TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson, Senior Director

RE: Palliative and End-of-Life Care Member Voting Results

DA: October 5, 2016

The CSAC will review recommendations from the *Palliative and End-of-Life Care* project at its October 11, 2016 conference call.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures ended on August 26, 2016.

Accompanying this memo are the following documents:

1. **Palliative and End-of-Life Care Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table.** Staff has identified themes within the comments received. This table includes 89 comments received during the 30-day post-evaluation commenting period, along with NQF and Standing Committee responses.

BACKGROUND

Palliative care is patient- and family-centered care that optimizes quality of life by anticipating, preventing, and alleviating suffering throughout the continuum of a person's illness by addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. With its focus on improving quality of life, palliative care is distinct from care intended to cure an illness or condition, although it can be delivered concurrently with curative therapies. End-of-life care is comprehensive care that addresses medical, emotional, spiritual, and social needs during the last stages of a person's terminal illness. Much end-of-life care is palliative in nature, when life-prolonging interventions are no longer be appropriate, effective, or desired.

Palliative care is holistic in nature, addressing the needs of the whole person. As such, palliative care requires an interdisciplinary, team-based approach that includes a variety of clinicians and other caregivers, including, but not limited to, physicians, nurses, social workers, chaplains, other mental health professionals, therapists, and pharmacists. Improving both access to, and quality of, palliative and end-of-life care is becoming increasingly important due to the aging of the U.S. population, the projected increases in the number of Americans with chronic illnesses, disabilities, and functional limitations, and the growth in ethnic and cultural diversity, which has intensified the need for individualized, person-centered care.

The National Quality Forum's (NQF) portfolio of measures for Palliative and End-of-Life Care includes measures addressing physical aspects of care, including the management of pain, dyspnea, and

constipation. The portfolio also includes measures addressing several of the other domains of care including spiritual, psychological, cultural, and legal aspects of care and care of the patient at the end of life.

DRAFT REPORT

The Palliative and End-of-Life Care Draft Report presents the results of the evaluation of 24 measures considered under the Consensus Development Process (CDP). Twenty-three of these measures were recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement. One previously-endorsed measure was withdrawn from consideration.

The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	16	8	24
Measures recommended for endorsement	15	8	23
Measures withdrawn from consideration	1	--	1

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of 23 candidate consensus standards.

Palliative and End-of-Life Care Measures Recommended for Endorsement:

Measure	Overall Suitability for Endorsement: Y=Yes, N=No
Physical aspects of care (pain, dyspnea, constipation)	
0209: Comfortable Dying: Pain Brought to a Comfortable Level within 48 hours of Initial Assessment	Y-18; N-0
1634: Hospice & Palliative Care: Pain Screening	Y-23; N-0
1637: Hospice & Palliative Care: Pain Assessment	Y-24; N-0
1628: Patients with advanced cancer screened for pain at outpatient visits	Y-24; N-0
1639: Hospice & Palliative Care: Dyspnea Screening	Y-18; N-0
1638: Hospice & Palliative Care: Dyspnea Treatment	Y-21; N-0
1617: Patients Treated with an Opioid who are Given a Bowel Regimen	Y-24; N-0
Spiritual, religious, and existential aspects of care	
1647: Beliefs and Values Documentation	Y-22; N-1
Ethical and legal aspects of care	
1626: Patients admitted to the ICU who have care preferences documented	Y-18; N-0
1641: Hospice & Palliative Care: Treatment Preferences	Y-22; N-0
Care of the patient at the end of life	
0210: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life	Y-22; N-0
0213: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life	Y-22; N-0

0215: Proportion of patients who died from cancer not admitted to hospice	Y-22; N-0
0216: Proportion of patients who died from cancer admitted to hospice for less than 3 days	Y-21; N-0
1625: Hospitalized Patients Who Die an Expected Death with an ICD that Has Been Deactivated	Y-24; N-0
2651: CAHPS® Hospice Survey (experience with care) PRO-PMs: o Hospice Team Communication; o Getting Timely Care; o Getting Emotional and Religious Support; o Getting Help for Symptoms o Getting Hospice Training; o Rating of the hospice care; o Willingness to recommend the hospice	Y-22; N-1
2651: CAHPS® Hospice Survey (experience with care) PRO-PM: o Treating Family Member with Respect	Y-18; N-0

COMMENTS AND THEIR DISPOSITION

NQF received 89 post-evaluation comments from 14 organizations (including 6 member organizations) and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Palliative and End-of-Life Care project page under the Public and Member Comment section.

Comment Themes and Committee Responses

Comments about measure specifications and rationale were forwarded to the developers, who were invited to respond.

During the August 3, 2016 Post-Comment Call, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Theme 1 - Support for the recommended measures

Overall, commenters supported the recommended measures. In addition to measure-specific comments expressing support, 50 comments expressed support for (but no additional questions or concerns regarding) the Committee's initial endorsement decisions. Several of the supportive comments also offered ideas for additional measure development.

Theme 2 - Consideration of Patient Choice in Measurement

Two commenters noted the importance of patient choice in measurement. One (ID #6045) noted that some patients will want to continue aggressive care near the end of life, stating that physicians should not be penalized when patients make this choice. This commenter emphasized the need for informed patient and family choice and acknowledged that 100% (or 0%) performance is not the goal for "aggressive care" measures (e.g., emergency department use). Another commenter (ID #6119) noted

that patient preferences for end-of-life care often change over time, thus highlighting the importance of affording frequent opportunities for modifying their formal care and treatment preferences.

Committee Response (ID #6045): Thank you for your comment. The Committee agrees that patients and their families should be encouraged and assisted in making informed decisions regarding end-of-life care and that palliative and end-of-life care measures and related measurement programs should take patient choice into account.

Committee Response (ID #6119): Thank you for your comment. The Committee agrees that patients should be given ample opportunity to modify their care and treatment preferences over time.

Theme 3 - Gaps in Palliative and End-of-Life Care Performance Measurement

Many of the submitted comments confirmed the gaps in measurement identified in the draft report and/or identified additional gaps, including:

- Measures addressing legacy support (e.g., evidence-based dignity therapy)
- Measures focusing on creativity (e.g., art or music therapy)
- Measures that address the NQS priorities of Effective Prevention and Treatment of Illness, Best Practices for Healthy Living, and Affordable Care
- Measures that consider hospice stays of less than 30 days
- Measures that consider social determinants of care (e.g., socioeconomic, educational, spiritual, cultural, etc.), particularly as related to advance care planning
- Measures related to bereavement care
- Measures for patients with chronic or life-limiting conditions (i.e., the patient population appropriate for palliative care), including those in settings other than hospice and hospital-based palliative care (e.g., home, nursing homes, ambulatory care, etc.)
- Measure of outcomes, particularly patient-reported outcomes
- Measures of alignment between care that is provided and patients' preferences, goals, values, and wishes
- Measures related to advance care planning
- Measures that assess care longitudinally and across care settings

Committee Response: Thank you for your comment. The Committee agrees with your suggestions for future measure development and the report will be updated accordingly.

ISSUES RESOLVED ON THE POST-COMENT CALL

During the in-person meeting, the Committee requested additional information from developers to help resolve issues related to one measure that initially was not recommended for continued endorsement and two measures where consensus was not reached. Also, during the commenting period, one developer requested a reconsideration of the Committee's initial recommendation against continued endorsement. Based on additional information provided by developers, as well as discussion during the post-comment call, the Committee's concerns regarding those measures were resolved and the Committee ultimately recommended the measures for endorsement. Details of the post-comment call discussions are included in Appendix B.

NQF MEMBER VOTING RESULTS

All of the recommended measures were approved by the voting councils with at least 60% approval. Representatives of 15 member organizations voted; no votes were received from the Consumer, Public/Community Health Agency, and Supplier/Industry Councils. Results for each measure are provided in Appendix A.

REMOVAL OF ENDORSEMENT

One measure previously endorsed by NQF was withdrawn from maintenance of endorsement:

Measure	Reason for Withdrawal
0211: Percentage of patients who died from cancer with more than one emergency room visit in the last days of life	Citing concerns related to the lack of risk-adjustment, the Committee agreed that the measure did not meet the Validity subcriterion as currently constructed, and instead opted to defer its endorsement decision, pending additional analysis regarding risk-adjustment. Although initially agreeing with this stipulation, in subsequent communication with NQF, the developers withdrew this measure from consideration, stating that they would not be able to explore risk-adjustment of the measure at this time. Endorsement will be removed from this measure.

Appendix A-NQF Member Voting Results

NQF MEMBER VOTING RESULTS

All of the recommended measures were approved with 100% approval or higher. Representatives of 15 member organizations voted; no votes were received from the Consumer, Public/Community Health Agency, and Supplier/Industry Councils. Results for each measure are provided below.

NQF Member Council	Voting Organizations	Eligible to Vote	Rate
Consumer	0	41	0%
Health Plan	1	17	6%
Health Professional	4	103	4%
Provider Organizations	5	108	5%
Public/Community Health Agency	0	17	0%
Purchaser	2	21	10%
QMRI	3	78	4%
Supplier/Industry	0	38	0%
All Councils	**15**	**423**	**3%**

Palliative and End-of-Life Care Measures Recommended for Endorsement:

0209: Comfortable Dying: Pain Brought to a Comfortable Level within 48 hours of Initial Assessment

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	3	1	0	4	75%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	1	0	3	67%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**2**	**1**	**15**	**86%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					85%

*equation: Yes/ (Total - Abstain)

1634: Hospice & Palliative Care: Pain Screening

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	

Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**1**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

1637: Hospice & Palliative Care: Pain Assessment

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**1**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

1628: Patients with advanced cancer screened for pain at outpatient visits

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	1	0	3	67%
Supplier/Industry	0	0	0	0	

All Councils	**13**	**1**	**1**	**15**	**93%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					92%

*equation: Yes/ (Total - Abstain)

1639: Hospice & Palliative Care: Dyspnea Screening

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	3	1	0	4	75%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**2**	**1**	**15**	**86%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					89%

*equation: Yes/ (Total - Abstain)

1638: Hospice & Palliative Care: Dyspnea Treatment

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**13**	**1**	**1**	**15**	**93%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

1617: Patients Treated with an Opioid who are Given a Bowel Regimen

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**15**	**0**	**0**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

1647: Beliefs and Values Documentation

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**13**	**1**	**1**	**15**	**93%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

1626: Patients admitted to the ICU who have care preferences documented

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	3	1	0	4	75%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	

Purchaser	1	0	1	2	100%
QMRI	2	1	0	3	67%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**2**	**1**	**15**	**86%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					88%

*equation: Yes/ (Total - Abstain)

1641: Hospice & Palliative Care: Treatment Preferences

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	4	0	0	4	100%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**1**	**0**	**15**	**93%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					96%

*equation: Yes/ (Total - Abstain)

0210: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	3	1	0	4	75%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**2**	**1**	**15**	**86%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					91%

*equation: Yes/ (Total - Abstain)

0213: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	3	1	0	4	75%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**2**	**1**	**15**	**86%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					91%

*equation: Yes/ (Total - Abstain)

0215: Proportion of patients who died from cancer not admitted to hospice

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**1**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

0216: Proportion of patients who died from cancer admitted to hospice for less than 3 days

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%

Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**1**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

1625: Hospitalized Patients Who Die an Expected Death with an ICD that Has Been Deactivated

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	1	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**12**	**1**	**2**	**15**	**92%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

2651: CAHPS® Hospice Survey (experience with care) PRO-PMs

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	1	1	
Health Professional	4	0	0	4	100%
Provider Organizations	5	0	0	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	3	0	0	3	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**1**	**15**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Appendix B: Details of Measure Evaluation

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

Measures Recommended

Physical aspects of care (pain)

0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment

Submission | Specifications

Description: Percentage of patients who report being uncomfortable because of pain at the initial assessment who, at the follow up assessment, report pain was brought to a comfortable level within 48 hours.

Numerator Statement: Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment.

Denominator Statement: Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment.

Exclusions: Patients who do not report being uncomfortable because of pain at initial assessment (i.e., patients who reply "no" to the question "Are you uncomfortable because of pain?"

Patients under 18 years of age

Patients who cannot self report pain

Patients who are unable to understand the language of the person asking the initial and follow up questions

Adjustment/Stratification:

Level of Analysis: Facility, Population : National

Setting of Care: Hospice

Type of Measure: PRO

Data Source: Patient Reported Data/Survey

Measure Steward: National Hospice and Palliative Care Organization

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **Y-21; N-1**; 1b. Performance Gap: **H-16**; **M-7**; **L-0**; **I-0**

Rationale:

- The rationale provided by the developer for this Patient-Reported Outcome-based Performance Measure (PRO-PM) notes that patients' beliefs about pain and pain management, along with cognitive factors such as the ability to follow instructions, affect adherence to pain interventions, suggesting that assessment of such factors is key to effective pain management. The developer described a pathway from self-reported pain to clinical and psychosocial assessment, then to intervention (e.g., pharmaceutical, non-pharmaceutical, counseling, and education), then to reassessment and additional intervention if needed, culminating in self-reported alleviation of pain.
- To demonstrate that the target population values the measured PRO and finds it meaningful, the developers cited a study (McMillan et al., 2002) that found a strong relationship between pain and distress among patients with cancer who were newly admitted to hospice.
- Committee members agreed that the developer identified at least one clinical action that could influence patient-reported pain levels and that hospice patients find questions regarding level of pain to be meaningful.

0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment

- Performance trends for hospice facilities that voluntarily submitted data to NHPCO between 2012 and 2015 were relatively stable, with a mean of 66.4 (SD=21.1) in 2012 across 143 reporting hospice facilities and a mean of 64.7 (SD=24.5) in 2015 across 46 reporting hospice facilities.
- Data presented by the developer suggest there are no disparities in care according to age group, sex, race, or condition (cancer vs. non-cancer).

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-3**; **M-18**; **L-2**; **I-0** 2b. Validity: **H-1**; **M-8**; **L-6**; **I-8**

<u>Rationale</u>:

- Committee members questioned excluding patients because of language barriers. The developer clarified that use of interpreters—including family interpreters—is allowable.
- Some Committee members voiced concern about the high number of patients who are excluded from the measure because they did not report being uncomfortable because of pain at initial assessment. The developer clarified that these patients are not actually excluded from the measure but instead are not eligible for the measure.
- Reliability testing at the time of the 2012 endorsement evaluation included score-level testing of agency-level between-versus-within variance using data from 58 hospice agencies and 38,000 patients (intra-class correlation coefficient= 0.71, 95% CI=0.63-0.77). For the current evaluation, developers updated their reliability testing by describing analyses that examined stability in performance over time; however, NQF does not consider analysis of data across time to be an appropriate method of testing the reliability.
- To demonstrate the validity of the measure for the 2012 endorsement evaluation, developers compared response rates obtained from 212 patients from 9 hospice agencies when using two different wordings for the measure (pain brought to a "comfortable" level versus an "acceptable" level). The developers reported that that 96% of patients provided the same answer to the two wordings of the question (kappa=0.91). Updated testing was not conducted. Committee members agreed that this analysis and the results were sufficient to validate the measure.
- One member expressed concern that the measure might not be specific enough to reflect improvement in pain resulting from the terminal condition, noting that it may not be possible to alleviate more generalized pain (e.g., from arthritis) within the 48-hour timeframe for the measure. Another member noted that use of slower-acting medications (e.g., methadone) is increasing. The developer acknowledged that it may not be possible to manage all types of pain within 48 hours and noted that 100% performance on the measure is not expected.
- Another member questioned whether a clinically appropriate outcome measure for pain would be to assess the number of patients whose pain was reduced by a threshold amount over the 48 hours rather than to expect pain to be brought to a completely comfortable level. The developer acknowledged the "high bar" set by the measure, but reiterated the importance of allowing the patient to define what is comfortable. The developer also noted that different patients will require different rating scales (e.g., 0-10 scale, faces, etc.) and that assessing equivalent improvement across the different scales would be difficult.
- Several Committee members expressed concern about the lack of risk adjustment for this measure. While the developer presented patient-level data indicating no statistically significant effects of age (>65 years old vs ≥65; >75 years old vs ≥75), gender, or race (Caucasian vs non-Caucasian) on the measure score, facility-level data are needed to demonstrate that risk-adjustment is not needed to achieve fair comparisons across facilities. Members were particularly interested in potential differences in performance by region, diagnosis, and co-morbidities, and encouraged the developer to bring these data (or a plan for future risk-adjustment) to the post-comment call. The developers noted that they receive aggregate-level data from facilities and were not sure if they could bring back the requested analysis.

0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment

They agreed to try to do so and to bring back a plan for risk-adjustment.

3. Feasibility: H-X; M-X; L-X; I-X

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures

- This measure is related to (potentially competing with) two measures:
  - 1634: Hospice and Palliative Care -- Pain Screening [*a clinician-level & facility-level process measure in hospice and hospital setting*]
  - 1637: Hospice and Palliative Care -- Pain Assessment. Description: Percentage of hospice or palliative care patients who screened positive for pain and who received a clinical assessment of pain within 24 hours of screening [*clinician-level & facility-level process measure in hospice and hospital setting*]
- Because this measure was not recommended for endorsement by this Committee during the in-person meeting, a best-in-class and harmonization discussion was not conducted.

Standing Committee Recommendation for Endorsement: **Not recommended**

Rationale:

- The Committee wants to see hospice-level analysis demonstrating that risk-adjustment is not needed, or, if analysis indicates risk-adjustment is needed, a plan for that risk-adjustment.

6. Public and Member Comment: June 20- July 19, 2016; Post-comment call August 3, 2016

Comments received:

- Four commenters supported the initial decision of the Committee not to endorse the measure, with two of these agreeing that additional analyses are needed.
- Two commenters did not support the Committee's initial decision not to endorse the measure. Both emphasized the importance of outcome measures for pain—particularly patient-reported outcome measures—in NQF's portfolio of palliative and end-of-life care.

Developer response to Committee's request for additional data analysis:

- The developers reiterated their position that risk adjustment is not necessary, maintaining that hospice providers are equally responsible for optimizing pain management for all patients who state they are uncomfortable on the initial pain screening.
- Per the Committee's request, the developer submitted results additional analyses of facility-level data. They examined several potential risk factors, including geographic location, service area, ownership, race and ethnicity, patient age, patient gender, patient principle diagnosis, and referral source. None of the factors examined were statistically significantly associated with the measure scores.

Committee response:

- After review of the additional information provided by the developer, the Committee agreed to re-vote on the Validity subcriterion. Upon re-vote, the Committee agreed that the rationale and analysis addressed their initial concerns with lack of risk-adjustment.
- Because the measure passed the Validity subcriterion upon re-vote, the Committee then discussed and voted on the Feasibility and Usability and Use criteria.
- Feasibility

0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment

- Hospices provide aggregate data to NHPCO through an on-line system. NHPCO provides a Data Submission Worksheet for hospice agency use, so that they can compile and aggregate their data. NHPCO also offers guidance for calculating the measure, without requiring licensing or fees. Required data elements are not necessarily kept electronically – some providers may use paper record system to track responses.
- Although some hospices had difficulty implementing the measure when it was required in the first year of reporting as part of the Hospice Quality Reporting Program (HQRP), the Committee did not voice concerns about the feasibility of the measure

- Usability and Use
  - Although specified at the facility level of analysis, this measure is in use in the PQRS program (a clinician program). NHPCO provides data collection and comparative reporting (i.e., benchmarking) for those hospices that voluntarily submit data to NHPCO. The developers note that in 2014, 156 hospices provided measure data for 20,548 patients. Although initially included in the HQRP, it was removed by CMS because of patient ineligibility for the measure and patients' denying pain at the initial assessment, which resulted in a small denominator and created validity concerns.
  - Committee members expressed concern that the measure is not publicly reported and that relatively few hospice agencies report on the measure.
  - Committee members also noted that no performance improvement over time had been observed.
  - The Committee did not report any unintended consequences from using the measure.
- Related/Competing discussion, comparing this measure to measures #1634 and #1637 (NOTE: Due to differences in care setting, level of analysis, and measure type, NQF did not ask the Committee to select a best-in-class measure or discuss harmonization, but instead asked members to consider the need for the process measures for pain in the hospice setting, given that an outcome measure is available).
  - Committee members agreed that for now, both the process and outcome measures are needed, but noted that this may change in the future.

Vote Following Consideration of Public and Member Comments:

Validity: **H-2**; **M-17**; **L-0**; **I-0**

Feasibility: **H-0; M-14; L-4; I-0**

Usability and Use: **H-0; M-5; L-13; I-0**

Standing Committee Overall Recommendation for Endorsement: **Y-18**; **N-0**

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1634 Hospice and Palliative Care -- Pain Screening

*Paired with #1637: Hospice and Palliative Care – Pain Assessment

Submission | Specifications

Description: Percentage of hospice or palliative care patients who were screened for pain during the hospice admission evaluation / palliative care initial encounter.

1634 Hospice and Palliative Care -- Pain Screening

*Paired with #1637: Hospice and Palliative Care – Pain Assessment

Numerator Statement: Patients who are screened for the presence or absence of pain (and if present, rating of its severity) using a standardized quantitative tool during the admission evaluation for hospice / initial encounter for palliative care.

Denominator Statement: Patients enrolled in hospice OR patients receiving specialty palliative care in an acute hospital setting.

Exclusions: Patients with length of stay < 1 day in palliative care.

Adjustment/Stratification:

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospice, Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: University of North Carolina-Chapel Hill

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **H-2**; **M-2**; **L-0**; **I-19**; 1b. Performance Gap: **H-1**; **M-19**; **L-2**; **I-1;**

Evidence Exception: **Y-23; N-0**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, the developers cited individual studies, systematic reviews, and clinical practice guidelines to support the effectiveness of medical treatment for pain, the effectiveness of expert pain assessment and specialty care teams to improve pain, and the importance of screening, assessing, and treating pain in seriously and terminally ill patient populations. For the most part, this evidence was tangential to the measure focus. The exception was the American Pain Society (APS) guidelines recommendation that all patients should be routinely screened for pain, and when present, pain intensity should be recorded; however, this guideline was not graded and the evidence for screening was not provided.
- For the current evaluation, the developer updated the evidence by referencing a 2011 British Columbia Medical Services Commission guideline calling for the assessment of pain using the OPQRSTUV mnemonic (onset, provoking, quality, region, severity, treatment, understanding, values), and a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults recommending inclusion of physical aspects into the palliative care plan
- One Committee member referenced a study not provided by the developer that found as the severity of pain increased, based on the Edmonton Symptom Assessment Scale, pain-related actions such as referrals, treatments, or prescriptions also increased (Seow, et al., 2012). While other Committee members found this information compelling, they were reluctant to accept it at face value without an opportunity to review. Instead, the Committee noted that screening is required prior to treatment and agreed that empirical evidence is not needed to hold providers accountable for the measure. Therefore, the Committee agreed to invoke the exception to the evidence subcriterion.
- Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 93.5%. Additional data presented by the developer indicate slight, yet statistically significant, disparities in care between genders and between socioeconomic subgroups.
- Developers did not provide clinician-level performance data for palliative care in the hospital setting.

1634 Hospice and Palliative Care -- Pain Screening

*Paired with #1637: Hospice and Palliative Care – Pain Assessment

However, they noted that the measure is being used in a variety of palliative care settings through on-going Center for Medicare & Medicaid Innovation (CMMI) and Palliative Care Research Cooperative projects, and indicated that clinician-level performance data will be available within the coming year.

- The Committee agreed that the measure showed clear opportunity for improvement in the hospice setting. Members also agreed that there may be room for improvement in the broader palliative care community.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-5**; **M-18**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-22**; **L-0**; **I-0**

<u>Rationale</u>:

- When last endorsed, patients with a hospice stay of <7 days were excluded from the measure denominator. Developers have changed this specification and now no longer exclude any hospice patients because of length of stay (although patients with <1 day in hospital palliative care are excluded from the clinician-level measure).
- Reliability testing at the time of the 2012 endorsement evaluation was limited to an inter-rater reliability analysis based on data from 20 patients in one hospital (kappa=1.0). For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.86, and a signal-to-noise analysis with a signal-to-noise ratio of 0.97). The Committee agreed testing results showed the measure is reliable. As with the other measures submitted by this developer, the Committee strongly recommended that reliability testing for the clinician-level measure in the palliative care setting be updated and the results provided to NQF when available.
- Validity testing at the time of the 2012 endorsement evaluation included both a face validity assessment and a score-level construct validity analysis for the palliative care setting. Although face validity results from a group of nursing and physician stakeholders indicated broad endorsement of the measure, results from the construct validity analysis were inconclusive, as almost all patients were screened for pain regardless of receipt of specialty palliative care services.
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission.
- Committee members did not express concern regarding the validity of the measure.

3. Feasibility: H-1; M-23; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Because the issues regarding feasibility for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program. However, members noted that feasibility of the measure for other settings is unclear.

4. Usability and Use: H-2; M-22; L-0; I-0

1634 Hospice and Palliative Care -- Pain Screening

*Paired with #1637: Hospice and Palliative Care – Pain Assessment

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Because the issues regarding usability and use for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays.
  - The measure is not currently in use for clinical-level accountability in the palliative care setting.
  - Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement.
  - The Committee did not report any unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure competes with three measures:
  - 0383: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain [*a clinician-level process measure in ambulatory setting*]
  - 1628: Adult patients with advanced cancer who are screened for pain with a standardized quantitative tool at each outpatient visit [*a facility-level, health plan, and integrated delivery system-level process measure in ambulatory setting*]
  - 1637: Percentage of hospice or palliative care patients who screened positive for pain and who received a clinical assessment of pain within 24 hours of screening [*clinician-level & facility-level process measure in hospice and hospital setting*]
- This measure is related to (potentially competing with) three measures:
  - 0209: Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment [a facility-level PRO-PM in the hospice setting]
  - 0384: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified [*a clinician-level process measure in ambulatory setting*]
  - 0420: Percentage of patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present [*a clinician-level process measure in ambulatory setting*]
- Because #0209 was not recommended for endorsement by this Committee during the in-person meeting, a best-in-class and harmonization discussion was not conducted.
- Due to differences in care settings for measures #0383, #0384, #0420, and #1628, the Committee was not asked to select a best-in-class measure.
- Patients identified as being in pain per this measure constitute the denominator for measure #1637. The measures are already harmonized.
- The Committee discussed the measures specified for the ambulatory care setting (#0383, #0384, #0420, 1628):
  - Members noted the narrow denominators for #1628 (stage IV cancer) and #0384 (cancer

1634 Hospice and Palliative Care -- Pain Screening

*Paired with #1637: Hospice and Palliative Care – Pain Assessment

patients undergoing chemotherapy or radiation). They questioned whether a separate measure for screening and assessment is needed. They suggested that including a focus on the care plan is a stronger measure. They noted that #0420 is already included in the PQRS program and has a much broader denominator (i.e., not limited to cancer patients). Finally, they recommended that all of these measures be combined so as to incorporate screening, assessment, documentation, and follow-up for the broadest patient population possible, with these things occurring at each visit, not just once.

Standing Committee Recommendation for Endorsement: **Y-23**; **N-0**

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

- NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure.
- One commenter expressed concern about inclusion of short-stay patients, recommending stratification of results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying.
    - ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1637 Hospice and Palliative Care -- Pain Assessment

*Paired with #1634: Hospice and Palliative Care – Pain Screening

Submission | Specifications

Description: This quality measure is defined as:

Percentage of hospice or palliative care patients who screened positive for pain and who received a clinical assessment of pain within 24 hours of screening.

Numerator Statement: Patients who received a comprehensive clinical assessment to determine the severity, etiology and impact of their pain within 24 hours of screening positive for pain.

Denominator Statement: Patients enrolled in hospice OR receiving specialty palliative care in an acute hospital setting who report pain when pain screening is done on the admission evaluation / initial encounter.

Exclusions: Patients with length of stay < 1 day in palliative care. Patients who screen negative for pain are excluded from the denominator.

Adjustment/Stratification:

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospice, Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: University of North Carolina-Chapel Hill

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1637 Hospice and Palliative Care -- Pain Assessment

*Paired with #1634: Hospice and Palliative Care – Pain Screening

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **H-0**; **M-0**; **L-0**; **I-23**; 1b. Performance Gap: **H-11**; **M-13**; **L-0**; **I-0;**

Evidence Exception: **Y-24; N-0**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, the developers cited individual studies, systematic reviews, and clinical practice guidelines to support the effectiveness of medical treatment for pain, the effectiveness of expert pain assessment and specialty care teams to improve pain, and the importance of screening, assessing, and treating pain in seriously and terminally ill patient populations. For the most part, this evidence was tangential to the measure focus. The exception was the American Pain Society (APS) guidelines recommending that all patients should be routinely screened for pain, and when present, pain intensity should be recorded; however, this guideline was not graded and the evidence for assessment was not provided.
- For the current evaluation, the developer updated the evidence by referencing a 2011 British Columbia Medical Services Commission guideline calling for the assessment of pain using the OPQRSTUV mnemonic (onset, provoking, quality, region, severity, treatment, understanding, values), and a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults recommending inclusion of physical aspects into the palliative care plan. The developer presented some additional information just prior to the in-person meeting. This included a brief summary of recommendations for pain assessment by the American College of Physicians and the Institute of Medicine, and a systematic review that some evidence that associates pain assessment with a shorter length of stay in the ICU, less time spent on mechanical ventilation, decreased pain intensity, fewer adverse events and complications, and reduced mortality. One member noted that this additional evidence was somewhat limited in terms of scope (e.g., cancer patients, critically ill patients).
- The additional evidence provided by the developer initially split the Committee's vote; after additional discussion, the Committee re-voted, unanimously agreeing that the evidence linking pain assessment to improved patient outcomes was insufficient. However, the Committee agreed that empirical evidence is not needed to hold providers accountable for the measure, and invoked the exception to the evidence subcriterion.
- Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 65.7%. Additional data presented by the developer indicate slight, yet statistically significant, disparities in care between geographic locations.
- Developers did not provide clinician-level performance data for palliative care in the hospital setting. However, they noted that the measure is being used in a variety of palliative care settings through on-going Center for Medicare & Medicaid Innovation (CMMI) and Palliative Care Research Cooperative projects, and indicated that clinician-level performance data will be available within the coming year.
- The Committee agreed that the measure showed clear opportunity for improvement in the hospice setting. Members also agreed that there may be room for improvement in the broader palliative care community.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-3; M-20; L-0; I-1** 2b. Validity: **H-0**; **M-24**; **L-0**; **I-0**

<u>Rationale</u>:

- When last endorsed, patients with a hospice stay of <7 days were excluded from the measure

1637 Hospice and Palliative Care -- Pain Assessment

*Paired with #1634: Hospice and Palliative Care – Pain Screening

denominator. Developers have changed this specification and now no longer exclude any hospice patients because of length of stay (although patients with <1 day in hospital palliative care are excluded from the clinician-level measure).

- Reliability testing at the time of the 2012 endorsement evaluation was limited to an inter-rater reliability analysis based on data from 20 patients in one hospital (kappa=0.94). For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.91, and a signal-to-noise analysis with a signal-to-noise ratio of 0.98). The Committee agreed testing results showed the measure is reliable. As with the other measures submitted by the developer of this measure, the Committee strongly recommended that reliability testing for the clinician-level measure in the palliative care setting be updated and the results provided to NQF when available.
- Validity testing at the time of the 2012 endorsement evaluation included both a face validity assessment and a score-level construct validity analysis for the palliative care setting. Results from the empirical analysis indicated that clinical assessments of pain were statistically significantly different for seriously ill patients seen in specialty interdisciplinary palliative care consultations (67%) compared to those who did not receive these services (42%). These results confirmed the developers' hypothesis that a formal palliative care intervention would result in more frequent treatment of pain.
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission.
- Committee members did not express concern regarding the validity of the measure.

3. Feasibility: H-1; M-23; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

Rationale:

- Because the issues regarding feasibility for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program. However, members noted that feasibility of the measure for other settings is unclear.

4. Usability and Use: H-2; M-22; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Because the issues regarding usability and use for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays.
  - The measure is not currently in use for clinical-level accountability in the palliative care setting.

1637 Hospice and Palliative Care -- Pain Assessment

*Paired with #1634: Hospice and Palliative Care – Pain Screening

- Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement.
- The Committee did not report any unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure competes with three measures:
  - 0383: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology. Description: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain [*a clinician-level process measure in ambulatory setting*]
  - 1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits. Description: Adult patients with advanced cancer who are screened for pain with a standardized quantitative tool at each outpatient visit [*a facility-level, health plan, and integrated delivery system-level process measure in ambulatory setting*]
  - 1634: Hospice and Palliative Care -- Pain Screening. Description: Percentage of hospice or palliative care patients who were screened for pain during the hospice admission evaluation / palliative care initial encounter. [*clinician-level & facility-level process measure in hospice and hospital setting*]
- This measure is related to (potentially competing with) three measures:
  - 0209: Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment [a facility-level PRO-PM in the hospice setting]
  - 0384: Oncology: Medical and Radiation - Pain Intensity Quantified. Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified [*a clinician-level process measure in ambulatory setting*]
  - 0420: Pain Assessment and Follow-Up. Description: Percentage of patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present [*a clinician-level process measure in ambulatory setting*]
- Because #0209 was not recommended for endorsement by this Committee during the in-person meeting, a best-in-class and harmonization discussion was not conducted.
- Due to differences in care settings for measures #0383, #0384, #0420, and #1628, the Committee was not asked to select a best-in-class measure.
- Patients identified as being in pain per measure #1634 constitute the denominator for this measure #. The measures are already harmonized.
- The Committee discussed the measures specified for the ambulatory care setting (#0383, #0384, #0420, 1628):
  - Members noted the narrow denominators for #1628 (stage IV cancer) and #0384 (cancer patients undergoing chemotherapy or radiation). They questioned whether a separate measure for screening and assessment is needed. They suggested that including a focus on the care plan is a stronger measure. They noted that #0420 is already included in the PQRS program and has a much broader denominator (i.e., not limited to cancer patients). Finally, they recommended that all of these measures be combined so as to incorporate screening, assessment, documentation, and follow-up for the broadest patient population possible, with these things occurring at each visit, not just once.

1637 Hospice and Palliative Care -- Pain Assessment

*Paired with #1634: Hospice and Palliative Care – Pain Screening

Standing Committee Recommendation for Endorsement: **Y-24**; **N-0**

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

- NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure.
- One commenter expressed concern about inclusion of short-stay patients, recommending stratification of results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying.
    - ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits

Submission | Specifications

Description: Adult patients with advanced cancer who are screened for pain with a standardized quantitative tool at each outpatient visit

Numerator Statement: Outpatient visits from the denominator in which the patient was screened for pain (and if present, severity noted) with a quantitative standardized tool

Denominator Statement: Adult patients with advanced cancer who have at least 1 primary care or cancer-related/specialty outpatient visit

Exclusions: None (other than those patients noted in 2a1.7. who did not survive at least 30 days after cancer diagnosis)

Adjustment/Stratification:

Level of Analysis: Facility, Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: RAND Corporation

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **H-1; M-2; L-0; I-21**; 1b. Performance Gap: **H-0; M-15; L-2; I-7**

Evidence Exception: **Y-24; N-0**

Rationale:

- For the 2012 endorsement evaluation, the developers cited non-graded systematic reviews pertaining to cancer pain management that underscored the importance of pain screening, although they did not link screening for pain to improved patient outcomes. The developer did not provide updated evidence for the current evaluation.

1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits

- As with the other pain screening and assessment measures (#1634 and #1637, respectively), the Committee agreed that there is no empirical evidence linking screening for pain to improved patient outcomes. Because the Committee acknowledged the importance of pain management in patients with cancer, members agreed that empirical evidence is not needed to hold providers accountable for the measure and therefore invoked the exception to the evidence subcriterion.
- The developers provided performance data from four individual studies, with measure results ranging from 37% to 79%. However, these results were based on data that are more than five years old, and no current data on performance were provided. One Committee member referenced a 2014 study from the Veteran's Administration (VA) that found a 98% performance on the measure, raising the possibility the measure may be topped out, at least in VA outpatient clinics.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-2; M-19; L-2; I-1 2b**. Validity: **H-0; M-20; L-3; I-1**

<u>Rationale</u>:

- The numerator for this measure requires screening with a standardized tool, although if pain is present, the severity of pain also should be noted (an activity that also may be thought of as "assessment" for pain.
- Some Committee members questioned whether the measure denominator, which is limited to persons with Stage IV cancer, is too narrow, particularly given that patients who do not survive at least 30 days post-diagnosis are excluded from the measure.
- Members noted that the developers did not provide information on how many patients were excluded from the measure (due to the 30-day survival requirement), so it isn't clear whether this exclusion is needed. However, the Committee did not think this exclusion threatens the validity of the measure.
- For the 2012 endorsement evaluation, the developers cited one reliability study that found a kappa value of 0.87 for the denominator and 0.86 for the numerator (the actual methodology was not described). The developers did not provide updated reliability testing. After considering these results, Committee members voiced no concerns regarding the reliability of the measure.
- For the 2012 endorsement evaluation, developers referenced two face validity assessment of the measure by the ASSIST and ACOVE expert panels. The modified Delphi method was used for these assessments. The developers did not conduct updated validity testing for the current evaluation.
- While the Committee recognized face validity as a weaker form of validity testing than empirical testing, members agreed that the testing meets NQF's requirements for validity testing.

3. Feasibility: H-2; M-22; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee did not note any concerns regarding feasibility, acknowledging that some data elements used to construct this measure are available in electronic sources.

4. Usability and Use: H-0; M-9; L-15; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- This measure is not currently in use, even though it was conditionally supported by the MAP in 2014 for inclusion in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) program.
- One Committee member suggested that because this measure is limited to those with stage IV cancer

1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits

only, providers might not screen other cancer patients for pain, a potential unintended consequence.

- When questioned as to why this measure is not being used, the developers hypothesized that there is a perception that pain is being assessed in advanced cancer patients; they also noted an emphasis in the primary care setting in reducing opioid use. Committee members encouraged the developer to continue to pursue opportunities for use of this measure.

5. Related and Competing Measures

- This measure competes with three measures:
  - 0383: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology. Description: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain [*a clinician-level process measure in ambulatory setting*]
  - 1634: Hospice and Palliative Care -- Pain Screening [*a clinician-level & facility-level process measure in hospice and hospital setting*]
  - 1637: Hospice and Palliative Care -- Pain Assessment. Description: Percentage of hospice or palliative care patients who screened positive for pain and who received a clinical assessment of pain within 24 hours of screening [*clinician-level & facility-level process measure in hospice and hospital setting*]
- This measure is related to (potentially competing with) three measures:
  - 0209: Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment [a facility-level PRO-PM in the hospice setting]
  - 0384: Oncology: Medical and Radiation - Pain Intensity Quantified. Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified [*a clinician-level process measure in ambulatory setting*]
  - 0420: Pain Assessment and Follow-Up. Description: Percentage of patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present [*a clinician-level process measure in ambulatory setting*]
- Because #0209 was not recommended for endorsement by this Committee during the in-person meeting, a best-in-class and harmonization discussion was not conducted.
- Due to differences in care settings for measures #0383, #0384, #0420, and #1628, the Committee was not asked to select a best-in-class measure.
- Patients identified as being in pain per this measure constitute the denominator for measure #1637. The measures are already harmonized.
- The Committee discussed the measures specified for the ambulatory care setting (#0383, #0384, #0420, 1628):
  - Members noted the narrow denominators for #1628 (stage IV cancer) and #0384 (cancer patients undergoing chemotherapy or radiation). They questioned whether a separate measure for screening and assessment is needed. They suggested that including a focus on the care plan is a stronger measure. They noted that #0420 is already included in the PQRS program and has a much broader denominator (i.e., not limited to cancer patients). Finally, they recommended that all of these measures be combined so as to incorporate screening, assessment, documentation, and follow-up for the broadest patient population possible, with each occurring at each visit, not just once.

Standing Committee Recommendation for Endorsement: **Y-24**; **N-0**

6. Public and Member Comment: June 20- July 19, 2016

1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits
Comments received: • NQF received 3 post-evaluation comments on this measure, all of which were supportive of the measure. • One commenter expressed concern about the denominator, suggesting both patients with less advanced cancers and those who die within a month of diagnosis would also benefit from outpatient screening.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Physical aspects of care (dyspnea)

1639 Hospice and Palliative Care -- Dyspnea Screening *Paired with #1638: Hospice and Palliative Care - Dyspnea Treatment
Submission | Specifications
Description: Percentage of hospice or palliative care patients who were screened for dyspnea during the hospice admission evaluation / palliative care initial encounter. **Numerator Statement**: Patients who are screened for the presence or absence of dyspnea and its severity during the hospice admission evaluation / initial encounter for palliative care. **Denominator Statement**: Patients enrolled in hospice OR patients receiving hospital-based palliative care for 1 or more days. **Exclusions**: Patients with length of stay < 1 day in palliative care. **Adjustment/Stratification**: **Level of Analysis:** Facility, Clinician : Group/Practice **Setting of Care:** Hospice, Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record **Measure Steward**: University of North Carolina-Chapel Hill
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: Consensus was not reached on the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-0**; **M-3**; **L-1**; **I-19**; 1b. Performance Gap: **H-0**; **M-11**; **L-12**; **I-0;** Evidence Exception: **Y-22; N-1** Rationale: • For the 2012 endorsement evaluation, the developers cited systematic reviews and clinical guidelines that support dyspnea treatment, and drew a causal link between screening and treatment. However, the studies did not directly examine the link between dyspnea screening and patient outcomes. For the current evaluation, the developer updated the evidence by referencing a 2011 British Columbia Medical Services Commission guideline calling for the assessment of dyspnea severity, and a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults that recommends frequent evaluation of the physical aspects of the patient's serious illness. • One Committee member referenced a study not provided by the developer that found as the severity of dyspnea increased, based on the Edmonton Symptom Assessment Scale, symptom-related actions such as referrals, treatments, or prescriptions also increased (Seow, et al., 2012). While other Committee members found this information compelling, they were reluctant to accept it at face value without an

1639 Hospice and Palliative Care -- Dyspnea Screening

*Paired with #1638: Hospice and Palliative Care - Dyspnea Treatment

opportunity to review. Instead, the Committee noted that screening is required prior to treatment and agreed that empirical evidence is not needed to hold providers accountable for the measure. Therefore, the Committee agreed to invoke the exception to the evidence subcriterion.

- Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 97.3%. Additional data presented by the developer indicate slight, yet statistically significant, disparities in care between certain racial, socioeconomic, and geographic subgroups in the hospice setting.
- Developers did not provide clinician-level performance data for palliative care in the hospital setting. However, they noted that the measure is being used in a variety of palliative care settings through on-going Center for Medicare & Medicaid Innovation (CMMI) and Palliative Care Research Cooperative projects, and indicated that clinician-level performance data will be available within the coming year.
- The Committee did not reach consensus on whether the measure results demonstrate opportunity for improvement, noting the high performance rate for the hospice setting but indication of disparities in care in that setting, but lack of information about opportunity for improvement for the clinician level of analysis in the hospital setting.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-4; M-19; L-0; I-0** 2b. Validity: **H-2; M-21; L-0; I-0**

Rationale:

- When last endorsed, patients with a hospice stay of <7 days were excluded from the measure denominator. Developers have changed this specification and now no longer exclude any hospice patients because of length of stay (although patients with <1 day in hospital palliative care are excluded from the clinician-level measure).
- Reliability testing at the time of the 2012 endorsement evaluation was limited to an inter-rater reliability analysis based on data from 20 patients in one hospital (kappa=.91). For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.83, and a signal-to-noise analysis with a signal-to-noise ratio of 0.98). The Committee voiced no concerns regarding reliability for the hospice setting. As with the other measures submitted by the developer of this measure, the Committee strongly recommended that reliability testing for the clinician-level measure in the palliative care setting be updated and the results provided to NQF when available.
- Validity testing at the time of the 2012 endorsement evaluation included both a face validity assessment and a score-level construct validity analysis for the palliative care setting. Results from the empirical analysis indicated that screening for dyspnea was statistically significantly different for seriously ill patients seen in specialty interdisciplinary palliative care consultations (100%) compared to those who did not receive these services (95%). These results confirmed the developers' hypothesis that a formal palliative care intervention would result in more frequent screening for dyspnea.
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission.
- Committee members did not express concern regarding the validity of the measure for either level of analysis.

3. Feasibility: H-1; M-23; L-0; I-0

1639 Hospice and Palliative Care -- Dyspnea Screening

*Paired with #1638: Hospice and Palliative Care - Dyspnea Treatment

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3d. Data collection strategy can be implemented)

Rationale:

- Because the issues regarding feasibility for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
    - The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program. However, members noted that feasibility of the measure for other settings is unclear.

4. Usability and Use: H-2; M-22; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Because the issues regarding usability and use for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
    - This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays.
    - The measure is not currently in use for clinical-level accountability in the palliative care setting.
    - Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement.
    - The Committee did not report any unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure is related to two measures:
    - 0179: Improvement in dyspnea. Description: Percentage of home health episodes of care during which the patient became less short of breath or dyspneic
    - 1638: Hospice and Palliative Care – Dyspnea Treatment. Description: Percentage of patients who screened positive for dyspnea who received treatment within 24 hours of screening
- Measure #0179 is an outcome measure used in the home health setting, and as such, there are no harmonization issues.
- Measure #1638 is paired with this measure. Patients identified as having shortness of breath per this measure constitute the denominator for measure #1638.
-

Standing Committee Recommendation for Endorsement: **Vote not taken.**

Rationale

- Because the Committee did not reach consensus on subcriterion 1b (Opportunity for Improvement), the Committee did not vote on a recommendation for endorsement. The Committee will vote on a recommendation for endorsement on the August 3, 2016 post-comment call.

6. Public and Member Comment: June 20- July 19, 2016; Post-Comment Call: August 3, 2016

Comments received:

1639 Hospice and Palliative Care -- Dyspnea Screening

*Paired with #1638: Hospice and Palliative Care - Dyspnea Treatment

- NQF received 5 post-evaluation comments on this measure, 4 of which were supportive of the measure.
- One commenter expressed concern about inclusion of short-stay patients, recommending stratification of results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying.
    - ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.

Developer response regarding performance gap (opportunity for improvement):

- To address the Committee's lack of consensus on opportunity for improvement, the developer submitted preliminary performance data for the measure in the hospital-based palliative care setting. These results, which were based on data from 895 patients admitted to an acute care hospital for at least 1 day from January 2014 to June 2015, indicated that 81.8% of patients were screened for dyspnea.

Committee response:

- After discussion, the Committee re-voted on the Performance Gap subcritierion. Upon revote, the Committee agreed that there is opportunity for improvement for dyspnea screening in the hospital-based palliative care setting. .

Vote Following Consideration of Public and Member Comments:

Performance Gap: **H-0**; **M-18**; **L-0**; **I-0**

Standing Committee Overall Recommendation for Endorsement: **Y-18**; **N-0**

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1638 Hospice and Palliative Care -- Dyspnea Treatment

*Paired with #1639: Hospice and Palliative Care - Dyspnea Screening

Submission | Specifications

Description: Percentage of patients who screened positive for dyspnea who received treatment within 24 hours of screening.

Numerator Statement: Patients who screened positive for dyspnea who received treatment within 24 hours of screening.

Denominator Statement: Patients enrolled in hospice OR patients receiving hospital-based palliative care for 1 or more days.

Exclusions: Patients with length of stay < 1 day in palliative care, patients who were not screened for dyspnea, and/or patients with a negative screening.

Adjustment/Stratification:

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospice, Hospital/Acute Care Facility

Type of Measure: Process

1638 Hospice and Palliative Care -- Dyspnea Treatment

*Paired with #1639: Hospice and Palliative Care - Dyspnea Screening

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: University of North Carolina-Chapel Hill

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-3**; **M-18**; **L-1**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developers summarized systematic reviews of studies supporting the use of coping or relaxation interventions, as well as opioids (for breathlessness), beta agonists (for COPD patients), and oxygen (for hypoxic patients). For the current evaluation, the developer updated the evidence by referencing a 2011 British Columbia Medical Services Commission guideline for palliative care for patients with incurable cancer or advanced disease that recommends both pharmacological and non-pharmacological treatment options for dyspnea, and a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults that recommends addressing physical aspects of care.
- The Committee agreed that the updated evidence appears to be directionally the same since the last NQF endorsement evaluation. The Committee accepted the prior evaluation of this criterion without further discussion.
- Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 93.3%. Additional data presented by the developer indicate possible disparities in care for non-white and lower-income hospice patients.
- Developers did not provide clinician-level performance data for palliative care in the hospital setting. However, they noted that the measure is being used in a variety of palliative care settings through on-going Center for Medicare & Medicaid Innovation (CMMI) and Palliative Care Research Cooperative projects, and indicated that clinician-level performance data will be available within the coming year.
- The Committee acknowledged the relatively high performance in most hospices but noted an opportunity for improvement for some. Members also agreed that there is likely still room for improvement in the broader palliative care community, even though clinician-level performance results are not yet available.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-0**; **M-20**; **L-2**; **I-0** 2b. Validity: **H-1**; **M-23**; **L-0**; **I-0**

Rationale:

- When last endorsed, patients with a hospice stay of <7 days were excluded from the measure denominator. Developers have changed this specification and now no longer exclude any hospice patients because of length of stay (although patients with <1 day in hospital palliative care are excluded from the clinician-level measure).
- Because implementation instructions for the HIS use the term "initiate" in reference to treatment, Committee members questioned whether continuation of treatment would meet the measure. The developer clarified that the measure specifies receipt of treatment, which would encompass both initiation and continuation or modification of treatment. Committee members recommended that the HIS instructions be clarified to match the specifications of the measure.
- One member questioned whether treatment should be initiated when the score on the dyspnea screening is very low. The developers acknowledged that there is not a clear threshold for initiation of dyspnea treatment and therefore constructed the measure to assess whether providers address any

1638 Hospice and Palliative Care -- Dyspnea Treatment

*Paired with #1639: Hospice and Palliative Care - Dyspnea Screening

patient who screened as being short of breath. They also noted that treatment, as specified in the measure, does not have to include medication therapy. Committee members noted that some patients who report being short of breath prefer not to be treated.

- Reliability testing at the time of the 2012 endorsement evaluation was limited to an inter-rater reliability analysis based on data from 20 patients in one hospital (kappa=0.89). For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.86, and a signal-to-noise analysis with a signal-to-noise ratio of 0.96).
- The Committee voiced no concerns regarding reliability for the hospice setting. However, members acknowledged the limited scope of testing for the palliative care setting and noted uncertainty around the ability to consistently identify patients for the denominator. The Committee strongly recommended that the developer update reliability testing for the clinician-level measure in the palliative care setting and provide those results to NQF when available.
- Validity testing at the time of the 2012 endorsement evaluation included both a face validity assessment and a score-level construct validity analysis for the palliative care setting. Results from this analysis indicated that treatment for dyspnea was not statistically significantly different for seriously ill patients seen in specialty interdisciplinary palliative care consultations (96%) compared to those who did not receive these services (93%). These results only partially confirmed the developers' hypothesis that a formal palliative care intervention would result in more frequent treatment of dyspnea.
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission. The Committee voiced no concerns regarding the validity testing results.
- Committee members questioned whether removal of the <7 day length of stay exclusion for the hospice setting might disadvantage agencies who tend to get referrals late in the day. The developers noted that their exclusion analysis indicated that this likely would not be a problem, as most hospices are able to treat dyspnea within the 24-hour period required by the measure.

3. Feasibility: H-1; M-23; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3d. Data collection strategy can be implemented)

Rationale:

- The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program. However, members noted that feasibility of the measure for other settings is unclear.

4. Usability and Use: H-2; M-22; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays.
- The measure is not currently in use for clinical-level accountability in the palliative care setting.

1638 Hospice and Palliative Care -- Dyspnea Treatment *Paired with #1639: Hospice and Palliative Care - Dyspnea Screening
• Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement. • The Committee did not report any unintended consequences associated with this measure.
5. Related and Competing Measures • This measure is related to two measures: o 0179: Improvement in dyspnea. Description: Percentage of home health episodes of care during which the patient became less short of breath or dyspneic o 1639: Hospice and Palliative Care – Dyspnea Screening. Description: Percentage of hospice or palliative care patients who were screened for dyspnea during the hospice admission evaluation / palliative care initial encounter • Measure #0179 is an outcome measure used in the home health setting, and as such, there are no harmonization issues. • Measure #1639 is paired with this measure. Patients identified as having shortness of breath in measure #1639 constitute the denominator for this measure (#1638).
Standing Committee Recommendation for Endorsement: **Y-21**; **N-2**
6. Public and Member Comment: June 20- July 19, 2016 Comments received: • NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure. • One commenter expressed concern about inclusion of short-stay patients, recommending stratification of results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying. o ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Physical aspects of care (constipation)

1617 Patients Treated with an Opioid who are Given a Bowel Regimen
Submission | Specifications
Description: Percentage of vulnerable adults treated with an opioid that are offered/prescribed a bowel regimen or documentation of why this was not needed **Numerator Statement**: Patients from the denominator that are given a bowel regimen or there is documentation as to why this was not needed **Denominator Statement**: Vulnerable adults who are given a prescription for an opioid **Exclusions**: Non-hospice outpatients who are already taking an opioid at the time of the study period opioid prescription **Adjustment/Stratification**:

1617 Patients Treated with an Opioid who are Given a Bowel Regimen

Level of Analysis: Facility, Clinician : Group/Practice, Health Plan, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records

Measure Steward: RAND Corporation/UCLA

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-2**; **M-15**; **L-2**; **I-5**

Rationale:

- For the 2012 endorsement evaluation, the developers provided two clinical practice guideline recommendations for prescribing a bowel regimen (i.e., offer or prescription of a laxative, stool softener, or high-fiber supplement or diet within 24 hours of opioid prescription) when treating patients with an opioid; these recommendations were supported by moderate to strong evidence. A bowel regimen is needed because opioids cause constipation.
- The Committee agreed that there has been no new evidence and accepted the prior evaluation of this criterion without further discussion.
- For the current evaluation, the developers provided performance data from two individual studies using data from 2007-2010. Performance results from these studies ranged from 44% to 71% (Hanson, et al, 2012; Walling, et al, 2013). Although this measure is collected through the Hospice Item Set for the CMS Hospital Quality Reporting Program, the developer did not have access to these more current data.
- The Committee acknowledged that the performance data reported by the developer was somewhat old, but for the most part agreed that there is still an opportunity for improvement for this measure.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-0; M-18; L-4; I-2** 2b. Validity: **H-0; M-17; L-3; I-4**

Rationale:

- Committee members expressed concerns that limiting the denominator of the measure to "vulnerable adults" as defined in the specifications (i.e., age 75 or older; score >2 on the Vulnerable Elder Survey-13, life expectancy <6 months, Stage IV cancer, receiving hospice care) would not capture important patient populations, such as those with acute respiratory failure. Committee members recommended broadening the denominator to include all palliative care and cancer patients.
- The developers clarified that non-hospice outpatients already taking an opioid at the time of measurement were excluded from the measure because they may not have needed a bowel regimen, having already been prescribed one.
- Some members expressed concern that those whose cancer had progressed to stage IV might inadvertently be excluded from the measure if they had not been formally re-staged. The developers clarified that the guidance for the measure does not rely on the term "stage IV" but instead uses various synonyms (e.g., metastatic) to identify patients with stage IV cancer.
- When questioned about the difficulty in abstracting the elements needed to define the denominator, the developers clarified that patients meeting any one of these criteria would be included in the denominator. They noted that in their testing of the measure, there is usually specific language in the medical record that identifies those with stage IV cancer or with a poor prognosis/terminal illness. They also stated that the Vulnerable Elder Survey-13 is used fairly widely, although they acknowledged that it is not available uniformly.

1617 Patients Treated with an Opioid who are Given a Bowel Regimen
• For the 2012 endorsement evaluation, the developers provided inter-rate reliability statistics from three studies in which the kappa value for the denominator was 0.87 and the kappa value for the numerator was 0.64 to 0.86, indicating acceptable agreement. The developers did not provide updated reliability testing. Because there was concern among some members about consistently identifying the patients eligible for the denominator, the Committee wanted to vote on the measure rather than accept the prior Committee's evaluation of this criterion. • For the 2012 endorsement evaluation, developers referenced four face validity assessments of the measure by expert panels. The modified Delphi method was used for these assessments. The developers did not conduct updated validity testing for the current evaluation.
3. Feasibility: H-0; M-24; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)* Rationale: • Although the measure is specified for paper medical records, the Committee suggested that the measure likely could be extracted from electronic medical records. The developers agreed, although they noted that identifying the exclusions in the EHR might be difficult as several of those data elements likely are not in structured data fields.
4. Usability and Use: H-3; M-20; L-1; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. • Longitudinal data for this measure are not yet available and there is therefore no information regarding improvement. • Committee members did not report any awareness of unintended consequences of the measure.
5. Related and Competing Measures • The definition of "vulnerable adults" is harmonized with measure #1626.
Standing Committee Recommendation for Endorsement: Y-24; N-0
6. Public and Member Comment: June 20- July 19, 2016 Comments received: • NQF received 3 post-evaluation comments on this measure, all of which were supportive of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Spiritual, religious, and existential aspects of care

1647 Beliefs and Values - Percentage of hospice patients with documentation in the clinical record of a discussion of spiritual/religious concerns or documentation that the patient/caregiver did not want to discuss.
Submission | Specifications
Description: This measure reflects the percentage of hospice patients with documentation of a discussion of spiritual/religious concerns or documentation that the patient/caregiver/family did not want to discuss.

1647 Beliefs and Values - Percentage of hospice patients with documentation in the clinical record of a discussion of spiritual/religious concerns or documentation that the patient/caregiver did not want to discuss.

Numerator Statement: Patients whose medical record includes documentation that the patient and/or caregiver was asked about spiritual/existential concerns within 5 days of the admission date.

Denominator Statement: Seriously ill patients 18 years of age or older enrolled in hospice.

Exclusions: Testing has only been done with the adult population; thus patients younger than 18 are excluded.

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospice

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: University of North Carolina-Chapel Hill

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **H-1; M-8; L-0; I-14**; 1b. Performance Gap: **H-0; M-23; L-0; I-0**

Evidence Exception: **Y-22; N-1**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, the developers noted that no formal studies of this care process exist. However, the developer cited a National Consensus Project guideline and an NQF-endorsed Preferred Practice as evidence for the measure. A non-published study presented to the 2012 Steering Committee showed that patients whose records documented a conversation of their spiritual or religious concerns demonstrated improvement in overall spiritual distress, as opposed to those whose records did not document this conversation. For the current evaluation, the developer updated the evidence by referencing a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults that states that "A spiritual assessment should be an integral part of the palliative care plan."
- The Committee agreed that based on expert opinion presented and other research, the care process measured is important, desired by patients and their family members, and may result in decreased spiritual distress, thereby warranting an exception to the evidence criteria.
- Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 92.2%. Additional data presented by the developer indicate statistically significant disparities in care between certain racial, socioeconomic, and geographic subgroups.
- The Committee agreed that the measure performance reflected a significant opportunity for improvement. One Committee member noted other settings of care for which this measure is not specified, such as acute care and outpatient settings, show a still greater opportunity for improvement.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-12; M-11; L-0; I-0** 2b. Validity: **H-0; M-21; L-0; I-2**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, developers conducted data element validity testing but no additional reliability testing for the facility level of analysis. For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.94, and a signal-to-noise analysis with a signal-to-noise ratio of 0.99). The Committee voiced no concerns regarding the

1647 Beliefs and Values - Percentage of hospice patients with documentation in the clinical record of a discussion of spiritual/religious concerns or documentation that the patient/caregiver did not want to discuss.

reliability of the measure.

- Validity testing at the time of the 2012 endorsement evaluation compared agency-abstracted data to that abstracted by a research study abstractor (the gold standard), yielding a kappa value of 0.795 and indicating acceptable agreement.
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. The developer clarified that the "modification" of the measure for testing allows 5-day allowance for the initial comprehensive assessment, as implemented by CMS for the Hospice Item Set (HIS). The developers noted that this is consistent with the measure specifications that require discussion of spiritual/existential concerns within 5 days of the admission date. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission.
- Committee members did not express concern regarding the validity of the measure.

3. Feasibility: H-1; M-23; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3d. Data collection strategy can be implemented)

Rationale:

- Because the issues regarding feasibility for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program.

4. Usability and Use: H-2; M-22; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Because the issues regarding usability and use for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
  - This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays.
  - Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement.
  - The Committee did not report awareness of unintended consequences associated with this measure.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-22; N-1**

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

1647 Beliefs and Values - Percentage of hospice patients with documentation in the clinical record of a discussion of spiritual/religious concerns or documentation that the patient/caregiver did not want to discuss.
• NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure. • One commenter expressed concern about inclusion of short-stay patients, recommending stratification of results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying. o ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Ethical and legal aspects of care

1626 Patients Admitted to ICU who Have Care Preferences Documented
Submission | Specifications
Description: Percentage of vulnerable adults admitted to ICU who survive at least 48 hours who have their care preferences documented within 48 hours OR documentation as to why this was not done. **Numerator Statement**: Patients in the denominator who had their care preferences documented within 48 hours of ICU admission or have documentation of why this was not done. **Denominator Statement**: All vulnerable adults admitted to ICU who survive at least 48 hours after ICU admission. **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Facility **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Paper Medical Records **Measure Steward**: RAND Corporation
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-0**; **M-24**; **L-0**; **I-0**; 1b. Performance Gap: **H-1; M-22; L-0; I-1;** <u>Rationale</u>: • For the 2012 endorsement evaluation, the developers cited two systematic reviews linking advance care planning to better patient outcomes and providing evidence that patients want to communicate their care preferences to their physicians. No updated evidence was submitted for the current evaluation. However, Committee members referenced additional guideline recommendations released since the 2012 evaluation and included in the submission for measure #1641; these recommendations support advance care planning and shared decision making. • The Committee noted that the evidence presented does not pertain to the *documentation* of the care preferences themselves as much as to the importance of care preferences and the discussion around those.

1626 Patients Admitted to ICU who Have Care Preferences Documented

- For the 2012 endorsement evaluation, the developers provided performance data from four individual studies with measure results ranging from 9% to 63.7%. However, these results were based on data that are more than five years old, and no updated performance data was presented for the current evaluation. However, using their own experience and judgement, Committee members agreed that there still is opportunity for improvement, and suggested there may be disparities in care for this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0**; **M-13**; **L-8**; **I-3** 2b. Validity: **H-0**; **M-8**; **L-11**; **I-5**

<u>Rationale</u>:

- Committee members expressed concerns that limiting the denominator of the measure to 'vulnerable adults' as defined in the specifications (i.e., age 75 or older; score >2 on the Vulnerable Elder Survey-13, life expectancy <6 months, Stage IV cancer, receiving hospice care) would not capture important patient populations, including patients with acute respiratory failure.
- The developer clarified that the timing of the admission to ICU "begins" when the admission orders are written.
- Committee members asked the developers to explain the numerator requirement of having "care preferences documented within 48 hours of ICU admission", noting that the submission also indicates that "simply having an advance directive or other advance care planning document or POLST in the medical record does not satisfy this criterion". The developers clarified that the measure assesses whether a discussion regarding care preferences with either the patient or the family occurred within 48 hours of ICU admission and that discussion could be with non-ICU providers and could occur during the hospitalization but prior to the ICU admission. The developers noted that care preference information may not always be included in an advance directive and further clarified that existence of an advance directive in the record is not sufficient.
- For the 2012 endorsement evaluation, the developers provided inter-rater reliability statistics from two studies in which the kappa value for the denominator was 0.87 to 0.95 and the kappa value for the numerator was 0.86 to 0.87 and 0.86, indication acceptable agreement. The developers did not provide updated reliability testing.
- The Committee <u>did not reach consensus</u> on reliability of the measure due to concerns about the ability to consistently apply the numerator specifications.
- Validity testing at the time of the 2012 endorsement evaluation included three face validity assessments by three expert panels using a modified Delphi method. Developers did not update validity testing for the current evaluation.
- This measure did not pass the validity subcriterion. Committee members noted that one of the face validity assessments was specific to cancer patients only, that none of the face validity assessments were specific to ICU patients, and that this measure was not assessed specifically but was instead discussed more generally.

3. Feasibility: H-X; M-X; L-X; I-X

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures

1626 Patients Admitted to ICU who Have Care Preferences Documented

- This measure is related to one measure:
  - 1617: Patients Treated with an Opioid who are Given a Bowel Regimen
- The definition of "vulnerable adults" is harmonized between this measure and #1617.

- This measure directly competes with two measures:
  - 0326: Advance Care Plan. Description: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan [*individual and clinician group/practice-level measure in various settings including hospital and hospice*]
  - 1641: Hospice and Palliative Care – Treatment Preferences. Description: Percentage of patients with chart documentation of preferences for life sustaining treatments [*clinician group/practice- and facility-level measure in hospitals and hospice*]
- Because this measure did not meet the Validity subcriterion, there was no need for a best-in-class discussion between this measure and the other competing measures.

Standing Committee Recommendation for Endorsement: **DID NOT PASS SCIENTIFIC ACCEPTABILITY**

Rationale

- The Committee did not feel that the face validity assessments that were conducted for this measure were specific enough.

6. Public and Member Comment: June 20- July 19, 2016; Post-comment call: August 3, 2016

Comments received:

- One commenter supported the Committee's decision not to recommend the measure for continued endorsement.
- Two commenters did not support the Committee's decision
- One commenter requested that the Committee reconsider the measure after obtaining additional information and clarification regarding the measure specification.
- One commenter noted the importance of emergency, critical, and advance care plans and provided specific suggestions on ensuring these are available to healthcare providers.
- The developer of the measure formally requested a reconsideration of the measure due to inappropriate application of the evaluation criteria:
  - We are requesting that the Committee reconsider the measure that was considered for maintenance. First, regarding the concerns about face validity, while it is true that one of the panels was cancer only, each measure was reviewed individually at each expert panel for face validity and only those that met the criteria as explained in provided documents were considered to be valid. This measure was considered to have face validity by these expert panels. I think the panel may have been confused by a paragraph in the measure testing document that talks about a higher level of evidence for validity (the process-outcome link). For this higher level of validity, there is only data in aggregate. Second, regarding the reliability of the measure we provided kappa statistics in the reliability section that showed high inter-rater reliability showing that we were able to reliably collect this data using the proposed specifications.

Committee response:

- To address its concerns regarding the reliability of the measure, the Committee asked the developer to clarify the numerator specifications so that members could understand how the measure can be met.

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The developer noted that simply having an advance directive in the record does not meet the measure numerator's inclusion criteria. However, annotation of a conversation with the patient or family (within the proper timeframe) regarding treatment preferences, would family satisfy the inclusion criteria, with the assumption that if an advance directive is available in the patient record, it would inform treatment choices and/or be reviewed with the patient or family. The developer also noted that documentation of a reason why the conversation did not occur would also meet the measure (e.g., surrogate decision maker is unavailable). Based on these clarifications regarding the measure numerator, the Committee agreed to re-vote on the Reliability subcriterion.

- Based on the developers clarification that the face validity of the measure was explicitly evaluated by three expert panels (using the same procedures as those described for measures #1617, #1624, and #1628) and on NQF staff clarification that updated validity testing is not required, the Committee agreed to re-vote on the Validity subcriterion. One member, however, expressed concern regarding the validity of the measure because the measure can be met if there documentation of a reason why a preferences conversation was not held.
- Because the measure passed the Reliability and Validity subcriteria upon re-vote, the Committee then discussed and voted on the Feasibility and Usability and Use criteria.
- Feasibility
    - The Committee questioned the developer about the feasibility of data collection for this measure by small hospitals. The developers responded that the feasibility of the measure should not vary by hospital size (if that hospital actually has an ICU).
    - The Committee asked the developer whether it was feasible to collect data for the measure from electronic health records (EHRs), even though the measure currently is specified for paper records only. The developers noted a study conducted by one of the developers where the measure was abstracted from the EHR system used within the Veterans Health Administration, stating that the process of abstraction was very similar to, and perhaps somewhat easier than, the process for paper records. which and reported that feasibility issues were not identified with for those abstracting data from an EHR
- Usability and Use
    - This measure is not currently in use, although it was supported by the MAP in 2013 for inclusion in the PQRS program (a clinician-level program).
    - Longitudinal data for this measure are not available and there is therefore no information regarding improvement.
    - The developer noted that the measure is referenced in the VA´s draft handbook for planned Life Sustaining Treatment policy, but knew of no other plans for use. The developers did note, however, that they are pursuing avenues to "convert" the measure to an eMeasure, potentially through use of natural language processing. The Committee encouraged the developer to seek out opportunities to implement this measure.
- Related/Competing discussion, comparing this measure to measures #0326 and #1641
    - Committee members noted the additional care settings for the measures, and justified the need for this measure as one that emphasizes the importance of advance care planning—and particularly the review of previously-recorded advance care plans—on admission to the ICU, which itself indicates a substantial change in treatment plan or clinical condition.

Vote Following Consideration of Public and Member Comments:

Reliability: **H-0**; **M-12**; **L-5**; **I-0**

Validity: **H-0**; **M-15**; **L-4**; **I-0**

Feasibility: **H-0; M-16; L-1; I-0**

1626 Patients Admitted to ICU who Have Care Preferences Documented
Usability and Use: **H-0; M-11; L-7; I-0** Standing Committee Overall Recommendation for Endorsement: **Y-18**; **N-0**
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

1641 Hospice and Palliative Care – Treatment Preferences
Submission | Specifications
Description: Percentage of patients with chart documentation of preferences for life sustaining treatments. **Numerator Statement**: Patients whose medical record includes documentation of life sustaining preferences **Denominator Statement**: Seriously ill patients enrolled in hospice OR receiving specialty palliative care in an acute hospital setting. **Exclusions**: Patients with length of stay < 1 day in hospice or palliative care **Adjustment/Stratification**: **Level of Analysis:** Facility, Clinician : Group/Practice **Setting of Care:** Hospice, Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record **Measure Steward**: University of North Carolina-Chapel Hill
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. **Previous Evidence Evaluation Accepted** 1b. Performance Gap: **H-2**; **M-18**; **L-2**; **I-0;** Rationale: • For the 2012 endorsement evaluation, the developers cited individual studies and systematic reviews that support the link between high-quality communication and reduced ICU utilization, family distress, and use of intensive treatments. However, the studies did not directly examine the link between *documentation* of care preferences and patient or family outcomes. For the current evaluation, the developer updated the evidence by referencing a 2014 Michigan Quality Improvement Consortium guideline calling for the incorporation of the patient's treatment preferences and choices into the Treatment Preferences portion of the Advance Directive, and a 2013 Institute for Clinical Systems Improvement (ICSI) guideline on palliative care for adults that recommends facilitating advance care planning along with regular review as for all adult patients and their families, as well as engaging in shared decision-making. • The Committee agreed that the updated evidence appears to be directionally the same since the last NQF endorsement evaluation. The Committee accepted the prior evaluation of this criterion without further discussion. • Facility-level data presented by the developer from the FY15 Hospice Item Set (HIS)—used to collect data from the more than 90% of hospices that participate in the CMS Hospice Quality Reporting Program—indicate an average hospice facility-level performance rate of 98.0%. Additional data presented by the developer indicate slight, yet statistically significant, disparities in care between certain racial, socioeconomic, and geographic subgroups. • Developers did not provide clinician-level performance data for palliative care in the hospital setting.

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However, they noted that the measure is being used in a variety of palliative care settings through on-going Center for Medicare & Medicaid Innovation (CMMI) and Palliative Care Research Cooperative projects, and indicated that clinician-level performance data will be available within the coming year.

The Committee agreed that there may be limited opportunity for further improvements in performance for the hospice setting, although members noted the possibility of disparities in care for this setting. Members also agreed that there may be room for improvement in the broader palliative care community.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-2**; **M-20**; **L-0**; **I-0** 2b. Validity: **H-0**; **M-22**; **L-0**; **I-0**

<u>Rationale</u>:

- When last endorsed, patients with a hospice stay of <7 days were excluded from the measure denominator. Developers have changed this specification and now no longer exclude any hospice patients because of length of stay (although patients with <1 day in hospital palliative care are excluded from the clinician-level measure).
- When questioned by the Committee, the developers clarified that the measure requires evidence of a <u>discussion</u> with the patient (or with the surrogate decision-maker if the patient has lost decisional capacity) and that simply having the preferences included in the patient record (e.g., via a living will or a Do-Not-Resuscitate order) is not sufficient to meet the quality measure. One member noted that the numerator requirements are well-described in the Hospice Item Set manual. Reliability testing at the time of the 2012 endorsement evaluation was limited to an inter-rater reliability analysis based on data from 20 patients in one hospital (kappa=1.0). For the current evaluation, developers updated their reliability testing by providing score-level testing results for the hospice setting from two different analyses (a split-half analysis with an intra-class correlation coefficient of 0.91, and a signal-to-noise analysis with a signal-to-noise ratio of 0.98). The Committee voiced no concerns regarding reliability for the hospice setting. As with the other measures submitted by this developer, the Committee strongly recommended that reliability testing for the clinician-level measure in the palliative care setting be updated and the results provided to NQF when available.
- Validity testing at the time of the 2012 endorsement evaluation included both a face validity assessment and a score-level construct validity analysis for the palliative care setting. Results from this analysis indicated documenting treatment preferences was statistically significantly different for seriously ill patients seen in specialty interdisciplinary palliative care consultations (91%) compared to those who did not receive these services (59%).
- For the current evaluation, developers updated their validity testing by conducting a non-parametric Spearman rank correlation analysis between this measure and 5 other hospice quality measures. Although the magnitude of the correlations from this analysis was lower than expected, they were positive and statistically significant, confirming the developers' hypothesis that hospice agencies perform similarly on various assessment activities conducted at the time of hospice admission.
- Committee members did not express concern regarding the validity of the measure.

3. Feasibility: H-1; M-23; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

<u>Rationale</u>:

- Because the issues regarding feasibility for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows:
    - The Committee noted that because data for this measure is part of the Hospice Item Set (HIS), the feasibility is high for the hospice setting. The HIS is a standardized, patient-level dataset used

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by CMS to collect data and calculate the seven performance measures included in the Medicare Hospice Quality Reporting Program. However, members noted that feasibility of the measure for other settings is unclear.
4. Usability and Use: H-2; M-22; L-0; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • Because the issues regarding usability and use for this measure are the same as those for measure #1638, the Committee agreed to carry over both the discussion and votes, as follows: o This measure is included in the CMS Hospice Quality Reporting Program (HQRP), an accountability program in which hospice providers are penalized financially if results are not reported to CMS. In FY2015, 3,992 hospice organizations provided measure data for 1,218,786 patient stays. o The measure is not currently in use for clinical-level accountability in the palliative care setting. o Because reporting of this measure for the hospice setting began in FY2015, longitudinal data for this measure for this setting are not yet available and there is therefore no information regarding improvement. o The Committee did not report awareness of any unintended consequences associated with this measure.
5. Related and Competing Measures • This measure competes with two measures: o 1626: Patients admitted to the ICU who have care preferences documented. Description: Percentage of vulnerable adults admitted to ICU who survive at least 48 hours who have their care preferences documented within 48 hours OR documentation as to why this was not done. o 0326: Advance Care Plan. Description: The percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. Because #1626 was not recommended for endorsement, the Committee was not asked to select the superior measure. • The Committee largely agreed that advance care planning—which can be done well in advance of a terminal illness may not be specific in regards to treatment preferences—and discussion of life-sustaining treatment preferences—which includes specific decisions such as use of feeding tubes, ventilators, hydration, etc. and is often done later in life or at a certain stage of a terminal illness—are sufficiently different to require two measures to appropriately capture healthcare provider performance. Several members also emphasized that preferences regarding treatment preferences often change over the course of a terminal illness. However, one Committee member suggested that advance care planning should be broaden to include specific treatment preferences, which could be revisited over time, and thus a consolidated measure could be constructed. Committee members noted that a strength of measure #0326 is its primary care setting and agreed that it should be broadened to include all patients 18 years and older.
Standing Committee Recommendation for Endorsement: **Y-22**; **N-0**
6. Public and Member Comment: June 20- July 19, 2016 Comments received: • NQF received 7 post-evaluation comments on this measure, all of which were supportive of the measure. • One commenter expressed concern about inclusion of short-stay patients, recommending stratification of

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results for patients with length of stay <7 days and an exclusion for those patients who are imminently dying. o ***Developer response*:** Results various statistical analyses show that applying or removing the inclusion of short-stay patients did not affect the measures scores. Moreover, a large portion of care processes, including pain screening, were performed on the first day of admission to hospice.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Care of the patient at the end of life

0210 Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life
Submission | Specifications
Description: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life **Numerator Statement**: Patients who died from cancer and received chemotherapy in the last 14 days of life **Denominator Statement**: Patients who died from cancer. **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Group/Practice **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data : Registry **Measure Steward**: American Society of Clinical Oncology
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-1**; **M-19**; **L-1**; **I-1**; 1b. Performance Gap: **H-1**; **M-21**; **L-0**; **I-0** <u>Rationale</u>: • For the 2012 endorsement evaluation, the developers cited three individual studies indicating continuing chemotherapy near death does not prolong survival and often results in undesirable outcomes (e.g. toxicity, inconvenience, increased costs, and lower patient rating of quality of care). The developer also cited a 2003 expert consensus statement that identified a short interval between last chemotherapy dose and death as an indicator of poor quality of end-of-life cancer care. • For the current evaluation, developers updated the evidence by referencing a 2013 Cochrane Collaborative systematic review that found that for patients with cancer, home-based palliative care services increases the chance of dying at home for patients with cancer and a 2012 provisional clinical opinion from the American Society of Clinical Oncology that recommends consideration of palliative care early in the course of illness for patients with metastatic cancer and/or high symptom burden • In general, the Committee agreed that the evidence presented during the 2012 evaluation was sufficient to support the measure at the time. However, some members noted that this older evidence does not speak to the relationship between newer chemotherapies (e.g., oral agents that may be less toxic than older chemotherapy options) to patient outcomes. One member cited a recent longitudinal, multi-site

0210 Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life

study by Prigerson et al. (2015) that was not included in the evidence submitted by the developer. Although this study demonstrated the relationship between chemotherapy at the end of-life and poor quality of life, it also did not include newer chemotherapies. Committee members noted that the performance rate for this measure should not be zero, as in some cases, a continuation of chemotherapy is beneficial. Members also noted that when considering this measure, the possibility of both potential harm as well as failure to benefit should be considered. The Committee eventually reached consensus that the evidence cited provided was sufficient for the measure.

- The developer provided group/practice level performance data from the ASCO Quality Oncology Practice Initiative registry (QOPI) for 2013-2015. The median performance score was 9.88 in 2013, 11.45 in 2014, and 11.95 in 2015, an increasing trend that might be explained by higher participation in the QOPI® registry. The developer provided additional practice-level disparities data after the Committee's workgroup call. The Committee agreed these data indicated potential disparities in care by sex and race. The Committee agreed there is substantial room for improvement for this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **H-22**; **M-0**; **L-0**; **I-0**

<u>Rationale</u>:

- This measure is specified for both claims and registry data. When questioned about identifying cancer deaths from claims data, the developer clarified that the denominator is derived from registry data (e.g., a death registry or other cancer registry that includes information on cancer deaths) while the numerator is derived from claims data.
- The Committee questioned the developer about inclusion of oral and other new biologics in the measure numerator. The developer clarified that the specifications include all anti-neoplastic agents except for hormonal therapies.
- For the 2012 evaluation, the developer conducted data element validity testing for the QOPI® registry data by, comparing QOPI® registry data to data that were re-abstracted from medical records by QOPI nurse abstractors, which was considered the gold standard (kappa=0.818, indicating acceptable agreement).
- For the 2012 evaluation, the developer conducted data element validity testing for the measure numerator for claims data by comparing claims for 150 consecutive patients treated for advanced cancer at Boston's Dana-Farber Cancer Institute and Brigham and Women´s Hospital to data from the full medical record (sensitivity=0.92; specificity=0.94). Although the developer did not conduct data element validity testing for the measure denominator, the Committee agreed that registry data (particularly death registry data), in general, are accurate and therefore additional testing is unnecessary.
- The developer did not provide any updated validity testing.
- The Committee again noted that the expected performance for this measure should not be zero, particularly for blood cancer. While members did not think this would be an argument for risk-adjustment at this point, the developers stated that they would consider this issue along with other risk-adjustment questions in the future
- The Committee agreed the previous validity testing demonstrated the scientific acceptability of the measure. Members accepted the prior evaluation of the reliability sub criterion without further discussion. Members did vote on validity because there was no empirical testing of the denominator (from claims or registry).

3. Feasibility: H-3; M-16; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Data collection strategy can be implemented)

0210 Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are available in claims and the QOPI® Registry.

4. Usability and Use: H-3; M-19; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used in the Quality Oncology Practice Initiative (QOPI), a practice-based quality improvement and benchmarking program, operated by the American Society of Clinical Oncology. The measure also is included in the PQRS program and is also a part of America's Health Insurance Plans (AHIP) Medical Oncology Core Measure Set. The AHIP effort is a collaboration of both public and private stakeholders to identify measures that are meaningful to patients, consumers, and physicians and to reduce variability in measure selection, collection burden, and cost. Payers involved in the collaboration have committed to using for reporting as soon as feasible. By virtue of being included in the AHIP measure set, CMS will consider this measure for inclusion in other Medicare quality programs.
- Data from 2013-2015 indicate mean practice performance slightly worsened from 11.47% of patients receiving chemotherapy in last 14 days of life to 13.16%. These results are based on data from the QOPI® registry and reflect slightly greater use of the registry over time, from 180 practices in 2013 to 222 in 2015.
- Neither the Committee nor the developers reported awareness of unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure is related to four measures:
  - 0213: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life
  - 0211: Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life
  - 0215: Proportion of patients who died from cancer not admitted to hospice
  - 0216: Proportion of patients who died from cancer admitted to hospice for less than 3 days
- These measures, all of which were developed by the American Society of Clinical Oncology, are harmonized to the extent possible.

Standing Committee Recommendation for Endorsement: **Y-22**; **N-0**

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

- NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0213 Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life

Submission | Specifications

Description: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life

Numerator Statement: Patients who died from cancer and were admitted to the ICU in the last 30 days of life

0213 Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life

Denominator Statement: Patients who died from cancer

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American Society of Clinical Oncology

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **H-2**; **M-20**; **L-0**; **I-0**; 1b. Performance Gap: **H-3**; **M-18**; **L-1**; **I-0;**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, the developers cited a 2011 study that examined trends in the aggressiveness of end-of-life (EOL) cancer care (including ICU admission within 30 days of death), and an expert consensus statement from 2003 that identified potential indicators of quality of end-of-life cancer care using administrative data.
- For the current evaluation, developers updated the evidence by referencing: a 2013 Cochrane Collaborative systematic review that evaluated the impact of home-based palliative care services on several patient and caregiver outcomes, which found that for patients with cancer, home-based palliative care services increases the chance of dying at home for patients with cancer; a 2012 provisional clinical opinion from the American Society of Clinical Oncology that recommends consideration of palliative care early in the course of illness for patients with metastatic cancer and/or high symptom burden; and two individual studies that support the relationship of reduced ICU visits to desired patient outcomes.
- The Committee also referenced an additional study of colorectal and lung cancer patients that found that ICU use in the last 30 days of life is did not align with patient preference and was associated with worse outcomes (Wright, et al., 2016). After considering this additional empirical evidence, the Committee agreed that there is a high certainty that benefits of avoiding the ICU in the last month of life outweighs undesirable effects.
- Although specified at the clinician group/practice level, the developers provided system-level performance data from two integrated health systems, one showing an increase from 20% in Fall 2011 to 37% in Spring 2013 and the other showing an average performance of 9.02% between June 2013 to May 2015.
- Given the variation in the results within and between the two systems, the Committee agreed that opportunity for improvement exists.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0**; **M-14**; **L-1**; **I-7** 2b. Validity: **H-0**; **M-20**; **L-1**; **I-1**

<u>Rationale</u>:

- This measure is specified for both claims and registry data. When questioned about identifying cancer deaths from claims data, the developer clarified that the denominator is derived from registry data (e.g., a death registry or other cancer registry that includes information on cancer deaths) while the numerator is derived from claims data.
- For the 2012 evaluation, the developer conducted data element validity testing for the measure numerator by comparing claims for 150 consecutive patients treated for advanced cancer at Boston's

0213 Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life

Dana-Farber Cancer Institute and Brigham and Women´s Hospital to data from the full medical record (sensitivity=0.87; specificity=0.97). Although the developer did not conduct data element validity testing for the measure denominator, the Committee agreed that registry data (particularly death registry data), in general, are accurate and therefore additional testing is unnecessary.

- The developer did not provide any updated validity testing.
- The developers did not conduct reliability testing for either the numerator or the denominator. However, per NQF guidance, because data element validity testing was done for the measure numerator, additional data element reliability testing for the numerator is not required. As noted, the Committee agreed that the registry data used in the measure denominator are accurate, and therefore members agreed that additional data element reliability testing is not needed.
- The Committee agreed that because admission to the ICU is, for the most part, under the control of the provider, risk-adjustment is not needed for this measure.

3. Feasibility: H-4; M-18; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are available in electronic sources.

4. Usability and Use: H-6; M-16; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is not currently in use. However, it is part of America's Health Insurance Plans (AHIP) Medical Oncology Core Measure Set. The AHIP effort is a collaboration of both public and private stakeholders to identify measures that are meaningful to patients, consumers, and physicians and to reduce variability in measure selection, collection burden, and cost. Payers involved in the collaboration have committed to using these measures for reporting as soon as feasible, and CMS has agreed to consider this measure for inclusion in Medicare quality programs.
- Because the developer provided limited longitudinal data, performance trends could not be inferred.
- Neither the Committee nor the developers reported awareness of unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure is related to four measures:
  - 0210: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life
  - 0211: Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life
  - 0215: Proportion of patients who died from cancer not admitted to hospice
  - 0216: Proportion of patients who died from cancer admitted to hospice for less than 3 days
- These measures, all of which were developed by the American Society of Clinical Oncology, are harmonized to the extent possible.

Standing Committee Recommendation for Endorsement: **Y-22**; **N-0**

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

- NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure.

0213 Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0215 Proportion of patients who died from cancer not admitted to hospice
Submission | Specifications
Description: Proportion of patients who died from cancer not admitted to hospice **Numerator Statement**: Proportion of patients not enrolled in hospice **Denominator Statement**: Patients who died from cancer. **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Group/Practice **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data : Registry **Measure Steward**: American Society of Clinical Oncology
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **Previous Evidence Evaluation Accepted** 1b. Performance Gap: **H-20**; **M-2**; **L-0**; **I-0** Rationale: • For the 2012 endorsement evaluation, the developers cited two studies indicating hospice admission did not have detrimental effect on survival among elderly patients with lung cancer and was associated with bereaved family members reporting a) higher quality of end-of-life care, b) no unmet need for help with anxiety or depression, and c) death in the decedent's died in preferred location. The developer also cited a 2003 expert consensus paper identifying hospice enrollment as an indicator of quality of end-of-life cancer care. • For the current evaluation, developers updated the evidence by referencing: a 2013 Cochrane Collaborative systematic review that evaluated the impact of home-based palliative care services on several patient and caregiver outcomes, which found that for patients with cancer, home-based palliative care services increases the chance of dying at home for patients with cancer; a 2012 provisional clinical opinion from the American Society of Clinical Oncology that recommends consideration of palliative care early in the course of illness for patients with metastatic cancer and/or high symptom burden; and four individual studies that support the relationship of hospice admission to desired patient outcomes. • The Committee agreed that the updated evidence appears to be directionally the same since the last NQF endorsement evaluation. The Committee accepted the prior evaluation of this criterion without further discussion. • The developer provided group/practice level performance data from the ASCO Quality Oncology Practice Initiative registry (QOPI) for 2013-2015. The median performance score was 40.0 in 2013, 41.67 in 2014, and 41.42 in 2015. The developer provided additional practice-level disparities data after the Committee's workgroup call. The Committee agreed these data indicated potential disparities in care men and racial/ethnic minorities. The Committee agreed that there is substantial room for improvement for this measure.

0215 Proportion of patients who died from cancer not admitted to hospice

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**

<u>Rationale</u>:

- This measure is specified for both claims and registry data. When questioned about identifying cancer deaths from claims data, the developer clarified that the denominator is derived from registry data (e.g., a death registry or other cancer registry that includes information on cancer deaths) while the numerator is derived from claims data or the ASCO Quality Oncology Practice Initiative (QOPI®) registry.
- For the 2012 evaluation, the developer conducted data element validity testing for the QOPI® registry data by, comparing QOPI® registry data to data that were re-abstracted from medical records by QOPI nurse abstractors, which was considered the gold standard (kappa=0.679, indicating acceptable agreement).
- For the 2012 evaluation, the developer conducted data element validity testing for the measure numerator for claims data by comparing claims for 150 consecutive patients treated for advanced cancer at Boston's Dana-Farber Cancer Institute and Brigham and Women´s Hospital to data from the full medical record (sensitivity=0.24; specificity=0.96). Although the developer did not conduct data element validity testing for the measure denominator, the Committee agreed that registry data (particularly death registry data), in general, are accurate and therefore additional testing is unnecessary.
- The developer did not provide any updated reliability or validity testing.
- The Committee agreed the previous reliability and validity testing were demonstrated the scientific acceptability of the measure and accepted the prior evaluation of this criterion without further discussion.

3. Feasibility: H-2; M-20; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are available in claims and the QOPI® Registry.

4. Usability and Use: H-2; M-20; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The measure is currently used in the QOPI® Registry, a practice-based quality improvement and benchmarking program, operated by the American Society of Clinical Oncology. It is also part of America's Health Insurance Plans (AHIP) Medical Oncology Core Measure Set. The AHIP effort is a collaboration of both public and private stakeholders to identify measures that are meaningful to patients, consumers, and physicians and to reduce variability in measure selection, collection burden, and cost. Payers involved in the collaboration have committed to using these measures for reporting as soon as feasible, and CMS has agreed to consider this measure for inclusion in Medicare quality programs.
- While the number of practices reporting to QOPI has increased between 2013 and 2015, the average performance has not changed.
- Neither the Committee nor the developers reported awareness of any unintended consequences associated with this measure.

5. Related and Competing Measures

- This measure is related to four measures:

0215 Proportion of patients who died from cancer not admitted to hospice
○ 0210: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life ○ 0213: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life ○ 0211: Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life ○ 0216: Proportion of patients who died from cancer admitted to hospice for less than 3 days • These measures, all of which were developed by the American Society of Clinical Oncology, are harmonized to the extent possible.
Standing Committee Recommendation for Endorsement: **Y-22**; **N-0**
6. Public and Member Comment: June 20- July 19, 2016 Comments received: • NQF received 5 post-evaluation comments on this measure, all of which were supportive of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0216 Proportion of patients who died from cancer admitted to hospice for less than 3 days
Submission | Specifications
Description: Proportion of patients who died from cancer, and admitted to hospice and spent less than 3 days there **Numerator Statement**: Patients who died from cancer and spent fewer than three days in hospice. **Denominator Statement**: Patients who died from cancer who were admitted to hospice **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Group/Practice **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility **Type of Measure**: Intermediate Clinical Outcome **Data Source**: Administrative claims, Electronic Clinical Data : Registry **Measure Steward**: American Society of Clinical Oncology
STANDING COMMITTEE MEETING [05/10/2016-05/11/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **Previous Evidence Evaluation Accepted** 1b. Performance Gap: **H-14**; **M-7**; **L-0**; **I-0;** <u>Rationale</u>: • For the 2012 endorsement evaluation, the developers cited two studies indicating hospice admission did not have detrimental effect on survival among elderly patients with lung cancer and was associated with bereaved family members reporting a) higher quality of end-of-life care, b) no unmet need for help with anxiety or depression, and c) death in the decedent's died in preferred location. The developer also cited a 2003 expert consensus paper identifying short hospice enrollment as an indicator of quality of end-of-life cancer care. • For the current evaluation, developers updated the evidence by referencing: a 2013 Cochrane

0216 Proportion of patients who died from cancer admitted to hospice for less than 3 days

Collaborative systematic review that evaluated the impact of home-based palliative care services on several patient and caregiver outcomes, which found that for patients with cancer, home-based palliative care services increases the chance of dying at home for patients with cancer; a 2012 provisional clinical opinion from the American Society of Clinical Oncology that recommends consideration of palliative care early in the course of illness for patients with metastatic cancer and/or high symptom burden; and three individual studies that support the relationship of hospice admission to desired patient outcomes such as increased survival times and reductions in aggressive end-of-life care.

- The Committee agreed that the updated evidence appears to be directionally the same since the last NQF endorsement evaluation. The Committee accepted the prior evaluation of this criterion without further discussion.
- The developer provided group/practice level performance data from the ASCO Quality Oncology Practice Initiative registry (QOPI) for 2013-2015. The median performance score was 12.97 in 2013, 14.64 in 2014, and 15.38 in 2015, an increasing trend that might be explained by higher participation in the QOPI® registry. The developer provided additional practice-level disparities data after the Committee's workgroup call. The Committee agreed these data indicated potential disparities in care for racial/ethnic. The Committee agreed that there is substantial room for improvement for this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0**; **M-18**; **L-3**; **I-0** 2b. Validity: **H-0**; **M-19**; **L-2**; **I-0**

<u>Rationale</u>:

- This measure is specified for both claims and registry data. When questioned about identifying cancer deaths from claims data, the developer clarified that the denominator is derived from registry data (e.g., a death registry or other cancer registry that includes information on cancer deaths) while the numerator is derived from claims data or the ASCO Quality Oncology Practice Initiative (QOPI®) registry.
- The Committee questioned limiting the measure to Medicare patients only. The developers noted that only Medicare data were available for testing, thus the requirement for Medicare hospice enrollment. They are hopeful, however, that with the measure's inclusion in the AHIP oncology core set, enrollment data for other payers will be available for use. They also noted that the QOPI® registry is not limited to Medicare hospice enrollees.
- The Committee questioned the developer about the rationale for specifying 3-days as the threshold for appropriate timeframe for hospice enrollment. The developers noted that the QOPI® registry actually collects both 3-day and 7-day enrollment information and future versions of this measure may consider a longer timeframe. One Committee member noted that that enough variation currently exists in hospice enrollment that continued improvement is needed within the 3 day timeframe. While acknowledging that longer hospice enrollment is better, the Committee found this rationale for the 3-day threshold acceptable.
- For the 2012 evaluation, the developer conducted data element reliability testing for the QOPI® registry data by comparing QOPI® registry data to data that were re-abstracted from medical records by QOPI nurse abstractors, which was considered the gold standard (kappa=0.551, indicating acceptable agreement).
- For the 2012 evaluation, the developer conducted data element validity testing for the measure numerator from claims data by comparing claims for 150 consecutive patients treated for advanced cancer at Boston's Dana-Farber Cancer Institute and Brigham and Women´s Hospital to data from the full medical record (sensitivity=0.97; specificity=1.00). Although the developer did not conduct data element validity testing for the measure denominator, the Committee agreed that registry data (particularly death registry data), in general, are accurate and therefore additional testing is unnecessary.
- The developer did not provide any updated reliability or validity testing.

0216 Proportion of patients who died from cancer admitted to hospice for less than 3 days

- The Committee was not concerned with the lack of risk-adjustment for this measure.

3. Feasibility: H-3; M-16; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are available in claims and the QOPI® Registry.

4. Usability and Use: H-13; M-8; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used in the QOPI® Registry, a practice-based quality improvement and benchmarking program, operated by the American Society of Clinical Oncology. It is also part of America's Health Insurance Plans (AHIP) Medical Oncology Core Measure Set. The AHIP effort is a collaboration of both public and private stakeholders to identify measures that are meaningful to patients, consumers, and physicians and to reduce variability in measure selection, collection burden, and cost. Payers involved in the collaboration have committed to using these measures for reporting as soon as feasible, and CMS has agreed to consider this measure for inclusion in Medicare quality programs.
- While the number of practices reporting to QOPI has increased between 2013 and 2015, the average performance has not changed.
- In its 2016 review, the MAP, supported by public comments, requested the Standing Committee consider a longer timeframe (e.g., 7 days) for this measure. However, the Committee agreed that very short hospice stays remain a concern and therefore did not recommend changing the timeframe for the measure at this time.
- The Committee acknowledged that the measure might create a disincentive to refer actively dying patients to hospice but agreed that the benefits of the measure outweigh the potential risk.

5. Related and Competing Measures

- This measure is related to four measures:
  - 0210: Proportion of patients who died from cancer receiving chemotherapy in the last 14 days of life
  - 0211: Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life
  - 0213: Proportion of patients who died from cancer admitted to the ICU in the last 30 days of life
  - 0215: Proportion of patients who died from cancer not admitted to hospice
- These measures, all of which were developed by the American Society of Clinical Oncology, are harmonized to the extent possible.

Standing Committee Recommendation for Endorsement: Y-21; N-0

6. Public and Member Comment: June 20- July 19, 2016

Comments received:

- NQF received 4 post-evaluation comments on this measure, all of which were supportive of the measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1625 Hospitalized Patients Who Die an Expected Death with an ICD that Has Been Deactivated

Submission | Specifications

Description: Percentage of hospitalized patients who die an expected death from cancer or other terminal illness and who have an implantable cardioverter-defibrillator (ICD) in place at the time of death that was deactivated prior to death or there is documentation why it was not deactivated.

Numerator Statement: Patients from the denominator who have their ICDs deactivated prior to death or have documentation of why this was not done

Denominator Statement: Patients who died an expected death who have an ICD in place

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records

Measure Steward: RAND Corporation

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **H-2; M-22; L-0; I-0**; 1b. Performance Gap: **H-1; M-23; L-0; I-0**

Rationale:

- For the 2012 endorsement evaluation, the developers provided a systematic review and a clinical practice guideline supporting care planning and communication for patients receiving an ICD. Although the developer did not provide additional evidence for the current evaluation, NQF Staff and Committee members identified two consensus statements from the U.S. and European Heart Rhythm Societies and several, as well as several systematic reviews and studies supporting ICD deactivation summarizing patient and provider attitudes on deactivation, and exploring barriers to deactivation. The Committee acknowledged the relatively small body of empirical evidence supporting ICD deactivation near the end of life, but particularly noted the expert consensus statements in favor of deactivation by both cardiologists and palliative care experts.
- Committee members discussed whether accountability for ICD deactivation very near time of death is appropriate, noting that expert consensus recommends a discussion about deactivation prior to implantation although typically such a discussion is not wanted by patients at that time. The Committee agreed that the optimal timing for this discussion is not yet known.
- For the current evaluation, the developers provided performance data from two individual studies using data from 2005-2006 and 2008. In one study, the one patient eligible did have the deactivation; in the other study, of the 12 patients eligible, only 25% had their ICDs deactivated prior to death.
- The Committee agreed that while the evidence presented on the performance gap was limited, clinical experience suggests that it is an area with opportunity for improvement. Members of the Committee agreed that, an expected death with an active ICD should be considered a "never event", given the suffering experienced by the patient and family due to repeated shocks during the terminal decline.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-0; M-22; L-0; I-2** 2b. Validity: **H-0; M-23; L-0; I-1**

Rationale:

- When questioned by the Committee, the developers clarified that this measure includes those who died in a hospital.

1625 Hospitalized Patients Who Die an Expected Death with an ICD that Has Been Deactivated
• For the 2012 evaluation, the developers attempted to assess inter-rater reliability of the data elements by obtaining medical charts for 47 inpatient decedents (a 10% sample of 496 patients, 12 of whom had an ICD in place). However, none of the 12 patients with an ICD were included in the sample and therefore the inter-rater reliability analysis for the numerator was not possible. • The Committee acknowledged that the relatively low prevalence of ICD implantation can affect the feasibility of empirical testing. However, Committee members strongly agreed that documentation of ICD deactivation in the medical record is clear and very easy to find. One member also noted that results of reliability testing from a large-scale study are forthcoming and promising. • Validity testing at the time of the 2012 endorsement evaluation included face validity assessments by two expert panels using a modified Delphi method. Developers did not update validity testing for the current evaluation.
3. Feasibility: H-0; M-21; L-3; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3d. Data collection strategy can be implemented)* Rationale: • While the Committee noted the measure is specified for paper medical records and that the required data likely are not yet included in structured electronic data, members again agreed that the required data elements would be easy to find in the paper records.
4. Usability and Use: H-4; M-19; L-1; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is not currently in use, although it was supported by the MAP in 2013 for inclusion in the PQRS program (a clinician-level program). • Longitudinal data for this measure are not yet available and there is therefore no information regarding improvement. • Committee members did not suggest any potential unintended consequences for the measure. • Committee members encouraged the developer to continue to pursue opportunities for inclusion in accountability programs.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: Y-24; N-0
6. Public and Member Comment: June 20- July 19, 2016 Comments received: • NQF received 2 post-evaluation comments on this measure, both of which were supportive of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2651 CAHPS® Hospice Survey (experience with care)
Submission | Specifications

2651 CAHPS® Hospice Survey (experience with care)

Description: The measures submitted here are derived from the CAHPS® Hospice Survey, which is a 47-item standardized questionnaire and data collection methodology. The survey is intended to measure the experiences of hospice patients and their primary caregivers. The measure proposed here includes the following six multi-item measures (1) Hospice team communication; (2) Getting timely care; (3) Treating family member with respect; (4) getting emotional and religious support; (5) Getting help for symptoms; and (6) Getting hospice training. In addition, there are two other measures, also called, "global ratings": (1) Rating of the hospice care and (2) Willingness to recommend the hospice

Numerator Statement:

Denominator Statement: The measure's denominator is the number of survey respondents who answered the item. The target population for the survey is primary caregivers of hospice decedents. The survey uses screener questions to identify respondents eligible to respond to subsequent items. Therefore, denomniators will vary by survey item (and corresponding multi-item measures, if applicable) according to the eligibility of respondents for each item.

Exclusions: Cases are excluded from the survey target population if:

•The hospice patient is still alive

•The decedent's age at death was less than 18

•The decedent died within 48 hours of his/her last admission to hospice care

•The decedent had no caregiver of record

•The decedent had a caregiver of record, but the caregiver does not have a U.S. or U.S. Territory home address

•The decedent had no caregiver other than a nonfamilial legal guardian

•The decedent or caregiver requested that they not be contacted (i.e., by signing a no publicity request while under the care of hospice or otherwise directly requesting not to be contacted)

•The caregiver is institutionalized, has mental/physical incapacity, has a language barrier, or is deceased

•The caregiver reports on the survey that he or she "never" oversaw or took part in decedent's hospice care

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospice

Type of Measure: PRO

Data Source: Patient Reported Data/Survey

Measure Steward: Centers for Medicare and Medicaid Services

STEERING COMMITTEE MEETING [05/11/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **Pass-23; No Pass-0**; 1b. Performance Gap: **H-6**; **M-17**; **L-0**; **I-0;**

<u>Rationale</u>:

- As evidence for this measure, the developer provided a table linking multiple processes or structures of care to the outcomes captured in the 8 measures that are derived from the Hospice CAHPS survey. The developer also summarized results from focus groups and individual interviews with family members of hospice decedents who reviewed the Survey and supported its contents.
- The Committee agreed the evidence presented met NQF's requirements for patient-reported outcome measures and passed all eight measures on the evidence criterion.
- The developer provided performance data from 2,512 hospice agencies serving at least 50 patients in second quarter of FY 2015. Mean measures scores ranged from 72.1 (Standard Deviation (SD) =12.8) for "Getting hospice care training" to 91.8 (SD=6.5) for "Getting emotional and religious support".
- The developers presented data from the first half of 2015 showing variations in the PRO-PM results by

2651 CAHPS® Hospice Survey (experience with care)

race, suggesting potential disparities in care, and noted cited several studies that have also found disparities in hospice care.

- The Committee agreed that variation in agency scores for each measure indicates a performance gap exists. Members also noted that the disparities data were particularly compelling, given the direction of the identified disparities varies across the measures.

2. Scientific Acceptability of Measure Properties: 7 of the 8 measures meet the Scientific Acceptability criteria

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

2a. Reliability: Two measures pulled out for separate voting:

- *Hospice team communication; getting timely care; Getting emotional and religious support; Getting hospice training; Rating of the hospice care; Willingness to recommend the hospice*-**H-1**; **M-20**; **L-2**; **I-0**
- *Treating family member with respect*)-**H-0; M-10; L-10; I-2 (Consensus not reached)**
- *Getting help for symptoms*-**H-0; M-14; L-7; I-2**

2b. Validity: **H-6**; **M-14**; **L-3**; **I-0**

Rationale:

- One member voiced concern about use of the "top-box" scoring approach, suggesting that it is too stringent, as some people never respond with the most positive answer on a survey. This member suggested that with this scoring approach, the results may not accurately reflect the quality of care provided. The developers' rationale for using top-box scoring was that (1) their testing showed that this scoring approach was the most easily understood and meaningful to consumers and (2) compared to a linear mean scoring approach, the ability to distinguish between providers is better when the top-box approach is used.
- Some Committee members expressed concern about combining emotional and religious items for the "Getting emotional and religious support" measure, seeing them as distinct concepts. The developer noted that in their testing of the survey instrument, including all three items into this domain improved the Cronbach's alpha reliability result.
- The Committee asked why of hospice agencies that have fewer than 50 decedents per year are exempted from fielding the Hospice CAHPS survey. The developers stated that the cost of the survey may be prohibitive for very small agencies. They also noted that because the response rate is relatively low, very small agencies may not have enough respondents to achieve reliable results on the measures. The developers also clarified that there are no payment penalties for small hospice agencies that do not field the survey.
- Another Committee member asked about the exclusion due to language barriers. The developers noted that the Hospice CAHPS survey is available in English, Spanish, two versions of Chinese, Vietnamese, Portuguese, and Russian, and that additional languages would be added over time.
- Reliability testing of the Hospice CAHPS survey (i.e., data element testing) included examination of the internal consistency of the multi-item measures using Cronbach's alpha and the item-total correlation using Pearson's correlation for the multi-item and single-item measures. Cronbach's alpha results ranged from 0.60 to 0.86.
- Measure score reliability was calculated using 1) intra-class correlations (ICCs) computed from the case mix-adjusted 0-100 top-box scores and 2) estimating reliability via the Spearman-Brown prophecy formula assuming 200 surveys were completed in each agency. ICC values ranged from 0.008 to 0.017, and the estimated reliability from the Spearman-Brown prophecy formula ranged from 0.61 to 0.78.
- Because the estimated reliability estimates were relatively lower for the "Treating family member with respect" and "Getting help for symptoms" measures, the Committee asked to vote on those separately. The Committee did not reach consensus on the reliability subcriterion for the "Treating family member with respect" measure; however, the remaining seven measures passed the reliability subcriterion.

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- Validity testing of the measure score included examination of the relationship of agency-level results from the 6 multi-item measures to the agency-level results of the global rating and willingness to recommend measures via linear regression analysis and examination of the Pearson correlations between the agency-level multi-item measures to assess the magnitude of association. Results indicated all relationships were statistically significant and in the expected direction.
- All 8 of the PRO-PMs are case-mix adjusted for 9 factors: (1) response percentile; (2) decedent age group; (3) payer; (4) primary diagnosis; (5) length of final hospice episode; (6) respondent age group; (7) respondent education;(8) decedent's relationship to respondent; and(9) a variable indicating survey language and respondent's home language. One member noted that low literacy and low socio-economic status might also affect response rate.
- The Committee questioned the developer about potential threats to validity related non-response bias, the developers stated that response bias is difficult to assess directly, but surveys of varying lengths were used during field testing, but this had no effect on response rates. The developers also noted that the measure results are adjusted for mode of administration, because mode affects response rates. Specifically, the mail-only mode is the least expensive but has lower response rates. Higher response rates are possible with the mixed mode of administration (mail with telephone follow-up, but this is the most expensive option.
- One Committee member also asked if the developers can be sure that the performance results from caregivers of decedents who resided in a nursing home reflect the quality of care provided by the hospice rather than the quality of care provided by the nursing home. The developers stated that they ask specific questions on the survey to try to ascertain whether information provided by the hospice team differed from that given by nursing home staff and whether the hospice team and nursing home staff worked well together.

3. Feasibility: H-0; M-17; L-6; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Data collection strategy can be implemented)

Rationale:

- The Committee questioned the developer as to whether feasibility of the measures varied by the mode administration (mail only, phone only, or mixed mode) or respondents' level of health literacy. The developer again noted that the responses are adjusted for mode of administration. With respect to health literacy, they developers stated that they were not certain as to the current reading level of survey, but believe it to be around at 10th grade reading level.
- The Committed voiced concern regarding the impact of cost on smaller hospice agencies' ability to participate in the survey. Committee members noted that agencies are required to contract with specific survey vendors and devote additional resources (e.g., staff time) to participate. The Committee asked the developer whether the Centers for Medicare and Medicaid considered provided monetary support to smaller agencies to enable their participation. The developers acknowledged the additional hospice agency resources required to conduct the survey, but stated they were not aware of any plans for offering monetary support to smaller hospice agencies.

4. Usability and Use: H-8; M-13; L-2; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measures are currently included in the Hospice Quality Reporting Program (HQRP). The Committee discussed the exclusion of small hospice agencies (i.e., those with less than 50 decedents per year) from reporting to the HQRP and that this is a potential limitation to the measures' usability and use.
- The Committee discussed a potential unintended consequence of the measures in that receiving the

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survey may be upsetting to the decedent's caregiver. The Committee agreed this may happen, but the benefits of the measures outweigh this undesirable effect, particularly if a hospice agency provides bereavement support to individuals who report upset at the survey.

5. Related and Competing Measures

- These measures compete with two other patient-reported outcome measures:
  - 0208: Family Evaluation of Hospice Care.
    - The result of the Family Evaluation of Hospice Care (FEHC) measure (#0208) is a single score that indicates a hospice agency's overall performance on symptom management, communication, provision of information, emotional support, and care coordination. Note that only hospice agencies exempt from the Hospice CAHPS survey (i.e., <50 decedents per year) utilize the FEHC.
  - 1623: Bereaved Family Survey
    - The result of the Bereaved Family Survey measure (#1623) is a single score that indicates the family's perceptions of the quality of care that veterans received from the VA during the last month of life; aspects of care included in the measure are communication, emotional and spiritual support, pain management, and personal care needs.
- Although these measures are competing, they are targeted to different groups of hospice patients and their families (i.e., those served by small agencies and those in the VA). Also, as these two measures were recently evaluated by another Standing Committee, NQF staff did not ask the Committee to choose a superior measure or discuss potential areas of harmonization.

Standing Committee Recommendation for Endorsement for: (1) Hospice team communication; (2) Getting timely care; (3) getting emotional and religious support; (4) Getting help for symptoms; and (5) Getting hospice training (6) Rating of the hospice care and (7) Willingness to recommend the hospice **Y-22**; **N-1**

Because the Committee did not reach consensus on the Reliability subcriterion for the "*Treating family member with respect*" measure , the Committee did not vote on an overall recommendation for endorsement for that measure. For this measure, the Committee will re-vote on the Reliability subcriterion and vote on a recommendation for endorsement on the August 3, 2016 post-comment call.

6. Public and Member Comment: June 20- July 19, 2016; Post-comment call: August 3, 2016

Comments received:

- NQF received 3 post-evaluation comments the 8 PRO-PMs under NQF #2651, all of which were supportive of the measures.
- NQF also sought feedback on the measure from the Person- and Family-Centered Care Standing Committee, as this Committee has extensive experience in evaluating PRO-PMs from CAHPS surveys and other PRO-PM/instrument-based measures. One of the PFCC Committee members expressed concern with the low ICC values for all of the measures.

Developer response regarding the *Treating Family Member with Respect* measure:

- To address the Committee's lack of consensus on reliability, the developer updated the reliability estimates for all 8 PRO-PMs based on data from April-September, 2015. The addition of an extra three months of data resulted in increased reliability estimates for 7 or the 8 PRO-PMs. For the "*Treating family member with respect"* measure*,* the estimate increased from 0.61 to 0.68).
- To address the concern regarding the low ICC values, the developer cited Lyratzopoulos et al. (2011), who suggested benchmarks such that ICCs less than 0.01 are labeled "Low" and ICCs greater than 0.10 are labeled "High." Lyratzopoulos, et al. also states that the ICC can be interpreted as the reliability of the quality measure with a sample size = 1 respondent per hospice. The developers therefore applied the

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Spearman-Brown prophecy formula to estimate the reliability assuming 200 respondents per hospice (with estimates for the 8 measures ranging from 0.66 to 0.81, based on the April-September, 2015 data). Committee response: • After discussion, the Committee re-voted on the Reliability subcritierion. Upon revote, the Committee agreed that the developer had demonstrated adequate reliability for the *Treating Family Member with Respect* measure, based on April-September, 2015 data . **Vote Following Consideration of Public and Member Comments:** Reliability: **H-0**; **M-17**; **L-1**; **I-0** Standing Committee Overall Recommendation for Endorsement: **Y-18**; **N-0**
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Withdrawn from Consideration

One measure previously endorsed by NQF has withdrawn during the endorsement evaluation process. Endorsement for this measure will be removed.

Care of the patient at the end of life

Measure	Reason for withdrawal
• **0211 Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life**	Other (unable to consider risk-adjustment at this time)

0211 Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life
Submission **|** Specifications
Description: Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life **Numerator Statement**: Patients who died from cancer and had at least one emergency department visit in the last 30 days of life **Denominator Statement**: Patients who died from cancer **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Group/Practice **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Hospice, Hospital/Acute Care Facility **Type of Measure**: Intermediate Clinical Outcome

0211 Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American Society of Clinical Oncology

STANDING COMMITTEE MEETING [05/10/2016-05/11/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

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

1a. Evidence: **H-1**; **M-4**; **L-1**; **I-16**; 1b. Performance Gap: **H-5**; **M-16**; **L-0**; **I-1**

Evidence Exception: **Y-21; N-1**

Rationale:

- For the 2012 endorsement evaluation, the developers cited a 2011 study (Ho, et al., 2011) that examined trends in the aggressiveness of end-of-life (EOL) cancer care (ED visits), and an expert consensus statement (Earle, et al., 2003) that identified potential indicators of quality of end-of-life cancer care using administrative data.
- For the current evaluation, developers updated the evidence by referencing: a 2013 Cochrane Collaborative systematic review that evaluated the impact of home-based palliative care services on several patient and caregiver outcomes, which found that for patients with cancer, home-based palliative care services increases the chance of dying at home for patients with cancer; a 2012 provisional clinical opinion from the American Society of Clinical Oncology that recommends consideration of palliative care early in the course of illness for patients with metastatic cancer and/or high symptom burden; and three individual studies providing estimates of ED utilization for cancer patients near the end of life, although these studies did not link ED utilization to other patient outcomes.
- In their discussion of the evidence, the Committee agreed that the empirical evidence provided did not link fewer ED visits in the last month of life to patient or family outcomes. One Committee noted that a primary cause of ED visits among cancer patients is pain and the Committee agreed that at least some ED visits likely are avoidable. Therefore, the Committee deemed it acceptable to hold providers accountable for this measure and agreed to invoke the exception to the evidence subcriterion.
- Although specified at the clinician group/practice level, the developers provided system-level performance data from two integrated health systems, one showing an increase from 35% in Fall 2011 to 43.90% in Spring 2013, along with differences in performance according to sex and race/ethnicity, and the other showing an overall average performance of 5.38% for June 2013 to May 2015 along with differences in performance according to payer.
- Given the variation in the results within and between the two systems and between population groups, the Committee agreed that there is opportunity for improvement.

2. Scientific Acceptability of Measure Properties: The measure did not meet the Scientific Acceptability criteria

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

2a. Reliability: **H-0**; **M-10**; **L-2**; **I-10** 2b. Validity: **H-0**; **M-6**; **L-5**; **I-11**

Rationale:

- This measure is specified for both claims and registry data. When questioned about identifying cancer deaths from claims data, the developer clarified that the denominator is derived from registry data (e.g., a death registry or other cancer registry that includes information on cancer deaths) while the numerator is derived from claims data.
- The developers did not conduct reliability testing for either the numerator or the denominator. However, per NQF guidance, because data element validity testing was done for the measure numerator, additional data element reliability testing for the numerator is not required.
- For the 2012 evaluation, the developer conducted data element validity testing for the measure numerator by comparing claims for 150 consecutive patients treated for advanced cancer at Boston's

0211 Proportion of patients who died from cancer with more than one emergency department visit in the last 30 days of life

Dana-Farber Cancer Institute and Brigham and Women´s Hospital to data from the full medical record. The developer reported the measure was 89% accurate (percent true positives + true negatives). Although the developer did not conduct data element validity testing for the measure denominator, several Committee members agreed that registry data (particularly death registry data), in general, are accurate and therefore additional testing is unnecessary.

- The developer did not provide any updated reliability or validity testing.
- The Committee did not reach consensus on reliability.
- The Committee questioned the developer on the lack of risk-adjustment for the measure. Members stated that appropriateness of ED admission may vary by patient characteristics such as age, morbidity status, and geographic location. In particular, Committee members highlighted a potential unintended consequence of limiting access to care for patients in rural areas where admission to the ED may be the only care option during an urgent situation. The developers agreed in principle with the need to risk-adjust the measure but did not have access to the appropriate resources to conduct those analyses before the Committee's meeting.
- As a result of the concerns related to the lack of risk-adjustment, the Committee did not pass the measure on the validity criterion but deferred their final endorsement decision, pending potential risk-adjustment of the measure. The Committee asked the measure developer to explore risk-adjustment of the measure over the next 12-month period. The developer agreed to consider the deferral option and respond to NQF with the formal decision within 14 business days of the in-person meeting. On May 27th, 2016, the measure developers communicated to NQF that they would not be pursuing the deferral option. Because as initially constructed the measure did not pass the validity subcriterion, the Committee's recommendation was changed from "Endorsement Decision Deferred" to "Not Endorsed".