the measure may be needed.</p> <p>We apologize for any confusion about the measure specifications. This measure uses a regular 3-month average, and not a 3-month rolling average. The four 3-month time periods will not be combined into a yearly measure. That is, each 3-month time period will be evaluated independently as to the proportion of patients with Hgb < 10 g/dl. We would also like to note that the 12-month calculation has been a common metric for reporting in the past (e.g. DFR).</p>

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Jason Spangler, MD, MPH Executive Director U.S. Health Policy and Reimbursement Amgen jspangle@amgen.com Comment submitted on behalf of Amgen
Type of organization	Pharmaceutical
Date submitted	4/26/2013
Comment	See Appendix 3_Amgen
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We note that The Anemia of Chronic Kidney Disease (CKD): Hemoglobin (Hb) < 10 g/dL measure is at the facility level, and the measure forms have been updated to provide clarification.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Lori Hartwell Founder and President Renal Support Network Lori@RSNhope.org Comment submitted on behalf of Renal Support Network
Type of organization	Patient advocacy organization
Date submitted	4/30/2013
Comment	See Appendix 4_ RenalSupportNetwork
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. Several commenters expressed concerns that dialysis providers are frequently not involved in the decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events and that in certain circumstances transfusions may be indicated as part of anemia management. We believe the measure is sensitive enough to capture improvement at the facility level over time.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Glenda Harbert, RN, CNN, CPHQ Executive Director ESRD Network of Texas Inc GHarbert@nw14.esrd.net Comment submitted on behalf of ESRD Network of Texas Inc
Type of organization	ESRD Network
Date submitted	4/30/2013
Comment	See Appendix 5_ESRDNetwork14
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. Several commenters expressed concerns that dialysis providers are frequently not involved in the decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events and that in certain circumstances transfusions may be indicated as part of anemia management. We believe the measure is sensitive enough to capture improvement at the facility level over time.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7__NationalForumofESRDNetworks
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Dori Schatell, MS Executive Director Medical Education Institute, Inc. schatell@meiresearch.org Comment submitted on behalf of Medical Education Institute, Inc.
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 8_ MedicalEducationInstitute
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb<10 g/dL
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input and agree that given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, and recent changes in anemia practice patterns, selecting a baseline time period for performance evaluation will need to be done carefully.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input and apologize for any confusion about the measure specifications. This measure uses a regular 3-month average, and not a 3-month rolling average. The four 3-month time periods will not be combined into a yearly measure. That is, each 3-month time period will be evaluated independently as to the proportion of patients with a Hgb < 10 g/dl. We would also like to note that the 12-month calculation has been a common metric for reporting in the past (e.g. DFR).

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree with the principle that patient care should be individualized. This measure is designed to evaluate facility practice, and was not designed to preclude individualization in patient care. We also agree that it would be quite challenging to target a 1 g/dl range in Hgb values, but the FDA package insert states that when Hgb values approach or exceed 11 g/dl, the ESA dose should be reduced or held. It does not state that the Hgb should be kept below 11 g/dl. Thus, we believe this measure harmonizes with other proposed and existing measures and does not create an unrealistic Hgb target. We appreciate the comments about reporting ranges of low hemoglobin values. While this would create more detailed information, it still defines a group of patients that are at increased risk of receiving a blood transfusion.</p> <p>With regards to the 3 month averages, this is a regular 3-month average, and not a 3-month rolling average. We are not combining the 3-month averages over a year. Rather, the performance period is 3-months and not 12-months, which has been a common metric used for reporting in the past (e.g DFR). The 3-month calculation follows closely with more recent reports (e.g. DFC). A 3-month average may be reported up to 4 times during a year, but are independent calculations. A data point is “flagged” during a 3-month period if the 3-month average exceeds the threshold of 12 g/dL, and so the assessment is addressing a shorter time frame.</p>

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input. We appreciate your support of the measure, which does use a three month average for calculating facility level outcomes. Although both 3-month and 3-month-rolling averages smooth data, the 3-month rolling average can be problematic in the context of calendar-year specific facility evaluations. We would also like to note that the 12-month calculation has been a common metric for reporting in the past (e.g. DFR). The calculation for this measure is similar to what is currently in use by the Dialysis Facility Compare.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Doug Johnson, MD Vice Chairman, Dialysis Clinic, Inc. (DCI) doug.johnson@dcinc.org Commenting on behalf of DCI
Type of organization	Large Dialysis Facility
Date submitted	5/2/2013
Comment	See Appendix 17_DialysisClinicInc
Recommendations/actions taken	Thank you for your comments in support of this measure. We believe that the standardized transfusion ratio will be complimentary to the hemoglobin < 10 g/dl measure given that some, but not all, transfusions may reflect facility anemia practice patterns.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Nancy Pelfrey, MSN, RN, ACNP-C, CNN-NP nancy.pelfrey@reliantrenalcare.com Submitting comments on behalf of self, not employer (Reliant Renal Care)
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	I am in agreement about reinstituting a hgb floor/lower limit. I am not convinced that 10 is the magic number.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input. We recognize that there is considerable debate over the specifics of a low hemoglobin value. The TEP convened in 2012 discussed this issue and ultimately was in favor of using the value of 10 g/dL.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Maria Regnier, RN, MSN, CNN Dialysis Director Sanford Health maria.regnier@sanfordhealth.org Comment submitted on behalf of Sanford Health
Type of organization	Dialysis organization
Date submitted	4/18/2013
Comment	See Appendix 16_SanfordHealth
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Hgb < 10 g/dL
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input. We recognize that gastrointestinal blood loss often can require additional anemia management resources with higher ESA or iron doses. The Prospective Payment System (PPS) bundle for ESRD allows for incremental facility payment for gastrointestinal bleeding to offset these costs. Therefore, we are not excluding these conditions from the measure, but do understand that some patients will not be able to reach an achieved hemoglobin of > 10 g/dl or that it may not be appropriate to do so.

Comments on Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	Network 5's Medical Review Board finds this measure acceptable.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled "Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio". Thank you.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Derrick Latos, MD Medical Director Wheeling Renal Care, LLC DLatos@wrc3.com Comment submitted on behalf of Wheeling Renal Care, LLC
Type of organization	Dialysis Facility
Date submitted	4/18/2013
Comment	See Appendix 21_WheelingRenalCare
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regard to your concerns about facility attribution, several commenters expressed concerns that dialysis providers are frequently not involved in the decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events such as gastrointestinal bleeding or trauma. However, our own research (Hirth 2012) as well as that by Sibbel, et al. (Sibbel 2013) identifies a strong association between achieved hemoglobin and subsequent transfusion events. In both patient and facility level risk-adjusted models, achieved hemoglobin is the strongest predictor of subsequent transfusions. These observational analyses are consistent with the findings of an earlier randomized controlled trial (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. That is, a patient who develops a gastrointestinal bleed is more likely to be transfused if the baseline hemoglobin is 8 g/dl compared to a baseline hemoglobin of 11 g/dl. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.</p>

	<p>Also, page 5 of the Measure Information Form under Denominator details clearly states how the algorithm for STrR measure attributes a patient to a facility and hence circumvents the issue of where the transfusion is administered (hospital-based unit, infusion center, inpatient stay, etc.). If a patient undergoes a transfusion event, the facility to which this patient is assigned to is responsible for it irrespective of where the event takes place.</p> <p>STrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.</p> <p>With regards to your request to use units of blood transfused over transfusion events, we agree that it would be helpful to know the number of units of blood transfused, however, units of blood are not reported on all Medicare claims with transfusion events . resulting in a data availability issue that would preclude an accurate calculation of a facility measure</p>
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Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Marsha Kimmer RN, CDN marsha.kimmer@gmail.com
Type of organization	Individual
Date submitted	4/12/2013
Comment	All patients are different. Patients should receive transfusions if they need them. ESRD patients who also have cancer often need transfusions and the dialysis units should be paid for that service. I often had to send the patient to a transfusion center because that center was paid for the transfusion. This is dangerous for the patient because blood has potassium in it and sometimes the patient couldn't be scheduled to be dialyzed right after the transfusion. It was also an inconvenience for the patient who was already so sick.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree with the principle that patient care should be individualized and that in certain situations transfusions may be required in the management of anemia. This measure is designed to evaluate facility practice by monitoring the rate of transfusions attributed to a facility, and was not designed to preclude individualization in patient care. We thank you for your general support and agree that transfusions may be inconvenient for patients and do have risks associated with them.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	<p>Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.</p>
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about individualization of care, we agree with the principle that patient care should be individualized. However, the dialysis facility participates in anemia management by administering ESA therapy and therefore there is a shared responsibility between the individual provider and the facility.</p> <p>With regards to your concerns about data availability, we agree that determination of blood transfusion from Medicare claims is a complex undertaking. In addition to other researchers, we have successfully performed research using claims-based blood transfusion metrics using standard Medicare-claims methodology.</p> <p>Regarding the timeliness of transfusion reporting to dialysis units, the STrR is developed as an annual measure. From this perspective, reported information (even with several months of lag) can lead to changes in quality at the facility level, from year to year.</p> <p>We agree that a transfusion model would require many variables to accurately predict transfusions. Correspondingly, our model adjusts for many patient characteristics. In addition, patients with conditions which put them at the highest inherent risk for transfusions have been excluded. It is important to note the distinction between two scenarios: (i) a model predicts</p>

	<p>events precisely at the patient level (ii) the model discriminates patients adequately to induce accurate center-level comparisons to an overall average.</p>
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	<p>Your comment pertains to (i), although (ii) is a less ambitious and more relevant goal.</p>
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	<p>We thank you for your recommendation that CMS and the USRDS continue its population based surveillance of transfusions and hemoglobin <10 g/dl.</p>
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Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	<p>Jason Spangler, MD, MPH Executive Director U.S. Health Policy and Reimbursement Amgen jspangle@amgen.com Comment submitted on behalf of Amgen</p>
Type of organization	Pharmaceutical
Date submitted	4/26/2013
Comment	See Appendix 3_Amgen
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We will take your feedback regarding regional practices into consideration as we continue refining our exclusions and risk adjustment strategies. We also agree considerations are necessary for small facilities and hence facilities with very few number of patients are excluded so that they not adversely impacted by this measure.</p> <p>With regards to your comment on undertreatment, we thank you for highlighting the difficulty that some facilities have with determining when patients are being transfused in other clinical venues such as a hospital setting. Even with annual reporting, the STrR will provide valuable information for these facilities so that they can evaluate their anemia management practices in an effort to minimize transfusions.</p> <p>We appreciate your suggestion that this measure is more suitable as a reporting measure for Dialysis Facility Compare and will take this into consideration while making decisions regarding its implementation.</p>

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Lori Hartwell Founder and President Renal Support Network Lori@RSNhope.org Comment submitted on behalf of Renal Support Network
Type of organization	Patient advocacy organization
Date submitted	4/30/2013
Comment	See Appendix 4_ RenalSupportNetwork
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Glenda Harbert, RN, CNN, CPHQ Executive Director ESRD Network of Texas Inc GHarbert@nw14.esrd.net Comment submitted on behalf of ESRD Network of Texas Inc
Type of organization	ESRD Network
Date submitted	4/30/2013
Comment	See Appendix 5_ESRDNetwork14
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We believe that even with annual reporting, the STeR data would assist facilities in evaluation their anemia management practices. Guidelines, such as those recently published by KDIGO, provide some direction for facilities in the effort to minimize transfusions.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. Several commenters expressed concerns that dialysis providers are frequently not involved in the decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events such as gastrointestinal bleeding or trauma. However, our own research (Hirth 2012) as well as that by Sibbel, et al. (Sibbel 2013) identifies a strong association between achieved hemoglobin and subsequent transfusion events. In both patient and facility level risk-adjusted models, achieved hemoglobin is the strongest predictor of subsequent transfusions. These observational analyses are consistent with the findings of an earlier randomized controlled trial (Foley, CJASN 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.</p> <p>Also, page 5 of the Measure Information Form under Denominator details clearly states how the algorithm for STtR measure attributes a patient to a facility and hence circumvents the issue of where the transfusion is administered (hospital-based unit, infusion center, inpatient stay, etc.). If a patient undergoes a transfusion event, the facility to which this patient is assigned to is responsible for it irrespective of where the event takes place.</p>

	<p>STrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.</p> <p>We also note that the FDA states that for patients with the anemia of chronic kidney disease on dialysis, initiate ESA treatment when the hemoglobin level is less than 10 g/dL.</p>
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Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7__NationalForumofESRDNetworks
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Dori Schatell, MS Executive Director Medical Education Institute, Inc. schatell@meiresearch.org Comment submitted on behalf of Medical Education Institute, Inc.
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 8_ MedicalEducationInstitute
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about exclusions, The exclusion list is based on recommendations of the Anemia Technical Expert Panel (TEP) convened in 2012; as well as recent peer reviewed publications evaluating transfusions (Ibrahim 2008). We have performed analyses to assess the strength and temporal relationship of the comorbidity exclusion categories with transfusion events using logistic regression models. All categories of cancer included in our models are significantly associated with transfusion risk. For example, head and neck cancer in the past year predicted (odds ratio 1.3 (1.2, 1.5)) transfusion events when compared to those detected two or more years earlier. We have found similar trends with other cancer categories.</p> <p>With regards to your concerns about inclusion in QIP, In addition to STrR there are other proposed measures like Hg < 10, Hg > 12, patient informed consent, ESA management to avoid transfusion to appropriately assess facilities' overall anemia management practices and more measures might give facilities more tools for quality improvement. But how many of the measures will ultimately be utilized and how they will be implemented is beyond the scope of this work.</p> <p>Finally, with regards to your concern that the measure may discourage transfusions in appropriate situations, the decision to transfuse a patient with an acute condition, in part, relates to the hemoglobin concentration present at onset, which is affected by the facility's anemia management. We acknowledge the unintended consequence of a measure but, as have been pointed out by multiple commenters to the proposed anemia measures, the vast majority of transfusions occur during acute care hospitalizations. Thus, the clinicians determining transfusion need are not likely to be influenced by a</p>

	measure designed to evaluate transfusion events at the dialysis facility level, other than taking the patient's achieved hemoglobin into consideration when determining whether transfusion is indicated.
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Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. With regards to your concerns about exclusions, The exclusion list is based on recommendations of the Anemia Technical Expert Panel (TEP) convened in 2012; as well as recent peer reviewed publications evaluating transfusions (Ibrahim 2008). We have performed analyses to assess the strength and temporal relationship of the comorbidity exclusion categories with transfusion events using logistic regression models. All categories of cancer included in our models are significantly associated with transfusion risk. For example, head and neck cancer in the past year predicted (odds ratio 1.3 (1.2, 1.5)) transfusion events when compared to those detected two or more years earlier. We have found similar trends with other cancer categories.</p> <p>We appreciate the comments identifying conditions associated with gastrointestinal bleeding as contributors to transfusions. In fact, the expanded Prospective Payment system recognizes this clinical effect by providing a payment multiplier when GI bleeding is present. Furthermore, dialysis provider practices, including but not limited to dose of intradialytic anticoagulation, dialysis adequacy and prescription of medications can potentially contribute to the incidence of GI bleeding in this patient population. Given the complex interplay between clinical practices, payment system reimbursement and anemia management, we feel that it is inappropriate to include comorbidity adjustment for conditions associated with GI bleeding at this time. We thank you for your input and will consider them as we refine our exclusions.</p> <p>In regards to your concerns about data availability and implementation, several commenters have highlighted the difficulty</p>

that some facilities have with determining when patients are being transfused in other clinical venues such as a hospital setting. The STTrR will provide facilities with information that they may not otherwise be able to obtain on their own. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, and since there is a strong association between achieved hemoglobin and subsequent transfusion events, the dialysis facility does have a shared responsibility in transfusion events.

We agree that determination of blood transfusion from Medicare claims is a complex undertaking. In addition to other researchers, we have successfully performed research using claims-based blood transfusion metrics using standard Medicare-claims methodology.

In addition, STTrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. As an illustration, dialysis facilities accept financial responsibility under the ESRD QIP for small solute adequate outcomes, but it is physicians that prescribe dialysis. Therefore facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. The goal is to provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.

With regards to your comment on the STTrR model and risk adjustment criteria, we note that the measure applies to all dialysis patients including both in-center and home dialysis patients. We recognize the limitations of the 2728, however including a comorbidity index variable based on 2728 has improved the model performance as it is highly significant in predicting transfusion events. In addition to the incident comorbidities that are highly predictive, we are in the process of refining our claims-based exclusions so that the risk adjustment model reflects more recent comorbidities.

We agree that time adjusted comorbidities are appropriate and we will take them into consideration as we pursue future refinement of the risk adjustment strategies.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.. We believe that even with annual reporting, the STTr data would assist facilities in evaluation their anemia management practices. Guidelines, such as those recently published by KDIGO, provide some direction for facilities in the effort to minimize transfusions. We agree that this measure should not be the only measure used to assess appropriate anemia management. Hence, we have other proposed measures like Hg < 10, Hg > 12, Informed Consent for ESA Treatment, and ESA Management to Avoid Transfusion in addition to STTr measure to appropriately assess facilities' anemia management practices.</p> <p>The STTr will provide facilities with information that they may not otherwise be able to obtain on their own. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, and since there is a strong association between achieved hemoglobin and subsequent transfusion events, the dialysis facility does have a shared responsibility in transfusion events.</p> <p>We agree that determination of blood transfusion from Medicare claims is a complex undertaking. In addition to other researchers, we have successfully performed research using claims-based blood transfusion metrics using standard Medicare-claims methodology.</p>

	<p>To add, STrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. If dialysis facilities are currently unable to reliably identify transfusion events in their patients, how can they be expected to appropriately modify the anemia management practices that contribute to transfusions? Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.</p>
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Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We clarified what comorbidity index means in the included measure justification forms. The availability of the data does not allow us to do physician adjustment; however we thank you for your inputs and will take them into consideration as we continue refining our exclusions and risk adjustment strategies.</p> <p>Thank you for your feedback on regional practices, we will take them into consideration as we continue refining our exclusions and risk adjustment strategies.</p> <p>STrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.</p>

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We appreciate you highlighting the difficulty that some facilities have with determining when patients are being transfused in other clinical venues such as a hospital setting. The STRR will provide facilities with information that they may not otherwise be able to obtain on their own. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, and since there is a strong association between achieved hemoglobin and subsequent transfusion events, the dialysis facility does have a shared responsibility in transfusion events.</p> <p>Several commenters expressed concerns that dialysis providers are frequently not involved in the decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events such as gastrointestinal bleeding or trauma. However, our own research, (Hirth 2012) as well as that by Sibbel, et al. (Sibbel 2013) identifies a strong association between achieved hemoglobin and subsequent transfusion events. In both patient and facility level risk-adjusted models, achieved hemoglobin is the strongest predictor of subsequent transfusions. These observational analyses are consistent with the findings of an earlier randomized controlled trial (Foley 2008) that identified marked differences in rates of transfusion related to targeted hemoglobin. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. The responsibility of the dialysis facility for</p>

achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

Also, page 5 of the Measure Information Form under Denominator details clearly states how the algorithm for STrR measure attributes a patient to a facility and hence circumvents the issue of where the transfusion is administered (hospital-based unit, infusion center, inpatient stay, etc.). If a patient undergoes a transfusion event, the facility to which this patient is assigned to is responsible for it irrespective of where the event takes place.

STrR is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.

We also note that the FDA states that for patients with the anemia of chronic kidney disease on dialysis, initiate ESA treatment when the hemoglobin level is less than 10 g/dL.

With regards to your concerns about the model and risk adjustment criteria, we clarified what comorbidity index means in the included measure justification forms. The availability of the data does not allow us to do physician adjustment; however we thank you for your inputs and will take them into consideration as we continue refining our exclusions and risk adjustment strategies.

The STTr is developed as an annual measure and reporting information even with several months of lag can lead to changes in quality at the year-to-year facility level. Using the dialysis adequacy argument, dialysis facilities accept financial responsibility under the QIP for small solute adequate outcomes, despite the fact that physicians prescribe dialysis. Facilities and physician-providers have shared responsibility for outcomes. We thank the commenters for pointing out another added benefit of this measure. Implementation of this measure will provide valuable feedback for dialysis facilities and nephrologists and bring in increased transparency especially vital for small and independent facilities as they continue to provide anemia management care to dialysis patients, working to prevent unnecessary transfusions.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree that this measure should not be the only measure used to assess appropriate anemia management. Hence, we have other proposed measures like Hg < 10, Hg > 12, and Informed Consent for ESA Treatment in addition to STrR measure to appropriately assess facilities' anemia management practices.

Measure/Measure set	Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
Commenter	David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. This measure is intended to assess the facilities' overall effectiveness in preventing transfusions through anemia management. However how this measure will be utilized and implemented is beyond the scope of this work. Also, page 5 of the Measure Information Form under Denominator details states how the algorithm for STrR measure attributes a patient to a facility and hence circumvents the issue of where the transfusion is administered (hospital-based unit, infusion center, inpatient stay, etc.) hence we disagree that hospital based units will be penalized by this measure for administering a transfusion to patient who is assigned to a different facility.

Comments received for Anemia of chronic kidney disease: Patient informed consent for ESA treatment

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	An unintended consequence of this draft measure may be a measurable increase in the rate of beneficiaries requiring transfusions due to a significant number of patients refusing treatments with ESAs. Network 5's Medical Review Board supports informing patients about the potential risks associated with aggressive treatment of anemia of CKD on dialysis with ESAs, however, the mechanism used to inform patients should be balanced between the known risks of aggressive use of ESAs and the benefits that appropriate use of ESAs can have on patient's quality of life. The current medication guide on ESA use contains information only on the risk of ESA therapy with no mention of any benefit. This is at cross purposes with the medical justification for the proposed Hgb<10 g/dl measure which cites patient quality of life.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We agree that informed consent requires balanced information about both risks and benefits. This proposed measure, as specified, does not define the specific content of the informed consent. It requires attestation by the facility that informed consent was updated annually. We disagree with the statement that this measure is "at cross purposes" with the medical justification for the proposed Hgb < 10 g/dL measure. Failure to inform a patient about the potential benefits to quality of life associated with increased hemoglobin levels would not be sufficient to fulfill the definition of true informed consent.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled 'Anemia of chronic kidney disease: Patient informed consent for ESA treatment'. Thank you
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Marsha Kimmer RN, CDN marsha.kimmer@gmail.com
Type of organization	Individual
Date submitted	4/12/2013
Comment	I believe that all patients should have informed consent for ESA treatment and have the right to refuse. The staff should know if the pt has a history of cancer and work with the patient's oncologist to decide if the pt should receive ESA therapy.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. We would like to clarify this measure was not proposed by the 2012 Anemia Management TEP. Subsequent to the TEP meeting and issuance of their recommendations to CMS, we received separate direction from CMS on the development of this measure. The posted measure specifications for this measure provide a clear statement of the principles of true informed consent. The Measure Justification Form and Measure Information Form do not propose components of the REMS Program be used or substituted for provision of a balanced informed consent for ESA use in this patient population. We agree with the comment that "...having such a discussion regarding individual risk and benefit, takes place between a health care provider such as a doctor or NP and the patient." We clarify that the proposed measure specifications do not require the facility staff to provide the informed consent. Rather, the facility is required to attest that the informed consent discussion was provided for patients in the facility and that it was updated annually. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seem prudent. CMS believes in promoting shared accountability. It is recognized that both dialysis facilities and physician providers receive payment from CMS for anemia management treatment as part of the ESRD bundled payment for services, and that ESAs are administered by dialysis facility staff. Therefore shared responsibility for adherence to the fundamental ethical principles of informed consent is appropriate. We agree and thank the commenter for suggestion a parallel metric for physician providers.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	<p>Jason Spangler, MD, MPH Executive Director U.S. Health Policy and Reimbursement Amgen jspangle@amgen.com Comment submitted on behalf of Amgen</p>
Type of organization	Pharmaceutical
Date submitted	4/26/2013
Comment	See Appendix 3_Amgen
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. The commenter correctly points out the absence of informed consent attestations as quality metrics to date. However we note it does not necessarily follow that an informed consent metric is inappropriate for the particular setting of ESA therapy of patients with CKD. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seem prudent. We also note that several other commenters have raised concerns with reliance on material included in the Patient Information document developed for use in the REMS Program, and that true informed consent requires balanced discussion of both the risks and the benefits of a proposed treatment. We also agree informed consent should include discussion of both the risks and benefits of a contemplated treatment.</p>

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Lori Hartwell Founder and President Renal Support Network Lori@RSNhope.org Comment submitted on behalf of Renal Support Network
Type of organization	Patient advocacy organization
Date submitted	4/30/2013
Comment	See Appendix 4_ RenalSupportNetwork
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input. The intent and subsequent development of this proposed measure was to address the specific interaction between the patient and provider regarding informed consent. We recognize there are multiple components of patient education that can each be individually captured in a quality measure but these are beyond the specific intent of this measure.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Dori Schatell, MS Executive Director Medical Education Institute, Inc. schatell@meiresearch.org Comment submitted on behalf of Medical Education Institute, Inc.
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 8_ MedicalEducationInstitute
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. The commenter raises several important limitations of the proposed measure. As specified, the measure does not define what the minimum components of informed consent should include, nor does it evaluate effectiveness of the informed consent provided. In addition, the commenter correctly notes the measure is an attestation rather than a measure of effectiveness of the informed consent process. However, we believe the attestation of obtaining informed consent presents an important starting point with the ultimate goal to ensure that dialysis patients are truly informed about both the risks and potential benefits of ESA use. We disagree with the statement that this measure is duplicative with the FDA REMS Program. Other commenters have also noted this disagreement about the REMS. We also note that comments from one large national dialysis organization strongly suggest that the FDA REMS program would be misapplied if used to define patient informed consent documentation for this proposed measure. We agree with that opinion. The REMS Patient Information document is focused on ensuring that patients are aware of the risks associated with aspects of ESA use in overall anemia management, particularly in the setting of cancer chemotherapy. Other commenters point out that true informed consent includes balanced discussion of both risks and potential benefits of a contemplated treatment. We agree with this definition. Thank you for your willingness to contribute to future refinements of this proposed measure.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. The commenter raises several important limitations of the proposed measure. As specified, the measure does not define what the minimum components of informed consent should include, nor does it evaluate effectiveness of the informed consent provided. However, we believe it remains an important beginning to ensure that dialysis patients are truly informed about both the risks and potential benefits of ESA use. We, as well as other commenters disagree with the statement that this measure is duplicative with the FDA REMS Program. We also note that comments from one large national dialysis organization strongly suggest that the FDA REMS program would be misapplied if used to define patient informed consent documentation for this proposed measure. We agree with that opinion. We as well as other commenters point out that true informed consent includes balanced discussion of both risks and potential benefits of a contemplated treatment. This is distinct from the REMS Patient Information document, which is focused on ensuring that patients are aware of the risks associated with aspects of ESA use in overall anemia management, particularly in the setting of cancer chemotherapy.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. This facility attestation measure does not specify whether the facility provider or medical provider or both should participate in the informed consent discussion with the patient. Rather, it requires the facility to attest that informed consent was provided. The attestation is to be updated annually. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seems prudent. Furthermore, several other commenters have objected to reliance on material included in the Patient Information document developed for use in the REMS Program, as they correctly point out that true informed consent requires balanced discussion of both the risks and the benefits of a proposed treatment. We agree that this measure, as designed, does not capture or evaluate the depth of patient understanding of the informed consent discussion pertaining to both risks and benefits. We appreciate the constructive comment on the last issue.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. This facility attestation measure does not specify whether the facility provider or medical provider or both should participate in the informed consent discussion with the patient. Rather, it requires the facility to attest that informed consent was provided and updated annually. Regarding the commenter's concern about measure details that remain unspecified, the measure will require specification of a mechanism for collection of the attestation (e.g. via CROWNWeb electronic attestation). Those specifications are not yet available, but we encourage commenters to evaluate the basic intent and goals of the proposed measure. We note that several commenters raised concerns about reliance on the Medication Guide associated with the FDA REMS program, as it does not provide an adequate amount of information to constitute true informed consent for patients contemplating ESA treatment in this setting. We also note that comments from one large national dialysis organization strongly suggest that the FDA REMS program would be misapplied if used to define patient informed consent documentation for this proposed measure. We agree with that opinion. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seem prudent. Furthermore, several other commenters have objected to reliance on material included in the Patient Information document developed for use in the REMS Program, as they correctly point out that true informed consent requires balanced discussion of both the risks and the benefits of a proposed treatment.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We note that several commenters raised concerns about reliance on the Medication Guide associated with the FDA REMS program, as it does not provide an adequate amount of information to constitute true informed consent for patients contemplating ESA treatment in this setting. We also note that comments from one large national dialysis organization strongly suggest that the FDA REMS program would be misapplied if used to define patient informed consent documentation for this proposed measure. We agree with that opinion. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seem prudent. Furthermore, several other commenters have objected to reliance on material included in the Patient Information document developed for use in the REMS Program, as they correctly point out that true informed consent requires balanced discussion of both the risks and the benefits of a proposed treatment. This facility attestation measure does not specify whether the facility provider or medical provider or both should participate in the informed consent discussion with the patient. Rather, it requires the facility to attest that informed consent was provided and updated annually. Regarding the commenter's concern about measure details that remain unspecified, the measure will require specification of a mechanism for collection of the attestation (e.g. via CROWNWeb electronic attestation). Those specifications are not yet available, but we encourage commenters to evaluate the basic intent and goals of the proposed measure.</p>

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	<p>David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center</p>
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. We note that several commenters have raised concerns about reliance on the Medication Guide associated with the FDA REMS program, as it does not provide an adequate amount of information to constitute true informed consent for patients contemplating ESA treatment in this setting. We also note that comments from one large national dialysis organization strongly suggest that the FDA REMS program would be misapplied if used to define patient informed consent documentation for this proposed measure. We agree with that opinion. Given the rapidly evolving state of knowledge related to ESAs and anemia management goals in this patient population, annual updates of the information for patient informed decision-making seems prudent. Furthermore, several other commenters have objected to reliance on material included in the Patient Information document developed for use in the REMS Program, as they correctly point out that true informed consent requires balanced discussion of both the risks and the benefits of a proposed treatment. Finally, this measure, as specified, does not require informed consent be provided for every administration of ESA. Rather, informed consent must be attested to by the facility and attestation updated annually for the reason noted above.</p>

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy Organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure and support of the principle of informed consent metrics.

Measure/Measure set	Anemia of chronic kidney disease: Patient informed consent for ESA treatment
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7__NationalForumofESRDNetworks
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input and agree with your comments.

Comments on the Standardized 30-day readmission ratio for dialysis facilities

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Brandy Vinson Quality Improvement Director Mid-Atlantic Renal Coalition, ESRD Network 5 bvinson@nw5.esrd.net Comment submitted on behalf of the Mid-Atlantic Renal Coalition
Type of organization	ESRD Network
Date submitted	4/15/2013
Comment	Network 5's Medical Review Board supports this measure being added to the ESRD Quality Incentive Program as a reporting measure only at this time. Once sufficient data has been collected, a performance measure may be beneficial. However, until communication systems between hospitals and dialysis facilities are in place with the addition of functional interoperability for cohesive and reliable health information exchange, facilities will face significant challenges in achieving meaningful positive change for beneficiaries with ESRD.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. It is CMS' view for this measure to encourage such conversation between dialysis facilities and hospitals. At this time, the measure is not being proposed for inclusion in the QIP.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Marsha Kimmer RN, CDN marsha.kimmer@gmail.com
Type of organization	Individual
Date submitted	4/12/2013
Comment	A standardized readmission rate is not a good idea. Every patient deserves to be treated as an individual. There are lots of people who unfortunately have nowhere else to go.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. One purpose of the measure is to encourage better patient management during and after initial hospitalization for all patients in the facility.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Mr. Robert J. Brassell, Jr. hu7138e4i1@aol.com
Type of organization	Individual
Date submitted	4/3/2013
Comment	Develop and implement as soon as independently-verified/confirmed as actually medically ethical, practicable, safe and possible all the measures that are independently-verified/confirmed as actually medically ethical, practicable, safe and effective in the usage of assessing and improving the quality of care for Americans with ESRD as stated within the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population draft measure titled "Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion".
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Derrick Latos, MD Medical Director Wheeling Renal Care, LLC DLatos@wrc3.com Comment submitted on behalf of Wheeling Renal Care, LLC
Type of organization	Dialysis Facility
Date submitted	4/18/2013
Comment	See Appendix 21_WheelingRenalCare
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding exclusions:</i> The TEP carefully considered the diagnoses to be excluded and determined that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate.</p> <p><i>In response to the comments regarding physician responsibility:</i> It is CMS' view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions.</p> <p>A) We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.</p> <p>B) So long as a patient who has been discharged to a SNF is still receiving care from a dialysis facility, any unplanned readmission to a hospital within 30 days would be attributed to that dialysis facility. This again would encourage</p>

	<p>communication among the dialysis facility, the SNF/LTACH and the hospital.</p> <p>C) This readmission measure focuses on the contribution of the dialysis facility to the overall care of the patient. There are other corresponding measures for other care providers (e.g., hospital measure for readmission) so the comment that the focus is only on the dialysis facility is true for this measure but not accurate for the overall measure development process.</p> <p><i>In response to the comments regarding reasons for admission and readmission:</i> The TEP carefully considered the diagnoses to be excluded and determined that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate. The TEP reviewed available evidence in both the ESRD and non-ESRD populations. There is sufficient evidence in the general population that suggests that readmissions can be reduced by care provided in the outpatient setting. In the ESRD population, the evidence is limited, but there is at least one publication (Chan 2009) that demonstrated reduced readmission with post-discharge care at the dialysis facility.</p>
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Maria Regnier, RN, MSN,CNN Dialysis Director, Sanford Health maria.regnier@sanfordhealth.org Commented on behalf of Sanford Dialysis Centers and Medical Directors
Type of organization	Dialysis Facility
Date submitted	4/17/2013
Comment	See Appendix 16_SanfordHealth
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding coordination between facilities:</i> One of CMS' goals for this measure is to encourage the development of care coordination between dialysis facilities and hospitals.</p> <p><i>In response to the comments regarding exclusions:</i> The TEP carefully considered the diagnoses to be excluded and determined that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate. As outlined in the Measure Information Form (MIF; found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip), the measure does indeed exclude discharges for cancer (AHRQ CCS: 42, 19, 45, 44, 17, 38, 39, 14, 40, 35, 16, 13, 29, 15, 18, 12, 11, 27, 33, 32, 24, 43, 25, 36, 21, 41, 20, 23, 26, 28, 34, 37, 22, 31, 30), as well as for psychiatric conditions (AHRQ CCS: 657, 659, 651, 670, 654, 650, 658, 652, 656, 655, 662) and rehabilitation for prosthesis (AHRQ CCS 254); these diagnoses are not in the denominator and thus are not eligible to be followed by a 30-day readmission. Details as to which ICD-9 diagnosis codes compose each CCS group are found at http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp.</p> <p>Furthermore, we also exclude a set of planned readmissions (i.e., readmissions with a certain set of diagnoses are</p>

	<p>excluded from the numerator). For example, we would never count a hospitalization involving a bone marrow transplant as a readmission, even if it occurred within 30 days of a preceding hospitalization; likewise, we would exclude a hospitalization for thyroidectomy if that hospitalization did not also include an acute diagnosis of septicemia. The full description of the algorithm determining planned readmissions is described in Appendix B of the MIF.</p>
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	<p><i>In response to the comments regarding maximum treatment reimbursement:</i> CMS acknowledges receipt of your comments and will take them into consideration in future policy decisions related to maximum treatment reimbursement</p>
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Allen R. Nissenson, MD, FACP Chief Medical Officer DaVita Healthcare Partners, Inc. Mahesh.Krishnan@davita.com Comment submitted on behalf of DaVita Healthcare Partners, Inc.
Type of organization	Large dialysis organization
Date submitted	4/25/2013
Comment	See Appendix 2_DaVita
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the general comments regarding a readmission measure and harmonization:</i> Although CMS aims to harmonize its readmission measures among different care settings as much as possible, there is nonetheless a recognition that it is important to reflect the individual differences in care settings. This has been the aim in formulating the ESRD readmission measure. Furthermore, the TEP carefully considered the diagnoses to be excluded and concluded that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate.</p> <p><i>In response to the comments regarding the methodology used in this measure:</i> We have described the specific methods in the publicly available Measure Information/Justification Forms on CMS' website (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip). Mixed effects hierarchical logistic models are extensively discussed in the statistical literature (Agresti 2002). Similar models have been tested for hospitals, nursing homes, long-term care hospitals, and inpatient rehabilitation facilities. The models (e.g., HWR) have undergone review by NQF, as well as by the contractors developing the post-acute readmission measures. We have recently completed a paper outlining the methodology behind this specific measure that has been accepted and is forthcoming in Lifetime Data Analysis (He 2013).</p>

In response to the comments regarding the exclusion of patients with early readmissions: The very fact that a high percentage of readmissions occurs in the first eight days suggest the importance of not excluding these first eight days from the measure. This is the most vulnerable period after a patient is discharged from the hospital. Exclusion of readmissions within the first eight days of discharge would create potential incentive for hospital referral during that time period and might provide a disincentive to coordinate care immediately following hospital discharge.

In response to the comments regarding the availability of claims data on hospitalization: We thank the commenter and their concern regarding promoting care coordination. CMS recognizes that real-time coordination is the responsibility of the providers involved in the transition of patients from one setting to another. CMS also understands that access to hospital claims data can facilitate care coordination.

In response to the comments regarding coordination between facilities: It is CMS' view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions. We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.

In response to the comments regarding the exclusion of diabetes and cardiovascular conditions: Diabetes and various cardiovascular disease diagnoses (e.g., Cardiac Arrest, Ventricular Fibrillation—both of which are included, among others, in CC 79) are included as covariates in the model; please see the Measure Information Form (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip>).

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Jason Spangler, MD, MPH Executive Director U.S. Health Policy and Reimbursement Amgen jspangle@amgen.com Comment submitted on behalf of Amgen
Type of organization	Pharmaceutical
Date submitted	4/26/2013
Comment	See Appendix 3_Amgen
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. There is a CMS measure focused on hospital readmissions. This measure, which is focused on dialysis facilities, accounts for the role of hospital but is not intended to profile hospitals.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Katrina Russell, RN, CNN President, National Renal Administrators Association (NRAA) nraa@nraa.org Commenting on behalf of the NRAA
Type of organization	Dialysis provider organization (small and medium-size dialysis organizations)
Date submitted	4/29/2013
Comment	See Appendix 18_NationalRenalAdministratorsAssociation
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding coordination between facilities:</i> This measure acknowledges the role of the dialysis facility in the reduction of readmission rates of dialysis facilities. There is a separate CMS measure focusing on hospital readmissions. This measure, which is focused on dialysis facilities, accounts for the role of hospital but is not intended to profile hospitals.</p> <p><i>In response to the comments regarding the use of CMS Medical Evidence Form (Form 2728) as a data source:</i> To clarify, the measure uses data from hospitals, dialysis facilities, and other providers in developing the patient's past year comorbidity profile.</p> <p><i>In response to the comments regarding denominator specifications:</i> Fewer than 2% of patients included in the demonstration measure (2009 hospitalizations) were discharged against medical advice. This number is in line with that found for the existing hospital-wide readmission measure, which includes the entirety of the Medicare population.</p> <p><i>In response to the comments regarding the exclusion of pediatric patients:</i> Thank you for your comment regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding the risk adjustments:</i> It is CMS' view that dialysis facilities should be encouraged to</p>

	<p>coordinate with the physicians with whom they work to reduce readmissions. We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.</p>
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Lori Hartwell Founder and President, Renal Support Network (RSN) Lori@RSNhope.org Commenting on behalf of RSN
Type of organization	Patient advocacy group
Date submitted	4/30/2013
Comment	See Appendix 4_RenalSupportNetwork
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. This measure focuses on the role of the dialysis facilities in readmissions. There is a separate measure that takes into account the role of the hospital. In regard to the contribution of the physician, it is CMS' view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions.</p> <p>We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.</p>

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Glenda Harbert, RN, CNN, CPHQ Executive Director, ESRD Network of Texas (Network 14) GHarbert@nw14.esrd.net Commenting on behalf of Network 14
Type of organization	ESRD Network
Date submitted	4/30/2013
Comment	See Appendix 5_ESRDNetwork14
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding unintended consequences:</i> One purpose of risk adjustment is to remove, or at least reduce, the disincentive for providing care to a particular type of patient whose poor health may put her at greater risk of being readmitted. Our risk adjustment model has carefully adjusted for relevant patient characteristics and comorbidities. The resulting standardized measure will provide a fair comparison among facilities with varying case-mix. There is, however, a need to educate facilities in this role of standardization as well as to continually monitor subgroups in order to update the measure and respond to unintended consequences.</p> <p>In response to the comments regarding the methodology used in this measure: We have described the specific methods in the publicly available Measure Information/Justification Forms on CMS' website (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip). Mixed effects hierarchical logistic models are extensively discussed in the statistical literature (Agresti 2002). Similar models have been tested for hospitals, nursing homes, long-term care hospitals, and inpatient rehabilitation facilities. The models (e.g., HWR) have undergone review by NQF, as well as by the contractors developing the post-acute readmission measures. We have recently completed a paper outlining the methodology behind this specific measure that has been accepted and is forthcoming in Lifetime Data Analysis (He 2013).</p>

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Robert Kossmann, MD President Renal Physicians Association abeckrich@renalmd.org Comment submitted on behalf of Renal Physicians Association
Type of organization	Professional organization
Date submitted	5/1/2013
Comment	See Appendix 6_RenalPhysiciansAssociation
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. There is an adjustment for hospitals that takes into account the quality of care provided during the hospitalization. It is CMS' view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions.</p> <p>We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.</p>

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Maggie Carey – Chair, Forum Beneficiary Advisory Council Derek Forfang - Vice-Chair, Forum Beneficiary Advisory Council Donald Molony, MD - Chair, Forum Medical Advisory Council Andrew Howard, MD, FACP – President, Forum of ESRD Networks The National Forum of ESRD Networks forumcoord@centurytel.net Comments submitted on behalf of the Beneficiary Advisory Council of the Forum
Type of organization	ESRD Networks
Date submitted	5/2/2013
Comment	See Appendix 7__NationalForumofESRDNetworks
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. To clarify, the readmission during which the patient died is included in the numerator of the measure. Such a readmission would therefore contribute to the facility's SRR. It should be noted, however, that a readmission is also viewed as potentially giving rise to an index discharge, which could lead to a potential additional readmission. If the original readmission resulted in death, however, during that hospitalization, it would not lead to an index discharge for a subsequent readmission, and would therefore not be included in the denominator of the measure.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Hrant Jamgochian, JD, LLM Executive Director Dialysis Patient Citizens jnagro@dialysispatients.org Comment submitted on behalf of Dialysis Patient Citizens
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 9_ DialysisPatientCitizens
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding home dialysis patients:</i> All patient modalities are included in the data from which the measure is created and in the measure itself. One aspect of such inclusion is to encourage facilities to keep in closer contact with home dialysis patients.</p> <p><i>In response to the comments regarding the incentivizing of “cherry picking”:</i> One purpose of risk adjustment is to remove, or at least reduce, the disincentive for providing care to a particular type of patient whose poor health may put her at greater risk of being readmitted. Our risk adjustment model has carefully adjusted for relevant patient characteristics and comorbidities. The resulting standardized measure will provide a fair comparison among facilities with varying case-mix. There is, however, a need to educate facilities in this role of standardization as well as to continually monitor subgroups in order to update the measure and respond to unintended consequences.</p> <p><i>In response to the comments regarding exclusions:</i> The list of planned readmission underwent thorough clinical review for the existing hospital-wide readmission measure, and then further review by a Technical Expert Panel and a nephrologist. Please see Appendix B of the Measure Information Form (MIF; found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip) for more details on the algorithm and its ESRD-specific refinements.</p>

	<i>In response to the comments regarding the importance of stakeholder input:</i> CMS appreciates your input, which will be important for the measure development process.
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	<p>Bruce A. Molitoris, MD, FASN President American Society of Nephrology rshaffer@asn-online.org Comment submitted on behalf of American Society of Nephrology</p>
Type of organization	Professional Organization
Date submitted	5/2/2013
Comment	See Appendix 10_ AmericanSocietyOfNephrology
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding the incentivizing of “cherry picking”:</i> One purpose of risk adjustment is to remove, or at least reduce, the disincentive for providing care to a particular type of patient whose poor health may put her at greater risk of being readmitted. Our risk adjustment model has carefully adjusted for relevant patient characteristics and comorbidities. The resulting standardized measure will provide a fair comparison among facilities with varying case-mix. There is, however, a need to educate facilities in this role of standardization as well as to continually monitor subgroups in order to update the measure and respond to unintended consequences.</p> <p><i>In response to the comments regarding all ESRD readmissions measures:</i> While it is true that the Hospital Readmissions Reduction Program mandated by Section 3025 of the Affordable Care Act includes condition-specific measures only for discharges following care for AMI, heart failure, and pneumonia, CMS has developed and implemented a Hospital-Wide Readmission measure (NQF# 1789) that incorporates all readmissions within 30 days of discharge from a hospital for the FY 2015 payment determination of the Hospital Inpatient Quality Reporting Program. The inclusion of readmissions following all discharges for the ESRD aligns with this measure, as well as others currently under development for other post-acute care settings.</p> <p><i>In response to the comments regarding early readmissions:</i> Exclusion of readmissions within the first two or three days of</p>

discharge would create potential incentive for hospital referral during that time period. Including these readmissions encourages contact between dialysis facilities and hospitals at the time of patient discharge.

In response to the comments regarding the exclusion of planned admissions/readmissions: We agree with the need for considering the classification of inpatient access procedures. Access procedures that are planned are much more likely to be performed in an outpatient setting rather than as a planned readmission, except during the initial access creation. This is supported by the data, which show that in 2009, 78.9% of all arteriovenous fistula (AVF), AV graft and peritoneal dialysis (PD) catheter placements among ESRD patients occurred in the outpatient setting. Among our sample of 2009 hospitalizations, only 1.9% of unplanned readmissions included such a placement. Thus, there would be no disincentives introduced for most planned access procedures.

Those access procedures performed during an inpatient hospitalization, even planned AVF creation and PD catheter placement, do not necessarily represent events that should be encouraged if, for example, they reflect poor management of an existing access. It is likely not possible to identify clinical practices and other factors that may contribute to access loss (and which, therefore, represent “poor management”) from administrative data. For example, the absence of an inpatient diagnosis of an infection or other access complication may not necessarily indicate that an inpatient access placement does not result from suboptimal management of an existing access.

Access-related complications (as captured by complication of device, implant or graft) represent one of the most common causes of hospitalization among dialysis patients, and potentially one of the areas of ESRD patient care that dialysis facilities are most able to influence. A potentially important goal for a dialysis facility readmission measure is to incentivize practices that may help to avoid unnecessary inpatient hospitalizations that involve or result from dialysis access complications. In the absence of sufficient information to suggest that an inpatient access procedure is a planned event that could not have been avoided through facility management of an existing access, including readmissions involving access procedures in the measure would be consistent with a goal of avoiding inpatient hospitalizations that involve or result from dialysis access complications.

Finally, we would like to clarify that the diagnosis codes we used have been consistent with CMS’ existing hospital readmission measure definitions, which have been reviewed by a nephrologist and do apply to the ESRD setting.

In response to the comments regarding the use of BMI data: Internal analyses have shown that the BMI value derived from current outpatient claims is similar to that from the 2728 form. On average, patients’ current BMI is lower than their incident BMI (M difference = -1.49; SD = 5.52), although the two values are highly correlated ($r = .71$, $p < .001$). In terms of BMI category (versus continuous BMI values), patients’ current BMI is in the same category in which they began dialysis,

with about 60% of patients remaining in the same category and 80% in the same BMI category or one category lower. Furthermore, incident BMI is highly predictive of readmission ($p < .0001$) and corresponds to a 9% increase in risk for underweight patients and a 12% decrease in risk for obese patients.

In response to the comments regarding the exclusion of ESRD patients who undergo kidney transplants: To clarify, patients are excluded from analyses after receiving a kidney transplant and return to analyses at the time of graft failure. Based on this approach, dialysis facilities are considered to be accountable for readmission outcomes once patients have returned to dialysis due to a graft failure and are under the care of the facility, regardless of the number of days that occurs post-transplant. This approach is consistent with encouraging facility practices that may involve monitoring patients closely and potentially limiting readmissions during a time when patients have recently resumed dialysis and may be especially vulnerable.

In response to the comments regarding the exclusion of patients who undergo any transplant: The current algorithm for identifying planned readmissions includes transplants for the following organs: lung (incl. combined heart/lung), heart, spleen, intestine, liver and pancreas. We will consider excluding a post-transplant period from this measure in the future.

In response to the comments regarding the inclusion of patients in the numerator and denominator: An event can only be included in the numerator if the associated hospital discharge is included in the denominator. We currently make use of all discharges within the calendar year and follow up the final discharge to determine whether or not there is a readmission within 30 days. For index discharges in December, this requires follow up into the next calendar year.

In response to the comments regarding the double random effects model: As the Measure Information Form states, the SRR is not based on a double random effects model; rather, it is based on a mixed effects model that uses the output from a random effects model to aid in the adjustment for hospitals. This mixed effects model is robust in an environment with only one dialysis facility or only one hospital. The random effects for hospital allows the identification of the facility effects, even when only a single hospital is associated with that facility.

In response to the comments regarding the testing results: There are wider confidence intervals for small facilities. Any testing procedures would account for the large standard errors associated with these small facilities.

In response to the comments regarding the exclusion of PPS-Exempt Cancer Hospitals: This exclusion is applied to be consistent with the existing hospital-wide all-cause unplanned readmission measure, whose rationale for such an exclusion is based on clinical reasoning. Specifically, "These hospitals care for a unique population of patients that cannot reasonably be compared to the patients admitted to other hospitals." We will review the suitability of this exclusion in the light of

	these comments.
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Joseph A. Vassalotti Chief Medical Officer National Kidney Foundation Anita.Viliusis@kidney.org Comment submitted on behalf of National Kidney Foundation
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 11_NationalKidneyFoundation
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding the differentiation between planned and unplanned admissions:</i> Please see Appendix B of the Measure Information Form (available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/30-Day-Hospital-Readmission-Measure-and-Anemia-Management-Measures-for-ESRD-Population-.zip) for the list of diagnoses—and the algorithm used—to qualify a readmission as “planned.”</p> <p><i>In response to the comments regarding the use of this measure and coordination between facilities:</i> One of CMS' goals for this measure is to encourage the development of care coordination between dialysis facilities and hospitals. At this time, the measure is not being proposed for inclusion in the QIP.</p>

Commenter	Ronald Kuerbitz Chairman Kidney Care Partners KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Partners
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 12: _KidneyCarePartners
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding harmonization with the SHR and SMR measures:</i> The original 90-day rule following beginning of ESRD was implemented to allow time for patients to stabilize; as a result, hospitalizations and deaths in this period were not counted in computing the SHR and the SMR. The situation is somewhat different when it comes to considering readmission. The readmission measure addresses the question as to how well the patient is managed once hospitalized and looks at the outcome of the discharge. Thus, the 90-day rule in this context has much less motivation. Similarly, when a patient changes facilities, the calculation of the SMR and the SHR allows a 60-day period during which hospitalizations and deaths are assigned to the originating facility and only after 60 days do the patient's exposure and events count for the destination facility. This lag also makes much less sense with readmission and is not implemented.</p> <p><i>In response to the comments regarding the exclusion cap for the number of readmissions per patient year:</i> We considered allowing a maximum of six readmissions per patient-year (<1% of our 2009 test population); however, this more stringent definition led to only small changes in the identification of outlier facilities (i.e., facilities who performed much better or much worse than the national average). Specifically, there was 99.0% agreement in the rate of flagging when using a cap of six compared with a cap of 12 readmissions. This is an issue that we will continue to monitor, especially with respect to small volume facilities.</p> <p><i>In response to the comments regarding the exclusion of patients with an incomplete claims history:</i> We considered making this exclusion for the SRR measure, but decided in the end against doing so. This exclusion would amount to about 1/3 of</p>

hospitalizations, which is a substantial loss. With readmissions, we have the data from the diagnoses of the index discharge, and this provides substantial detail on comorbidities that is available for all patients.

In response to the comments regarding certain conditions in the risk model: The adjustment for “high-risk” diagnoses is based on the primary diagnosis at a given discharge. We will investigate the appropriateness of including in the model the other adjusters mentioned. To clarify, “poisoning by no medicinal substances” does not include ICD-9 codes for ongoing alcohol or drug abuse. Please refer to the breakdown of this CCS group on AHRQ’s website: <http://www.hcup-us.ahrq.gov/toolssoftware/ccs/AppendixASingleDX.txt>.

In response to the comments regarding physician responsibility in the measure: It is CMS’ view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions.

We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.

CMS has decided that adjusting for local hospitalization practices is a policy matter and not appropriate for risk adjustment in this measure. Regional variation in utilization not related to characteristics of the population are not viewed as justifying differences in dialysis facility readmission rates.

In response to the comments regarding the limitation of the measure to readmissions related to ESRD: The TEP carefully considered the diagnoses to be excluded and determined that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate.

In response to the comments regarding the exclusion of patients with early readmission: The fact that a high percentage of readmissions occurs in the first eight days suggest the importance of not excluding these first eight days from the measure. This is the most vulnerable period after a patient is discharged from the hospital. Exclusion of readmissions within the first eight days of discharge would create potential incentive for hospital referral during that time period and might provide a disincentive to coordinate care immediately following hospital discharge.

In response to the comments regarding the bias of the measure between urban and rural facilities: Such factors may be

	<p>important and have not been systematically considered in the development of this measure. Nor are they included to our knowledge as adjustment factors in other readmission measures. The existence of the measure would encourage facilities to keep in contact with patients even during non-dialysis days, and this seems an appropriate incentive. Other details, such as co-pay for transportation, would be hard to incorporate. In monitoring the measure, we will look at various subgroups for systematic differences; when such differences are found, there is still a policy question as to whether they should be adjusted away.</p>
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	<p><i>In response to the comments regarding concerns with the approach and assumptions of the measure:</i> Future versions of the model may be able to reflect clinical data more completely, as sources for such data become more readily available.</p>
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	<p>Thomas L. Weinberg Chairman Kidney Care Council KLester@PattonBoggs.com Comment submitted on behalf of Kidney Care Council</p>
Type of organization	Dialysis provider council
Date submitted	5/2/2013
Comment	See Appendix 13: _KidneyCareCouncil
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding harmonization with the SHR and SMR measures:</i> The original 90-day rule following beginning of ESRD was implemented to allow time for patients to stabilize; as a result, hospitalizations and deaths in this period were not counted in computing the SHR and the SMR. The situation is somewhat different when it comes to considering readmission. The readmission measure addresses the question as to how well the patient is managed once hospitalized and looks at the outcome of the discharge. Thus, the 90-day rule in this context has much less motivation. Similarly, when a patient changes facilities, the calculation of the SMR and the SHR allows a 60-day period during which hospitalizations and deaths are assigned to the originating facility and only after 60 days do the patient's exposure and events count for the destination facility. This lag also makes much less sense with readmission and is not implemented.</p> <p><i>In response to the comments regarding the exclusion cap for the number of readmissions per patient year:</i> We considered allowing a maximum of six readmissions per patient-year (<1% of our 2009 test population); however, this more stringent definition led to only small changes in the identification of outlier facilities (i.e., facilities who performed much better or much worse than the national average). Specifically, there was 99.0% agreement in the rate of flagging when using a cap of six compared with a cap of 12 readmissions. This is an issue that we will continue to monitor, especially with respect to small volume facilities.</p>

In response to the comments regarding the limitation of the measure to readmissions related to ESRD: The TEP carefully considered the diagnoses to be excluded and determined that an all-cause measure—with certain exclusions (e.g., planned readmissions)—was the most appropriate.

In response to the comments regarding the exclusion of patients with an incomplete claims history: We considered making this exclusion for the SRR measure, but decided in the end against doing so. This exclusion would amount to about 1/3 of hospitalizations, which is a substantial loss. With readmissions, we have the data from the diagnoses of the index discharge, and this provides substantial detail on comorbidities that is available for all patients.

In response to the comments regarding certain conditions in the risk model: The adjustment for “high-risk” diagnoses is based on the primary diagnosis at a given discharge. We will investigate the appropriateness of including in the model the other adjusters mentioned. To clarify, “poisoning by nonmedicinal substances” does not include ICD-9 codes for ongoing alcohol or drug abuse. Please refer to the breakdown of this CCS group on AHRQ’s website: <http://www.hcup-us.ahrq.gov/toolssoftware/ccs/AppendixASingleDX.txt>.

In response to the comments regarding physician responsibility in the measure: It is CMS’ view that dialysis facilities should be encouraged to coordinate with the physicians with whom they work to reduce readmissions.

We have incorporated an adjustment for hospital in this measure. This is practicable since there is typically a unique hospital and a unique dialysis facility associated with each discharge. The situation with physicians is much more difficult. A patient may be managed by different physicians each month. From a clinical perspective, it is not clear whether it is more appropriate to adjust for the nephrologist seeing the patient immediately before the index admission or the nephrologist seeing the patient immediately after the discharge or both. In addition, ESRD patients are often under the care of multiple physicians and attribution to a particular physician is often not possible.

CMS has decided that adjusting for local hospitalization practices is a policy matter and not appropriate for risk adjustment in this measure. Regional variation in utilization not related to characteristics of the population are not viewed as justifying differences in dialysis facility readmission rates.

In response to the comments regarding the exclusion of patients with early readmission: The fact that a high percentage of readmissions occurs in the first eight days suggest the importance of not excluding these first eight days from the measure. This is the most vulnerable period after a patient is discharged from the hospital. Exclusion of readmissions within the first eight days of discharge would create potential incentive for hospital referral during that time period and might provide a disincentive to coordinate care immediately following hospital discharge.

	<p><i>In response to the comments regarding the bias of the measure between urban and rural facilities:</i> Such factors may be important and have not been systematically considered in the development of this measure. Nor are they included to our knowledge as adjustment factors in other readmission measures. The existence of the measure would encourage facilities to keep in contact with patients even during non-dialysis days, and this seems an appropriate incentive. Other details, such as co-pay for transportation, would be hard to incorporate. In monitoring the measure, we will look at various subgroups for systematic differences; when such differences are found, there is still a policy question as to whether they should be adjusted away.</p> <p><i>In response to the comments regarding concerns with the approach and assumptions of the measure:</i> Future versions of the model may be able to reflect clinical data more completely, as sources for such data become more readily available.</p>
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Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Carol LaFleur Executive Director Northeast Kidney Foundation northeastkidney@gmail.com Comment submitted on behalf of Northeast Kidney Foundation
Type of organization	Advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 14_NortheastKidneyFoundation
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Doug Johnson, MD Vice Chairman, Dialysis Clinic, Inc. (DCI) doug.johnson@dcinc.org Commenting on behalf of DCI
Type of organization	Large Dialysis Facility
Date submitted	5/2/2013
Comment	See Appendix 17_DialysisClinicInc
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input.</p> <p><i>In response to the comments regarding coordination between facilities:</i> The measure is to encourage the development of care coordination between dialysis facilities, the nephrologist, other care-providers and the patient. A goal of this, and similar measures for other providers such as hospitals is to encourage the development of processes and communication protocols that can help to effectively improve readmission rates.</p> <p><i>In response to the comments regarding the exclusion of patients with early readmission:</i> Exclusion of readmissions within the first two or three days of discharge would create potential incentive for hospital referral during that time period. Including these readmissions encourages contact between dialysis facilities and hospitals at the time of patient discharge.</p> <p><i>In response to the comments regarding the inclusion of facilities with a small number of patients in QIP:</i> The development of this measure is not specifically directed at its potential inclusion in the QIP and we have not included specific recommendations in this regard. Confidence intervals for these measures would reflect the uncertainty in small facilities.</p> <p><i>In response to the comments regarding the capacity for small facilities to absorb risk of patients with repeat readmissions:</i> We considered allowing a maximum of six readmissions per patient-year (<1% of our 2009 test population); however, this more stringent definition led to only small changes in the identification of outlier facilities (i.e., facilities who performed much better or much worse than the national average). Specifically, there was 99.0% agreement in the rate of flagging</p>

when using a cap of six compared with a cap of 12 readmissions. This is an issue that we will continue to monitor, especially with respect to small volume facilities.

In response to the comments regarding the impact of post-transplant patients on the readmission rate: To clarify, patients are excluded from analyses after receiving a kidney transplant and return to analyses at the time of graft failure. Based on this approach, dialysis facilities are considered to be accountable for readmission outcomes once patients have returned to dialysis due to a graft failure and are under the care of the facility, regardless of the number of days that occurs post-transplant. This approach is consistent with encouraging facility practices that may involve monitoring patients closely and potentially limiting readmissions during a time when patients have recently resumed dialysis and may be especially vulnerable.

In response to comments regarding the exclusion of PPS-Exempt Cancer Hospitals: This exclusion is applied to be consistent with the existing hospital-wide all-cause unplanned readmission measure, whose rationale for such an exclusion is based on clinical reasoning. Specifically, “These hospitals care for a unique population of patients that cannot reasonably be compared to the patients admitted to other hospitals.”

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	<p>David E. Henner, DO Division Chief of Nephrology Medical Director of Dialysis Units Berkshire Medical Center, South Berkshire County Dialysis Center, Southwestern Vermont Medical Center dhenner@bhs1.org Comment submitted on behalf of Berkshire Medical Center, South Berkshire County Dialysis Center, and Southwestern Vermont Medical Center</p>
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	See Appendix 15_Berkshire
Recommendations/actions taken	<p>Thank you for your comments regarding this ESRD measure. We appreciate your input. One of CMS' goals for this measure is to encourage the development of care coordination between dialysis facilities and hospitals. This measure recognizes the contribution of dialysis facilities in the management of dialysis patients upon discharge in order to reduce the risk of readmission. This is separate from the contribution of the hospitals, and which is measured by the hospital readmission rate.</p>

Measure/Measure set	Standardized 30-day readmission ratio for dialysis facilities
Commenter	Nancy Pelfrey, MSN, RN, ACNP-C, CNN-NP nancy.pelfrey@reliantrenalcare.com Submitting comments on behalf of self, not employer (Reliant Renal Care)
Type of organization	Dialysis facility
Date submitted	5/2/2013
Comment	I am in favor of this. Again I think the lack of consistent info from the hospital is a potential problem. Certainly the info doesn't come at the time of discharge. If staff at a dialysis center don't have info about the hospital course how can they help to prevent a avoidable re-admission? CMS needs to help improve the flow of info from the hospital to the dialysis center.
Recommendations/actions taken	Thank you for your comments regarding this ESRD measure. We appreciate your input. One of CMS' goals for this measure is to encourage the development of care coordination between dialysis facilities and hospitals.

General Measure Comments

Measure/Measure set	Anemia management
Commenter	Lana Schmidt Kidney Patients Support Group lanasch@yahoo.com Comments from kidney patients
Type of organization	Patients
Date submitted	4/12/2013
Comment	See Appendix 19_KidneyPatientsSupportGroup
Recommendations/actions taken	Thank you for your comment. We will take your thoughts into consideration during the remainder of the measure development cycle.

Measure/Measure set	Anemia management
Commenter	Nancy Smith nancyellis smith@me.com
Type of organization	Individual
Date submitted	5/1/2013
Comment	Anemia management should be chosen by a doctor. Transfusions should not be used in place of medications such as Epo. Transfusions make it more difficult for someone to 'match' for a kidney transplant.
Recommendations/actions taken	Thank you for your comment regarding this ESRD measure. We appreciate your input.

Measure/Measure set	ESRD Measures (General Comment)
Commenter	Nikia Okoye Director of Government Relations American Kidney Fund NOkoye@kidneyfund.org Comment submitted on behalf of American Kidney Fund
Type of organization	Patient advocacy organization
Date submitted	5/2/2013
Comment	See Appendix 20_AmericanKidneyFund
Recommendations/actions taken	Thank you for your comment. We appreciate your consideration of the issues at hand with regards to ESRD measure development, and will take your comments under advisement during the remainder of the measure development cycle.

Measure/Measure set	Anemia management and readmission measures (General Comment)
Commenter	Mary Ann Chard maryannchard@gmail.com
Type of organization	Patient
Date submitted	4/26/2013
Comment	I am a long time dialysis patient and twice kidney transplant recipient. I am not in favor of the 30 day hospital readmission for anemia management. Maybe I am interpreting this incorrectly but I feel that if the patient has the ability to go home and has support from family members and friends there is no need for them to be hospitalized. I feel most dialysis patients will do much better in an at home setting where they are in familiar surroundings and less gloom and doom. Furthermore, I think the hgb levels should be at least 12 I think it is crazy to have it lowered to 10 it just puts the patient on a roller coaster ride and their quality of life suffers. Also, it puts more work on the staff at the unit not to say its probably more costly to keep having to run blood tests.
Recommendations/actions taken	Thank you for your comment. Please note that the readmission measure is meant to measure hospital readmissions as an undesirable event. We will take your comments regarding hemoglobin levels into consideration during the remainder of the measure development cycle.

Measure/Measure set	Anemia management (General Comment)
Commenter	Katrina Russell, RN, CNN President National Renal Administrators Association (NRAA) rich.meade@prime-policy.com Comment submitted on behalf of National Renal Administrators Association
Type of organization	Dialysis provider organizations
Date submitted	4/29/2013
Comment	<p>NRAA is concerned about the TEP's proposal to develop multiple additional anemia management measures. Although the NRAA agrees that ESRD patients should be monitored for anemia, the measures developed by the TEP are too numerous, especially since all the proposed measures are essentially pointed toward the same goal. Additionally, having multiple anemia measures may not account for the individualization of care. There are some patients who can thrive with a hemoglobin level of 9.5 g/DL while others require adjustment in their dosing of Epogen at those levels. There is also not sufficient evidence based research to support some of these measures. NRAA urges the agency to support more research in this area so we better understand how to evaluate anemia management in a way that leads to the best patient care, patient safety, and outcomes for the patient. NRAA is also concerned about the efforts to develop quality measures for dialysis facilities around blood transfusions. As the TEP discussed, there are instances where a transfusion is the most appropriate course of care. We are concerned that a blood transfusion measure would not take into account acute episodes unrelated to ESRD or an acute traumatic injury that requires blood transfusions. Also, many patients are followed by a primary care physician in addition to the care provided by a nephrologist. The primary care physician could be prescribing blood transfusions without consulting the nephrologist.</p> <p>See Appendix 18_NationalRenalAdministratorsAssociation</p>
Recommendations/actions taken	Thank you for your comment. We will take these comments into consideration for the remainder of the measure development cycle.

Measure/Measure set	Comments regarding the CMS measure development process
Commenter	N/A
Type of organization	N/A
Date submitted	3/18/2013-5/2/2013
Comment	Comments regarding the CMS measure development process
Recommendations/actions taken	CMS remains committed to a transparent, evidence-based measure development process. As part of this work, we maintain a measure blueprint that is continuously receiving revision due stakeholder input. We welcome feedback and input regarding the process, and have forwarded the received comments regarding the development process to our blueprint maintenance contractor. Additional input may be directed to aclancy@hsag.com or eclark@hsag.com

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