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Renal, Spring 2021 Cycle: Public and Member Comments

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NQF #3615 Unsafe Opioid Prescriptions at the Prescriber Group Level, Comment #7758

Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7758

Commenter: Submitted by Don May, Federation of American Hospitals

Council / Public: Provider Organization

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/7/2021

Developer Response Required? Yes ☐ No ☒

Level of Support: N/A

Theme: Concerns persist related to insufficient evidence supporting the measure as specified.

Comment

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.

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF Standing Committee Response

N/A

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level, Comment #7757
Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7757

Commenter: Submitted by Don May, Federation of American Hospitals

Council / Public: Provider Organization

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/7/2021

Developer Response Required? Yes ☐ No ☒

Level of Support: N/A

Theme: Concerns persist related to insufficient evidence supporting the measure as specified.

Comment
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.

Developer Response
N/A

NQF Response
Thank you for your comment.

NQF Standing Committee Response
N/A

NQF #3615 Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level,

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level, Comment #7746

Standing Committee Recommendation: Not Recommended for Endorsement

Comment ID#: 7746

Commenter: Submitted by Lisa McGonigal, Kidney Care Partners (KCP)

Council / Public: Quality Measurement, Research and Improvement Council

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 8/24/2021

Developer Response Required? Yes ☐ No ☒

Theme: The focus of the measure does not address patient-centric clinical issues and does not adequately include clinical circumstances, pharmaceudical restrictions, and pain characteristics and needs specific to patients with ESRD on renal dialysis. 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. Moreover, there are concerns that the scientific acceptability results and risk model is not satisfactory, and the measure will not improve dialysis care or outcomes for patients or providers.

Comment

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

- NQF 3615: Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level (CMS)
- NQF 3616: Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level (CMS)

Overarching Comments

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

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

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

Our specific concerns with the measures follow.

Potential for Unintended Consequences is Substantial

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

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

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

population.

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

Double Penalties

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

Sociodemographic and Geographic Disparities

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

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

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

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

impacting quality of life for our most vulnerable patients.

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

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

[2] Raghavan D, Holley JL. Conservative care of the elderly CKD patient: A practical guide. Adv Chronic Kidney Dis. 2016;23:51–56.

[3] Davison SN. Pain in hemodialysis patients: Prevalence, cause, severity, and management. AJKD. 2003;42:1239–1247.

[4] Santoro D et al. Pain in end-stage renal disease: A frequent and neglected clinical problem. Clin Nephrol. 2013;79[Suppl 1]:S2–S11.

[5] Shayamsunder AK et al. Sleepiness, sleeplessness, and pain in end-stage renal disease: Distressing symptoms for patients. Semin Dial. 2005;18:109–118.

[6] Davison SN. Pain in hemodialysis patients: Prevalence, cause, severity, and management. AJKD. 2003;42:1239–1247.

[7] Harris TJ et al. Pain, sleep disturbance and survival in hemodialysis patients. Nephrol Dial Transplant. 2012;27:758–765.

[8] Davison SN. Chronic kidney disease: Psychosocial impact of chronic pain. Geriatrics. 2007;62:17–23.

[9] Davison SN, Jhangri GS. Impact of pain and symptom burden on the health-related quality of life of hemodialysis patients. J Pain Symptom Manage. 2010;39:477–485.

[10] Barakzoy AS, Moss AH. Efficacy of the world health organization analgesic ladder to treat pain in end-stage renal disease. JASN. 2006;17:3198–3203.

[11] Claxton RN et al. Undertreatment of symptoms in patients on maintenance hemodialysis. J Pain Symptom Manage. 2010;39:211–218.

[12] Davison SN, Koncicki H, Brennan F. Pain in chronic kidney disease: A scoping review. Semin Dial. 2014;27:188–204.

[13] Barakzoy AS, Moss AH. Efficacy of the world health organization analgesic ladder to treat pain in end-stage renal disease. JASN. 2006;17:3198–3203.

[14] Merboth MK, Barnason S. Managing pain: The fifth vital sign. Nurs Clin North Am. 2000;35:375–383.

[15] Per CMS, biologic differences (e.g., genetic, hormonal, metabolic) may account for differences in pain perception between male and female, suggesting a physiologic effect rather than a disparity in care.

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

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF Standing Committee Response

N/A

NQF #3615 Unsafe Opioid Prescriptions at the Dialysis Prescriber Group Level,

NQF #3616 Unsafe Opioid Prescriptions at the Dialysis Practitioner Group Level, Comment #7769

Standing Committee Recommendation: Not Recommended for Endorsement

Comment ID#: 7769

Commenter: Submitted by Max Horowitz, Fresenius Medical Care North America

Council / Public: Provider Organization

Comment Period: Post-Evaluation Member and Public Commenting

Date Comment was Submitted: 9/9/2021

Developer Response Required? Yes ☐ No ☒

Theme: Concerns persist related to insufficient evidence supporting the measure as specified. The measure is not patient-centric or tailored to the needs of patients with ESRD on renal dialysis specific to medication availability, clinical limitations, and the management of pain in this population.

Comment

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

The NQF Renal Standing Committee evaluated two newly submitted measures:

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

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

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

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

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

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

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF Standing Committee Response

N/A