NATIONAL QUALITY FORUM
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Memo

November 30, 2021

To: Consensus Standards Approval Committee (CSAC)

From: Renal Project Team

Re: Renal Spring 2021 Cycle

CSAC Action Required

The CSAC will review recommendations from the Renal project at its November 30 and December 1, 2021, meeting and vote on whether to uphold the recommendations from the Renal Standing Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the National Quality Forum (NQF) member expression of support (or non-support). The following document accompanies this memo:

1. **Renal Draft Report**. The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.

Background

Quality measurement plays a significant role in facilitating improvement in the quality of care received by chronic kidney disease (CKD) patients, especially those on HD. The NQF Renal Standing Committee oversees NQF's portfolio of endorsed measures associated with CKD. NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare & Medicaid Services (CMS), such as Dialysis Facility Compare and the End-Stage Renal Disease (ESRD) Quality Incentive Program (ESRD QIP).

The NQF Renal Standing Committee evaluated two newly submitted measures against NQF's standard evaluation criteria.

The Standing Committee did not recommend the following measures:

- NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (CMS/University of Michigan Kidney Epidemiology and Cost Center (UMKECC))
- NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC)

Draft Report

The renal draft report presents the results of the evaluation of two measures considered under the Consensus Development Process (CDP). Two were not recommended for endorsement.

The measures were evaluated against the 2019 version of the measure evaluation criteria.

Measures under Review	Maintenance	New	Total
Measures under review	0	2	2
Measures recommended for endorsement	0	0	0
Measures not recommended for endorsement	0	2	2
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measure – 0	Importance – 2 Scientific Acceptability – 0 Overall – 0 Competing Measure – 0	2

CSAC Action Required

Pursuant to the CDP, the CSAC is asked to consider two candidate measures that were not recommended for endorsement.

Measures Not Recommended for Endorsement

(See Appendix B for the Committee's votes and rationale)

- NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (CMS/UMKECC) [New]

  Evidence: H-0; M-5; L-13; I-2 (denominator = 20)

- NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC) [New]
  - **Evidence: H-0; M-1; L-15; I-4 (denominator = 20)**

Comments and Their Disposition

NQF received four post-evaluation meeting comments from four organizations (including four NQF-member organizations) pertaining to the measures under review. No post-evaluation meeting comments were received specific to the draft report.

Comments submitted during this comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, can be found in the Renal, Spring 2021 Cycle: CDP Report - DRAFT REPORT FOR CSAC REVIEW, November 30, 2021.

Comment Themes and Committee Responses

NQF received comments related to the measures that agreed with the Standing Committee's decision not to recommend both measures for endorsement. No further Standing Committee and developer follow up was required. No comments were received related to the draft report.

Themed Comments

The themed comments below were applicable to both measures #3615 and #3616. All comments received were in support of the Standing Committee's recommendations not to recommend the measure for endorsement.

Theme 1 – Insufficient evidence supporting the measure

The commenters stated the evidence recommends measures related to increased opioid use, rather than reducing opioid use without consideration of the target population (e.g., "recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering").

Committee Response

"Thank you for your comments." No further action was required by the Standing Committee.

Developer Response

No developer response was required.

Theme 2 – Patient centric needs of the population are not addressed

The focus of the measure does not address patient-centric clinical issues and does not adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving hemodialysis report pain as their primary symptom and their clinical scenario often limits pain management options.

Committee Response

"Thank you for your comments." No further actions were required by the Standing Committee.

Developer Response

No developer response was required.

Theme 3 – The Potential for Unintended Consequences is Substantial

The commenters stated the use of the measure as specified may lead to significant unintended consequences to patients based on illness severity, underlying conditions, and sociodemographic and geographic disparities. Further, the measure attribution for both measures assign accountability to the nephrologist group who prescribes approximately ten percent of the opioid prescriptions to this population. In implementing both #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.

Committee Response

"Thank you for your comments." No further actions were required by the Standing Committee.

Developer Response

No developer response was required.

Theme 4 – The risk adjustment is insufficient to meet population and provider needs

The commenters expressed concerns that the scientific acceptability and risk adjustment are not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters state the risk model insufficiently considers providers who care for medically complex patients. The commenters also state that although the measure does adjust for gender, no other social risk factors were included in the model (e.g., evidence-based state and regional geographic variations).

Committee Response

"Thank you for your comments." No further actions were required by the Standing Committee.

Developer Response

No developer response was required.

Member Expression of Support

Throughout the 16-week continuous public commenting period, which includes pre- and post-evaluation meeting comments, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Standing Committee's recommendations. Four NQF members provided their expressions of non-support. Two members provided expressions of non-support in both the pre- and post-evaluation meeting comments. Appendix C details the expression of non-support.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	no	*
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	no	*
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	no	*
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	n/a	*
Were any measurement gap areas addressed? If so, identify the areas.	no	The two measures sought to fill opioid overuse measure gaps.
Are there additional concerns that require CSAC discussion? If so, briefly explain.	no	*

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Appendix B: Measures Not Recommended for Endorsement

The Renal Standing Committee did not recommend the two candidate measures for endorsement.

The table below lists the Standing Committee's vote and rationale for measures not recommended for endorsement.

Legend: H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
#3615 UNSAFE OPIOID PRESCRIPTIONS AT THE PRESCRIBER GROUP LEVEL (CMS/UMKECC)	**Evidence** Total Votes: 20; H-0; M-5; L-13; I-2 *Must-Pass: Did Not Pass* **Insufficient Evidence with Exception** n/a **Gap** Vote not taken **Reliability** Vote not taken **Validity** Vote not taken **Feasibility** Vote not taken **Usability and Use** *Use* Vote not taken *Usability* Vote not taken **Post Comment Call Vote:** A post-comment meeting was not held.	• The submitted evidence targets the care of chronic pain in primary care, not patients with ESRD receiving hemodialysis. • The use of Part D Medicare claims attributes all opioid prescriptions to the nephrologist overseeing the hemodialysis, rather than the opioid prescribing clinician. • The empirical evidence links unsafe opioid prescribing to serious adverse events (e.g., hospitalizations and mortality), yet the submitted evidence does not demonstrate causality or how modifying pain management will alter the pattern of serious adverse events. • The measure conceptually seeks to reduce unsafe opioid use, yet adequate alternatives to pain management, which is very high in patients with ESRD receiving hemodialysis, are not provided. • The selection of unsafe chronic opioid dose and duration did not align with the population's clinical needs, and that the thresholds were sensitive to outliers based on prescribing patterns. • Evidence-based exclusions (i.e., sickle cell disease and cancer) were not excluded, yet were adjusted in the risk model as complex conditions. • The members agreed that unsafe opioid use is a national health issue yet managing pain for ESRD patients on hemodialysis is critical. • The must-pass Importance: Evidence criterion did not pass, and the measure was not recommended for endorsement.

Measure	Voting Results	Standing Committee Rationale
#3616 UNSAFE OPIOID PRESCRIPTIONS AT THE DIALYSIS PRACTITIONER GROUP LEVEL (CMS/UMKECC)	**Evidence** Total Votes: 20; H-0; M-1; L-15; I-4 *Must-Pass: Did Not Pass* **Insufficient Evidence with Exception** n/a **Gap** Vote not taken **Reliability** Vote not taken **Validity** Vote not taken **Feasibility** Vote not taken **Usability and Use** *Use* Vote not taken *Usability* Vote not taken **Post Comment Call Vote:** A post-comment meeting was not held.	• The Standing Committee stated that the evidence, discussion, and constraints for this measure were similar to those presented in 3615. • The Standing Committee stated it is not clear that nephrologist group, which accountability is attributed to this measure, might be able to advise the patient on opioid prescription but is unable to change the prescription or the pain outcome. • The patient's quality of life and the characteristics of pain that evolve over time are not presented in the submitted evidence or in the measure, which are especially important considering the limited pain management options available for this population. • The members agreed that unsafe opioid use is a national health issue yet managing pain for ESRD patients on hemodialysis is critical. • The must-pass Importance: Evidence criterion did not pass, and the measure was not recommended for endorsement.

Appendix C: NQF Member Expression of Support Results

Four NQF members provided their expression of non-support for two measures under review. No measures reviewed received expressions of support. Results for each measure are provided below.

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (CMS/UMKECC)

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1
Provider Organization	0	2	2
Quality Measurement, Research, and Improvement	0	1	1

#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC)

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1
Provider Organization	0	2	2
Quality Measurement, Research, and Improvement	0	1	1

Appendix D: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable; **Y**=Yes; **N**=No

Vote totals may differ between measure criteria and between measures as Standing Committee members often join calls late or leave calls early. NQF ensures that quorum is maintained for all live voting. All voting outcomes are calculated using the number of Standing Committee members present during the meeting for that vote as the denominator. Denominator vote counts may vary throughout the criteria due to intermittent Standing Committee attendance fluctuation. The vote totals reflect members present and eligible to vote at the time of the vote. If quorum is not achieved or maintained during the meeting, the Standing Committee receives a recording of the meeting and a link to submit online votes. Voting closes after 48 hours with at least the number of votes required for quorum. Quorum (17 out of 25 active Standing Committee members) was reached and maintained for the duration of the full measure evaluation meeting on June 23, 2021.

Measures Not Recommended

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level

Measure Worksheet

Description: Percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an opioid prescription written during the year that met one or more of the following criteria: duration >90 days, Morphine Milligram Equivalents (MME) >50, or overlapping prescription with a benzodiazepine.
Please note that the opioid prescriber is the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient. This provider is usually not the nephrologist who is overseeing the patient's dialysis care. This is in contrast to NQF submitted measure #3616, which is at the dialysis provider level (the clinician who receives the Monthly Capitated Payment for overseeing dialysis care). While the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and that doses are safe and appropriate for level of kidney function.
The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g. age, gender, risk factors). Here, "national" refers to all opioid prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model.
Numerator Statement: The numerator is the number of patients in the denominator who were prescribed an opioid that was either >90 days duration during the year, >50 MME, or overlapped in time with a benzodiazepine prescription.
Denominator Statement: The denominator is the number of patients associated with an opioid prescriber's group practice who are receiving maintenance dialysis (in-center or home dialysis) for any duration who receive an opioid prescription during the one year reporting period.
Exclusions: Patients who have a hospice claim at any time (either before or after the opioid prescription date) during the one year reporting period are excluded.
Adjustment/Stratification: Statistical risk model
Level of Analysis: Clinician : Group/Practice
Setting of Care: Other
Type of Measure: Process
Data Source: Claims, Other, Registry Data
Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/23/2021

1. Importance to Measure and Report: The measure did not meet the Importance criteria
(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes: 20; H-0; M-5; L-13; I-2**; 1b. Performance Gap: **Vote Not Taken**
Rationale:

- The Standing Committee observed this is a process measure that focuses on determining the percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an unsafe opioid prescription written within the year. The Standing Committee noted the opioid prescriber is the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient and is usually not the nephrologist who is overseeing the patient's dialysis care
- The Standing Committee acknowledged the developer provided empirical evidence from the literature to link unsafe opioid prescription practices to serious adverse event, such as hospitalization and mortality, in the dialysis population. Particularly, the developer provided the search terms/query that was conducted in PubMed in February 2019, which yielded 268 articles that were reviewed and of these 43 were selected for presentation to the Technical Expert Panel that was convened to make recommendations regarding this measure. The developer provided a list of references for relevant articles and a summary synthesizing the evidence to support this measure.
- One Standing Committee member questioned whether the developers looked at significantly limited medication options for ESRD patients, which might lead to opioid prescription in this population. The Standing Committee also questioned whether the goal of the UMKECC-convened TEP was to reduce opioid use or to manage pain appropriately. The developer acknowledged the concern and agreed that, as literature suggested, there are limited pain management options for this population. The developer clarified that the measure does not intend to reduce or eliminate opioid prescriptions for patients on dialysis; rather, the goal of the measures is to identify and monitor high risk opioid prescriptions. The developer noted that the measure primarily looks at the prescriptions themselves and how efficacious those prescriptions are in controlling pain.
- The Standing Committee raised several concerns regarding the developer's rationale for selecting the cutoff criteria that define unsafe opioid use, particularly, the dosage of greater than 50 Morphine Milligram Equivalents (MME) and the chronicity threshold of 90 days of opioid use. The Standing Committee also noted thaet the measure, as specified, does not indicate the timeframe of "per day" for the 50 MME cutoff (which is suggested by Centers for Disease Control and Prevention [CDC] guidelines) anywhere in the measure submission form. The Standing Committee expressed concerns regarding the lack of evidence supporting 90 days in the aggregate opioid dose was unsafe use.
- The developers also noted that the CDC guidelines were used that to help construct the definition of a high risk of opioid prescription; however, the evidence submitted for this measure comes from the literature, particularly the observational studies that look at the chronicity of prescriptions and higher dose prescriptions and associates that with adverse outcomes. The developer stated that the selection of both cutoffs was based on the CDC guidelines and their findings from the literature, with a goal to maximize their safety margin. The developers also clarified that both 50 MME cutoff and the 90 day of opioid use were endorsed by UMKECC-convened TEP. The developer also noted that the cutoff is not setting the sensitivity of flagging the outliers; rather they have used statistical techniques in the measure to identify outliers based on the prescribing practices.
- The Standing Committee agreed that the evidence shows a correlation between unsafe prescription, as defined in the measure specifications, and the important clinical outcomes. However, the Standing Committee agreed that the evidence was not sufficient enough in showing that changing the prescription patterns will lead to different outcomes in the target population for this measure.
- The Standing Committee also raised concerns about the exclusions in the denominator and failed to see how the measure construction was supported by the evidence and guidelines that exist today. The Standing Committee questioned why the developers did not exclude sickle cell disease and cancer as they were specifically cited in the submission form. The developer stated that they limited the exclusion criteria to patients that are enrolled in hospice at any point during the reporting period. They explained that they chose to be a bit more specific in the exclusion criteria and to use a risk adjustment strategy so that we could have a more broadly applicable measure to the patient population and to try and account for the differences and comorbidities that exist between patient populations.
- The Standing Committee asked to see if there was background literature that show overall level of (subjective) pain in this population compared to the general Medicare population, which would help

understand the use of opioids in this population. The developer responded that there is literature that addresses the frequency of pain in the proportion of patients on dialysis who have pain and those are both greater than in the general population, but there isn't literature that specifically addresses the degree of pain in terms of severity.

- The Standing Committee agreed that inappropriate opioid use and prescribing are a major problem in this country and that appropriate pain management is critical. However, given the concerns discussed above, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

2. Scientific Acceptability of Measure Properties

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)

2a. Reliability: **Vote Not Taken**; 2b. Validity: **Vote Not Taken**

Rational

The measures were reviewed by the Scientific Methods Panel (SMO) prior to the measure evaluation meeting, although the details were not discussed by the Standing Committee as the measure did not pass the Importance: Evidence criterion in 1a., a "must-pass" criterion. A summary of the SMP discussion is provided below.

The SMP subgroup passed the measure on reliability and validity. The measure was pulled for discussion during the March 2021 SMP meeting. A summary of the measure and the Panel review and discussion is provided below.

Reliability

- The SMP passed the measure on reliability with High rating **(Total votes: 9; H-6; M-1; L-1; I-1)**.
- The developer conducted validity testing at the performance measure score level using inter-unit reliability (IUR) for the annual performance scores.
- The developer used CROWNWeb, Medicare Claims, the CMS Medical Evidence form 2728, Medicare Part D Claims as data sources to test the measure. The analysis included 103,157 physicians in 5,123 groups (range: 1-2,328 clinicians) with an average of 40 patients per group (range: 11-2,411).
- Physician groups must have more than 10 eligible patients to be included in the measure or the analysis.
- The developer noted that the IUR calculated at the group level is 0.86 which means 86% of the total variation of this prescriber group level measure can be explained by the differences among prescribers and not by random noise.
- To assess further whether the measure can identify prescriber groups with extreme values, we computed the Profile inter-unit reliability (PIUR), which is 0.98. The developer stated that the discrepancy between the IUR (0.86) and PIUR (0.98) indicates the existence of outlier prescriber groups that can be identified by the measure.

Validity

- The SMP passed the measure on validity with Moderate rating **(Total votes: 9; H-2; M-4; L-1; I-2).**
- Validity testing was conducted at the score level:
    - The developer conducted a concordance analysis of the relationship between measure scores, hospitalization, and mortality.
    - Hospitalization rate at the practitioner group level is 1.49, 1.46 and 1.41 for T1, T2, and T3 respectively (trend test $p<0.001$), while the average number of hospital days per year and patient at the practitioner group level is 6.1, 5.1 and 4.1 respectively (trend test $p<0.001$).
    - The practitioner group level average mortality rate is 0.19, 0.20, and 0.18 per patient-year for T1, T2, and T3 groups, respectively.
- SMP Subgroup pilled this measure for discussion specifically to address an overarching question: To what extent is the validity analysis confounded by unmeasured case mix, considering that dialysis physicians with sicker patients (e.g., those with comorbid cancer) have higher mortality rates, hospitalization rates, and opioid use. The two measures were therefore discussed concurrently.
- During the SMP meeting, concerns were raised regarding the use of a risk adjustment model for a process measure. They noted it would be more appropriate for risks to be made into exclusions (e.g., cancer); and the other factors that are endogenous (e.g., drug dependence, substance use disorder, anxiety disorders,

and previous opioid poisoning) may increase risk and are confounders that may be difficult to understand or differentiate. The risk adjustment model was noted as appropriate in terms of performance statistics but lacked an underlying theory to justify the selection of factors for the model.

- The SMP also expressed concerns that the validation of the measure is based on dividing provider groups into tertiles that showed the top tertile with a failure rate over 46 percent, the middle at 30-36 percent, and the best tertile under 30 percent. The submission noted that patients in the worst performing tertile have a slightly higher hospitalization odds ratio, 1.49 versus 1.41 and a few more hospital days per year, 6.1 versus 4.1, as well has a higher death rate. They also noted these findings were reported under an unadjusted analysis when the developer has suggested that risk adjustment is essential for the measure's application.
- The SMP elected not to revote on the measure but passed along the concerns to the Renal Standing Committee. A full summary of the SMP discussion is linked SMP webpage.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Vote Not Taken** 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- The commenters stated the evidence recommends measures related to increased opioid use, rather than reducing opioid use without consideration of the target population (e.g., "recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering").
- The commenters stated the focus of the measure does not address patient-centric clinical issues and does not adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving hemodialysis report pain as their primary symptom and their clinical scenario often limits pain management options.
- The commenters stated that use of the measure as specified may lead to significant unintended consequences to patients based on illness severity, underlying conditions, and sociodemographic and geographic disparities. Further, the measure attribution for both measures assign accountability to the nephrologist group who prescribes approximately ten percent of the opioid prescriptions to this population. In implementing both #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.
- The commenters expressed concerns that the scientific acceptability and risk adjustment are not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters state the risk model insufficiently considers providers who care for medically complex patients. The commenters also state that although the measure does adjust for gender, no other social risk factors were included in the model (e.g., evidence-based state and regional geographic variations).

- **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**
- **9. Appeals**

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

Measure Worksheet

Description: Percentage of all dialysis patients attributable to a dialysis provider's group practice who had an opioid prescription written during the year that met one or more of the following criteria: duration >90 days, Morphine Milligram Equivalents (MME) >50, or overlapping prescription with a benzodiazepine.

Please note that this measure is at the dialysis provider level (the clinician who receives the Monthly Capitated Payment for overseeing dialysis care). While the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and that doses are safe and appropriate for level of kidney function. This is in contrast to NQF submitted measure #3615, which is at the opioid prescriber level (the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient) who is typically not the nephrologist who is overseeing the patient's dialysis care.

The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g. age, gender, risk factors). Here, "national" refers to all opioid prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model.

Numerator Statement: The numerator is the number of patients in the denominator who were prescribed an opioid that was either >90 days duration during the year, >50 MME, or overlapped in time with a benzodiazepine prescription.

Denominator Statement: The denominator is the number of patients associated with a dialysis provider's group practice who are receiving maintenance dialysis (in-center or home dialysis) for any duration who receive an opioid prescription during the one year reporting period.

Exclusions: Patient months are excluded if there is more than one MCP provider claim in a given month. In addition, patients who have a hospice claim at any time (either before or after the opioid prescription date) during the one year reporting period are excluded.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician : Group/Practice

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Other, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/23/2021

1. Importance to Measure and Report: The measure did not meet the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes: 20; H-0; M-1; L-15; I-4**; 1b. Performance Gap: **Vote Not Taken**

Rationale

- The Standing Committee observed that this process measure focuses on determining the percentage of all dialysis patients attributable to a dialysis provider's group practice who had an unsafe opioid prescription written within the year.
- The Standing Committee acknowledged that the developer provided empirical evidence from the literature to link unsafe opioid prescription practices to serious adverse event, such as hospitalization and mortality, in the dialysis population. Particularly, the developer provided the search terms/query that was conducted in PubMed in February 2019, which yielded 268 articles that were reviewed and of these 43 were selected for presentation to the Technical Expert Panel that was convened to make recommendations regarding this measure. The developer provided a list of references for relevant articles and a summary synthesizing the evidence to support this measure.
- The Standing Committee noted that the evidence to support this measure was very similar to that for measure, NQF #3615, and that the same concerns apply to this measure (NQF #3616).
- The Standing Committee noted that the denominator of this measure excludes the number of patients in a group practice on dialysis who received an opioid during the year, in addition to excluding the hospice patients.
- The Standing Committee noted that there is not enough evidence to support the claim that the monthly capitation payment (MCP) physicians affect the outcome/numerator of this measure since the MCP

physician might be able to advise the patient on opioid prescription, but they can't change the prescription or the outcome.
- The Standing Committee agreed that it's important to look at the benefit of opioid use in this population and its positive affect on the quality of life of a dialysis patient, especially in the absence other pain management medication options.
- The Standing Committee agreed that the same concerns as those raised for NQF #3615 apply for this measure (NQF #3616). Based on those concerns, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

2. Scientific Acceptability of Measure Properties

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)

2a. Reliability: **Vote Not Taken**; 2b. Validity: **Vote Not Taken**

Rational

The measures were reviewed by the Scientific Methods Panel (SMP) prior to the measure evaluation meeting, although the details were not discussed by the Standing Committee as the measure did not pass the Importance: Evidence criterion in 1a., a "must-pass" criterion. A summary of the SMP discussion is provided below.

Reliability

- The SMP passed the measure on reliability with Moderate rating **(Total votes: 9; H-1; M-6; L-1; I-1)**.
- The developer conducted reliability testing at the performance measure score level using inter-unit reliability (IUR) for the annual performance scores.
- The developer used CROWNWeb, Medicare Claims, the CMS Medical Evidence form #2728, and Medicare Part D Claims as data sources to test the measure. A total of 6784 physicians in 3323 groups (range: 1-51 clinicians) with an average of 46 patients per group (range: 11-1022) were included in the analysis.
- Physician groups must have more than 10 eligible patients to be included in the measure or the analysis.
- The developer states that the IUR calculated at the group level is 0.60 which means 60% of the total variation of this group level measure can be explained by the differences among physician groups and not by random noise.
- To assess further whether the measure can identify prescriber groups with extreme values, the developer computed the Profile inter-unit reliability (PIUR) of 0.81. The developer stated that the discrepancy between the IUR (0.60) and PIUR (0.81) indicates the existence of outlier physician groups that can be identified by the measure.
- The developer states that the PIUR being larger than the IUR demonstrates that the measure can detect differences in performance scores across physician groups as well as outlier groups.
- The SMP generally conceded that the testing approach was appropriate, but it was noted that the variation between providers within provider group does not appear to have been handled by the methods reported (i.e., the error term appears not to include between providers across patients within practice).

Validity

- The SMP passed the measure on validity with Moderate rating **(Total votes: 9; H-1; M-5; L-1; I-2)**.
- Validity testing was conducted at the score level:
    - The developer conducted a concordance analysis of the relationship between measure scores, hospitalization, and mortality.
    - The hospitalization rate at the dialysis provider group level is 1.55, 1.48, and 1.47 for tercile 1 (T1), T2, and T3, respectively (trend test $p<0.001$), while the average number of hospital days per year and patient at the dialysis provider group level is 8.3, 7.5, and 7.7, respectively (trend test $p<0.001$).
    - The dialysis provider group level average mortality rate is 0.26, 0.29, and 0.33 per patient-year for T1, T2, and T3 groups, respectively.
- SMP noted that no specific correlation test between #3616 and hospitalization and mortality was specified which would be an appropriate validity test. The relationships are stated with descriptive statistics.

- The SMP stated that the risk adjustment model was noted as appropriate in terms of performance statistics but lacked an underlying theory to justify the selection of factors for the model.
    - It was noted that it would be more appropriate for risks to be made into exclusions (e.g., cancer), and other endogenous factors (e.g., drug dependence, SUD, anxiety disorders, and previous opioid poisoning) may increase risk and are confounders that may be difficult to understand or differentiate.
- The SMP elected not to revote on the measure but passed along the concerns to the Renal Standing Committee. A full summary of the SMP discussion is linked SMP webpage.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Vote Not Taken** 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- The commenters stated the evidence recommends measures related to increased opioid use, rather than reducing opioid use without consideration of the target population (e.g., "recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering").
- The commenters stated the focus of the measure does not address patient-centric clinical issues and does not adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving hemodialysis report pain as their primary symptom and their clinical scenario often limits pain management options.
- The commenters stated that use of the measure as specified may lead to significant unintended consequences to patients based on illness severity, underlying conditions, and sociodemographic and geographic disparities. Further, the measure attribution for both measures assign accountability to the nephrologist group who prescribes approximately ten percent of the opioid prescriptions to this population. In implementing both #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.
- The commenters expressed concerns that the scientific acceptability and risk adjustment are not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters state the risk model insufficiently considers providers who care for medically complex patients. The commenters also state that although the measure does adjust for gender, no other social risk factors were included in the model (e.g., evidence-based state and regional geographic variations).

- **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**
- **9. Appeals**

Renal Spring 2021 Review Cycle

CSAC Review

November 30 – December 1, 2021
Funded by the Centers for Medicare & Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001

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Renal Standing Committee Recommendations

- **Two measure reviewed for spring 2021**
  - Two measures reviewed by the Scientific Methods Panel
    - » #3615 and #3616 passed SMP on reliability and validity.
- **Two measures were not recommended for endorsement**
  - **#3615** Unsafe Opioid Prescriptions at the Prescriber Group Level (Centers for Medicare & Medicaid Services [CMS]/University of Michigan Kidney Epidemiology and Cost Center [UMKECC]) (new)
  - **#3616** Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC) (new)

Overarching Issues for Renal Measures

- **Evidence must be strong, unambiguous, represent the target population, and demonstrate how it supports improved care delivery and outcomes**
  - The evidence must directly represent the measure focus of interest specified in the constructs (i.e., numerator, denominator, exclusions/exceptions, and performance calculation), including the applicable diagnosis(es), patient characteristics/needs/barriers, setting, and care delivery.
  - The primary evidence focuses on reducing unsafe opioid misuse, abuse, and addictions for patients with chronic pain being treated by primary care providers, rather than patients receiving hemodialysis.
  - The submitted evidence states that patients with end stage renal disease (ESRD) report pain as their primary symptom and report higher rates of pain than the general population. Considering this fact and the target population, the Standing Committee questioned whether the measure should focus on appropriate pain management, rather than reducing unsafe opioid use.

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Overarching Issues for Renal Measures *(continued)*

- **Measures should eliminate or significantly reduce unintended consequences to all applicable stakeholders, whenever possible.**
  - Measures used to improve care delivery (e.g., reduction in opioid abuse and additions with reduced opioid prescriptions) should not simultaneously contribute to poorer outcomes (e.g., patients receiving renal dialysis with increased pain and adverse outcomes, depression, anxiety, and emergence of other mental health disorders, loss of function, and the ability to perform daily activities, and even suicide).
  - Patients receiving hemodialysis have very limited pain relief options due to the clinical limitations of end stage renal disease (ESRD).
  - The accountable entity should be the clinician conducting the clinical action or outcome of interest. The evidence demonstrates that only about ten percent of opioid prescriptions for patients receiving hemodialysis are written by nephrologists.
  - Providers implementing both measures would be double penalized for inappropriate attribution.

Renal Public and Member Comment and Member Expressions of Support

- Four comment(s) received
  - Four non-supportive comments due to concerns about the misalignment of the presented evidence and the needs of target population (measure #3615, measure #3616)
  - Four non-supportive comments due to concerns about the unintended consequences to patients and providers (measure #3615, measure #3616)
- Four NQF members provided expressions of non-support for two measure(s) under review
  - Four members expressed non-support of (measure #3615, measure #3616)

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Renal Contact Information

- NQF Project Team:
  - Matt Pickering, PharmD, Senior Director
  - Oroma Igwe, MPH, Manager
  - Kim Murray, Coordinator
  - Mike DiVechhia, MBA, PMP, Senior Project Manager
  - Sharon Hibay, RN, DNP, Senior Consultant

- Project Webpage: https://www.qualityforum.org/Renal.aspx
- Project email address: renal@qualityforum.org

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Renal, Spring 2021 Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW
NOVEMBER 30, 2021

This report is funded by the Centers for Medicare & Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-TO001.

https://www.qualityforum.org

Contents

Executive Summary

More than 15 percent of United States (U.S.) adults, or 37 million people, are estimated to have chronic kidney disease (CKD).[1] Untreated CKD can result in end-stage renal disease (ESRD) and a host of other health complications. In 2018, about 131,600 people in the U.S. started treatment for ESRD. In patients suffering from moderate-to-severe CKD or ESRD, who were subjected to hemodialysis (HD), pain is quite common, but often underestimated. Opioid use is common among patients receiving dialysis with estimates of use indicating that more than 60 percent receive an opioid prescription each year.[2] In addition, over 20 percent of ESRD patients use opioids chronically, defined as more than 90 days in a calendar year.[2] These rates of opioid prescription in the ESRD population are approximately three times that seen in the general Medicare population.[2] Therefore, the need to focus on quality measures for the safe use of opioids for patients with renal disease is particularly important.

Quality measurement plays a significant role in facilitating improvement in the quality of care received by CKD patients, especially those on HD. The National Quality Forum (NQF) Renal Standing Committee oversees NQF's portfolio of endorsed measures associated with CKD. NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare & Medicaid Services (CMS), such as Dialysis Facility Compare and the ESRD Quality Incentive Program (ESRD QIP).

The NQF Renal Standing Committee evaluated two newly submitted measures against NQF's standard evaluation criteria.

The Standing Committee did not recommend the following measures:

- NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (Centers for Medicare & Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UMKECC))
- NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC)

Brief summaries of the measures currently under review are included in the body of the report; detailed summaries of the Standing Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Renal disease is a leading cause of morbidity and mortality in the U.S. Approximately 37 million adults in the U.S. have CKD, which is associated with premature mortality, decreased quality of life, and increased healthcare costs.[3] Untreated CKD can result in ESRD and a host of other health complications. In 2018, about 131,600 people in the U.S. started treatment for ESRD (e.g., dialysis). Pain is among the most commonly reported symptom of patients on dialysis, and opioid use is among the most commonly used treatments for pain within the dialysis population. It is estimated that more than 60 percent of dialysis patients receive an opioid prescription in a given year.[2] In addition, over 20 percent of ESRD patients use opioids chronically, defined as greater than 90 days in a calendar year.[2] These rates of opioid prescription in the ESRD population are approximately three times that seen in the general Medicare population.

Unsafe opioid use and prescribing have been shown to cause serious adverse events. Dialysis patients with chronic opioid prescriptions (i.e., greater than 90 days) are more likely to have increased mortality, dialysis discontinuation, and hospitalization when compared with patients without an opioid prescription.[4] Additionally, higher doses of opioids have been associated with increased risk of falls and fractures in the ESRD population compared with lower doses.[5]

In an effort to ensure safe and effective treatment of chronic pain, while reducing the risk of addiction, overdose, and death, the Centers for Disease Control and Prevention (CDC) released guidelines for safe and appropriate opioid prescribing.[6] These guidelines call for increased discussion and follow-up between patients and providers, use of the lowest dose/duration possible, and consideration for non-opioid treatment modalities.

This project sought to identify and endorse performance measures for accountability and quality improvement to address unsafe opioid prescribing in patients with kidney disease. On June 23, 2021, NQF convened a multistakeholder Standing Committee composed of 25 individuals to evaluate two newly submitted measures for NQF endorsement consideration.

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of Renal measures (Appendix B). This portfolio contains 16 measures: five process measures, six intermediate outcome measures, and five outcome measures (see table below).

Table 1. NQF Renal Portfolio of Measures

Level of Analysis	Process	Intermediate Outcome	Outcome
Clinician: Group/Practice	0	1*	1*
Clinician: Individual	0	1*	1*
Facility	5	5	4
Total	**5**	**6**	**5**

*NQF #1662 (intermediate outcome measure) and NQF #1667 (outcome measure) are tested and specified at both the Clinician: Group/Practice and Clinician: Individual level.

Additional measures have been assigned to other portfolios. These include measures related to admissions, readmissions and emergency department (ED) utilization (All-Cause Admissions and Readmissions), various diabetes assessment and screening measures (Primary Care & Chronic Illness), eye care measures (Primary Care & Chronic Illness), angiotensin-converting enzyme inhibitors/angiotensin receptor blockers (ACEI/ARB) medication measures (Cardiovascular and Primary Care & Chronic Illness), complications and outcomes measures (Cardiovascular, Patient Experience & Function, and Surgery), and cost and resource use measures (Cost and Efficiency).

Renal Measure Evaluation

On June 23, 2021, the Renal Standing Committee evaluated two new measures against NQF's standard measure evaluation criteria.

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under review	0	2	2
Measures not recommended for endorsement	0	2	2
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measure – 0	Importance – 2 Scientific Acceptability – 0 Overall Suitability – 0 Competing Measure – 0	

Comments Received Prior to Standing Committee Evaluation

NQF accepts comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 1, 2021, and closed on September 9, 2021. The pre-evaluation meeting commenting period closed on June 3, 2021. As of that date, three comments were submitted which applied to both measures under review. All the commenters agreed that opioid use needs to be minimized and managed; however, they raised several concerns with the two measures as specified. The commenters raised concerns regarding the misalignment of the numerator requirements with the evidence and the need for additional precision in the denominator. The commenter mentioned the misapplication of the recommendations from the CDC guidelines in support of the two measures and recommended reframing the measures to focus on adequate pain assessments and treatments to better understand the true problem rather than removing a downstream intervention. They noted the measure as specified will incentivize inappropriately abrupt reductions of opioid medications and

undermanagement of chronic pain in complex dialysis patients while exacerbating the existing sociodemographic, economic, and geographic disparities related to opioid use. These comments were shared with the Standing Committee prior to the measure evaluation meeting and the Standing Committee considered the comments related to evidence during their review of the measures (Appendix F).

Comments Received After Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on September 9, 2021. Following the Committee's evaluation of the measures under review, NQF received three comments from three organizations (including three member organizations) and individuals pertaining to the draft report and to the measures under review (Appendix G). All comments for each measure under review have also been summarized in Appendix A.

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Committee's recommendations. Expressions of support (or not) during the commenting period replace the member voting opportunity that was previously held subsequent to committee deliberations. Four NQF members expressed that they are not in support of the either NQF #3615 or #3616.

Overarching Issues

During the Standing Committee's discussion of the measures, one overarching issue emerged, which was factored into the Standing Committee's ratings and recommendations for both measures.

Insufficient Evidence

The Standing Committee raised concerns during the review of the importance to measure and report criterion, specifically the evidence sub-criterion, for both process measures under review this cycle (NQF #3615 and NQF #3616). Per the 2019 NQF Evaluation Criteria and Guidance, the evidence sub-criterion for process measures evaluates whether a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence have been conducted, showing that the measured healthcare process leads to a desired health outcome in the target population. In addition, does the evidence show that the benefits of the process outweigh any potential harms? The Standing Committee noted the developer did not include a systematic review of the evidence specific to this measure nor was a grading applied to the body of evidence provided. The Standing Committee raised several concerns regarding the rationale for selecting the thresholds in the numerator statement that define unsafe opioid use, particularly, the dosage of greater than 50 Morphine Milligram Equivalents (MME) and the chronicity threshold of 90 days of opioid use. Although the developer clarified the selection of both cutoffs was based on the CDC guidelines and their findings from both the literature and observational studies, the Standing Committee agreed the evidence submitted was not sufficient to support the definitions presented in the numerator statement. The Standing Committee observed that the evidence shows a correlation between unsafe prescription, as defined in the measure specifications, and the important clinical outcomes. However, the Standing Committee questioned whether the evidence provided

demonstrated that changing the prescription patterns will truly lead to different outcomes in this patient population.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues the Standing Committee considered. Details of the Standing Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (CMS/ UMKECC): Not Recommended

Description: This measure reports the percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an opioid prescription written during the year that met one or more of the following criteria: a duration greater than 90 days, Morphine Milligram Equivalents (MME) greater than 50, or overlapping prescription with a benzodiazepine. Please note that the opioid prescriber is the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient. This provider is usually not the nephrologist who is overseeing the patient's dialysis care. This is in contrast to NQF measure #3616, which is at the dialysis provider level (the clinician who receives the Monthly Capitation Payment [MCP] for overseeing dialysis care). Although the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and ensure that doses are safe and appropriate for the level of kidney function. The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g., age, gender, and risk factors). Here, the term "national" refers to all opioid-prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model. **Measure Type**: Process; **Level of Analysis**: Clinician : Group/Practice; **Setting of Care**: Other; **Data Source**: Claims, Other, Registry Data

The Standing Committee did not vote on the recommendation for endorsement because it did not pass the measure on evidence—a must-pass criterion.

The Standing Committee observed that this is a process measure that focuses on determining the percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an unsafe opioid prescription written within the year. The Standing Committee noted the opioid prescriber is the clinician identified from Part D Medicare Claims who provides an opioid prescription to a dialysis patient. In addition, this provider is not the nephrologist who is overseeing the patient's dialysis care. One Standing Committee member questioned whether the developers looked at how individuals with end-stage renal disease (ESRD) cannot take other pain medications, including non-steroidal pain medications. This significantly limits medication options for ESRD patients, which might be one of the reasons for opioid prescription in this population. The Standing Committee also questioned whether the goal of the UMKECC-convened TEP was to reduce opioid use or to manage pain appropriately. The developer acknowledged the concern and agreed, as literature suggested, that pain management options are limited for this population. The developer noted almost half of the UMKECC-convened

Technical Expert Panel (TEP) was represented by dialysis patients and noted the measure does not intend to reduce or eliminate opioid prescriptions for patients on dialysis; rather, the goal of the measures is to identify and monitor high-risk opioid prescriptions.

One of the Standing Committee members questioned whether the developer utilized any type of measurement (e.g., a survey) to determine patients' pain management techniques and whether it was included in the measure. The developer noted the measure primarily looks at the prescriptions themselves and how efficacious those prescriptions are in controlling pain. The Standing Committee raised questions regarding the developer's rationale for selecting the cutoff criteria that define unsafe opioid use, particularly, the dosage of greater than 50 MME and the chronicity threshold of 90 days of opioid use. Additionally, the Standing Committee highlighted that the CDC guidelines suggest 50 MME cutoff per day. However, the measure, as specified, does not indicate the timeframe of per day for the 50 MME cutoff anywhere in the measure submission form. The Standing Committee expressed concerns regarding the lack of evidence supporting those 90 days in the aggregate opioid dose, which was unsafe use. The developer stated the selection of both cutoffs was based on the CDC guidelines and their literature findings, with a goal to maximize their safety margin. The developers also clarified the 50 MME cutoff was indeed a per day cutoff and the 90 days of opioid use was defined in terms of aggregate use. In addition, the UMKECC-convened TEP endorsed both of these cutoffs. Furthermore, the developer stated that the discussion had been focused on the use of thresholds in the measure's numerator statement, specifically the dosage of 50 MME, but that cutoff is not setting the sensitivity of flagging the outliers, rather they have used statistical techniques in the measure to identify outliers based on the prescribing practices.

The developers also noted the CDC guidelines were used to help construct the definition of a high-risk opioid prescription. However, the evidence submitted for this measure comes from the literature, particularly the observational studies that look at the chronicity of prescriptions and higher dose prescriptions, and it associates that with adverse outcomes. The Standing Committee agreed the evidence shows a correlation between unsafe prescription, as defined in the measure specifications, and the important clinical outcomes. However, the evidence does not sufficiently demonstrate that the causation of changing the prescription patterns will lead to different outcomes in the target population. The developer highlighted that the observational studies presented as evidence to support this measure have demonstrated consistent findings across studies, and they look at gradations of opioid prescriptions and different markers of chronicity. Additionally, the developer stated they developed a specific definition for the numerator statement modeled after the CDC guidelines, and the definition is encompassed in the peer-reviewed literature. However, there is not one study that used those exact criteria. The developers also noted that NQF's evidence algorithm does not explicitly require process measures to prove causation. Many NQF-endorsed measures utilize observational studies that show association because that might be the only evidence that exists. Especially for the dialysis population, there are not many studies that can provide a higher degree of causation. NQF staff added that for the evidence criterion in process measures, the Standing Committee should consider the quality, quantity, and consistency of evidence and whether the evidence reflects the measure focus, population, and accountable entity. The Standing Committee should further consider whether the measure process, in this case, leads to a desired health outcome.

The Standing Committee also raised concerns about the exclusions in the denominator and requested the developers provide their input on how the measure construction is supported by the evidence and guidelines that exist today. The Standing Committee questioned why the developers decided to not include sickle cell disease and cancer, as they were specifically cited in the submission form. The developer stated that they limited the exclusion criteria to patients enrolled in hospice at any point during the reporting period. They also explained they chose to be slightly more specific in the exclusion criteria and to use a risk adjustment strategy. The developer stated that they wanted to have a more broadly applicable measure to the patient population and to account for the differences and comorbidities that exist between patient populations. The Standing Committee asked to see whether there was background literature showing the overall level of (subjective) pain in this population compared with the general Medicare population, which would help to understand the use of opioids in this population. The developer replied that there is literature that addresses the frequency of pain in the proportion of patients on dialysis who have pain, and those are both greater than in the general population. However, there is no literature that specifically addresses the degree of pain in terms of severity.

The Standing Committee agreed inappropriate opioid use and prescribing is a major problem in this country and appropriate pain management is critical. However, given the evidence concerns to support the measure, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

NQF received three pre-evaluation meeting comments from NQF-member organizations that related to both measures #3615 and #3616. No pre-evaluation meeting comments were received from the public. Comments received recommended the measure not be endorsed. Commenters stated concerns related to the lack of patient centricity of the measure and unintended consequences of care that is not tailored to a patient's specific clinical issues, such as pain control, functional improvement, and appropriate pain therapies, and that measures should not target opioid use reductions in a "one size fits all" model. Commenters also discussed the likely patient harm associated with a misapplication of the guidelines. Based on known instances of misapplication, the authors are updating the chronic pain in primary care guideline for improved clarity and intended use. Commenters were expressly concerned for increased patient harm and suffering, including worsening pain, reduced quality of life and functional outcomes, increased depression, and other mental health needs, that accompany chronic unmanaged pain. Commenters were also concerned with the unintended consequences to providers with that include attribution misalignment to the opioid prescribing provider and the potential double penalty for implementing both measures, #3615 and #3616. These concepts were also discussed by the Standing Committee during the measure evaluation meeting.

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC): Not Recommended

Description: This measure reports the percentage of all dialysis patients attributable to a dialysis provider's group practice who had an opioid prescription written during the year that met one or more of the following criteria: a duration greater than 90 days, Morphine Milligram Equivalents (MME) greater than 50, or overlapping prescription with a benzodiazepine. Please note that this measure is at

the dialysis provider level (the clinician who receives the Monthly Capitation Payment [MCP] for overseeing dialysis care). Although the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and ensure that doses are safe and appropriate for the level of kidney function. This is in contrast to NQF measure #3615, which is at the opioid prescriber level (the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient who is typically not the nephrologist who is overseeing the patient's dialysis care). The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g., age, gender, and risk factors). Here, the term national refers to all opioid prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model. **Measure Type**: Process; **Level of Analysis**: Clinician : Group/Practice; **Setting of Care**: Other; **Data Source**: Claims, Other, Registry Data

The Standing Committee did not vote on the recommendation for endorsement because they did not pass the measure on evidence—a must-pass criterion.

The Standing Committee observed that this process measure focuses on determining the percentage of all dialysis patients attributable to a dialysis provider's group practice who had an unsafe opioid prescription written within the year. The Standing Committee noted the evidence to support this measure was very similar to NQF #3615, and the same concerns apply to NQF #3616. The Standing Committee noted the denominator of this measure excludes the number of patients in a group practice on dialysis who received an opioid during the year, in addition to excluding the hospice patients. The Standing Committee further noted there is insufficient evidence to support that the MCP physician affects the outcome/numerator of this measure since the MCP physician might be able to advise the patient on opioid prescription but cannot change the prescription or the outcome. Some Standing Committee members noted it is important to consider how long a person has been on dialysis as the pain varies based on period of time. The Standing Committee agreed it is important to look at the benefit of opioid use in this population and its positive effect on the quality of life of a dialysis patient, especially in the absence of other pain management medication options. Based on the concerns raised for NQF #3615, which also apply to NQF #3616, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

NQF received three pre-evaluation meeting comments from NQF-member organizations. All three of these comments related to both measures #3615 and #3616. No pre-evaluation meeting comments were received from the public. Comments received recommended that the measures are not endorsed. Commenters stated concerns related to the lack of patient centricity of the measure and unintended consequences of care that is not tailored to a patient's specific clinical issues, such as pain control, functional improvement, and appropriate pain therapies, and that measures should not target opioid use reductions in a "one size fits all" model. Commenters also discussed the likely patient harm associated with a misapplication of the guidelines. Based on known instances of misapplication, the authors are updating the chronic pain in primary care guideline for improved clarity and intended use. Commenters were expressly concerned for increased patient harm and suffering, including worsening

pain, reduced quality of life and functional outcomes, increased depression, and other mental health needs, that accompany chronic unmanaged pain. Commenters were also concerned with the unintended consequences to providers with that include attribution misalignment to the opioid prescribing provider and the potential double penalty for implementing both measures, #3615 and #3616. These concepts were also discussed by the Standing Committee during the measure evaluation meeting.

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Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Vote totals may differ between measure criteria and between measures as Standing Committee members often have to join calls late or leave calls early. NQF ensures that quorum is maintained for all live voting. All voting outcomes are calculated using the number of Standing Committee members present during the meeting for that vote as the denominator. Denominator vote counts may vary throughout the criteria due to intermittent Standing Committee attendance fluctuation. The vote totals reflect members present and eligible to vote at the time of the vote. If quorum is not achieved or maintained during the meeting, the Standing Committee receives a recording of the meeting and a link to submit online votes. Voting closes after 48 hours with at least the number of votes required for quorum. Quorum (17 out of 25 Standing Committee members) was reached and maintenance during the full measure evaluation meeting on June 23, 2021.

Measures Not Recommended

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level

Measure Worksheet **| Specifications**

Description: Percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an opioid prescription written during the year that met one or more of the following criteria: duration >90 days, Morphine Milligram Equivalents (MME) >50, or overlapping prescription with a benzodiazepine.

Please note that the opioid prescriber is the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient. This provider is usually not the nephrologist who is overseeing the patient's dialysis care. This is in contrast to NQF submitted measure #3616, which is at the dialysis provider level (the clinician who receives the Monthly Capitated Payment for overseeing dialysis care). While the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and that doses are safe and appropriate for level of kidney function.

The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g. age, gender, risk factors). Here, "national" refers to all opioid prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model.

Numerator Statement: The numerator is the number of patients in the denominator who were prescribed an opioid that was either >90 days duration during the year, >50 MME, or overlapped in time with a benzodiazepine prescription.

Denominator Statement: The denominator is the number of patients associated with an opioid prescriber's group practice who are receiving maintenance dialysis (in-center or home dialysis) for any duration who receive an opioid prescription during the one year reporting period.

Exclusions: Patients who have a hospice claim at any time (either before or after the opioid prescription date) during the one year reporting period are excluded.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician : Group/Practice

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Other, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/23/2021

1. Importance to Measure and Report: <u>The measure did not meet the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes: 20; H-0; M-5; L-13; I-2**; 1b. Performance Gap: **Vote Not Taken**

<u>Rationale</u>:

- The Standing Committee observed this is a process measure that focuses on determining the percentage of all dialysis patients attributable to an opioid prescriber's group practice who had an unsafe opioid prescription written within the year. The Standing Committee noted the opioid prescriber is the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient and is usually not the nephrologist who is overseeing the patient's dialysis care
- The Standing Committee acknowledged the developer provided empirical evidence from the literature to link unsafe opioid prescription practices to serious adverse event, such as hospitalization and mortality, in the dialysis population. Particularly, the developer provided the search terms/query that was conducted in PubMed in February 2019, which yielded 268 articles that were reviewed and of these 43 were selected for presentation to the Technical Expert Panel that was convened to make recommendations regarding this measure. The developer provided a list of references for relevant articles and a summary synthesizing the evidence to support this measure.
- One Standing Committee member questioned whether the developers looked at significantly limited medication options for ESRD patients, which might lead to opioid prescription in this population. The Standing Committee also questioned whether the goal of the UMKECC-convened TEP was to reduce opioid use or to manage pain appropriately. The developer acknowledged the concern and agreed that, as literature suggested, there are limited pain management options for this population. The developer clarified that the measure does not intend to reduce or eliminate opioid prescriptions for patients on dialysis; rather, the goal of the measures is to identify and monitor high risk opioid prescriptions. The developer noted that the measure primarily looks at the prescriptions themselves and how efficacious those prescriptions are in controlling pain.
- The Standing Committee raised several concerns regarding the developer's rationale for selecting the cutoff criteria that define unsafe opioid use, particularly, the dosage of greater than 50 Morphine Milligram Equivalents (MME) and the chronicity threshold of 90 days of opioid use. The Standing Committee also noted thaet the measure, as specified, does not indicate the timeframe of "per day" for the 50 MME cutoff (which is suggested by Centers for Disease Control and Prevention [CDC] guidelines) anywhere in the measure submission form. The Standing Committee expressed concerns regarding the lack of evidence supporting 90 days in the aggregate opioid dose was unsafe use.
- The developers also noted that the CDC guidelines were used that to help construct the definition of a high risk of opioid prescription; however, the evidence submitted for this measure comes from the literature, particularly the observational studies that look at the chronicity of prescriptions and higher dose prescriptions and associates that with adverse outcomes. The developer stated that the selection of both cutoffs was based on the CDC guidelines and their findings from the literature, with a goal to maximize their safety margin. The developers also clarified that both 50 MME cutoff and the 90 day of opioid use were endorsed by UMKECC-convened TEP. The developer also noted that the cutoff is not setting the sensitivity of flagging the outliers; rather they have used statistical techniques in the measure to identify outliers based on the prescribing practices.
- The Standing Committee agreed that the evidence shows a correlation between unsafe prescription, as defined in the measure specifications, and the important clinical outcomes. However, the Standing Committee agreed that the evidence was not sufficient enough in showing that changing the prescription patterns will lead to different outcomes in the target population for this measure.
- The Standing Committee also raised concerns about the exclusions in the denominator and failed to see how the measure construction was supported by the evidence and guidelines that exist today. The Standing Committee questioned why the developers did not exclude sickle cell disease and cancer as they were specifically cited in the submission form. The developer stated that they limited the exclusion criteria to patients that are enrolled in hospice at any point during the reporting period. They explained that they chose to be a bit more specific in the exclusion criteria and to use a risk adjustment strategy so that we could have a more broadly applicable measure to the patient population and to try and account for the differences and comorbidities that exist between patient populations.

- The Standing Committee asked to see if there was background literature that show overall level of (subjective) pain in this population compared to the general Medicare population, which would help understand the use of opioids in this population. The developer responded that there is literature that addresses the frequency of pain in the proportion of patients on dialysis who have pain and those are both greater than in the general population, but there isn't literature that specifically addresses the degree of pain in terms of severity.
- The Standing Committee agreed that inappropriate opioid use and prescribing are a major problem in this country and that appropriate pain management is critical. However, given the concerns discussed above, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

2. Scientific Acceptability of Measure Properties

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)

2a. Reliability: **Vote Not Taken**; 2b. Validity: **Vote Not Taken**

Rational

The measures were reviewed by the Scientific Methods Panel (SMO) prior to the measure evaluation meeting, although the details were not discussed by the Standing Committee as the measure did not pass the Importance: Evidence criterion in 1a., a "must-pass" criterion. A summary of the SMP discussion is provided below.

The SMP subgroup passed the measure on reliability and validity. The measure was pulled for discussion during the March 2021 SMP meeting. A summary of the measure and the Panel review and discussion is provided below.

Reliability

- The SMP passed the measure on reliability with High rating **(Total votes: 9; H-6; M-1; L-1; I-1)**.
- The developer conducted validity testing at the performance measure score level using inter-unit reliability (IUR) for the annual performance scores.
- The developer used CROWNWeb, Medicare Claims, the CMS Medical Evidence form 2728, Medicare Part D Claims as data sources to test the measure. The analysis included 103,157 physicians in 5,123 groups (range: 1-2,328 clinicians) with an average of 40 patients per group (range: 11-2,411).
- Physician groups must have more than 10 eligible patients to be included in the measure or the analysis.
- The developer noted that the IUR calculated at the group level is 0.86 which means 86% of the total variation of this prescriber group level measure can be explained by the differences among prescribers and not by random noise.
- To assess further whether the measure can identify prescriber groups with extreme values, we computed the Profile inter-unit reliability (PIUR), which is 0.98. The developer stated that the discrepancy between the IUR (0.86) and PIUR (0.98) indicates the existence of outlier prescriber groups that can be identified by the measure.

Validity

- The SMP passed the measure on validity with Moderate rating **(Total votes: 9; H-2; M-4; L-1; I-2).**
- Validity testing was conducted at the score level:
    - The developer conducted a concordance analysis of the relationship between measure scores, hospitalization, and mortality.
    - Hospitalization rate at the practitioner group level is 1.49, 1.46 and 1.41 for T1, T2, and T3 respectively (trend test $p<0.001$), while the average number of hospital days per year and patient at the practitioner group level is 6.1, 5.1 and 4.1 respectively (trend test $p<0.001$).
    - The practitioner group level average mortality rate is 0.19, 0.20, and 0.18 per patient-year for T1, T2, and T3 groups, respectively.
- SMP Subgroup pilled this measure for discussion specifically to address an overarching question: To what extent is the validity analysis confounded by unmeasured case mix, considering that dialysis physicians with sicker patients (e.g., those with comorbid cancer) have higher mortality rates, hospitalization rates, and opioid use. The two measures were therefore discussed concurrently.

- During the SMP meeting, concerns were raised regarding the use of a risk adjustment model for a process measure. They noted it would be more appropriate for risks to be made into exclusions (e.g., cancer); and the other factors that are endogenous (e.g., drug dependence, substance use disorder, anxiety disorders, and previous opioid poisoning) may increase risk and are confounders that may be difficult to understand or differentiate. The risk adjustment model was noted as appropriate in terms of performance statistics but lacked an underlying theory to justify the selection of factors for the model.
- The SMP also expressed concerns that the validation of the measure is based on dividing provider groups into tertiles that showed the top tertile with a failure rate over 46 percent, the middle at 30-36 percent, and the best tertile under 30 percent. The submission noted that patients in the worst performing tertile have a slightly higher hospitalization odds ratio, 1.49 versus 1.41 and a few more hospital days per year, 6.1 versus 4.1, as well has a higher death rate. They also noted these findings were reported under an unadjusted analysis when the developer has suggested that risk adjustment is essential for the measure's application.
- The SMP elected not to revote on the measure but passed along the concerns to the Renal Standing Committee. A full summary of the SMP discussion is linked SMP webpage.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Vote Not Taken** 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- The commenters stated the evidence recommends measures related to increased opioid use, rather than reducing opioid use without consideration of the target population (e.g., "recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering").
- The commenters stated the focus of the measure does not address patient-centric clinical issues and does not adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving hemodialysis report pain as their primary symptom and their clinical scenario often limits pain management options.
- The commenters stated that use of the measure as specified may lead to significant unintended consequences to patients based on illness severity, underlying conditions, and sociodemographic and geographic disparities. Further, the measure attribution for both measures assign accountability to the nephrologist group who prescribes approximately ten percent of the opioid prescriptions to this population. In implementing both #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.
- The commenters expressed concerns that the scientific acceptability and risk adjustment are not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters state the risk model insufficiently considers providers who care for medically complex patients. The commenters also state that although the measure does adjust

for gender, no other social risk factors were included in the model (e.g., evidence-based state and regional geographic variations).

- **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**
- **9. Appeals**

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

Measure Worksheet

Description: Percentage of all dialysis patients attributable to a dialysis provider's group practice who had an opioid prescription written during the year that met one or more of the following criteria: duration >90 days, Morphine Milligram Equivalents (MME) >50, or overlapping prescription with a benzodiazepine.

Please note that this measure is at the dialysis provider level (the clinician who receives the Monthly Capitated Payment for overseeing dialysis care). While the dialysis provider is usually not the clinician who is prescribing opioids, the MCP physician does have a responsibility to be aware of dialysis patients medications and that doses are safe and appropriate for level of kidney function. This is in contrast to NQF submitted measure #3615, which is at the opioid prescriber level (the clinician identified from Part D Medicare Claims who actually provides an opioid prescription to a dialysis patient) who is typically not the nephrologist who is overseeing the patient's dialysis care.

The proposed measure is a directly standardized percentage, which is adjusted to the national distribution of covariates (e.g. age, gender, risk factors). Here, "national" refers to all opioid prescriber groups combined. Specifically, the standardized rate for a given prescriber's group is an estimate of the group's percentage of unsafe opioid prescriptions if their case-mix were equal to that of the national population. Case-mix adjustment is based on a logistic regression model.

Numerator Statement: The numerator is the number of patients in the denominator who were prescribed an opioid that was either >90 days duration during the year, >50 MME, or overlapped in time with a benzodiazepine prescription.

Denominator Statement: The denominator is the number of patients associated with a dialysis provider's group practice who are receiving maintenance dialysis (in-center or home dialysis) for any duration who receive an opioid prescription during the one year reporting period.

Exclusions: Patient months are excluded if there is more than one MCP provider claim in a given month. In addition, patients who have a hospice claim at any time (either before or after the opioid prescription date) during the one year reporting period are excluded.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician : Group/Practice

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Other, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/23/2021

1. Importance to Measure and Report: ***The measure did not meet the Importance criteria***

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes: 20; H-0; M-1; L-15; I-4**; 1b. Performance Gap: **Vote Not Taken**

Rationale

- The Standing Committee observed that this process measure focuses on determining the percentage of all dialysis patients attributable to a dialysis provider's group practice who had an unsafe opioid prescription written within the year.
- The Standing Committee acknowledged that the developer provided empirical evidence from the literature to link unsafe opioid prescription practices to serious adverse event, such as hospitalization and mortality, in the dialysis population. Particularly, the developer provided the search terms/query that was conducted in PubMed in February 2019, which yielded 268 articles that were reviewed and of these 43 were selected for presentation to the Technical Expert Panel that was convened to make

recommendations regarding this measure. The developer provided a list of references for relevant articles and a summary synthesizing the evidence to support this measure.

- The Standing Committee noted that the evidence to support this measure was very similar to that for measure, NQF #3615, and that the same concerns apply to this measure (NQF #3616).
- The Standing Committee noted that the denominator of this measure excludes the number of patients in a group practice on dialysis who received an opioid during the year, in addition to excluding the hospice patients.
- The Standing Committee noted that there is not enough evidence to support the claim that the monthly capitation payment (MCP) physicians affect the outcome/numerator of this measure since the MCP physician might be able to advise the patient on opioid prescription, but they can't change the prescription or the outcome.
- The Standing Committee agreed that it's important to look at the benefit of opioid use in this population and its positive affect on the quality of life of a dialysis patient, especially in the absence other pain management medication options.
- The Standing Committee agreed that the same concerns as those raised for NQF #3615 apply for this measure (NQF #3616). Based on those concerns, the Standing Committee did not pass the measure on evidence, a must-pass criterion. Therefore, the measure was not recommended for endorsement.

2. Scientific Acceptability of Measure Properties

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)

2a. Reliability: **Vote Not Taken**; 2b. Validity: **Vote Not Taken**

Rational

The measures were reviewed by the Scientific Methods Panel (SMP) prior to the measure evaluation meeting, although the details were not discussed by the Standing Committee as the measure did not pass the Importance: Evidence criterion in 1a., a "must-pass" criterion. A summary of the SMP discussion is provided below.

Reliability

- The SMP passed the measure on reliability with Moderate rating **(Total votes: 9; H-1; M-6; L-1; I-1)**.
- The developer conducted reliability testing at the performance measure score level using inter-unit reliability (IUR) for the annual performance scores.
- The developer used CROWNWeb, Medicare Claims, the CMS Medical Evidence form #2728, and Medicare Part D Claims as data sources to test the measure. A total of 6784 physicians in 3323 groups (range: 1-51 clinicians) with an average of 46 patients per group (range: 11-1022) were included in the analysis.
- Physician groups must have more than 10 eligible patients to be included in the measure or the analysis.
- The developer states that the IUR calculated at the group level is 0.60 which means 60% of the total variation of this group level measure can be explained by the differences among physician groups and not by random noise.
- To assess further whether the measure can identify prescriber groups with extreme values, the developer computed the Profile inter-unit reliability (PIUR) of 0.81. The developer stated that the discrepancy between the IUR (0.60) and PIUR (0.81) indicates the existence of outlier physician groups that can be identified by the measure.
- The developer states that the PIUR being larger than the IUR demonstrates that the measure can detect differences in performance scores across physician groups as well as outlier groups.
- The SMP generally conceded that the testing approach was appropriate, but it was noted that the variation between providers within provider group does not appear to have been handled by the methods reported (i.e., the error term appears not to include between providers across patients within practice).

Validity

- The SMP passed the measure on validity with Moderate rating **(Total votes: 9; H-1; M-5; L-1; I-2)**.
- Validity testing was conducted at the score level:
    - The developer conducted a concordance analysis of the relationship between measure scores, hospitalization, and mortality.

    - The hospitalization rate at the dialysis provider group level is 1.55, 1.48, and 1.47 for tercile 1 (T1), T2, and T3, respectively (trend test p<0.001), while the average number of hospital days per year and patient at the dialysis provider group level is 8.3, 7.5, and 7.7, respectively (trend test p<0.001).
    - The dialysis provider group level average mortality rate is 0.26, 0.29, and 0.33 per patient-year for T1, T2, and T3 groups, respectively.
- SMP noted that no specific correlation test between #3616 and hospitalization and mortality was specified which would be an appropriate validity test. The relationships are stated with descriptive statistics.
- The SMP stated that the risk adjustment model was noted as appropriate in terms of performance statistics but lacked an underlying theory to justify the selection of factors for the model.
    - It was noted that it would be more appropriate for risks to be made into exclusions (e.g., cancer), and other endogenous factors (e.g., drug dependence, SUD, anxiety disorders, and previous opioid poisoning) may increase risk and are confounders that may be difficult to understand or differentiate.
- The SMP elected not to revote on the measure but passed along the concerns to the Renal Standing Committee. A full summary of the SMP discussion is linked SMP webpage.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Vote Not Taken** 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- The commenters stated the evidence recommends measures related to increased opioid use, rather than reducing opioid use without consideration of the target population (e.g., "recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering").
- The commenters stated the focus of the measure does not address patient-centric clinical issues and does not adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving hemodialysis report pain as their primary symptom and their clinical scenario often limits pain management options.
- The commenters stated that use of the measure as specified may lead to significant unintended consequences to patients based on illness severity, underlying conditions, and sociodemographic and geographic disparities. Further, the measure attribution for both measures assign accountability to the nephrologist group who prescribes approximately ten percent of the opioid prescriptions to this population. In implementing both #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.

- The commenters expressed concerns that the scientific acceptability and risk adjustment are not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters state the risk model insufficiently considers providers who care for medically complex patients. The commenters also state that although the measure does adjust for gender, no other social risk factors were included in the model (e.g., evidence-based state and regional geographic variations).

- **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**
- **9. Appeals**

Appendix B: Renal Portfolio—Use in Federal Programs[a]

NQF #	Title	Federal Programs: Finalized or Implemented as of June 30, 2021
0249	Delivered Dose of Hemodialysis Above Minimum	Dialysis Facility Compare (Implemented 2020)
0255	Measurement of Phosphorus Concentration	None
0256	Hemodialysis Vascular Access - Minimizing Use of Catheters as Chronic Dialysis Access	None
0257	Hemodialysis Vascular Access - Maximizing Placement of Arteriovenous Fistula (AVF)	None
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	Dialysis Facility Compare (Implemented 2020)
0369	Dialysis Facility Risk-Adjusted Standardized Mortality Ratio	Dialysis Facility Compare (Implemented 2020)
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Dialysis Facility Compare (Implemented 2020)
1424	Monthly Hemoglobin Measurement for Pediatric Patients	None
1425	Measurement of nPCR for Pediatric Hemodialysis Patients	Dialysis Facility Compare (Implemented 2020)
1454	Proportion of Patients With Hypercalcemia	None
1460	Bloodstream Infection in Hemodialysis Outpatients	None
1662	Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	None
1667	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	None
2701	Avoidance of Utilization of High Ultrafiltration Rate (>=13 ml/kg/hour)	End-Stage Renal Disease Quality Incentive Program (Implemented 2018) Note that the active measure in ESRD QIP is based on NQF 2701.
2706	Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V	None
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate	End-Stage Renal Disease Quality Incentive Program (Implemented 2021) Dialysis Facility Compare (Implemented 2021)

[a] Per CMS Measures Inventory Tool as of 07/01/2021

Appendix C: Renal Standing Committee and NQF Staff

STANDING COMMITTEE

Constance Anderson, BSN, MBA (Co-Chair)
Vice President of Clinical Operations, Northwest Kidney Centers
Seattle, Washington

Lorien Dalrymple, MD, MPH (Co-Chair)
Associate Professor, University of California Davis
Sacramento, California

Andrew Chin, MD
Health Science Clinical Professor, University of California, Davis Medical Center
Sacramento, California

Annabelle Chua, MD
Medical Director of Pediatric Dialysis, Duke University
Durham, North Carolina

Rajesh Davda, MD, MBA, CPE
National Medical Director, Senior Medical Director, Network Performance Evaluation and Improvement, Cigna Healthcare
Washington, District of Columbia

Gail Dewald, BS, RN, CNN
Nephrology Nurse, Gail Dewald & Associates LLC
San Antonio, Texas

Renee Garrick, MD, FACP
Professor of Clinical Medicine, Vice Dean, and Renal Section Chief, Renal Physicians Association/ Westchester Medical Center, New York Medical College
Hawthorne, New York

Stuart Greenstein, MD
Professor of Surgery, Montefiore Medical Center
Bronx, New York

Mike Guffey (Patient/Caregiver Perspective)
Vice President, Business Continuity Manager, UMB Bank (Board of Directors Treasurer, Dialysis Patient Citizens)
Overland Park, Kansas

Lori Hartwell (Patient/Caregiver Perspective)
President/Founder, Renal Support Network
Glendale, California

Frederick Kaskel, MD, PhD
Chief Emeritus, Past Division Director, Children's Hospital at Montefiore
Bronx, New York

Myra Kleinpeter, MD, MPH
Associate Professor of Clinical Medicine, Tulane University School of Medicine
New Orleans, Louisiana

Alan Kliger, MD
Clinical Professor of Medicine, Yale University School of Medicine
Vice President Medical Director Clinical Integration and Population Health, Yale New Haven Health System
New Haven, Connecticut

Mahesh Krishnan, MD, MPH, MBA, FASN
Group Vice President of Research and Development, DaVita, Inc.
McLean, Virginia

Karilynne Lenning, MHA, LBSW
Sr. Manager Health Management, Telligen
West Des Moines, Iowa

Precious McCowan
National Advocate, ESRD Network
Chicago, Illinois

Andrew Narva, MD, FASN
Adjunct Associate Professor
Uniformed Services University of the Health Sciences
Bethesda, Maryland

Jessie Pavlinac, MS, RDN-AP, CSR, LD, FAND
Clinical Instructor, Graduate Programs in Human Nutrition, Oregon Health & Science University (OHSU)
Portland, Oregon

Jeffrey Silberzweig, MD
Chief Medical Officer, The Rogosin Institute (New York Presbyterian)
New York, New York

Michael Somers, MD
Associate Professor in Pediatrics/Director, Renal Dialysis Unit, Associate Chief Division of Nephrology, American Society of Pediatric Nephrology/Harvard Medical School/Boston Children's Hospital
Boston, Massachusetts

Cher Thomas, RDH
Patient Advocate
Galveston, Texas

Jennifer Vavrinchik, MSN, RN, CNN
Chief Operating Officer, National Dialysis Accreditation Commission
Lisle, Illinois

Bobbi Wager, MSN, RN (Patient/Caregiver Perspective)
Renal Care Coordinator, American Association of Kidney Patients, Vice President on the Board of Directors, Texas Renal Coalition
Boerne, Texas

John Wagner, MD, MBA
Director of Service, Associate Medical Director, Kings County Hospital Center
Brooklyn, New York

Gail Wick, MHSA, BSN, RN, CNNe
Consultant, GWA
Atlanta, Georgia

NQF STAFF

Kathleen Giblin, RN
Acting Senior Vice President, Quality Measurement

Tricia Elliott, MBA, CPHQ, FNAHQ
Senior Managing Director, Quality Measurement

Matt Pickering, PharmD
Senior Director, Quality Measurement

Poonam Bal, MHSA
Senior Director, Quality Innovation

Oroma Igwe, MPH
Manager, Quality Measurement

Kim Murray
Coordinator, Quality Measurement

Mike DiVechhia, MBA, PMP
Senior Project Manager, Quality Measurement

Sharon Hibay, DNP, RN
Senior Consultant, Quality Measurement

Shalema Brooks, MS, MPH
Previous Director, Quality Measurement

Janaki Panchal, MSPH
Previous Manager, Quality Measurement

Monika Harvey, MBA
Previous Project Manager, Quality Measurement

Sean Sullivan, MS
Previous Project Manager, Quality Measurement

Appendix D: Measure Specifications

Both measures under review were not recommended for endorsement.

Appendix E: Related and Competing Measures

Both measures under review were not recommended for endorsement.

Appendix F: Pre-Evaluation Comments

Comments received as of June 3, 2021. The three pre-evaluation comments were submitted for both #3615 and #3616.

The American Medical Association (AMA)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

The American Medical Association (AMA) appreciates the opportunity to comment on this measure. We have significant concerns as we believe that it is not aligned with the evidence as specified and there are significant unintended negative consequences that could be experienced with its use. The AMA believes that all care provided to patients must be individualized and quality measurement should not focus on preventing and/or reducing opioid use. Rather measurement should address the larger clinical issue—how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of addiction and developing an opioid use disorder.

The ongoing singular focus on the dose and duration of opioid prescriptions disregards the important steps that have already been taken to address the national epidemic of opioid-related overdose deaths, which the AMA strongly supports. The final report of the Department of Health and Human Services (HHS) Interagency Pain Management Best Practices Task Force, for example, made a compelling case for the need to focus on patients experiencing pain as individuals and to develop treatment plans that meet their individual needs and not employ one-size-fits-all approaches that assume prescriptions of long duration are indications of overuse (HHS, 2019). Likewise, a Centers for Disease Control and Prevention (CDC) publication in the New England Journal of Medicine (Dowell, 2019) expressed concern that its opioid prescribing guidelines have been misapplied and wrongly used to discontinue or reduce prescriptions for patients with pain, with some actions likely to result in patient harm and the CDC stated that its guideline should not be used to create hard and fast policy. In fact, the CDC is currently in the process of updating the guideline and the AMA provided in-depth feedback on our concerns to the CDC during last year's public comment (AMA, 2020).

The AMA disagrees with the fundamental premise of measures that focus on daily dose and duration of therapy involving prescription opioid analgesics because on its own it is not a valid indicator of high quality patient care. In fact, since the CDC guideline (Dowell, 2016) was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time, and in whom the benefits of such therapy exceed the risks, of being forced to abruptly reduce or discontinue their medication regimens. Such involuntary tapers are associated with sometimes extremely adverse outcomes, including depression, anxiety and emergence of other mental health disorder, loss of function and the ability to perform daily activities, and even suicide. There has been considerable discussion of these unintended consequences at meetings of the HHS Interagency Pain Management Best Practices Task Force. In addition, research continues to demonstrate that individuals may or may not have access to pain management therapies based on their race/ethnicity and measures that may further exacerbate this issue should be avoided (Goshal, 2020).

As a result, the AMA believes that there is a significant risk for performance to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may

be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

Our specific concerns with this measure include the misalignment of the numerator requirements with the evidence and the need for additional precision in the denominator.

Measures that call for hard limits and lead to abrupt tapering or discontinuation of opioids for those already receiving these medications are not consistent with the guideline recommendations (Dowell, 2019). For example, identifying those patients for whom the daily prescribed morphine milligram equivalents (MME) are considered high may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but it alone is not an appropriate marker of the quality of care provided. The CDC recommendations allow physicians to document a clinical rationale or justification when suggested dose levels are exceeded; yet, the inclusion of an absolute MME requirement does not capture if a justification exists nor does it provide a well-defined and targeted denominator. We have similar concerns with the inclusion of prescriptions that exceed 90 days as it does not address the needs of those individuals with chronic pain.

The AMA believes that there is a significant risk for the performance of groups and physicians to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The measure developer should explore more appropriate methods to assess a patient's chronic pain such as the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and use this patient-reported data on areas as the basis for performance measures. This tool utilizes the Patient Reported Outcomes Measurement Information System (PROMIS) and through the use of Computer Adaptive Testing, key domains such as sleep disturbance and physical function can be assessed in a targeted and patient-directed way.

In addition, this measure as currently specified lacks the precision needed to ensure that only those patients as defined by the clinical recommendations are included in the denominator. The AMA believes that no measure addressing opioid use should be endorsed and/or used until each is reviewed against the guideline to ensure consistency with its intent. Specifically, the CDC clarified that the guideline is intended to apply to primary care clinicians who treat adult patients for chronic pain (Dowell, 2019). In addition, the CDC stated in a letter to three specialty societies on February 28, 2019 that the recommendations do not apply to those patients receiving active cancer treatment, palliative care, and end-of-life care as well as those with a diagnosis of sickle cell disease (CDC, 2019).

On review of the specifications, the denominator population does not reflect the right population of patients consistent with the evidence. We do not believe that inclusion of some of these conditions within the risk adjustment approach such as individuals with a cancer diagnosis or sickle cell disease is sufficient; rather, these individuals and those receiving palliative care and not just hospice must be excluded.

The measure also lacks the precision needed to ensure that only those patients for whom inappropriate concurrent prescribing of an opioid and benzodiazepine are included in the denominator. Specifically, the patient population could likely include patients for whom concurrent prescribing of these medications may be appropriate, particularly those with chronic pain.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of significant doses of these medications, then that is an indication of good patient care but the measure must precisely define the patients for which it is appropriate. We do not believe that this measure as specified addresses appropriate goals as it may leave patients without access to needed therapies.

Given these significant concerns, the AMA does not support the endorsement of this measure.

References:

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The Federation of American Hospitals (FAH)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

The Federation of American Hospitals (FAH) and its members actively seek to prevent unintentional opioid overdose fatalities and support measures that address the opioid epidemic but we also believe that any measure in this area must be aligned with current clinical guidelines and its potential unintended consequences must be addressed prior to endorsement.

In response to the misapplication of the recommendations from the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, the guideline

authors published an article in the New England Journal of Medicine seeking to clarify its intent and are also in the process of updating the guidelines to address some of these issues (Dowell 2016, Dowell 2019). Specifically, the authors were concerned that these discrepancies could potentially lead to patient harms through abrupt tapering or discontinuation of opioids for current users of high opioid dosages and/or inclusion of patient populations for whom chronic use or higher dosages may be warranted. Based on the FAH's comparison of this measure against the CDC guideline recommendations, we believe that it is not currently supported by the recommendations.

Specifically, the intent of the CDC guideline was to address the care provided by primary care providers for patients with chronic pain and the current population captured in the measure is not aligned with the evidence. For example, the measure is likely to include patients who are already receiving both an opioid and a benzodiazepine or opioids that exceed the morphine milligram equivalents threshold or the 90-day timeframe. The FAH does not believe that there is strong evidence to support abrupt discontinuation of these therapies, instead tapering should be considered. Requiring that these drugs be discontinued to meet performance on a measure alone is not appropriate and has the potential to compromise patient safety and lead to patient harm.

In addition, the patient population must be further narrowed to capture the additional diagnoses where it is appropriate to use these medications including those with sickle cell disease, active cancer, and palliative care. These additional exclusions are supported in the NEJM article as they explicitly state that the recommendations do not apply to these populations. While we note that some of the clinical variables for these diagnoses are included in the risk adjustment approach, the FAH believes that it would be more appropriate to exclude these populations from the measure.

This measure could result in providers not offering suitable pain solutions to patients receiving dialysis, which is contrary to the goal of a positive patient care experience if these treatments are needed. Reframing this measure to focus on adequate pain assessments and treatments would assist all of us in understanding the true problem rather than removing a downstream intervention.

Thank you for the opportunity to comment.

Kidney Care Partners (KCP)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

Kidney Care Partners (KCP) appreciates the opportunity to submit early (pre-Standing Committee meeting) comments on the measures under consideration for endorsement in the National Quality Forum's Renal Project Spring 2021 Cycle. KCP is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and end stage renal disease. We commend NQF for undertaking this important work. The following comments apply to both measures under review this cycle:

NQF 3615: Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level (CMS)

NQF 3616: Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS)

Overarching Comments

KCP recognizes the profound importance of minimizing opioid overuse in dialysis patients and appreciates the underlying intent of these measures; however, we have serious concerns with both as currently specified and cannot offer our support of either. Recognizing that opioids have been overused previously, it is important to note that national efforts have resulted in a substantial decrease in prescription opioid use in the past several years. Based on CDC data, prescription opioid dispensing rate in 2019 was 57% of the peak in 2012, and these data do not account for the changes in prescribing patterns that also have resulted in fewer opioids being dispensed per prescription in recent years. Critically, there are many reasons for extended use of opioids in the dialysis population, where the burden of symptoms is extremely high, life expectancy in many patients is half that in the age-similar general population, and options for pain medications are limited due to safety factors with other agents—for example, gabapentin and pregabalin may have serious neurologic consequences in dialysis patients, while non-steroidal anti-inflammatory drugs may be contraindicated in many individuals with ESRD (e.g., those with residual kidney function and at heightened bleeding risk). These factors question the assertion in the name of the proposed metrics that all opioid use for more than 90 days is 'unsafe.' KCP believes these proposed metrics will incentivize inappropriately abrupt reductions of opioid medications and undermanagement of chronic pain in complex dialysis patients, particularly in the absence of existing knowledge on how to reduce opioid use while sufficiently treating pain in the hemodialysis population. We also believe the measures as specified will exacerbate existing sociodemographic, economic, and geographic disparities related to opioid use, and will result in untenable and specious double penalties for many nephrology groups. Finally, we highlight critical ongoing research from the NIH in the hemodialysis population evaluating patient-centered strategies for promoting safe and durable opioid use reduction while adequately managing pain (HOPE Consortium Trial to Reduce Pain and Opioid Use in Hemodialysis, NCT04571619).

The history of pain management in the United States is complex, oscillating between extremes. While in the midst of an unprecedented opioid epidemic, it is easy to lose sight of our past. Millions of Americans with advanced and debilitating disease suffered needlessly in the 1980s because physicians were overly cautious about prescribing narcotics. We fear these measures portend a return to such days and will ultimately do more harm than good.

Our specific concerns with the measures follow.

Potential for Unintended Consequences is Substantial

We note that, pursuant to the 2018 SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) Act, HHS contracted with the National Quality Forum (NQF) to convene a Technical Expert Panel (TEP) to review quality measures related to opioids. In its February 2020 report, that TEP explicitly recommended opioid measures to be used in Federal quality programs should address any of a number of patient-centric clinical issues, such as recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering. The two proposed opioid safety measures address none of those topics, instead focusing exclusively on reducing opioid use—without regard for clinical decision-making or consideration of the etiology or severity of the pain, or the impact on the patient’s quality of life.

While the research by Kimmel et al,1 cited as evidence supporting both measures, did find an association between opioid prescription and death, dialysis discontinuation, and hospitalization in

dialysis patients, the authors make clear that an opioid prescription may merely be a marker of more severe or advanced illness in dialysis patients and that a causal relationship with these adverse outcomes cannot be inferred. Importantly, Kimmel also referred to evidence that pain is pervasive in individuals with ESRD2,3,4,5 and is linked to a significantly diminished quality of life,6,7,8,9, and that while aggressive pain treatment has been advocated,10,11,12 underestimation and undertreatment of pain still occur in dialysis patients.13,14 These truths are not taken into consideration in these measures.

We note that the NIH-sponsored Hemodialysis Opioid Prescription Effort (HOPE) Consortium (NCT04571619), shepherded by Dr. Kimmel, is actively researching pain and opioid use in the ESRD population and how to safely decrease dependence in dialysis patients, including such behavioral/ cognitive interventions as pain coping skills and use of medications such as buprenorphine. This research aims to develop personalized treatments based on individual patient needs—a critical consideration, given the varied and notoriously persistent nature of pain in this complex and vulnerable population.

Understanding the epidemiology of pain in patients on dialysis—as well as patients' unique needs and preferences—is crucial for further improvement in managing pain. These proposed measures clearly miss that mark. We believe the development of more appropriate measures may be feasible once findings from the HOPE Study are disseminated and digested. Adoption of measures addressing such a crucial aspect of care prematurely, absent this critical knowledge, will do little to improve dialysis care or patient outcomes; rather, we fear these performance measures may induce a range of unintended, deleterious, and potentially profound adverse consequences.

Double Penalties

From the specifications and supporting measure information, it appears that the attributable entity for the Practitioner Measure is the treating nephrologist's group practice, irrespective of who prescribed the opioid—whether the nephrologist herself or a physician entirely unrelated to her group. The nephrologist is thus held accountable for other providers' prescriptions. Additionally, as the attributable entity with the Prescriber Measure is the opioid prescriber, implementation of both measures together in a payment program would seemingly result in nephrology groups being penalized twice when the nephrologist is also the opioid prescriber. We see no indication in the measure materials that this would not be the case.

Sociodemographic and Geographic Disparities

Finally, while unsafe opioid use was found to be associated with White race, non-Hispanic ethnicity, dual eligible status, and unemployment in UM-KECC's analyses, gender was the only SDS/SES factor15 included in the final risk models because "… it is unclear whether [these] associations… are due to underlying biological or other patient factors or represent disparities in care. Adjusting for these social risk factors could have the unintended consequence of creating or reinforcing disparities and facilitating unsafe prescribing practices." As KCP has commented in the past (see, for example, KCP's August 2018 QIP comment letter to CMS), we agree CMS must strike the correct balance to ensure that it meets the goals of both fairly assessing providers while also not masking potential disparities or disincentivizing the provision of care to more medically complex patients. However, we reiterate our strong preference for adopting an SDS adjustment for measures where it has been shown that SDS factors are driving differences in the outcomes being reported. Given the associations noted above, KCP believes gender as the only sociodemographic risk variable is insufficient and is concerned the measures risk potentiating

existing health inequities. We believe other biological and demographic variables are important, and not accounting for them is a significant threat to the validity of both measures.

In a similar vein, Kimmel et al [2017] reported geographic trends in opioid use in patients with ESRD are comparable to those in the general population, with eight states having chronic opioid prescription rates of 30% or more. “Chronic opioid prescription rates ranged from 9.5% of patients on dialysis in Hawaii to 40.6% of patients in West Virginia in 2010. Seven other states had prescription rates >30% (Michigan, Oklahoma, Oregon, Kentucky, Idaho, Indiana, and Alabama):”16

Yet it does not appear from the supplied risk model data that geography itself (distinct from the Area Deprivation Index) was examined. The failure to do so when such regional variations in opioid use is well-documented is puzzling, at best.

Given these empirically demonstrated sociodemographic and geographic opioid use disparities, KCP is not convinced that these measures have been sufficiently adjusted to avoid exacerbating existing inequities, disincentivizing the provision of care to more medically complex patients, and adversely impacting quality of life for our most vulnerable patients.

Technical Concerns

In addition to our above core conceptual issues, we also note the following technical concerns with the measures:

Patient Exclusions. Again, KCP is concerned that the measures as specified may result in the under-treatment of pain in patients in whom longer-term use of opioids is warranted. As such, we believe the single patient-level exclusion for hospice is insufficient in measures addressing opioid use, overlooking the many patients suffering with debilitating chronic pain (even unrelated to ESRD) and those with a life-threatening comorbidity not yet eligible for hospice care. Notably, this metric again highlights the real-world limitations in accessing hospice services among patients receiving maintenance hemodialysis. We believe additional exclusions for patients with claims for palliative care and for those under the care of a pain management specialist during the reporting period would strengthen the measure considerably.

Reliability—Profile Inter-Unit Reliability (PIUR). KCP has consistently opposed CMS’s use of the PIUR for accountability metrics intended to distinguish performance between providers. CMS crafted this novel metric of reliability to “assess more directly the value of performance measures in identifying facilities with extreme outcomes.”17 Per CMS: “The PIUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. . . . [When] there are outlier providers, even measures with a low IUR can have a relatively high PIUR and can be very useful for identifying extreme providers.” KCP strongly concurs, however, with NQF’s Scientific Methods Panel (SMP) that the PIUR is not an appropriate reliability metric for measures in any accountability program intended to distinguish performance between providers falling in the middle of the curve, along a continuum. The ability to reliably distinguish outliers is inconsistent with the purpose of such programs, and the SMP concluded the IUR is and remains the appropriate reliability statistic for this purpose. While in this instance the measures’ IURs are acceptable, KCP on principle reiterates its general opposition to use of the PIUR to demonstrate reliability in accountability metrics used in programs intended to distinguish performance along a curve.

Validity: Validity was tested at the performance measure scores by evaluating the concordance between the measure scores, hospitalization metrics, and mortality rates. With mortality, to account for potential

selection bias stemming from the fact that the definition of chronic opioid use requires patients survive at least 90 days (e.g., those who survived 90+ days may be healthier), patients were instead stratified based on length of time at risk during the 12-month performance period. It is not clear to us, however, how the ensuing time at risk stratification was performed, and we are unable to replicate the results with the information provided. We also note that p-values were not included for the mortality stratification, and we thus cannot confirm the results are statistically significant. We request clarification on UM-KECC's approach to these calculations, accompanied by an appropriate assessment of significance to allow for a thorough assessment of the measures' validity.

Another essential component of measure validity is demonstration of meaningful differences in performance, allowing end-users of public reporting or value-based purchasing programs to make informed decisions about the quality of care delivered by various providers. Here, for each provider group the proportion of patient-months with a high-risk opioid prescription was calculated at the year-level and then was compared to the overall national distribution, yielding the following results:

Practitioner Groups

- Better than Expected - 122 (3.67%)
- As Expected - 3,092 (93.05%)
- Worse than Expected - 109 (3.28%)

Prescriber Groups

- Better than Expected - 309 (6.03%)
- As Expected - 4,635 (90.47%)
- Worse than Expected - 179 (3.49%)

While UM-KECC concludes its analysis demonstrates both practical and statistically significant differences in performance, it should be noted that the measures only distinguish performance in <7% and <10% of practitioner and prescriber groups, respectively, with the overwhelming majority of measured entities performing "as expected." A performance measure in which greater than 90% of all measured entities are reported as performing "as expected" provides little meaningful, actionable information to patients, and we are not convinced these statistics are sufficiently compelling to support the measures' use in publicly reported accountability programs.

Risk Model: In prior comments to UM-KECC and CMS on measures with similar risk models, KCP has noted that many of the prevalent comorbidities in the final model have p-values significantly greater than 0.05 (e.g., prostate, and renal cancer, headaches, osteomyelitis). While in the past CMS/UM-KECC has responded that the large number of clinical factors in such models generates multicollinearity among covariates, likely resulting in some unexpected results, we remain concerned that this strategy results in a model that will not be generalizable. In the opioid models, for example, allergic reactions are associated with a higher risk of unsafe opioid use than breast or peritoneal cancers. While KCP has consistently voiced its support of prevalent comorbidity adjustment, we have in the past posited that these illogical findings are a function of collinearity and coding idiosyncrasies that may result in the proposed collection of adjusters becoming less robust with each year that passes from initial model development.

KCP also notes that validity testing yielded c-statistics of 0.70 and 0.74 for the practitioner and prescriber measures, respectively. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-6

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 encourage continuous improvement of the model.

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 203.539.9524).

Renal Physicians Association (RPA)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

RPA appreciates the opportunity to provide comments on the Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level and Unsafe Opioid Prescriptions at the Prescriber Group Level Measures. RPA believes these measures as proposed are fundamentally flawed and therefore not a reliable indicator of quality. While we agree that there is a need to minimize opioid use and reverse the ravages that over-prescribing of opioids has inflicted, there is serious risk that blunt measures such as these will result in undermanagement of pain syndromes in kidney patients. The measures focus only on opioid use and have no adjustment for etiology and severity of pain, or patients' quality of life, thereby making the measures divorced from patient-centered care. Therefore, we believe there is a high risk of unintended adverse consequences should these be adopted as written.

RPA's specific concerns are outlined below.

Assumptions about Safety and Clinical Decision Making

The use of the term "unsafe" in the measure titles and elsewhere imply that the use of an opioid and a benzodiazepine is, by definition an unsafe practice, and that the two agents should never be used together. This has medical and legal implications, since approximately 30% of patients receiving an opioid also receive a benzodiazepine, therefore implying poor clinical decision-making. Yet physicians are well accustomed to using high risk medications in high-risk situations. Doctors investigate and understand the risks and benefits, and when the benefits of the medications outweigh their risks, and with consent of a fully informed patient, they may choose to use the medications. These proposed measures countenance no opportunity for such a clinical decision process. Therefore, RPA recommends the term "unsafe" be replaced with "high risk."

Evidence and Need

Both measures include an oft-cited article by Kimmel et al. [Kimmel PL, Fwu CW, Abbott KC, Eggers AW, Kline PP, Eggers PW. Opioid Prescription, Morbidity, and Mortality in United States Dialysis Patients. J Am Soc Nephrol. 2017 Dec;28(12):3658-3670.] While that article found an association between opioid prescription and death, dialysis discontinuation and hospitalization in our patients, it did not establish causality. To quote from the conclusion of that article: "We conclude that opioid drug prescription is associated with increased risk of death, dialysis discontinuation, and hospitalization in dialysis patients.

Causal relationships cannot be inferred, and opioid prescription may be an illness marker. Efforts to treat pain effectively in patients on dialysis yet decrease opioid prescriptions and dose deserve consideration." Similar relationships of adverse outcomes have also been seen with the use of agents used to minimize opioid use, such as gabapentin and pregabalin. RPA's understanding is that there has already been a marked reduction in opioid use among dialysis patients such that it affected the design of the NIH-sponsored HOPE Consortium study that was set up to address opioid overuse in dialysis patients.

Risk Adjustment

While RPA appreciates the complex statistical model with many comorbidity variables, it is unclear there is an adjustment for severity of those comorbidities. For example, there are multiple malignancies included – but there is a significant difference between a patient with a diagnosis of localized cancer effectively treated with resection and a patient with the same cancer that is widely metastatic.

Denominator Exclusion

As written, the measures exclude patient months in which there is more than one MCP provider claim in a given month and patients who have a hospice claim at any time. However, RPA believes patients who are under the care of a pain management specialist should also be excluded, as well as patients who are receiving palliative care or palliative dialysis.

Real World Applicability

It is unclear whether these measures could be implemented in dialysis facilities with the technology currently in use. Opioid prescription and management requirements vary by state. Furthermore, interoperability between systems remains a challenge; patient data collected in the dialysis facility is not necessarily available in the clinician's office. For example, New Jersey requires the use of a prescription drug monitoring program (PDMP) for opioid and gabapentinoid prescriptions. However, there is no way to indicate that the PDMP has been checked and appropriately documented within the dialysis facility electronic health record (EHR). Meanwhile, in North Carolina, the prescribing of more than 5 days of narcotics is now essentially mandated to be from a specialized pain clinic. Even for short term prescriptions of less than 5 days, the administrative and counselling burdens are high, and may not be possible to document in the facility EHR. Thus, current limitations on the prescription of opioids have already forced patients to obtain needed pain management from providers outside of the dialysis facility raising questions as to the appropriateness and utility of this performance measure focused on dialysis practitioner groups who may no longer be prescribing these agents. Furthermore, to the extent that dialysis practitioner groups are still prescribing medications for pain management, this, or similar measures may have the unintended consequence of creating additional barriers to adequate pain management for the dialysis population.

Prior to implementation of these measures, RPA recommends extensive field testing that also incorporates patient reported outcomes to demonstrate that the use of the measures actually drives improvement from the patient's perspective.

Appendix G: Post-Evaluation Comments

Comments received as of September 9, 2021. The three post-evaluation comments were submitted for both #3615 and #3616.

Federation of American Hospitals (FAH)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

The Federation of American Hospitals (FAH) supports the Standing Committee's recommendation not to endorse this measure. We share the same concerns on the lack of adequate evidence to support the measure as specified.

Kidney Care Partners

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

Kidney Care Partners (KCP) appreciates the opportunity to submit comments on the measures under consideration for endorsement in the National Quality Forum's Renal Project Spring 2021 Cycle. KCP is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and end stage renal disease. We commend NQF for undertaking this important work. The following comments apply to both measures under review this cycle:

NQF 3615: Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level (CMS)

NQF 3616: Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS)

Overarching Comments

KCP recognizes the profound importance of minimizing opioid overuse in dialysis patients and appreciates the underlying intent of these measures; however, as stated in our earlier comments, we have serious concerns with both as currently specified and agree with the Standing Committee's recommendation against endorsement. Recognizing that opioids have been overused previously, it is important to note that national efforts have resulted in a substantial decrease in prescription opioid use in the past several years. Based on CDC data, prescription opioid dispensing rate in 2019 was 57% of the peak in 2012, and these data do not account for the changes in prescribing patterns that also have resulted in fewer opioids being dispensed per prescription in recent years. Critically, there are many reasons for extended use of opioids in the dialysis population, where the burden of symptoms is extremely high, life expectancy in many patients is half that in the age-similar general population, and options for pain medications are limited due to safety factors with other agents—for example, gabapentin and pregabalin may have serious neurologic consequences in dialysis patients, while non-steroidal anti-inflammatory drugs may be contraindicated in many individuals with ESRD (e.g., those with residual kidney function and at heightened bleeding risk). These factors question the assertion in

the name of the proposed metrics that all opioid use for more than 90 days is 'unsafe.' KCP believes these proposed metrics will incentivize inappropriately abrupt reductions of opioid medications and undermanagement of chronic pain in complex dialysis patients, particularly in the absence of existing knowledge on how to reduce opioid use while sufficiently treating pain in the hemodialysis population. We also believe the measures as specified will exacerbate existing sociodemographic, economic, and geographic disparities related to opioid use, and will result in untenable and specious double penalties for many nephrology groups. Finally, we highlight critical ongoing research from the NIH in the hemodialysis population evaluating patient-centered strategies for promoting safe and durable opioid use reduction while adequately managing pain (HOPE Consortium Trial to Reduce Pain and Opioid Use in Hemodialysis, NCT04571619).

The history of pain management in the United States is complex, oscillating between extremes. While in the midst of an unprecedented opioid epidemic, it is easy to lose sight of our past. Millions of Americans with advanced and debilitating disease suffered needlessly in the 1980s because physicians were overly cautious about prescribing narcotics. We fear these measures portend a return to such days and will ultimately do more harm than good.

Our specific concerns with the measures follow.

Potential for Unintended Consequences is Substantial

We note that, pursuant to the 2018 SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) Act, HHS contracted with the National Quality Forum (NQF) to convene a Technical Expert Panel (TEP) to review quality measures related to opioids. In its February 2020 report, that TEP explicitly recommended opioid measures to be used in Federal quality programs should address any of a number of patient-centric clinical issues, such as recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering. The two proposed opioid safety measures address none of those topics, instead focusing exclusively on reducing opioid use—without regard for clinical decision-making or consideration of the etiology or severity of the pain, or the impact on the patient's quality of life.

While the research by Kimmel et al,[1] cited as evidence supporting both measures, did find an association between opioid prescription and death, dialysis discontinuation, and hospitalization in dialysis patients, the authors make clear that an opioid prescription may merely be a marker of more severe or advanced illness in dialysis patients and that a causal relationship with these adverse outcomes cannot be inferred. Importantly, Kimmel also referred to evidence that pain is pervasive in individuals with ESRD[2],[3],[4],[5] and is linked to a significantly diminished quality of life,[6],[7],[8],[9] and that while aggressive pain treatment has been advocated,[10],[11],[12] underestimation and undertreatment of pain still occur in dialysis patients.[13],[14] These truths are not taken into consideration in these measures.

We note that the NIH-sponsored Hemodialysis Opioid Prescription Effort (HOPE) Consortium (NCT04571619), shepherded by Dr. Kimmel, is actively researching pain and opioid use in the ESRD population and how to safely decrease dependence in dialysis patients, including such behavioral/ cognitive interventions as pain coping skills and use of medications such as buprenorphine. This research aims to develop personalized treatments based on individual patient needs—a critical consideration, given the varied and notoriously persistent nature of pain in this complex and vulnerable population.

Understanding the epidemiology of pain in patients on dialysis—as well as patients' unique needs and preferences—is crucial for further improvement in managing pain. These proposed measures clearly miss that mark. We believe the development of more appropriate measures may be feasible once findings from the HOPE Study are disseminated and digested. Adoption of measures addressing such a crucial aspect of care prematurely, absent this critical knowledge, will do little to improve dialysis care or patient outcomes; rather, we fear these performance measures may induce a range of unintended, deleterious, and potentially profound adverse consequences.

Double Penalties

From the specifications and supporting measure information, it appears that the attributable entity for the Practitioner Measure is the treating nephrologist's group practice, irrespective of who prescribed the opioid—whether the nephrologist herself or a physician entirely unrelated to her group. The nephrologist is thus held accountable for other providers' prescriptions. Additionally, as the attributable entity with the Prescriber Measure is the opioid prescriber, implementation of both measures together in a payment program would seemingly result in nephrology groups being penalized twice when the nephrologist is also the opioid prescriber. We see no indication in the measure materials that this would not be the case.

Sociodemographic and Geographic Disparities

Finally, while unsafe opioid use was found to be associated with White race, non-Hispanic ethnicity, dual eligible status, and unemployment in UM-KECC's analyses, gender was the only SDS/SES factor[15] included in the final risk models because "… it is unclear whether [these] associations… are due to underlying biological or other patient factors or represent disparities in care. Adjusting for these social risk factors could have the unintended consequence of creating or reinforcing disparities and facilitating unsafe prescribing practices." As KCP has commented in the past (see, for example, KCP's August 2018 QIP comment letter to CMS), we agree CMS must strike the correct balance to ensure that it meets the goals of both fairly assessing providers while also not masking potential disparities or disincentivizing the provision of care to more medically complex patients. However, we reiterate our strong preference for adopting an SDS adjustment for measures where it has been shown that SDS factors are driving differences in the outcomes being reported. Given the associations noted above, KCP believes gender as the only sociodemographic risk variable is insufficient and is concerned the measures risk potentiating existing health inequities. We believe other biological and demographic variables are important, and not accounting for them is a significant threat to the validity of both measures.

In a similar vein, Kimmel et al [2017] reported geographic trends in opioid use in patients with ESRD are comparable to those in the general population, with eight states having chronic opioid prescription rates of 30% or more. "Chronic opioid prescription rates ranged from 9.5% of patients on dialysis in Hawaii to 40.6% of patients in West Virginia in 2010. Seven other states had prescription rates >30% (Michigan, Oklahoma, Oregon, Kentucky, Idaho, Indiana, and Alabama)."[16]

Yet it does not appear from the supplied risk model data that geography itself (distinct from the Area Deprivation Index) was examined. The failure to do so when such regional variations in opioid use is well-documented is puzzling, at best.

Given these empirically demonstrated sociodemographic and geographic opioid use disparities, KCP is not convinced that these measures have been sufficiently adjusted to avoid exacerbating existing

inequities, disincentivizing the provision of care to more medically complex patients, and adversely impacting quality of life for our most vulnerable patients.

KCP again thanks you for the opportunity to comment on this important work.

[1] Kimmel PL et al. Opioid prescription, morbidity, and mortality in United States Dialysis Patients. JASN. 2017;28(12):3658-3670.

[2] Raghavan D, Holley JL. Conservative care of the elderly CKD patient: A practical guide. Adv Chronic Kidney Dis. 2016;23:51

Fresenius Medical Care North America (FMNCA)

#3615 Unsafe Opioid Prescriptions at the Prescriber Group Level
#3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level

Fresenius Medical Care North America (FMNCA) welcomes the opportunity to comment on the National Quality Forum (NQF) Renal Standing Committee Spring 2021 Cycle: Consensus Development Process (CDP) Draft Report for Comment. FMNCA is the largest integrated supplier in the US of services and products for patients with End Stage Renal Disease (ESRD) undergoing dialysis treatment both in an outpatient clinic and at home. Both measures considered in the report address opioid prescriptions for dialysis patients. We strongly agree that there is a need to minimize opioid use and over-prescribing of opioids for dialysis patients. However, given concerns about each measure under consideration in the Spring 2021 Cycle, we support the Renal Standing Committee's (Standing Committee) action to not recommend either measure for NQF endorsement.

The NQF Renal Standing Committee evaluated two newly submitted measures:

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level (Centers for Medicare & Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UMKECC); and

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS/UMKECC).

The Standing Committee did not vote on the recommendation for endorsement for either measure because the Committee did not pass either measure on the evidence criteria, a prerequisite to voting for endorsement. As a result, neither measure was recommended for endorsement. The Standing Committee raised numerous concerns with both measures. We agree with the Standing Committee and offer the following comments.

NQF #3615. We agree with concerns raised by the Standing Committee about the definition of "unsafe opioid prescription" in the measure's numerator. We believe additional evidence would be needed to support the measure's cutoff criteria that define unsafe opioid use at a dosage of greater than 50 MME for ESRD patients. We agree with commenters that highlight the CDC opioid prescribing guidelines on which the measure specifications are based are not specific to dialysis patients and do not consider their unique needs. We note that ESRD patients are more likely to experience pain and have significantly limited medication options for pain compared to non-ESRD patients. As discussed below, future measures considered in this area should take a more patient-centered approach that is specific to the needs of ESRD patients as opposed to a blunt measure focused only on opioid use in dialysis patients.

NQF #3616. We share the Standing Committee's concern that there is insufficient evidence to support that the nephrologist affects the outcome/numerator. We agree that the nephrologist might be able to advise the patient on opioid prescription but cannot change the prescription or the outcome. We believe any accountability should be broader than the dialysis doctor since the opioid prescription is not something they directly control. As with NQF #3615, we are concerned the lack of patient-centeredness and the limited evidence underpinning the definition of unsafe opioid use for the dialysis population. Further, we are concerned that both measures could incent abrupt reductions of opioid medications and undermanagement of chronic pain in complex dialysis patients. This could lead to unintended increased suffering if patients already suffering from pain and ESRD experience withdrawal symptoms.

As NQF considers future work in this area, we would be supportive of a tiered approach that measures whether the prescriber first considered alternates before prescribing opioids. Evidence supporting opioid measure specifications should consider the unique and medically complex needs of the ESRD population. Finally, we agree with commenters that suggest quality measurement should focus on patient-centered aspects of care, including how well patients' pain is controlled, whether functional improvement goals are met, changes in quality of life, and what therapies are being used to manage pain. Thank you for the opportunity to comment.

National Quality Forum
1099 14th Street NW, Suite 500
Washington, DC 20005
https://www.qualityforum.org