

**Public Comment Summary Report for ESRD Hospital Readmission and Anemia
Management Measures**

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Introduction

The Centers for Medicare & Medicaid Services (CMS) has contracted with Arbor Research/UM-KECC to develop a 30-day hospital readmission measure and anemia management measures for the ESRD population. The purpose of the project is to develop quality measures that can be used to promote the delivery of high quality care to Medicare beneficiaries with ESRD.

On March 18, 2013, the following measures developed under this contract were posted for public comment on the Center for Medicare and Medicaid Services (CMS) public comment website (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>).

- Anemia of chronic kidney disease: Patient informed consent for ESA treatment
- Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion
- Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
- Anemia of chronic kidney disease: Hgb > 12 g/dL
- Anemia of chronic kidney disease: Hgb < 10 g/dl
- Standardized 30-day readmission ratio for dialysis facilities

The public comment period provided an opportunity for the widest array of interested parties to provide input on the measures under development and can provide important suggestions not previously considered by the measure contractor or its technical expert panels (TEPs). In order to notify stakeholders and the general public of the public comment period, we sent numerous email notifications to stakeholder groups, including medical associations and societies, patient organizations, and nephrology news outlets. We also informed the Technical Expert Panel (TEP) members of the public comment period, and provided an advanced copy of the materials to be posted. TEP members were encouraged to submit any additional comments on the measure specifications during the public comment period.

The comment period was open from March 18-May2, 2013, and during that time public comments were submitted by 36 individuals or organizations, resulting in a total of 127 individual measure comments. Total comments received for each measure is summarized in the table below.

Measure	Comments received
Anemia of chronic kidney disease: Patient informed consent for ESA treatment	18
Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion	20
Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio	19
Anemia of chronic kidney disease: Hgb > 12 g/dL	19
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Summary of Stakeholder Comments

General Summary of Comments

Anemia Management

The following are some common themes regarding anemia treatment that are reflected in the comments on the four anemia management measures:

- Individualization of care/accountability of the dialysis facility
- Facility vs. patient level measurement
- Revisions to the exclusion criteria
- Value of the Hgb floor (9, 9.5, or 10 g/dL)

These issues are addressed further in the measure specific comment summaries provided below. We note that there were also a number of comments that supported these measures as written.

Hospital Readmission

The comments received on the Standardized 30-day readmission ratio for dialysis facilities included questions/comments regarding:

- Accounting for physician behavior/decision making (adjustment for physician)
- Revisions to exclusion criteria based on diagnoses and days after discharge

These issues are addressed further in the measure specific comment summaries. We note that there were also a number of comments that supported this measure as written.

Proposed Actions

Arbor Research/UM-KECC has carefully reviewed each of the comments received and made revisions to the measure specifications where necessary. Further discussion (including actions taken as a result of these comments) is included in the measure specific comment summaries.

Measure-Specific Comment Summaries

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

Summary of Comments

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report.

Quantifying “informed consent”

We received a number of comments regarding the difficulty in defining and measuring informed consent. One commenter explains that “it may well not be possible to establish a uniform definition of what constitutes patient “informed” status, as this would vary based on patient experience with dialysis and ESAs, knowledge base, whether or not patients have full mental capacity, and a multitude of other variables”.

Conflict with REMS guidelines

A number of commenters expressed concern that the measure as written does not reflect the REMS guidelines. One commenter said that “We believe that Arbor’s management of the TEP failed to clarify the differences between the FDA approved REMS program involving the medication guide and the concept of informed consent. As a result, Arbor is proposing a measure that contradicts the guidance of another federal agency, namely the FDA [...] this materially differs from the concept of informed consent, where a patient signature is required. We therefore believe that the proposed measure is not consistent with FDA regulatory guidance and further does not address the level of detail of that guidance, specifically that regarding the frequency of distribution of the medication guide”.

Relatedly, several commenters noted that this should be a physician level measure, as the REMS guidelines places emphasis on the physicians-patient relationship, rather than placing burden the dialysis facility. One commenter noted that “because the REMS focuses on the physician- patient relationship, any measure in this area should be a physician level measure, not a facility level one because it is not actionable by the facility”. We noted in our response that 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.

Proposed Actions

We have carefully reviewed the comments received on this measure, and do not plan on revising the measure specifications at this time. Please see the verbatim public comments report for detailed responses to every comment received.

Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion

Summary of Comments

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report.

ESA Dosage (<75 units/kg/session)

A number of commenters expressed concern over the dosage threshold (<75/units/kg/session) specified in the measure. One commenter said that “there is no evidence to support the precise dose or dosing strategy that is specified in the measure description”, and that high EPO doses are more likely to be prescribed to patients with poor response to ESA therapy and most likely to have low Hgb levels.

Another commenter states “with regards to the low dose of <75 units/kg/session of ESA’s mentioned in the first measure, it should be noted that EPO has a 40 fold pharmacokinetic variance such that specifying a single value across a patient populations will not be reasonable.” They also note that their facilities, they are seeing an increased number of patients “whose doses are held in accordance with the ESA label guidance which makes the metric of low dose difficult to interpret.”

A third commenter expressed concern that the dosage implied by the measure violates the FDA guidelines by insinuating that physicians should increase ESA dosage too rapidly.

Measurement at the facility- level

Some of the comments we received question whether this measure is appropriate at the facility-level. According to one commenter, “the fact that transfusion occurs proportional to that individual patients mean hemoglobin³ and that patients individual comorbidities, believe that holding a facility to a transfusion metric is difficult.” The commenter goes on to say that care is being individualized by a physician, based on decisions made by that physician and not the dialysis unit.

Another commenter notes that “In my experience, dialysis facilities are typically not the ones that prescribe or administer transfusions and often do not know when patients receive them in other settings such as hospitals”

Individualized care

We received a number of comments questioning whether this measure violates the principle of individualized care. A patient commenter states that “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.”

Exclusions

Commenters expressed concern that the exclusion criteria for these measures currently do not include conditions that cause chronic GI bleeding, including intestinal angiodysplasia, chronic erosive esophagitis or gastritis, peptic ulcer disease and other conditions currently included in the list of comorbid condition adjusters used for ESRD facility billing.

Another commenter notes that they 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.”

Proposed Actions

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.

Please see the verbatim public comments report for detailed responses to every comment received.

Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio

Summary of Comments

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report.

Accountability of the dialysis facility for transfusions

A number of commenters expressed concerns that dialysis facilities cannot always be held responsible for transfusions that take place in their facility, due to complicating factors. One commenter notes that only circumstances that fall under the physician and facility's control should be included in the denominator. "Many conditions resulting in the need for blood transfusion are outside the control of the dialysis facility staff, such as acute GI bleeding, surgical blood loss, drug-induced hemolytic anemia, etc. Many, but not all, transfusions are administered in the in-patient setting. Patients who are hospitalized often have multiple physicians involved in their care (primary care physician, surgeon, other consultants), not just the nephrologist. It would be unusual for a non-nephrologist to order blood transfusion for an ESRD patient in the non-hospital setting, except in the instance of oncology care."

Another commenter states that "Most notably, the majority of transfusions are administered outside of the dialysis facility, and therefore dialysis facilities may not always be aware when patients receive the transfusions until the end of the reporting period, likely up to a year later. Thus, there would be little opportunity for such a metric to enable effective intervention, and therefore it would not result in timely and meaningful improvements to dialysis patient care."

Implementation concerns

Several commenters questioned whether this measure could be implemented due to data concerns. One commenter notes that "Discussion for this measure centered on concerns over STtR data which would be outdated and irrelevant for measuring current performance as well as the lack of data from randomized controlled trials. In summary, it was the consensus [...] that there is insufficient data and a lack of CMS guidelines to allow direction for facilities related to this measure." Further details regarding these comments can be found in the verbatim public comments report.

Multiple commenters also noted that they were concerned about the ability of reporting agencies and dialysis facilities to obtain accurate information about transfusions, especially smaller dialysis facilities.

Risk Adjustment/Model Adjustment

There were a number of concerns raised about the risk adjustment model used in the measure. One commenter "feels strongly that a dialysis patient-specific risk adjustment method that takes into account important relevant time-adjusted co-morbidities and clinical variables as possible in a manner be developed" and should be considered for this measure. Several commenters also note that it is not clear from the measure specifications which comorbidity index is used in the model.

Several commenters would like the model to adjust for physician and hospital related factors. One commenter notes "the measure does not adjust for hospital- or physician-related factors. As described

above, as well as in clinical literature, hospitals and physicians play a central role in the decision to order a blood transfusion. There is no rationale as to why these variables are not accounted for in the measure.

Another commenter noted that an adjustment for region may be necessary, as “the absolute transfusion rate experienced by patients cared for at any specific facility may be influenced by region, making application of a uniform rate to all dialysis units as described in this measure problematic at this time.”

Proposed Actions

The measure specifications have been revised to clarify the comorbidity index being used in the model. We took into consideration the suggestions regarding adjustments for small facilities and regional facility practices suggested by commenters and decided not to revise specifications at this time. We will continue to investigate the possibility of including these adjustments in future revisions to the measure. Please see the verbatim comment report for detailed responses to every comment received.

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

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report.

Summary of Comments

Individualized care

Several commenters shared the concern that the measure does not allow for individualization of care. One commenter explains “it is not clear to what extent the study evaluated the contribution of specific individual physicians and physician groups that practice in the same facility. The facility implements physician orders and respects treatment options in the physicians’ practice of medicine”. Another says “the patients should have their anemia managed by their physician, not CMS. Every patient's level should be individualized.”

Three month average

We received a high volume of comments that question the reporting period of the measure. Several commenters questioned the use of a three month reporting period, noting that the specifications were not clear on whether this is a rolling 3 month average, or a quarterly measure. There were also questions about the reason for choosing the 3 month time period (as opposed to one year).

Topped out

We received comments that questioned whether this measure was “topped out”, in the sense that very few patients will be included in the numerator as Hgb >12 is being reported less frequently in dialysis patients. One commenter explains “We acknowledge the potential safety concerns involved in raising Hb > 12 g/dL. We also realize that the FDA has rejected as inconclusive study data assessing the effect of levels >12 g/dL on quality of life, either because the data were not reported directly by patients or because the instrument used to collect these data was not validated. We believe that Hb levels have already decreased significantly and that physicians are no longer trying to attain levels > 12 g/dL. As a result, we believe that the metric should become a process measure rather than a performance measure. The percentage of the 2% withhold that has been diverted to incentivizing physicians not to maintain Hb > 12 g/dL could be used to incentivize other areas of care.”

Proposed Actions

We have carefully reviewed the comments received on this measure, and revised the measure specifications to provide more clarity on the reporting period for this measure. Please see the verbatim public comments report for detailed responses to every comment received.

Anemia of chronic kidney disease: Hgb < 10 g/dl

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report. We would like to note that there was broad support from the commenters for a hemoglobin floor measure.

Summary of Comments

Value of the Hgb floor

A number of commenters suggested that 10 may not be the most appropriate value for this measure. We received a number of recommendations for using a lower floor (9 or 9.5). One commenter explains “the Agency has been rightly placed on the upper level of patients’ hemoglobin. This focus is consistent with the FDA’s actions under the REMS and black box warnings. As a result, physicians seek to manage upper hemoglobin levels to 11 g/dL. If the lower level were set by CMS at 10 g/dL, it would create a very tight window of only 1 g/dL in which the entire ESRD population would need to be managed. It is possible to achieve that 1 g/dL goal for only about 40 percent of the population at a given time because of the inherent variability in managing patients on an ESA. By creating a floor, CMS would be setting an impossible task and creating inappropriate clinical expectations for patients that could put them at greater risk. In fact, by setting such a lower hemoglobin limit, physicians would have to respond by moving the population hemoglobin curve to the right (higher hemoglobins), likely increasing the number of patients with hemoglobin above the limit FDA states is safe.”

Reporting period

Several commenters questioned the use of a three month reporting period, noting that the specifications were not clear on whether this is a rolling 3 month average, or a quarterly measure. There were also questions about the reason for choosing the 3 month time period (as opposed to one year).

Proposed Actions

We have carefully reviewed the comments received on this measure, and revised the measure specifications to provide more clarity on the reporting period for this measure. Please see the verbatim public comments report for detailed responses to every comment received.

Standardized 30-day readmission ratio for dialysis facilities

Below, we summarize comments received on this measure by topic area. This is not an exhaustive list; for a full list of comments, please see the verbatim comments report.

Summary of Comments

Physician Adjustment

We received comments regarding the need for physician adjustment in the SRR model, to account for physician decision making. One commenter explains that they believe “the model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns—in particular because the decision to admit/readmit is a physician decision. Geographic variability in this regard is well documented in other areas, and there is no reason to believe the situation is different for ESRD patients. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for.”

Exclusions

A number of commenters expressed concern regarding the all-cause nature of this measure. They felt that the dialysis facility would be unable to modify all illnesses and that only hospitalizations involving illnesses considered “actionable” by the facility should be considered as index hospitalizations (i.e., should be excluded from the denominator). A few commenters felt that the measure should take into account the specific reason for the patient’s readmission, and readmissions for conditions that are totally unrelated to the previous admission should not be counted against the facility (i.e., should be excluded from the numerator). Further details regarding these comments can be found in the verbatim public comments report.

Several commenters also supported excluding readmissions occurring in the first 1-3 days after discharge from a hospital. One commenter explains that “Our internal data suggest that the percent of readmits that occur within 1-3 days is 11%, while at 3-8 days, it’s 30%. Given that dialysis occurs on a three times a week cycle, these early readmissions are not amenable to dialysis unit intervention as the patient may have been seen in the unit from as little to zero times after discharge.”

Proposed Actions

We have carefully reviewed the comments received on this measure, and decided not to revise the measure specifications at this time. We will continue to consider the following issues prior to submitting the measure for NQF submission:

- The effect of excluding hospitalizations as index discharges for a period following organ transplantation of any type.
- The suitability of the exclusion of PPS-exempt cancer hospitals.

- 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.
- The appropriateness of including in the model the other adjustors mentioned in the comments (including sickle cell trait, not just sickle cell anemia, as well as angiodysplasia, myelodysplasia, diverticular bleeding, asthma, as well as adjust for nursing home status).
- In monitoring the measure, we will look at various subgroups for systematic differences. However, when such differences are found, there is still a policy question as to whether they should be adjusted away.

Please see the verbatim public comments report for detailed responses to every comment received.

Overall Analysis of the Comments and Recommendations to CMS

Based on the comments received, below is a summary of the changes made to the candidate measures.

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

- Based on our review of these comments, we do not suggest revisions to this measure at this time. Please see the verbatim comment report for detailed responses to every comment received.

Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion

- 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.

Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio

- The measure specifications have been revised to clarify the comorbidity index being used in the model. We took into consideration the suggestions regarding adjustments for small facilities and regional facility practices suggested by commenters and decided not to revise specifications at this time. We will continue to investigate the possibility of including these adjustments in future revisions to the measure. Please see the verbatim comment report for detailed responses to every comment received.

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

- We have carefully reviewed the comments received on this measure, and have revised the measure specifications to provide more clarity on the reporting period for this measure. Please see the verbatim public comments report for detailed responses to every comment received.

Anemia of chronic kidney disease: Hgb < 10 g/dl

- We have carefully reviewed the comments received on this measure, and have revised the measure specifications to provide more clarity on the reporting period for this measure. Please see the verbatim public comments report for detailed responses to every comment received.

Standardized 30-day readmission ratio for dialysis facilities

Based on our review of these comments, we do not suggest revisions to this measure at this time; however the following is a list of issues we will consider further prior to NQF submission:

- The effect of excluding hospitalizations as index discharges for a period following organ transplantation of any type.
- The suitability of the exclusion of PPS-exempt cancer hospitals.
- 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.
- The appropriateness of including in the model the other adjustors mentioned in the comments (including sickle cell trait, not just sickle cell anemia, as well as angiodysplasia, myelodysplasia, diverticular bleeding, asthma, as well as adjust for nursing home status).
- In monitoring the measure, we will look at various subgroups for systematic differences. However, when such differences are found, there is still a policy question as to whether they should be adjusted away.