NATIONAL QUALITY FORUM
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Meeting Summary

Renal Standing Committee – Measure Evaluation Web Meeting

The National Quality Forum (NQF) convened the Renal Standing Committee for a web meeting on June 23, 2021 to evaluate two new measures and to consider pre-evaluation comments received on the two measures.

Welcome, Introductions, and Review of Meeting Objectives

Shalema Brooks, NQF director, welcomed the Standing Committee and participants to the web meeting. Ms. Brooks reviewed the meeting objectives to discuss two new measures submitted for the spring 2021 cycle. The Standing Committee members each introduced themselves and disclosed any conflicts of interest. No Renal Standing Committee members were recused for either of the two new measures under review for the spring 2021 cycle.

Some Committee members were unable to attend the entire meeting due to early departures and late arrivals. The vote totals reflect members present and eligible to vote. Quorum (20 out of 25 Standing Committee members) was met and maintained for the entire meeting.

Topic Area Introduction and Overview of Evaluation Process

Janaki Panchal, NQF manager, provided an overview of the topic area and the current NQF portfolio of endorsed measures. There are currently 21 measures in the Renal portfolio. Additionally, NQF reviewed the Consensus Development Process (CDP) and the measure evaluation criteria.

Measure Evaluation

During the meeting, the Renal Standing Committee evaluated two new measures submitted for endorsement consideration. The summary of the Standing Committee's deliberations below will also be provided in the draft technical report. NQF will post the draft technical report on August 10, 2021 for public comment on the NQF website. The draft technical report will be posted for 30 calendar days.

A measure is recommended for endorsement by the Standing Committee when the vote margin on all must-pass criteria (i.e., Importance, Scientific Acceptability, and Use [maintenance measures only]), and overall, is greater than 60 percent of eligible voting members in favor of endorsement. A measure is not recommended for endorsement when the vote margin on any must-pass criterion, or overall, is less than 40 percent of voting members in favor of endorsement. The Standing Committee has not reached consensus if the vote margin on any must-pass criterion, or overall, is between and inclusive of 40 and 60 percent in favor of endorsement. When the Standing Committee has not reached consensus, all measures for which consensus was not reached will be released for NQF member and public comment. The Standing Committee will consider the comments and re-vote on those measures during a webinar convened after the commenting period closes.

Rating Scale: H – High; M – Medium; L – Low; I – Insufficient; NA – Not Applicable

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])

Description: This measure focuses on determining 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: duration greater than 90 days, Morphine Milligram Equivalents (MME) greater than 50, or an 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 (i.e.,the clinician who receives the Monthly Capitationed 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

CMS (Steward) and UMKECC (Developer) Representatives at the Meeting

Jesse Roach, MD, CMS
Jon Segal, MD, UMKECC
Joe Messana, MD, UMKECC
Claudia Dahlerus, PhD, UMKECC
Jennifer Sardone, PMP, UMKECC

Standing Committee Votes

- **Evidence**: H-0; M-5; L-13; I-2 (denominator = 20)
- **Performance Gap**: Vote Not Taken
- **Reliability**: Vote Note Taken
- **Validity**: Vote Note Taken
- **Feasibility**: Vote Note Taken
- **Use**: Vote Note Taken
- **Usability**: Vote Note Taken

Standing Committee Recommendation for Endorsement: Vote Not Taken

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

Jon Segal from UMKECC represented the measure developer and provided the opening remarks to jointly introduce the two measures submitted by UMKECC: NQF #3615 and NQF #3616. The developer provided an overview of the measures, highlighting the measure specifications, rationale, evidence provided, and testing approach. The developers also stated their rationale for developing and submitting two measures that are closely related. They noted the recommendations from the Technical

Expert Panel (TEP) that UMKECC convened in 2019. The UMKECC-convened TEP suggested developing a measure that focuses on the provider who writes the prescription (regardless of their specialty), in addition to having an opioid measure that applies to the dialysis physicians, since only 10 percent of the opioid prescriptions for dialysis patients were written by the dialysis physicians.

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. One Standing Committee member questioned whether the developers looked at how individuals with end-stage renal disease (ESRD) cannot take other pain medications, including non steroidal pain medications, which significantly limits their medication options; this is potentially one of the reasons for opioid prescription in this population. The Standing Committee also questioned whether the goal of the UMKECC-convened TEP was to reduce opioid use or to manage pain appropriately. The developer acknowledged this concern and agreed that, as the literature suggested, pain management options for this population. The developer noted that almost half of the UMKECC-convened TEP was represented by dialysis patients and noted that the measure does not intend to reduce or eliminate opioid prescriptions for patients on dialysis; rather, the goal of the measures is to identify and monitor high risk opioid prescriptions.

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 that 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 Centers for Disease Control and Prevention (CDC) guidelines suggest a 50 MME cutoff "per day"; however, the measure, as specified, does not indicate the timeframe of per day for the 50 MME cutoff anywhere in the measure submission form. The Standing Committee also expressed concerns regarding the lack of evidence, specifically that supporting 90 days in the aggregate opioid dose was unsafe use. The developer stated that the selection of both cutoffs was based on CDC's guidelines and their findings from the literature, with a goal to maximize their safety margin. The developers also clarified that the 50 MME cutoff was indeed a per day cutoff, and the 90 days of opioid use were defined in terms of aggregate use; and both of these cutoffs were endorsed by the UMKECC-convened TEP. 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 that CDC's 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 associates that with adverse outcomes. The Standing Committee agreed that the evidence shows a correlation between an unsafe prescription, as defined in the measure specifications, and the important clinical outcomes; however, it fails to demonstrate causation that changing the prescription patterns will necessarily lead to different outcomes. Specifically, the Standing Committee failed to see evidence that supported the definitions presented in the numerator statement. 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 developers stated that they developed a specific definition for the numerator statement modeled after CDC's guidelines. Although the definition is encompassed in the peer-reviewed literature, there is not one study that used those exact criteria. The developers also noted that NQF's evidence algorithm does not explicitly require process measures to prove causation. Many NQF-endorsed measures utilize observational studies that show association because that might be the only evidence that exist; specifically, for the dialysis population, there are not many studies that provide a higher degree of causation.

The Standing Committee requested clarification from NQF staff as they evaluated the evidence criteria on whether the Standing Committee was being asked to consider whether the evidence submitted generally supports the concept of unsafe opioid doses and whether prescribing monitoring can potentially decrease harm related to unsafe opioid prescribing. In addition, the Standing Committee requested clarification as to whether they were being asked to evaluate the evidence much more specifically, not just conceptually, as it relates to the numerator as specified, noting the exclusions as well. NQF staff stated that for the evidence criterion, the Standing Committee should consider the quality, quantity, and consistency of evidence and whether the evidence reflects the measure focus, population, and accountable entity. The Standing Committee should further consider whether the measure process, in this case, leads to a desired health outcome. DR. Matthew Pickering, NQF senior director, walked through the evidence algorithm to provide guidance on NQF staff's preliminary rating for the evidence criterion. Dr. Pickering noted that since the developer did not provide systematic review or grading for the evidence, the highest possible rating for the evidence criterion would be moderate.

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 exclude sickle cell disease and cancer, as they were specifically cited in the submission form. The developer stated that they limited the exclusion criteria to patients who are enrolled in hospice at any point during the reporting period. They explained that they chose to be slightly more specific in the exclusion criteria and to use a risk adjustment strategy so that they could have a more broadly applicable measure to the patient population and attempt 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 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 those are both greater than in the general population; however, there is no literature that specifically addresses the degree of pain in terms of severity.

The Standing Committee considered the pre-evaluation comments in both their discussion and rating of the measure. The Standing Committee agreed that inappropriate opioid use is an enormous problem in this country; they understand that appropriate pain management and dialysis are critical. However, given the concerns discussed above, the Standing Committee did not pass the measure on evidence a must-pass criterion. Therefore, the measure was not recommended for endorsement.

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

Description: This measure focuses on determining 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: duration greater than 90 days, Morphine Milligram Equivalents (MME) greater than 50, or an overlapping prescription with a benzodiazepine. Please note that this measure is at the dialysis provider level (i.e., the clinician who receives the Monthly Captioned 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-submitted measure #3615, which is at the opioid-prescriber level (i.e.,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

Measure Steward/Developer Representatives at the Meeting

Jesse Roach, MD, CMS (Steward)
Jon Segal, MD, UMKECC (Developer)
Joe Messana, MD, UMKECC (Developer)
Claudia Dahlerus, PhD, UMKECC (Developer)
Jennifer Sardone, PMP, UMKECC (Developer)

Standing Committee Votes

- **Evidence**: H-0; M-1; L-15; I-4 (Denominator = 20)
- **Performance Gap**: Vote Not Taken
- **Performance Gap**: Vote Not Taken
- **Reliability**: Vote Note Taken
- **Validity**: Vote Note Taken
- **Feasibility**: Vote Note Taken
- **Use**: Vote Note Taken
- **Usability**: Vote Note Taken

Standing Committee Recommendation for Endorsement: Vote Not Taken

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

Jon Segal from UMKECC represented the measure developer and did not provide any additional comments, considering that the opening remarks for the previous measure, NQF #3615, applied to this measure as well.

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 that the evidence to support this measure was very similar to the evidence for NQF #3615, and that the same concerns apply to this measure (NQF #3616).

The Standing Committee noted that the denominator of this measure excludes the number of patients in a group practice on dialysis who received an opioid during the year, in addition to the hospice patients. The Standing Committee further noted that there is not 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 is unable to change the prescription or the outcome. The Standing Committee members noted that it is important to consider how long a person has been on dialysis as the pain varies based on that time period. 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 other pain management medication options.

The Standing Committee considered the pre-evaluation comments in both their discussion and rating of the measure. The Standing Committee agreed that the same concerns raised for NQF #3615 apply to this measure (NQF #3616). Based on those concerns, the Standing Committee did not pass the measure on evidence a must-pass criterion. Therefore, the measure was not recommended for endorsement.

Public Comment

No public or NQF member comments were provided during the measure evaluation meeting.

Next Steps

Ms. Panchal provided the next steps, noting that NQF staff will prepare a draft technical report, which will detail the Renal Standing Committee's discussion and recommendations on both of the measures. NQF will post the draft technical report on August 10, 2021, for public comment for 30 calendar days. The continuous public commenting period with member support will close on September 8, 2021. NQF will reconvene the Standing Committee for the post-comment web meeting on October 9, 2021, to review and discuss public comments received during the commenting period.

Pre-Evaluation Comments

Comments received as of June 3, 2021.

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level

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

The American Medical Association (AMA)

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 these 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.

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level

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

The Federation of American Hospitals (FAH)

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.

NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level

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

Kidney Care Partners (KCP)

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 (NQF) 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 (ESRD). We commend NQF for undertaking this important work. The following comments apply to both measures under review this cycle.

NQF #3615 Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level (Centers for Medicare & Medicaid Services [CMS]).

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

Overarching Comments

KCP recognizes the profound importance of minimizing opioid overuse in dialysis patients and appreciates the underlying intent of these measures; however, we have serious concerns with both as currently specified and cannot offer our support of either. Recognizing that opioids have been overused previously, it is important to note that national efforts have resulted in a substantial decrease in prescription opioid use in the past several years. Based on CDC data, prescription opioid dispensing rate in 2019 was 57 percent 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 National Institutes of Health (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 (U.S.) 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, the Department of Health and Human Servoces (HHS) contracted with NQF to convene a Technical Expert Panel (TEP) to review quality measures related to opioids. In its February 2020 report, that TEP explicitly recommended that opioid measures to be used in fedderal quality programs should address any of a number of patient-centric clinical issues, such as recovery from opioid use disorder (OUD), assessment and treatment of physical and mental health comorbidities to OUD, co-prescription of naloxone, patient-centered analgesia, and appropriate opioid tapering. The two proposed opioid safety measures address none of those topics, instead focusing exclusively on reducing opioid use—without regard for clinical decision making, or consideration of the etiology or severity of the pain, or the impact on the patient's quality of life.

While the research by Kimmel et al,1 cited as evidence supporting both measures, did find an association between opioid prescription and death, dialysis discontinuation, and hospitalization in dialysis patients, the authors make clear that an opioid prescription may merely be a marker of more

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

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

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

Double Penalties

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

Sociodemographic and Geographic Disparities

Finally, while unsafe opioid use was found to be associated with White race, non-Hispanic ethnicity, dual eligible status, and unemployment in UM-KECC's analyses, gender was the only sociodemographic status/ socioeconomic status (SDS/SES) factor15 included in the final risk models because "…it is unclear whether [these] associations… are due to underlying biological or other patient factors or represent disparities in care. Adjusting for these social risk factors could have the unintended consequence of creating or reinforcing disparities and facilitating unsafe prescribing practices." As KCP has commented in the past (see, for example, KCP's August 2018 Quality Incentive Program [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 that 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 percent 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 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 to 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 it 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 less than 7 percent and less than 10 percent of practitioner and prescriber groups, respectively, with the overwhelming majority of measured entities performing "as expected." A performance measure in which greater than 90 percent 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, and 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).