

Public Comment Summary Report

Project Title:

End-Stage Renal Disease Evaluation of Potential Prevalent Comorbidity Adjustments in the Standardized Hospitalization Ratio (SHR) and the Standardized Mortality Ratio (SMR)

Dates:

- The Call for Public Comment ran from 2/8/2016 to 2/29/16
- The Public Comment Summary was made available on 3/25/2016

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan- Kidney Epidemiology and Cost Center (UM-KECC) to evaluate the potential of including prevalent comorbidities in the SHR and SMR risk adjustment models. The contract name is End-Stage Renal Disease Evaluation of Potential Prevalent Comorbidity Adjustments in the Standardized Hospitalization Ratio (SHR) and the Standardized Mortality Ratio (SMR). The contract number is HHSM-500-2013-13017I. As part of its measure development process, CMS has requested interested parties to submit comments on the candidate measures that may be suitable for this project.

Project Objectives:

The University of Michigan Kidney Epidemiology and Cost Center, through its contract with the Centers for Medicare and Medicaid Services, convened a technical expert panel to evaluate the potential of including prevalent comorbidities in the SMR (NQF 0369) and SHR (NQF 1463) risk adjustment models. Specific objectives included:

- Review of the comorbidity adjustment in the current NQF endorsed SMR and SHR measures
- Consideration of what, if any, prevalent comorbidities would be appropriate to include in each measure.

Information About the Comments Received:

- Public comments were solicited by email.
- Four responses were received on this topic.

Stakeholder Comments—General and Measure-Specific

General Comments

One commenter expressed general agreement with the prevalent comorbidities selected for inclusion as adjustments in both SMR and SHR measures.

Two commenters supported the denominator for both measures being limited to Medicare patients.

Three commenters expressed their desire to report standardized rates instead of standardized ratios.

Response: The measure has been specified and calculated as a standardized ratio, but could be expressed as a standardized rate (as stated in the MIFs for each measure). We are considering how to present the measures as rates in future public reporting.

Two commenters suggested patients should not be counted at either the new facility or at the original facility 60 days after the transfer to a new facility.

Response: We recognize that a transfer may indicate a period of clinical instability for the patient which is why patients are not counted at the new facility until day 61, in order to allow the new facility to complete a full patient assessment and modify, if needed, dialysis therapy. There is, however, an expectation that the original facility should continue to be accountable for the patient's health status in the immediate period after transfer, as a decline in clinical outcomes during this transition period may reflect the care provided by the original facility prior to transfer. This is a fundamental inclusion parameter of the metric for over a decade which reasonably reflects appropriate transition of patient care. Both measures, including this patient assignment algorithm, have been previously vetted by NQF on multiple occasions.

One commenter expressed concern regarding the accuracy of prevalent comorbidity data based on Medicare claims, noting that facilities do not have control over the accuracy of that data compared to data obtained from form 2728.

Response: CMS has incorporated risk adjustment for prevalent comorbidities into the SMR and SHR models. The additional risk adjustment for these comorbidities is directly in response to consistent and strong interest from the dialysis community that using prevalent comorbidities better reflected the multiple conditions that chronic dialysis patients develop in their disease progression. The prevalent comorbidities were also reviewed by an external TEP (see TEP summary report at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html>). There was strong consensus among the

TEP members who investigated this issue that prevalent comorbidities from Medicare claims represent an appropriate opportunity to improve the risk adjustment strategy for these measures. While there was some concern about potential threats to validity, it was felt these did not outweigh the benefit of using Medicare claims, as they are the only available source of data on prevalent comorbidities. Claims-based comorbidities are the best practical solution at present, but the TEP did express interest in pursuing a mechanism for collecting regular updates to comorbidity data in the future. We note that Medicare claims data have been used for risk adjustment in the Standardized Readmission Ratio (NQF #2496), as well as for post-acute settings, including skilled nursing facilities (NQF #2510), inpatient rehabilitation facilities (NQF #2502), long-term care hospitals (NQF #2512), and home health agencies (NQF #0171, #0173, #2380, and #2505).

One commenter expressed concern with the face validity of some of the prevalent comorbidities that have been added to the SMR and SHR risk adjustment models.

Response: The first step for identifying the comorbidities used systematic empirical methods which demonstrated a statistically significant association with mortality and hospitalization. This list of comorbidities based on this variable selection method was provided to the TEP. The TEP was asked to evaluate these comorbidities on the basis of whether or not the comorbidity was likely the result of care provided by the dialysis facility.

Close examination of the association between the Medicare claims data and some of the seemingly less proximate (or anomalous) comorbidities suggests they are still indicative of clinically relevant comorbidities. For these reasons face validity may not be as germane for the determination of validity.

Two commenters requested clarification regarding why at least two outpatient claims or one inpatient claim are required to identify prevalent comorbidities.

Response: The TEP discussed how best to identify a prevalent comorbidity taking into account the source of these data from claims. The initial recommendation of two outpatient claims or one inpatient claim was made by one TEP member based on their extensive examination of claims based comorbidity reporting. This definition is also supported by the literature. The TEP voted 6-1 (with one abstaining) in favor of the proposed prevalent comorbidity definition. A summary of the TEP discussion can be found in Appendix D of the TEP summary report. Sensitivity analyses performed using alternative less restrictive diagnostic criteria had little impact.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html>)

Two commenters requested clarification regarding whether prevalent comorbidities from claims on the previous calendar year will be factored in for all patient time intervals.

Response: To clarify, the measures look for prevalent comorbidities from the previous calendar year for all patients (including incident patients). The claims comorbidities are included if a patient has at least 6 months of Medicare claims information in the calendar year prior to the year used to observe for the outcome of interest.

Two commenters requested for more specificity for the time period (i.e. 1 year, 4 years, etc) required to calculate both measures, considering the variability in IUR results based on facility size and the time period of data used.

Response: We appreciate the comments on the specified time period and reliability of these measures. The time period for which the measure is ultimately implemented depends upon the purpose and the context of the program in which it is implemented.

Commenters expressed concerns about the risk model, including

- Questioning the C-statistic for both SMR and SHR models
- Clarification on the definition of the adjustment for nursing home patients
- Clarification for how categories for the Age and Duration of ESRD covariates were developed

Response: We believe that the C-statistics of 0.72 (SMR) and 0.65 (SHR) are considered to be a good fit, and note that they are similar in magnitude to other current NQF endorsed quality measures implemented by CMS and are based on recent literature. As we refine the risk model in the future, we will work to improve the model's ability to discriminate performance between facilities.

In regard to the adjustment for nursing home patients, we will clarify in the MIF that the look-back period is the previous calendar year.

The categories for the Age and Duration of ESRD covariates in the risk adjustment models were empirically derived when the SMR and SHR models were first developed, and are based on model fit specific to each outcome. This accounts for the different groupings for each model.

One commenter expressed a concern about the validity of the 2728 data used to adjust for incident comorbidities in both models.

Response: The recent TEP considered the validity of the incident comorbidities from the 2728, and felt strongly that the incident comorbidities should be retained in the model.

One commenter recommended that a beneficiary's Medicare status be taken into consideration, noting that for commercial patients who switch to Medicare in a current calendar year, the current reporting year prevalent comorbidities should be included in the

risk model.

Response: The strategy presented was a synthesis of TEP member opinions, informed by analyses of alternative strategies for the claims period defining the inclusion. The proposed methodology represents a level of general agreement reached by the TEP after extensive discussion of the potential benefits and risks to model accuracy presented by the alternative claims data inclusion options. We thank you for your thoughtful comment.

SMR

Two commenters recommended that patients who initiate dialysis while also in hospice be excluded from the SMR.

Response: We appreciate this suggestion, and are examining the feasibility of adding this exclusion to the SMR.

SHR

One commenter requested clarification on the strength of validity results for the SHR, which were similar to the SMR.

Response: We have revised the interpretation in the MJF to accurately reflect the strength of the correlation.

Preliminary Recommendations

Based on the comments received, no substantive material changes will be made to the SMR and SHR measure specifications. However, there will be ongoing investigation into the impact and potential need in SMR for exclusion of patients who initiate dialysis while also in hospice.

Overall Analysis of the Comments and Recommendations

CMS and UM-KECC appreciate the time dedicated to reviewing and providing comments on these measures.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Actions Taken
3/25/16	SMR/SHR	See Appendix	David E. Henner, DO – South Berkshire County Dialysis Center	Provider	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
3/25/16	SMR/SHR	See Appendix	Allen R. Nissenson, MD, FACP, FASN, FNKF – DaVita	Provider	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
3/25/16	SMR/SHR	See Appendix	Kidney Care Partners	Professional Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
3/25/16	SMR/SHR	See Appendix	Jeffrey L. Hymes, MD – Fresenius Medical Services	Provider	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

Thank you for allowing me the opportunity to comment on these 2 updated measures. I have 2 comments/concerns which relate to both the proposed updated SMR and SHR measures for the CMS ESRD Program:

1. I agree with not including patients in these measures during the 1st 90 days of dialysis, and the 1st 60 days of dialysis in a particular dialysis facility. However, the measures proposed state that if a patient transfers from one facility to another, it won't be counted in the new facility's measure for 60 days, but during those 1st 60 days will be attributed to the previous facility. I have great concern with this, as the original facility really has no control over the care of the patient, once the patient transfers out to a new facility, yet will still be counted in their SHR and SMR for 60 days after transfer. I would propose not counting the patient for these measures during the 1st 60 days after the transfer to a new facility, at neither the transferring facility or the new facility.

2. The prevalent comorbidities counted in the risk adjustment formula for both SHR and SMR (all 210) are based on claims data specifically. This differs from the incident comorbidities which are based on 2728 data reviewed and certified by Nephrologist when the patient starts dialysis. There is no one reviewing the prevalent comorbidities, and these will likely vary greatly from Providers documenting on these (including Surgeons, Hospitalists, Residents, Interns, etc..) and from hospital to hospital, leading potentially to erroneous data which will likely skew the SHR and SMR data. Again, facilities have no control over the accuracy of this prevalent comorbidity data, whereas they do have control over accuracy of incident comorbidities. I would propose not incorporating the prevalent comorbidities until there is a more accurate way for dialysis facilities to insure the accuracy of the data.

Please feel free to contact me any time with any questions or concerns. Thank you.

Sincerely,

David E. Henner, DO

Division Chief of Nephrology

Medical Director of Dialysis Department:

Berkshire Medical Center, Pittsfield, MA Medical Director of Dialysis Facilities:

South Berkshire County Dialysis Center, Great Barrington, MA Southwestern Vermont Medical Center, Bennington, VT Office Phone: (413) 447-2764

Allen R. Nissenson, MD
Chief Medical Officer

Steven Brunelli, MD
VP, Health Economics & Outcomes
Research

Lorne Holland, MD
Chief Laboratory Officer

Mark Kaplan, MD
VP, Medical Affairs

Mahesh Krishnan, MD
Chief Medical Officer, International
Group VP, Research & Development

Stephen McMurray, MD
VP, Clinical Integrated Care
Management Services

Robert Merrell, MD
VP, Clinical Risk Support

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John Robertson, MD
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Martin Schreiber, MD
VP, Clinical Affairs –
Home Modalities

David Van Wyck, MD
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VP, Clinical Affairs –
Hospital Services

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Stefan H. Jacobson, MD
Consultant, Europe

February 17, 2016

Patrick Conway, M.D.
Principal Deputy Administrator
Chief Medical Officer
Director, Center for Clinical Standards and Quality
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Patrick,

On behalf of DaVita HealthCare Partners, the 176,000 patients with end-stage renal disease (ESRD) that we serve, and our 65,000 teammates dedicated to their care, we are pleased to respond to the ESRD Evaluation of Potential Prevalent Comorbidity Adjustments Standardized Hospitalization (SHR) and the Standardized Mortality Ratio (SMR).

We share a common goal with the Centers for Medicare and Medicaid Services (CMS): to strengthen the ESRD quality program and payment system so that beneficiaries with kidney disease have access to information regarding the highest quality care.

Comorbidity adjustment of SHR and SMR

We reviewed the revised measure information for both SHR and SMR and generally support the inclusion of claims based prevalent comorbidities as a covariate(s) in the risk model. Expansion of risk adjusting factors mitigates our concern regarding the accuracy of comorbidities at the time of ESRD incidence, as reported on the form 2728. Further we believe that this method allows for appropriate adjustment as patients develop additional comorbidities as a result of increase age and vintage.

It is unclear in the measure documentation whether prevalent comorbidities from claims on the previous calendar year will be factored in for all patient time intervals. Specifically we request clarification whether prevalent comorbidities will be factored into the risk model for a patient who initiated dialysis in the previous year.

Additional Prevalent Comorbidities

We do not dispute any of the comorbidities included in the recommendation, but do recommend adding to the risk model the presence of a central venous catheter at ESRD incidence. Even though patients are not included in the calculations during the first 90 days of ESRD, the presence of a central venous catheter increases the risk of hospitalizations and mortality and therefore should be included in the model.

Additional comments

The measure information form states “This measure is calculated as a ratio but can also be expressed as a rate.” As mentioned in prior commentary we oppose the use of standardized ratios, but we fully support migrating from the use of ratios to standardized rates. There are three primary reasons we believe standardized rates are preferred in this setting: 1) rates are easier to replicate 2) rates provide greater transparency and are easier to understand and 3) physicians and dialysis staff can better drive improvement when monitoring progress relative to rates.

We also support limiting the SMR metric to only Medicare patients, which matches the hospitalization metric.

Conclusion

We thank CMS for the opportunity to comment on this matter.

Once again we commend the Agency for its increased transparency and willingness to work with us and the entire ESRD community. This mutual collaboration ensures that ESRD beneficiaries receive the best possible care, and that these patients are presented with sufficient publically-reported data to allow for meaningful conversations with their caregivers in facilities and their physicians to assess the quality of care they currently receive or wish to receive. Measures such as hospitalizations and mortality are clear examples of this data but can only be strengthened by attention to the concerns we have raised and the policy improvements we have proposed.

Sincerely,



Allen R. Nissenson, MD, FACP, FASN, FNKF
Chief Medical Officer, DaVita Healthcare Partners Inc.
David Geffen School of Medicine at UCLA



February 29, 2016

Joel Andress, PhD
Centers for Medicare and Medicaid Services
University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

RE: Public Comment on Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR)

Fresenius Medical Care North America (Fresenius Medical Care) is the largest provider of renal dialysis services in the United States, providing dialysis treatments to over 170,000 individuals with end stage renal disease (ESRD) at over 2,200 dialysis facilities nationwide. We appreciate the opportunity to comment on the draft specifications for the SMR and SHR measures developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on February 8, 2016. Fresenius Medical Care is a member of the Kidney Care Partners, and we support its comments on these measures.

Regarding specifications, Fresenius Medical Care recommends that the SMR measurement time period should be adjusted to remove ambiguity. One year is inadequate and we strongly recommend an exact and stated period of at least 4 years. We believe that limiting the SMR and SHR denominators to Medicare patients is appropriate, and we believe that patients who initiate dialysis while also in hospice should be excluded from the SMR.

Fresenius Medical Care supports the use of prevalent co-morbidities in the risk models for the SMR and SHR. Specifically, we share KCP's concerns that the existence of a prevalent co-morbidity requires at least two outpatient claims or one inpatient claim, and we urge CMS to furnish the underlying rationale for this approach. We believe this risk model will not adequately

discriminate performance, potentially penalizing smaller dialysis facilities unfairly. We urge CMS to work with providers to improve the model.

Fresenius Medical Care recommends that CMS clarify the look-back period for co-morbidities, stated as one year prior to the given event or in the previous calendar year. We recommend the current reporting year be included, not just the previous one. Additionally, we believe that it is important that a beneficiary's Medicare status be taken into consideration. For commercial patients who switch to Medicare in a current calendar year, we recommend that the current reporting year prevalent comorbidities be included. Otherwise, the patient would have no Medicare claims for the previous year, and therefore no documented comorbidities.

Regarding the duration of ESRD, we reiterate our past concerns regarding facility attribution that does not adequately reflect the chain of responsibility for a patient. For example, if a patient sustains a fall either at a skilled nursing facility or at a dialysis facility to which they have been transferred, and is hospitalized within 60 days with a fractured hip, the fall will be attributed to the original facility. We strongly urge CMS to reconsider the flawed logic of this look-back approach.

Respectfully,



Jeffrey L. Hymes, MD

Chief Medical Officer, Senior Vice President

Fresenius Medical Services

Chair, Pharmacy & Therapeutics Committee



TO: Joel Andress, PhD
Centers for Medicare and Medicaid Services

University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

DA: February 24, 2016

RE: Public Comment on Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio (SHR)

Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care – patient advocates, health care professionals, dialysis providers, researchers, and manufacturers and suppliers – organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We appreciate the opportunity to comment on the draft specifications for the SMR and SHR developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on February 8, 2016.

Because the measures share much in common, we have organized the comments in five areas; when a comment pertains only to one of the measures, we specifically note this. The six areas are:

1. Specifications
2. Co-Morbidities
3. Risk Model Fit
4. Reliability and Validity Testing
5. Ratio vs. Rate Measures

1. SPECIFICATIONS

KCP offers several comments on the specifications

- **SMR Measurement Period.** The SMR specifications for the time period state “at least one year.” As a principle, KCP believes specifications should be unambiguous – i.e., the construction is imprecise. We believe the time period should be an exact period, and we further believe the 1-year period is inappropriate based on the testing data. We recommend, at minimum, a 4-year period.

CMS’s reliability testing for the 1-year SMR yielded IURs of 0.26-0.32 for each of 2010, 2011, 2012, and 2013 – a low degree of reliability, where only about 30% of the variation in a score can be attributed to between-facility differences. Using the 4-year SMR yielded an IUR of 0.66 (2009-2012) – i.e., about 60% of the variation can be attributed to between-facility differences; for 2010-2013 data, the IUR was only 0.59. We further note

a reliability statistic of 0.70 is often considered as “good” reliability,¹ though the characterization also depends on the analytic method. The overall reliability, even for the 4-year SMR, falls short in this regard.

Not surprisingly, reliability depends on facility size. Even with the 4-year SMR, the testing results still indicate poor reliability for small (IUR=0.30) and medium (IUR=0.45) facilities – i.e., only large facilities have a reasonable IUR of 0.73 for 2010-2013 data. Given these results, we also believe it is incumbent on CMS to address the lack of reliability and use an adjuster or otherwise account the poor reliability in small and medium facilities before the measure is implemented.

- **SHR Measurement Period.** The SHR specifications for the time period also state “at least one year.” Again, as a principle, KCP believes specifications should be unambiguous. We believe the time period should be an exact period. Further, based on the results from the reliability testing, we have significant concerns about the reliability of the 1-year SHR for small and medium facilities (IUR range of 0.46-0.65, depending on the year. Given there are a significant number of facilities that have fewer than 87 patients, KCP requests that CMS reanalyze the data and set the time period so the reliability/IUR is satisfactory, even for small facilities.
- **SMR and SHR Denominator.** KCP supports limiting the denominator to Medicare patients. As you know, KCP has long advocated that the measures should account for more current co-morbidity data, and we understand and support the trade-off to now limit the denominator population due to claims data availability.
- **SMR Exclusion for Incident Hospice Patients.** The NQF Measure Applications Partnership (MAP) recently did not support the SMR in part because the measure did not exclude patients who are already in hospice when they initiate dialysis. During the MAP deliberations, it was noted that occasionally incident patients begin dialysis treatments while in hospice, but then choose to discontinue them after a period of time. KCP supports MAP’s recommendation that patients who initiate dialysis while also in hospice be excluded from the SMR. As currently constructed, such patients are attributed to the facility providing the dialysis.

2. CO-MORBIDITIES

We strongly support the use of prevalent co-morbidities in the risk models for the SMR and SHR, and commend CMS for moving to incorporate prevalent co-morbidities in the proposed specifications – an approach for which KCP has long advocated. We also encourage CMS to review co-morbidities as they relate to the ESRD population under the age of 18 years, since these measures include all ESRD patients. We comment separately on the approaches for incident vs. prevalent co-morbidities.

- **Incident Co-morbidities.** Incident co-morbidities will continue to be derived from the 2728, but the new model proposes adjustments for each incident comorbidity separately instead of using a “comorbidity index.” Diabetes also is proposed as a single comorbidity, whereas before the model used four separate indicators. KCP supports treating each incident comorbidity separately, including diabetes. As we have noted before, however, we continue to be concerned about the validity of the 2728 as a data source. We urge CMS to work with the community to assess this matter.

¹ Adams, JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

- **Prevalent Co-morbidities.** KCP supports the inclusion of prevalent co-morbidities derived from Medicare claims data, but the review time does not permit us to comment specifically on the 555 co-morbidities originally considered, nor the 210 ultimately included. While we may in the future (e.g., during NQF review) comment on specific items, we note the face validity of some co-morbidities that have been included in the model is puzzling (e.g., “urinostomy status not elsewhere classified [NEC]”, “sacroiliitis NEC”). One approach might be to assess posterior probability. In sum, while we appreciate the details provided in the TEP report, we believe there are anomalies among the 210 co-morbidities and suggest a transparent process to refine the list.

Further, in reviewing the approach used to identify appropriate prevalent co-morbidities, the TEP report indicates an initial assessment was applied to the ESRD Hierarchical Comorbidity Conditions (HCCs) with a prevalence of at least 0.1% in the patient population in order to identify those with a statistically significant relationship to mortality and/or hospitalization ($p < 0.05$). However, we note that many of the co-morbidities included in the final model appear to have p-values significantly greater than 0.05 (e.g., paralytic ileus [$p = 0.5007$], episodic mood disorder NOS [$p = 0.8254$]) and so are puzzled as to the rationale for their inclusion. We seek clarification on this apparent discrepancy between the described approach to co-morbidity selection and the end-product.

- **Determination of Co-morbidities.** The determination that a prevalent co-morbidity exists requires at least two outpatient claims or one inpatient claim. No TEP justification or empirical analyses were offered to justify this algorithm. KCP requests the underlying rationale for the approach.

3. RISK MODEL

KCP is pleased the model incorporates prevalent co-morbidities, but we have a few concerns related to the model’s details.

- **Model Fit.** Testing yields a c-statistic for the SMR of 0.724, and a c-statistic for the SHR of 0.65. We are concerned the model will not adequately discriminate performance – particularly that smaller units, including pediatric units, might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model’s goodness of fit and validity to represent meaningful differences among facilities, and seek an ongoing commitment from CMS to improve the model.
- **Nursing Home Status:** The Measure Information Form (MIF) indicates patient characteristics included in the stage 1 model as covariates include “Nursing home status in *previous* year.” It is unclear to us if this means that patients moving into a nursing home for the first time *during* the measurement year would not be adjusted for “nursing home status”. KCP seeks clarification as to whether the look-back is *one year prior to the given event* (inclusive of the data year) or if this verbiage means the look-back is *in the previous calendar year* (not inclusive of the data year); we recommend the current reporting year be included, not just the previous one.
- **Age:** The age groups for the SMR ($n = 3$) differ from those for the SHR ($n = 6$). No TEP justification or empirical analyses were offered to justify this difference. KCP requests the underlying rationale and empirical justification for the approach, given the general principle that specifications should be harmonized when appropriate and possible.
- **Duration of ESRD.** Similarly, the number of groups for ESRD duration for the SMR ($n = 4$) differs from that for the SHR ($n = 6$). No TEP justification or empirical analyses

were offered to justify this difference. KCP requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

4. RELIABILITY AND VALIDITY

As we noted under Item 1, Specifications, we have significant concerns about the reliability of both the SMR and SHR and make recommendations on the specifications.

We noted the Spearman's correlation coefficients for SHR-SMR ranged from 0.27-0.30; SHR-SRR = 0.48-0.54; SHR-AVF = -0.15 to -0.12; SHR-catheter = 0.16-0.21; SHR- Kt/V \geq 1.2 = -0.13 to -0.10. Again, these correlations are directionally as expected. However, KCP believes the Measure Justification Form (MJF) overstates these correlations, concluding, "the SHR correlates strongly with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care." By convention, Spearman's rho of 0-0.19 appears to be considered "very weak" and must be 0.60-0.79 to be considered "strong."² We request the results be more accurately characterized, as they were for SMR – i.e., that the correlations were directionally as expected.

Additionally, for the facility minimum data requirements, the MJF notes at least 3 expected deaths must occur for inclusion in the SMR calculations. No TEP justification or empirical analyses were offered to justify this threshold. KCP requests information on the underlying analysis – e.g., how many clinics were excluded using this approach and what is the impact on scoring because of the exclusion? Similarly, for SHR the minimum requirement is 5 patient-years at risk. KCP notes the STeR uses 10 patient-years at risk. No TEP justification or empirical analyses are offered to justify this difference. KCP again requests the underlying rationale for the approach and empirical justification, given the general principle that specifications should be harmonized when appropriate and possible.

5. RATIO VS. RATE MEASURES

The proposed specifications for the SMR and SHR indicate the measures can be calculated as rates. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology. We note that MAP also did not support the SMR because, in addition to the lack of a hospice exclusion, as previously noted, MAP felt "mortality rates would be more meaningful to consumers and actionable for facilities."

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.298.0567).

Sincerely,

AbbVie
Akebia
American Kidney Fund
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology

² Stats Tutor, *Spearman's Correlation*. Available at www.statstutor.ac.uk. Last accessed February 2016.

Amgen
Astra Zeneca
Baxter
Board of Nephrology Examiners Nursing Technology
Centers for Dialysis Care
DaVita
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care
Fresenius Medicare Care Renal Therapies
Greenfield Health Systems
Keryx
Kidney Care Council
National Kidney Foundation
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Nephrology Nursing Certification Commission
Northwest Kidney Centers
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