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Renal, Spring 2021 Cycle: CDP Report

TECHNICAL REPORT
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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. began treatment for ESRD.[1] For 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. Both measures were not endorsed:

- 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 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.[1] 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. began treatment for ESRD (e.g., dialysis).[1] Pain is among the most commonly reported symptoms of patients on dialysis, and opioid use is among the most commonly used treatments for pain within the dialysis population.[8] 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.[9]

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.

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 at the facility, clinician group, and/or individual clinician levels: five process measures, six intermediate outcome measures, and five outcome measures.

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 1. Renal Measure Evaluation Summary

-	Maintenance	New	Total
Measures under review	0	2	2
Measures not endorsed	0	2	2
Reasons for not endorsing	-	Importance – 2	-

Cells marked by a dash (-) are intentionally left blank.

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 29, 2021, and pre-commenting closed on June 3, 2021. As of June 3, 2021, three comments were submitted and shared with the Standing Committee prior to the measure evaluation meeting (Appendix F).

Comments Received After Standing Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on September 9, 2021. Following the Standing Committee's evaluation of the measures under review, NQF received three comments from three member organizations 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 Standing Committee's recommendations. Expressions of support (or not) during the commenting period replace the member voting opportunity that was previously held subsequent to the Standing Committee's deliberations. Four NQF members expressed "do not support" for NQF #3615 and four NQF members expressed "do not support" for NQF #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 that the evidence submitted was insufficient 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 would 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 Endorsed

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 that 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 ESRD cannot take other pain medications, including nonsteroidal 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 University of Michigan Kidney Epidemiology and Cost Center (UMKECC)-convened Technical Expert Panel (TEP) was to reduce opioid use or to manage pain appropriately. The developer acknowledged the concern and agreed, as the literature suggested, that pain management options are limited for this population. The developer noted that almost half of the UMKECC-convened TEP was represented by dialysis patients and further noted the measure does not intend to reduce or eliminate opioid prescriptions for patients on dialysis; rather, the goal of the measure 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 time frame 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 that 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; however, 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 that 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 developed a specific definition for the numerator statement modeled after the CDC guidelines, and the definition is encompassed in the peer-reviewed literature. However, not one study 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, not many studies 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 the evidence and whether it reflects the measure's 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 to 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, considering 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. Furthermore, they chose to be slightly more specific in the exclusion criteria and to use a risk adjustment strategy. Ultimately, the developer 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 them 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 both the population specified in the measure and the general Medicare population experienced greater frequency of pain than the general population. However, there is no literature that specifically addresses the degree of pain in terms of severity.

The Standing Committee agreed that inappropriate opioid use and prescription 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. All three of these comments related to NQF #3615 and NQF #3616. The commenters agreed with the Standing Committee's decision to not endorse the measure. Since the commenters agreed with the Standing Committee and neither of the measures required further discussion or voting from the Standing Committee, the post-comment web meeting scheduled for October 7, 2021, was cancelled. During the Consensus Standards Approval Committee (CSAC) meeting on December 1, 2021, the CSAC upheld the Standing Committee's recommendation and did not endorse the measure.

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

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 it 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 similarity between the evidence to support this measure and that of NQF #3615, and the same concerns apply to NQF #3616 as well. 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 the 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 the importance of considering how long a person has been on dialysis because the pain varies based on the period of time. The Standing Committee agreed that 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 NQF #3615 and NQF #3616. The commenters agreed with the Standing Committee's decision to not endorse the measure. Since the commenters agreed with the Standing

Committee and neither of the measures required further discussion or voting from the Standing Committee, the post-comment web meeting scheduled for October 7, 2021, was cancelled. During the CSAC meeting on December 1, 2021, the CSAC upheld the Standing Committee's recommendation and did not endorse the measure.

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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. Quorum (17 out of 25 Standing Committee members) was reached and maintained during the full measure evaluation meeting on June 23, 2021.

Measures Not Endorsed

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 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 that 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 that the developer provided empirical evidence from the literature to link unsafe opioid prescription practices to serious adverse events, 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 articles, 43 were selected for presentation to the TEP 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 University of Michigan Kidney Epidemiology and Cost Center (UMKECC)-convened TEP was to reduce opioid use or to manage pain appropriately. The developer acknowledged the concern and agreed that, as the 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 measure 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 MME and the chronicity threshold of 90 days of opioid use. The Standing Committee also noted that the measure, as specified, does not indicate the time frame of "per day" for the 50 MME cutoff (which is suggested by the 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 that 90 days in the aggregate opioid dose was unsafe use.
- The developers also noted that the CDC guidelines were used 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 the 50 MME cutoff and the 90 days of opioid use were endorsed by the 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 insufficient to show that changing the prescription patterns would 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, considering they were specifically cited in the submission form. The developer stated that they limited the exclusion criteria to patients who are enrolled in hospice at any point during the reporting period. They chose to be slightly more specific in the exclusion criteria and to use a risk adjustment strategy. Ultimately, the developer wantedto 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 that shows the overall level of (subjective) pain in this population compared to the general Medicare population, which would help them 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 both the population specified in the measure and the general Medicare population experienced greater frequency of pain than the general population; however, there is no 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 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 did not pass on evidence.

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**

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

- Since the commenters agreed with the Standing Committee and none of the measures required further discussion or voting from the Standing Committee, the post-comment web meeting scheduled for October 7, 2021, was cancelled.
- The commenters stated that the evidence recommends measures related to increased opioid use rather than reduced 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 that the focus of the measure does not address patient-centric clinical issues, nor does it adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving HD 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. Furthermore, the measure attribution for both measures assigns accountability to the nephrologist group that prescribes approximately 10 percent of the opioid prescriptions to this population. In implementing both NQF #3615 and NQF #3616, a nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.
- The commenters expressed concerns that both the scientific acceptability and risk adjustment are unsatisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters stated that the risk model insufficiently considers providers who care for medically complex

patients. The commenters also stated 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-9; N-1 (December 1, 2021): Not Endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

9. Appeals

- No appeals were received.

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 events, 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 articles, 43 were selected for presentation to the TEP 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 the similarity between the evidence to support this measure and that of NQF #3615, and the same concerns apply to 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 the insufficient evidence to support the claim that the MCP physicians affect 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.
- The Standing Committee agreed that 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.
- The Standing Committee agreed that the same concerns raised for NQF #3615 apply to this measure (NQF #3616) as well. 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**

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

- Since the commenters agreed with the Standing Committee, and neither of the measures required further discussion or voting from the Standing Committee, the post-comment web meeting scheduled for October 7, 2021, was cancelled.
- The commenters stated that the evidence recommends measures related to increased opioid use rather than reduced 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 that the focus of the measure does not address patient-centric clinical issues, nor does it adequately include pain characteristics and the pain needs for patients with ESRD. Patients receiving HD report pain as their primary symptom, and their clinical scenario often limits pain management options.
- The commenters stated that 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. Furthermore, the measure attribution for both measures assigns accountability to the nephrologist group that prescribes approximately 10 percent of the opioid prescriptions to this

population. In implementing both NQF #3615 and #3616, the nephrologist group would be accountable and penalized for both measures based on inappropriate attribution.

- The commenters expressed concerns that both the scientific acceptability and risk adjustment are unsatisfactory, and the measure will not improve dialysis care or outcomes for patients or providers. The commenters stated that the risk model insufficiently considers providers who care for medically complex patients. The commenters also stated 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-9; N-1 (December 1, 2021): Not Endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

9. Appeals

- No appeals were received.

Appendix B: Renal Portfolio—Use in Federal Programs*

NQF #	Title	Federal Programs (Finalized or Implemented)
0249	Delivered Dose of Hemodialysis Above Minimum	Dialysis Facility Compare
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
0369	Dialysis Facility Risk-Adjusted Standardized Mortality Ratio	Dialysis Facility Compare
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Dialysis Facility Compare
1424	Monthly Hemoglobin Measurement for Pediatric Patients	None
1425	Measurement of nPCR for Pediatric Hemodialysis Patients	Dialysis Facility Compare
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
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 Dialysis Facility Compare

*CMS Measures Inventory Tool Last Accessed January 21, 2022

Appendix C: Renal Standing Committee and NQF Staff

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Appendix D: Measure Specifications

Both measures under review were not endorsed; therefore, specifications have not been provided.

Appendix E: Related and Competing Measures

Both measures under review were not endorsed, and related measures were not identified.

Appendix F: Pre-Evaluation Comments

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

AMA letter to CDC re: 2016 Guideline for Prescribing Opioids for Chronic Pain. Dated June 16, 2020. Available at: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-6-16-Letter-to-Dowell-re-Opioid-Rx-Guideline.pdf

CDC letter to NCCN, ASCO, and ASH. Dated February 28, 2019. Available at: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf

Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med. 2019;380:2285–7. https://doi.org/10.1056/NEJMp1904190.

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

Goshal M, Shapiro H, Todd, K, Schatman ME. Chronic noncancer pain management and systemic racism: Time to move toward equal care standards. J Pain Res. 2020;13:2825-2836.

U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

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 time frame. 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 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, the 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.

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' 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 overprescribing 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 five 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 NQF #3615 and NQF #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 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, the 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 U.S. 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 overprescribing 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)

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 with 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.

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