TO: Consensus Standards Approval Committee (CSAC)

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RE: Patient Safety Standing Committee

DA: December 13, 2016

CSAC ACTION REQUIRED

The CSAC will review recommendations from the Patent Safety, 2015-2017 project on its December 13th conference call. This memo includes a summary of the project activities, recommended measures, and themes identified from the public and member comments. Member voting on these recommended measures ended on November 21, 2016.

Accompanying this memo are the following documents:

1. **Patient Safety 2015-2017 Draft Report.** The draft report has been updated to reflect the changes made following the 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 lists comments received and the NQF/Standing Committee responses.

BACKGROUND

Patient Safety related events due to medical errors result in tens of thousands of premature deaths each year. Currently, NQF's portfolio of safety measures spans a variety of topic areas including, but not limited to, health care associated infections, falls, pressure ulcers, surgical complications, and workforce issues. However, significant gaps remain in the measurement of patient safety and how providers approach minimizing the risk of patient safety events. There is also a recognized need to expand avoidable patient safety measures beyond the hospital setting and to harmonize safety measures across sites and settings of care. NQF has a 10-year history of focusing on patient safety. Through various projects, NQF has previously endorsed over 100 consensus standards related to patient safety; these measures are important tools for tracking and improving patient performance. The 25-member Patient Safety Standing Committee has been charged with overseeing the NQF Patient Safety measure portfolio, evaluating both newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifying gaps in the measurement portfolio, providing feedback on how the portfolio should evolve, and serving on any ad hoc or expedited projects in its designated topic areas.

DRAFT REPORT

The Patient Safety Draft Report presents the results of the evaluation of 15 measures considered under the CDP. On July 27-28, 2016, during a 2-day in-person meeting, the Patient Safety Standing Committee evaluated 13 newly submitted measures and 2 measures undergoing maintenance review against NQF's standard evaluation criteria. During the July meeting, 10 measures were recommended for endorsement, 2 measures were not recommended, and one measure was recommended for trial use approval. The Committee did not initially reach consensus on one measure, and deferred a final decision on 1 measure until after the public comment period.

During the October 25, 2016 post comment call, the Committee re-voted on the measure where consensus (Measure #3025) was not reached and voted on the deferred measure (Measure #3000). The Committee did not reach consensus on the reliability of measure #3025 during the in-person meeting. After the developer provided additional support for the measure on the post-comment call the Committee re-voted and agreed it meets the criteria for NQF endorsement. Measure #3000 had been deferred because the Committee had concerns about the validity of the assessment underlying the measure (which initially included stage 1 and 2 pressure ulcers), contradicting language in the measures inclusion and exclusion criteria, and whether there was evidence of a performance gap. The developer revised the measure specification and provided additional information to address these concerns. The Committee voted on the measure and agreed it met the criteria for NQF endorsement. Therefore, twelve measures are recommended for endorsement, one measure was recommended for trial use approval, and two measures were not recommended. The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under	2	13	15
Measures recommended for endorsement	2	10	12
Measures approved for trial use	0	1	1
Measures withdrawn from consideration	0	1	1
Measures not recommended for	0	2	2
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – 0	Importance – 1 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of twelve candidate consensus standards, plus one eMeasure recommended for approval for trial use.

Patient Safety Measures Recommended for Endorsement:

- 0022: Use of High-Risk Medications in the Elderly (DAE) (NCQA)
  Overall Suitability for Endorsement: Y-19; N-0
- 2950: Use of Opioids from Multiple Providers in Persons without Cancer (PQA)
  Overall Suitability for Endorsement: Y-20; N-0
- 0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12) (AHRQ)
  Overall Suitability for Endorsement: Y-17; N-0
- 2940: Use of Opioids at High Dosage in Persons without Cancer (PQA)
  Overall Suitability for Endorsement: Y-21; N-0
- 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer (PQA)
  Overall Suitability for Endorsement: Y-18; N-0
- 2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (KCQA)
  Overall Suitability for Endorsement: Y-17; N-2
- 2993: Potentially Harmful Drug-Disease Interactions in the Elderly (DDE) (NCQA)
  Overall Suitability for Endorsement: Y-17; N-3
- 3001: PACE-Participant Fall Rate (Econometrica, Inc.)
  Overall Suitability for Endorsement: Y-17; N-1
- 3003: PACE-Participants Falls with Injury (Econometrica, Inc.)
  Overall Suitability for Endorsement: Y-18 N-1
- 2909: Perioperative Hemorrhage or Hematoma Rate (PSI 09) (AHRQ)
  Overall Suitability for Endorsement: Y-15; N-0
- 3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate (Econometrica, Inc.)
  Overall Suitability for Endorsement: Y-12; N-4
- 3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure (CDC)
  Overall Suitability for Endorsement: Y-12; N-4

The Committee recommended the following eMeasure for trial use approval:

- 2983: Potassium Sample Hemolysis in the Emergency Department (Cleveland Clinic)
  Overall Suitability for Endorsement: Y-19; N-0

The Committee did not recommend the following measures for endorsement:

- 3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission (Pediatric Consultants, LLC)

- 3006: Initial Baseline Screen of Nutritional Status for Every Patient within 24 Hours of PICU Admission (Pediatric Consultants, LLC)

COMMENTS AND THEIR DISPOSITION

NQF received eight comments from three member organizations and three members of the public. These included measure specific comments as well as comments about the draft report in general. The Committee discussed these comments during a post-comment conference call on October 25, 2016. Overall, the comments received on the draft report were in support of the Committee's recommendations.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationales were forwarded to the developers, who were invited to respond. During the review of all comments, 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.

Many comments on the maintenance measures under review were in favor of continued endorsement. There were also several comments in support of the newly recommended measures that assess opioid use.

No overarching comment themes were identified; however, a number of measure-specific comments that were discussed and addressed by the Committee are presented below.

Measure Specific Comments

Measure #0022: Use of High-Risk Medications in the Elderly (DAE)

This measure received public comments from the American Society of Health-System Pharmacists (ASHP) and the Center for Disease Control and Prevention (CDC) related to the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, on which the measure is based. The commenters noted that anticoagulants and antidiabetic agents are not comprehensively captured in the Beers Criteria, despite being the two most common high risk medication classes used in this population and warrant very close monitoring and follow up for these patients. The CDC also noted that the Beers criteria are intended to support quality improvement efforts, but were not designed for the purposes of performance measurement.

Developer Response: The commenter is correct that anticoagulants and antidiabetic agents are not comprehensively captured in the American Geriatrics Society Beers Criteria, which are meant to address medications that should generally be avoided in older adults. While not included in the Beers Criteria, we agree that these medications should be carefully prescribed and their use should be monitored in

older adults. We have current work underway at the National Committee on Quality Assurance (NCQA) to explore development of quality measures in these areas.

The recommendations in the 2015 American Geriatrics Society Beers Criteria are based on a systematic evidence review conducted by American Geriatrics Society Beers Criteria Expert Panel. The review is focused on the evidence for potential harms of medications in older adults. Medications then included in the Beers Criteria recommendations are those that the panel found evidence indicating that the medications should in general be avoided in all older adults or avoided in older adults with certain conditions or diseases, due to their associated risks for these populations. The Beers Criteria is updated regularly based on currently available literature. We believe it's important for this quality measure to be based on the systematic evidence review that is conducted by the Beers Criteria Expert Panel. The complete evidence tables for the systematic review can be accessed on the American Geriatrics Society's website here: http://geriatricscareonline.org/toc/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CL001

NCQA recognizes that some of the medications that are most attributable to adverse drug events in older adults that result in ED visits and hospitalizations are not included in the Beers Criteria as medications to be generally avoided (e.g., warfarin, antidiabetics and oral antiplatelet - although some oral antiplatelet are in fact included in the Beers Criteria and this measure: Dipyridamole, Ticlopidine). These other high-risk medications should be addressed in separate quality measures that focus on safe prescribing and appropriate monitoring, rather than this measure which focuses on medications that should be generally avoided. We agree with the need for such quality measures to improve safe prescribing of anticoagulants, antidiabetics, and opioids and have current work underway at NCQA to explore development of measures in these areas. Of note, the Pharmacy Quality Alliance has several measures addressing opioid prescribing that are currently being considered for NQF endorsement as part of this Patient Safety project. NCQA supports the endorsement of these measures and has plans to adapt them for health plan reporting in the near future.

In terms of the way this measure is currently specified to include a number of different medications, we believe that creating separate quality measures or indicators for all the specific medications in the Beers Criteria, or for each drug-disease interaction, would be burdensome for measurement and reporting by health plans. Plans can look at medications on an individual basis to see where improvements and interventions are needed, however we do not think this level of detail would be desirable for national reporting by health plans.

As a measure of potentially inappropriate medication use, NCQA does not expect this measure's performance to ever reach 0% (i.e., no prescribing of high-risk medications). There will always be cases where the benefits of prescribing a high-risk medication may outweigh the risks for certain patients. Clinicians should take into account various factors when considering the risk-benefit ratio of prescribing a high-risk medication to an individual. A companion paper to the Beers Criteria was published by the American Geriatrics Society Workgroup on Improving Use of the Beers Criteria in 2015. The paper specifically states "the AGS 2015 Beers Criteria are reasonable to use for performance measurement

across large groups of patients and providers but should not be used to judge care for any individual" (Steinman et al., 2015, JAGS). We believe measuring this concept of potentially inappropriate medication use among elderly at the health plan (i.e., population) level is an important and useful medication safety measure that health plans can use to identify high-risk medication prescribing.

Committee Response: The Committee agreed that measurement related to adverse drug events should address anticoagulants and antidiabetic agents, and that there are there are limitations to this measure as currently specified. However, Committee members noted that there are few endorsed measures focused on medication safety, and suggested that this measure remains a good start for addressing the issue. The Committee maintained its recommendation for endorsement, and emphasized that they look forward to the development and submission of additional medication safety measures, particularly outcome measures focused on adverse drug events.

Measure #2940: **Use of Opioids at high Dosage in Persons without Cancer**

This measure received 3 comments. The commenters noted that the measure may be too inclusive and the developer should consider narrowing the measure to specific chronic conditions or diagnoses to be more meaningful.

Developer Response: PQA appreciates the feedback received on measure 2940: Use of Opioids at High Dosage in Persons Without Cancer during the comment period, and has considered Highmark's comment, "This measure is very broad for all diagnosis outside of cancer. May want to consider narrowing down this measure for specific chronic conditions or diagnoses to be more meaningful." Considering the safety concern for high-dose opioids and the supporting evidence and CDC guidelines, the measures' criteria are intentionally broad to include all potentially excessive uses of opioids for conditions other than cancer. Further, PQA convenes its Measure Update Panel, which is charged with reviewing all PQA-endorsed measures on a regular basis to ensure they reflect current evidence and clinical practice guidelines, and also to consider feedback received on the measures. PQA will share Highmark's comment with the PQA Measure Update Panel for consideration, and welcomes any specific suggestions to make the measure more meaningful.

Committee Response: The Committee accepted the developer's response and maintained their decision to recommend this measure for continued endorsement.

Measure #2988: **Medication Reconciliation for Patients Receiving Care at Dialysis Facilities**

This measure received 2 comments. One comment expressed that medication reconciliation as a quality measure becomes too burdensome for providers without actually demonstrating that meaningful reconciliation has taken place. Another comment noted that the measure may not be harmonized with existing measures.

Developer Response: KCQA agrees that medication reconciliation is a critical domain for patient safety and shares RPA's belief that, ideally, a systematic approach to medication management would optimize care. We note that the publication referenced in RPA's comment (Pai, 2013) suggests that the optimal model for such a systematic approach to medication management therapy (MTM) services for ESRD patients should be structured around the dialysis facility and provided by a pharmacist; the authors acknowledge that most dialysis facilities do not have ready access to a pharmacist. Recognizing this, the KCQA measure specifications permit medication reconciliation by appropriate, qualified professionals.

We disagree that NQF 2988 will be a "paper chase," and note that during testing in 5,292 facilities, approximately 4.5% of facilities scored 0 on the measure over the 6-month period for which data were examined. We believe it is a crucial first step towards improving medication management processes in the ESRD population that will improve patient safety. Going forward, we look forward to continuing to work with RPA, a KCQA member, and other members to improve medication management and this measure.

Committee Response: The Committee accepted the developer's response and maintained their decision to recommend this measure for continued endorsement.

Measure #2909: Perioperative Hemorrhage or Hematoma Rate (PSI 09)

A commenter noted a recent article questioning the validity of this measure, suggesting that the measure did not meet validity thresholds when assessed against the reference standard of medical chart review.

Developer response: AHRQ is aware of the Winters et al. article, has carefully reviewed it and has discussed its strengths and limitations with the NQF Patient Safety Standing Committee. As noted during the review of this indicator, in communications with the editors of Medical Care, and external correspondents, Winters et al have acknowledged methodologic errors that required re-doing all of the quantitative analyses reported in their original paper. Until these corrections are published and all conversations regarding the article are completed, Winters et al's paper should not be used to evaluate the measure's validity. Notably, the Winters et al article failed to account for causes of heterogeneity among source studies, such as whether "present on admission" status was taken into account and whether the same data was used in two different papers. For example, two of the three studies cited for PSI 09, namely Rosen et al and Borzecki et al, are based on the same data from the VA. Preliminary corrected results suggest a revised meta-analytic PPV estimate for PSI 09 of 81.2%, exceeding the 80% proposed cutoff in the article More generally, it is important to note that many studies cited in the meta-analysis are based on older versions of the PSIs that do not include present on admission information nor take into account the most recent specifications. In fact, the findings and the subsequent suggestions for improvement to the indicators noted in many of the original studies cited in Winters et al. informed the current specifications of the indicators.

Committee response: The Committee agreed that this issue has been discussed and resolved during its initial deliberations; the Committee maintained its decision to recommend this measure for endorsement.

NQF MEMBER VOTING RESULTS

Of the thirteen recommended measures nine were approved with 100% approval. All measures received greater 85% approval. Representatives of twenty-one member organizations voted; no votes were received from the Public/Community Health Agency and Supplier/Industry Councils. Results for each measure are provided in Appendix B.

REMOVE ENDORSEMENT OF MEASURES

Five measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement.

Measure	Description	Reason for removal of endorsement
0035 : Fall Risk Management (FRM)	Assesses different facets of fall risk management: The percentage of adults 75 years of age and older, or 65–74 years of age with balance or walking problems or a fall in the past 12 months, who were seen by a practitioner in the past 12 months and who discussed falls or problems with balance or walking with their current practitioner. The percentage of adults 65 years of age and older who had a fall or had problems with balance or walking in the past 12 months, who were seen by a practitioner in the past 12 months and who received fall risk intervention from their current practitioner.	Measure was not submitted for maintenance review.

Measure	Description	Reason for removal of endorsement
0267 : Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant event	Measure was not submitted for maintenance review. They have forgone maintenance to focus on developing new measures.
0263 : Patient Burn	Percentage of ASC admissions experiencing a burn prior to discharge	Measure was not submitted for maintenance review. They have forgone maintenance to focus on developing new measures.
0301 : Surgery patients with appropriate hair removal	Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal.	Measure was not submitted for maintenance review. Measure is considered "topped out, meaning it no longer addresses a performance gap area.
0515 : Ambulatory surgery patients with appropriate method of hair removal	Percentage of ASC admissions with appropriate surgical site hair removal.	Measure was not submitted for maintenance review. They have forgone maintenance to focus on developing new measures.

Appendix A – Measures Not Recommended for Endorsement

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

Measure	Voting Results	Rationale:
3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission	**Evidence: 0-H; 6-M; 9-L; 4-I** *The measure failed on evidence and the Committee did not discuss the other criteria.	During the in-person meeting, the Standing Committee voiced several concerns including: - There is insufficient evidence to demonstrate a link between the assessment and outcomes. There was no systematic review of the evidence nor any grading provided by the developer. - The assessment used for assessing pressure ulcers, the Braden Q Scale, may overburden providers given that there are 28 questions.
3006: Initial Baseline Screen of Nutritional Status for Every Patient within 24 Hours of PICU Admission	**Evidence**: 2-H; 8-M; 7-L; 3-I **Performance Gap:** 0-H; 10-M; 9-L; 1-I **Reliability** 7-M; 8-L;4-I *The measure failed on reliability and the Committee did not discuss the other criteria.	During the in-person meeting, the Standing Committee voiced several concerns including: - There is insufficient evidence that the use of the nutritional status assessment in the PICU leads to improved outcomes. - The developer only tested measure in a single facility at the data element level. The inter-rater reliability was only tested on 5 patient charts. Ultimately, the Committee did not reach consensus on the evidence or the performance gap criteria and did not agree the measure met the reliability criteria.

Appendix B: NQF Member Voting Results

Nine of the twelve recommended measures received 85% approval or higher. Representatives of twenty-one member organizations voted; no votes were received from the Public/Community Health Agency and Supplier/Industry Councils. Results for each measure are provided in Appendix B.

NQF Member Council	Voting	Eligible to Vote	Rate
Consumer	2	40	5%
Health Plan	0	18	0%
Health Professional	6	105	6%
Provider Organizations	5	110	5%
Public/Community Health Agency	0	14	0%
Purchaser	3	22	14%
QMRI	5	78	6%
Supplier/Industry	0	36	0%
All Councils	**21**	**423**	**4%**

0022: Use of High-Risk Medications in the Elderly (DAE) (NCQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	2	2	2	6	50%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	1	3	100%
QMRI	3	0	2	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**13**	**2**	**6**	**21**	**87%**
Percentage of councils approving (>60%)					80%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

2950: Use of Opioids from Multiple Providers in Persons without Cancer (PQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	2	0	4	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	4	0	1	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**15**	**0**	**6**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12) (AHRQ)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	2	0	4	6	100%
Provider Organizations	3	1	1	5	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	1	0	4	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**11**	**1**	**9**	**21**	**92%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					95%

2940: Use of Opioids at High Dosage in Persons without Cancer (PQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%

Health Plan	0	0	0	0	
Health Professional	2	0	4	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	4	0	1	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**15**	**0**	**6**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer (PQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	2	0	4	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	4	0	1	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**15**	**0**	**6**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (KCQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	2	0	4	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	

Purchaser	3	0	0	3	100%
QMRI	3	0	2	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**7**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

2993: Potentially Harmful Drug-Disease Interactions in the Elderly (DDE) (NCQA)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	3	0	3	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	4	0	1	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**16**	**0**	**5**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

3001: PACE-Participant Fall Rate (Econometrica, Inc.)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	1	0	5	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	1	3	100%
QMRI	1	0	4	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**10**	**0**	**11**	**21**	**100%**
Percentage of councils approving (>60%)					100%

Average council percentage approval	100%

3003: PACE-Participants Falls with Injury (Econometrica, Inc.)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	1	0	5	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	1	0	4	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**11**	**0**	**10**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

2909: Perioperative Hemorrhage or Hematoma Rate (PSI 09) (AHRQ)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	1	0	5	6	100%
Provider Organizations	4	1	0	5	80%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	1	0	4	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**11**	**1**	**9**	**21**	**92%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					96%

3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate (Econometrica, Inc.)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	1	0	5	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	1	0	4	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**11**	**0**	**10**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure (CDC)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	2	0	0	2	100%
Health Plan	0	0	0	0	
Health Professional	3	0	3	6	100%
Provider Organizations	4	0	1	5	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	3	0	0	3	100%
QMRI	2	0	3	5	100%
Supplier/Industry	0	0	0	0	
All Councils	**14**	**0**	**7**	**21**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

Member Comment: The Association for Professionals in Infection Control and Epidemiology (APIC) supports NQF endorsement of Measure #3025 Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure. We note, however, that because the measure is limited to ambulatory surgical centers (ASCs) and not inclusive of other outpatient surgery facilities, it would result in inaccurate data due to undercounting. We also caution that many ASCs are not yet equipped with information technology necessary to transfer surgical data to NHSN. However, we believe that an NQF-endorsed

measure would be an important first step in improving healthcare quality in ASCs and encouraging identification and reporting of outpatient surgical site infections.

Appendix C- Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

Measures Recommended

0022: Use of High-Risk Medications in the Elderly (DAE)
Submission | Specifications
Description: There are two rates for this measure: the percentage of patients 65 years of age and older who received at least one high-risk medication. The percentage of patients 65 years of age and older who received at least two prescriptions for the same high-risk medication. For both rates a lower rate represents better performance. **Numerator Statement**: Numerator 1: Patients who received at least one high-risk medication during the measurement year. Numerator 2: Patients who received at least two prescriptions for the same high-risk medication during the measurement year. **Denominator Statement**: All patients 65 years of age and older. **Exclusions**: Patients who were enrolled in hospice care at any time during the measurement year. **Adjustment/Stratification**: N/A **Level of Analysis: Health Plan, Integrated Delivery System** **Setting of Care: Ambulatory Care: Clinician Office/Clinic, Pharmacy** **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Pharmacy **Measure Steward**: National Committee for Quality Assurance
STEERING COMMITTEE MEETING 07/27-07/28/2016 **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-X**; **M-X**; **L-X**; **I-X**; 1b. Performance Gap: **H-12**; **M-7**; **L-0**; **I-0;** Rationale: • The Committee chose not to vote on the evidence because there had not been any significant changes in the evidence since the last time the measure was endorsed. The measure is based on the American Geriatrics Society's 2015 Beers Criteria. • The average performance for the first rate (at least one high-risk medication) has decreased from 21.0% in 2012 to 13.2%. • The average performance for the second rate (dispensing two different high-risk medications) has decreased from 6.5% in 2012 to 2.1% in 2014. In 2014, for both populations the eligible population was 22,043. • The gap in performance seems to be closing over time but there is still room for improvement.

0022: Use of High-Risk Medications in the Elderly (DAE)

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-15**; **M-4; L-0; I-0** 2b. Validity: **H-X**; **M-X**; **L-X**; **I-X**

Rationale:

- The Committee reviewed the revised measure specifications which now include multiple prescribing events for the same high-risk medication. The measures reliability was tested at the measure score level with a signal to noise analysis using a beta binomial method.
- Using 2014 HEDIS Health Plan performance data, reliability for this measure was calculated as 0.99814 for receipt of one or more high-risk prescriptions and 0.99594 for receipt of two or more high-risk prescriptions

3. Feasibility: H-19; M-0; L-0; I-0

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

Rationale:

- The required data elements are routinely generated and used during care delivery.
- All data elements are in defined fields in a combination of electronic sources.

4. Usability and Use: H-9; M-11; 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 several accountability programs. There were no identified unintended consequences for this measure during testing or since implementation.
- If this measure were to be implemented poorly, there is concern that it could lead to reduced access to medications.

5. Related and Competing Measures

- Measure 2993 and NQF 0022 have a similar focus (measuring potentially inappropriate medication use in the elderly) and reporting level (health plan), however they have different target populations. Measure 2993 targets patients with a specific condition or disease that can experience adverse effects when combined with certain medications that are recommended to be avoided for that condition. This measure (NQF 0022) targets a larger population of all older adults and assesses use of high-risk medications that have been recommended to be avoided in all older adults.

Steering Committee Recommendation for Endorsement: **Y-19**; **N-0**

6. Public and Member Comment

Comment:

This measure received 1 public comment from ASHP related to the Beer's Criteria that the measure is based. The commenter noted that anticoagulants and antidiabetic agents are not comprehensively

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captured in Beers Criteria but are the two most common high risk medication classes used in this population and warrant very close monitoring and follow up for these patients. **Developer Response:** The developer noted that the commenter is correct that anticoagulants and antidiabetic agents are not comprehensively captured in the American Geriatrics Society Beers Criteria, which are meant to address medications that should generally be avoided in older adults. While not included in the Beers Criteria, we agree that these medications should be carefully prescribed and their use should be monitored in older adults. We have current work underway at NCQA to explore development of quality measures in these areas. **Comment Response:** The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12)
Submission | Specifications
Description: Perioperative pulmonary embolism or proximal deep vein thrombosis (secondary diagnosis) per 1,000 surgical discharges for patients ages 18 years and older. Excludes cases with principal diagnosis for pulmonary embolism or proximal deep vein thrombosis; cases with secondary diagnosis for pulmonary embolism or proximal deep vein thrombosis present on admission; cases in which interruption of vena cava occurs before or on the same day as the first operating room procedure; and obstetric discharges. **Numerator Statement**: Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with a secondary ICD-9-CM or ICD-10-CM diagnosis code for proximal deep vein thrombosis or a secondary ICD-9-CM or ICD-10-CM diagnosis code for pulmonary embolism. **Denominator Statement**: Surgical discharges, for patients ages 18 years and older, with any-listed ICD-9-CM or ICD-10-PCS procedure codes for an operating room procedure. Surgical discharges are defined by specific MS-DRG codes. **Exclusions**: • with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for proximal deep vein thrombosis

0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12)

- with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for pulmonary embolism
- where a procedure for interruption of vena cava occurs before or on the same day as the first operating room procedure*
- any-listed ICD-9-CM or ICD-10-PCS procedure code for extracorporeal membrane oxygenation (ECMO)
- any-listed ICD-9-CM or ICD-10-CM diagnosis code for acute brain or spinal injury present on admission
- MDC 14 (pregnancy, childbirth, and puerperium)
- with missing gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing), or principal diagnosis (DX1=missing)

*If day of procedure is not available in the input data file, the rate may be slightly lower than if the information was available

Adjustment/Stratification: N/A

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **H-X; M-X; L-X; I-X**; 1b. Performance Gap: **H-7; M-11; L-0; I-0;**

<u>Rationale</u>:

- The Committee chose not to revote on the evidence because there had not been significant updates to the evidence since the measure was last endorsed.
- There are also clearly very many interventions that can be performed to reduce the incidence of perioperative pulmonary embolism and deep vein thrombosis.
- The developer provided a summary of performance data from 2011-2013 populated from the Healthcare Cost and Utilization Project database from a very large sample. The mean rate was 3.437 per 1000 surgical discharges in for 2011-2012 and 3.620 per 1000 surgical discharges in 2012-2013.

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: **2-H; 14-M; 2-L; 0-I** 2b. Validity: **3-H; 13-M; 1-L; 0-I**

<u>Rationale</u>:

- The developer in this version of the measure had further refined the measure to exclude less clinical significant deep vein thrombosis, specifically those in the calf and had also updated the risk-adjustment methodology.

0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12)
• The measures reliability was tested at the measure score level using a signal-to-noise analysis, with a result of 0.74, which was deemed adequate by the Committee. • When it came to studies on PPV regarding the validity of this measures, older studies described lower PPVs in the 40% range, however, studies that were more recent had much higher rates (80-90%). • Given the variation in PPV, the committee mentioned that some hospitals have the resources to adjudicate reporting of some of these measures and that some quality therefore, may be adjudication rather than actual variation in important patient outcomes. • There was some concern raised by the Committee that this measure used ICD-9 data rather than ICD-10, however, the developer mentioned that there was not enough history with ICD-10 to update the PSI measures. In addition, it was mentioned by NQF staff that other metrics had not been held to similar standards of ICD-10, particularly given this was so new. • There was also some concern by the committee about bias in terms of the exclusions for the metrics, specifically if there is an IVC filter in place. In some hospitals this may occur prior to the patient's arrival rather than during the hospitalization so there was concern that some patients may be inappropriately included.
3. Feasibility: 13-H; M-4; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • This measure is generated or collected by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims) • The required data elements are largely available in electronic health records or other electronic sources or existing electronic sources, a credible, near-term path to electronic collection is specified. • ALL data elements are in defined fields in electronic claims. • The indicator is based on readily available administrative billing and claims data. • This version of the indicator requires present-on-admission (POA) data for risk-adjustment and for specification of the numerator and denominator. • In 2007 POA indicators were added as data elements to the uniform bill form. A payment penalty was initiated on hospitals who did not include POA status on Medicare records beginning October 1, 2008. • The developers' QI software has been publicly available at no cost since 2001; Users have over ten years of experience using the developers' QI software in SAS and Windows. • There are no fees associated with this measure. Software is freely available from the developers Quality Indicators website. • There were no concerns about the feasibility of this measure.
4. Usability and Use: 12-H; 5-M; 0-L; 0-I *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • There were no concerns about the usability and use of this measure. The measure is used in several accountability programs.
5. Related and Competing Measures

0450: Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12)
• This measure directly competes with [NQF # and Title] [Description]. [Summarize the related/competing measure issue here, and the disposition of it] OR • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: **17-Y; 0-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2909: Perioperative Hemorrhage or Hematoma Rate
Submission | Specifications
Description: Perioperative hemorrhage or hematoma cases involving a procedure to treat the hemorrhage or hematoma, following surgery per 1,000 surgical discharges for patients ages 18 years and older. Excludes cases with a diagnosis of coagulation disorder; cases with a principal diagnosis of perioperative hemorrhage or hematoma; cases with a secondary diagnosis of perioperative hemorrhage or hematoma present on admission; cases where the only operating room procedure is for treatment of perioperative hemorrhage or hematoma; obstetric cases. **Numerator Statement**: Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any secondary ICD-9-CM or ICD-10-CM diagnosis codes for perioperative hemorrhage or hematoma and any-listed ICD-9-CM or ICD-10-PCS procedure codes for treatment of hemorrhage or hematoma Note that the ICD-10-CM specification is limited to postoperative hemorrhage or hematoma, whereas the ICD-9-CM specification captures both intraoperative and postoperative hemorrhage or hematoma (due to diagnosis codes that are less specific). **Denominator Statement**: Surgical discharges, for patients ages 18 years and older, with any-listed ICD-9-CM or ICD-10-PCS procedure codes for an operating room procedure. Surgical discharges are defined by specific MS-DRG codes. **Exclusions**: • with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission (1) for perioperative hemorrhage or postoperative hematoma • where the only operating room procedure is for treatment of perioperative hemorrhage or hematoma • with any secondary ICD-9-CM or ICD-10-CM diagnosis codes for perioperative hemorrhage or hematoma and any-listed ICD-9-CM or ICD-10-PCS procedure codes for treatment of perioperative hemorrhage or hematoma occurring before the first operating room procedure (2) • with any-listed ICD-9-CM or ICD-10-CM diagnosis codes for coagulation disorder

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- MDC 14 (pregnancy, childbirth, and puerperium)
- with missing gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing), or principal diagnosis (DX1=missing)

_____

1. Only for cases that otherwise qualify for the numerator.

2. If day of procedure is not available in the input data file, the rate may be slightly lower than if the information were available.

Adjustment/Stratification: N/A

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **16-Y; 0-N**; 1b. Performance Gap: **6-H**; **9-M**; **0-L**; **0-I**

<u>Rationale</u>:

- The developers conducted an environmental scan to identify studies relevant to the outcome of interest. Several studies have examined the scientific acceptability of the PSI09 measure. These studies have demonstrated moderate to high positive and negative predicative values. They also present results from several studies that demonstrate that perioperative hemorrhage is preventable.
- Between 2011-2012 the mean rate per 1000 surgical discharges was 3.432 (n=11,0043,343) and between 2012-2013 the mean rate was 3.613 per 1000 surgical discharges (n=10,780,407).
- While the committee agreed that there was evidence to demonstrate that one or more actions could impact this outcome measure, there was concern about the balance of post-operative hemorrhage and risk of other outcomes, particularly where there may be a balance such as in acute myocardial infarction where the use of medications such as clopidogrel may be indicated. The developer did describe that the measure does exclude people with congenital clotting problems – such as factor deficiencies – that it does not exclude people on medications that impact clotting. Despite these concerns, the committee passed the measure on evidence.
- The committee agreed that there were ways that providers could impact this outcome metric.

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: **6-H**; **9-M; 0-L;0-I** 2b. Validity: **5-H; 10-M; 0-L; 0-I**

<u>Rationale</u>:

- The committee agreed that the specifications for this metric were clear.
- A signal to noise analysis was performed with an overall result of 0.63, which was found to be adequate by the committee.

2909: Perioperative Hemorrhage or Hematoma Rate
• The developer conducted face validity assessments with an expert panel who agreed this was a valid metric of quality. • The committee did not have concerns about the scientific acceptability of this metric.
3. Feasibility: 12-H; 3-M; 0-L; 0-I *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • This measure is generated or collected by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims) • ALL data elements are in defined fields in electronic claims. • Because the indicator is based on readily available administrative billing and claims data, feasibility is not an issue. • This version of the indicator requires present-on-admission (POA) data for risk-adjustment and for specification of the numerator and denominator. • POA indicators were added as data elements to the uniform bill form (UB-04) effective October 1, 2007. Hospitals incurred a payment penalty for not including POA status on Medicare records beginning October 1, 2008. Each of the secondary diagnoses in a discharge record can be flagged as "present at the time the order for inpatient admission occurs" or not. • The committee was not concerned about the feasibility of this measure.
4. Usability and Use: 13-H; 2-M; 0-L; 0-I *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • There were no concerns about the usability and use of this measure. The measure is used in several accountability programs.
5. Related and Competing Measures • There are no related or competing measures.
Steering Committee Recommendation for Endorsement: **15-Y; 0-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2940: Use of Opioids at high Dosage in Persons without Cancer

Submission | Specifications

Description: The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer.

Numerator Statement:

Any member in the denominator with opioid prescription claims where the MED is greater than 120mg for 90 consecutive days or longer* MED calculation is included in S.6 Numerator Details

Denominator Statement: Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.

Exclusions: Any member with a diagnosis for Cancer or a Prescription Drug Hierarchical Condition Category (RxHCC) 8, 9, 10, or 11 for Payment Year 2015; or RxHCC 15, 16, 17, 18, or 19 for Payment Year 2016 (see list in S.11 and S.2b); or a hospice indicator (Medicare Part D) from the enrollment database.

Adjustment/Stratification: N/A

Level of Analysis: Health Plan, Population: National, Population: State

Setting of Care: Other, Pharmacy

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **16-H; 3-M; 0-L; 0-I**; 1b. Performance Gap: **13-H**; **7-M**; **0-L**; **0-I**

Rationale:

- The developer provided a systematic review of the evidence demonstrating the benefits of high-dose opioids for chronic pain are not established and the risks for serious harm related to opioid therapy increases at higher doses.
- Lower dosages of opioids reduce the risk for overdose, but a single dosage threshold for safe opioid use has not been identified.
- The measure was tested in three different health plan data sources – the Medicare population (mean rate=39.27 per 1,000), one commercial heath plan (mean rate= 32.003 per 1,000), and the Medicaid population (mean rate =34.04 per 1,000). The Committee noted that these rates demonstrate a significant performance gap.
- The Committee noted this is highly important to measure given the current national opioid overuse problem.

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: **13-H**; **7-M; 0-L; 0-I** 2b. Validity: **14-M**; **7-L**; **0-I**

Rationale:

- The developer used several data sets for reliability testing:

2940: Use of Opioids at high Dosage in Persons without Cancer
- For Medicare testing, the analysis included a convenience sample of over 700 Medicare Part D prescription drug plans (comprising a total of 7,067,445 individuals aged 18 and older)   - Testing was also conducted in one Commercial health plan (comprising a total of 209,191 individuals age 18 and older)   - For Medicaid testing, the analysis included 8 state-based prescription drug plans covering 6 states (comprising a total of 1,437,410 individuals age 18 and older)   - The mean reliability score across all plans is 0.9938.   - The developer assessed the face validity (only) of the measure using a technical expert panel from the Pharmacy Quality Alliance (PQA). 67 percent strongly agreed that the measure results reflected quality of care. Five PQA member organizations also tested the measure using their own data, and all strongly agreed that the measure reflected the quality of care provided for their populations.
3. Feasibility: 13-H; 8-M; 0-L; 0-I *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: - Pilot test sites indicated the measure was feasible and results were able to be reported efficiently and accurately.   - All the data elements are in defined fields in electronic claims
4. Usability and Use: 11-H; 9-M; 1-L; 0-I *(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 being used in the Medicare Part D Overutilization Monitoring System to monitor the utilization of opioids for members with the Medicare drug benefit.   - Although no unintended negative consequences to individuals or populations were identified during testing, concerns have been raised that prescribing changes such as dose reduction (without offering or arranging evidence-based treatment for patients with opioid use disorder) might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (1,2) or interference with appropriate pain treatment.
5. Related and Competing Measures **Related measures:**   - Measure 2950: Use of Opioids from Multiple Providers in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.   - Measure 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.   - These measures are also being considered for endorsement. The Committee determined that they are related but not competing.

2940: Use of Opioids at high Dosage in Persons without Cancer

Steering Committee Recommendation for Endorsement: **21-Y**; **0-N**

6. Public and Member Comment

Comments:

This measure received 3 comments. The commenters noted that the measure may be too inclusive and the developer should consider narrowing the measure to specific chronic conditions or diagnoses to be more meaningful.

Developers Response:

The recommendations in the 2015 American Geriatrics Society Beers Criteria are based on a systematic evidence review conducted by American Geriatrics Society Beers Criteria Expert Panel. The review is focused on the evidence for potential harms of medications in older adults. Medications then included in the Beers Criteria recommendations are those that the panel found evidence indicating that the medications should in general be avoided in all older adults or avoided in older adults with certain conditions or diseases, due to their associated risks for these populations. The Beers Criteria is updated regularly based on currently available literature. We believe it's important for this quality measure to be based on the systematic evidence review that is conducted by the Beers Criteria Expert Panel. The complete evidence tables for the systematic review can be accessed on the American Geriatrics Society's website here: http://geriatricscareonline.org/toc/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CL001

NCQA recognizes that some of the medications that are most attributable to adverse drug events in older adults that result in ED visits and hospitalizations are not included in the Beers Criteria as medications to be generally avoided (e.g., warfarin, antidiabetics and oral antiplatelets - although some oral antiplatelets are in fact included in the Beers Criteria and this measure: Dipyridamole, Ticlopidine). These other high-risk medications should be addressed in separate quality measures that focus on safe prescribing and appropriate monitoring, rather than this measure which focuses on medications that should be generally avoided. We agree with the need for such quality measures to improve safe prescribing of anticoagulants, antidiabetics, and opioids and have current work underway at NCQA to explore development of measures in these areas. Of note, the Pharmacy Quality Alliance has several measures addressing opioid prescribing that are currently being considered for NQF endorsement as part of this Patient Safety project. NCQA supports the endorsement of these measures and has plans to adapt them for health plan reporting in the near future.

In terms of the way this measure is currently specified to include a number of different medications, we believe that creating separate quality measures or indicators for all the specific medications in the Beers Criteria, or for each drug-disease interaction, would be burdensome for measurement and reporting by health plans. Plans can look at medications on an individual basis to see where improvements and interventions are needed, however we do not think this level of detail would be desirable for national reporting by health plans.

As a measure of potentially inappropriate medication use, NCQA does not expect this measure's performance to ever reach 0% (i.e., no prescribing of high-risk medications). There will always be cases where the benefits of prescribing a high-risk medication may outweigh the risks for certain patients. Clinicians should take into account various factors when considering the risk-benefit ratio of prescribing a

2940: Use of Opioids at high Dosage in Persons without Cancer
high-risk medication to an individual. A companion paper to the Beers Criteria was published by the American Geriatrics Society Workgroup on Improving Use of the Beers Criteria in 2015. The paper specifically states "the AGS 2015 Beers Criteria are reasonable to use for performance measurement across large groups of patients and providers but should not be used to judge care for any individual" (Steinman et al., 2015, JAGS). We believe measuring this concept of potentially inappropriate medication use among elderly at the health plan (i.e., population) level is an important and useful medication safety measure that health plans can use to identify high-risk medication prescribing. **Committee Response:** The Committee agrees with the developer response and maintains their decision to recommend this measure for continued endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2950: Use of Opioids from Multiple Providers in Persons without Cancer
Submission | Specifications
Description: The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies. **Numerator Statement**: Any member in the denominator who received opioid prescription claims from 4 or more prescribers AND 4 or more pharmacies. **Denominator Statement**: Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15. **Exclusions**: Any member with a diagnosis for Cancer or a Prescription Drug Hierarchical Condition Category (RxHCC) 8, 9, 10, or 11 for Payment Year 2015; or RxHCC 15, 16, 17, 18, or 19 for Payment Year 2016; (see list in S.11 and S.2b); or a hospice indicator from the enrollment database. **Adjustment/Stratification**: N/A **Level of Analysis: Health Plan, Population: National, Population: State** **Setting of Care: Other, Pharmacy** **Type of Measure**: Process **Data Source**: Administrative claims **Measure Steward**: Pharmacy Quality Alliance
STEERING COMMITTEE MEETING 07/27-07/28/2016 **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

2950: Use of Opioids from Multiple Providers in Persons without Cancer

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

1a. Evidence: **0-H; 20-M; 0-L; 0-I** 1b. Performance Gap: **13-H; 7-M; 0-L; 0-I**

Rationale:

- The evidence suggests that prescriptions for opioids from multiple prescribers and pharmacies correlate with undesired health outcomes. The use of multiple prescribers and pharmacies are associated with increased risks for opioid overdose. The Committee noted this is highly important to measure given the current national opioid overuse problem.
- The measure was tested in three different health plan data sources – the Medicare population (mean was 23.31 per 1,000 and the median was 26.12 per 1,000), one commercial heath plan (rate for this plan was 20.57 per 1,000), and the Medicaid population (mean was 72.28 per 1,000 and the median was 69.93 per 1,000). The Committee noted that these rates demonstrate a significant performance gap.

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: **9-H; 11-M; 0-L;0-I** 2b. Validity: **19-M; 0-L; 1-I**

Rationale:

- The developer tested the measure at the score level using several data sets for reliability testing:
  - For Medicare testing, the analysis included a convenience sample of over 700 Medicare Part D prescription drug plans (comprising a total of 7,067,445 individuals aged 18 and older)
  - Testing was also conducted in one Commercial health plan (comprising a total of 209,191 individuals age 18 and older)
  - For Medicaid testing, the analysis included 8 state-based prescription drug plans covering 6 states (comprising a total of 1,437,410 individuals age 18 and older)
- To demonstrate reliability, the developer conducted a signal-to-noise analysis of the computed measure score using a beta-binomial model.
- The mean reliability score across all plans is 0.9355.
- The developer assessed the face validity (only) of the measure using a technical expert panel from the Pharmacy Quality Alliance (PQA). 67 percent strongly agreed that the measure results reflected quality of care. Five PQA member organizations also tested the measure using their own data, and all strongly agreed that the measure reflected the quality of care provided for their populations.

3. Feasibility: 18-H; 2-M; 0-L; 0-I

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

Rationale:

- All data elements are in defined field in electronic claims.
- Pilot test sites indicated the measure was feasible and results were able to be reported efficiently and accurately.

4. Usability and Use: 10-H; 9-M; 1-L; 0-I

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

Rationale:

2950: Use of Opioids from Multiple Providers in Persons without Cancer
• The measure is currently being used in the Medicare Part D Overutilization Monitoring System to monitor the utilization of opioids for members with the Medicare drug benefit. • Although no unintended negative consequences to individuals or populations were identified during testing, , concerns have been raised that prescribing changes such as dose reduction (without offering or arranging evidence-based treatment for patients with opioid use disorder) might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (1,2) or interference with appropriate pain treatment
5. Related and Competing Measures • Measure 2940: Use of Opioids at high Dosage in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer. • Measure 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies. • These measures are also being considered for endorsement. The Committee determined that they are related but not competing.
Steering Committee Recommendation for Endorsement: **20-Y; 0-N**
6. Public and Member Comment **Comment:** The measure received 1 comment in support of the measure with a few recommendations for how the measure could be improved. **Developer Response:** The recommendations in the 2015 American Geriatrics Society Beers Criteria are based on a systematic evidence review conducted by American Geriatrics Society Beers Criteria Expert Panel. The review is focused on the evidence for potential harms of medications in older adults. Medications then included in the Beers Criteria recommendations are those that the panel found evidence indicating that the medications should in general be avoided in all older adults or avoided in older adults with certain conditions or diseases, due to their associated risks for these populations. The Beers Criteria is updated regularly based on currently available literature. We believe it's important for this quality measure to be based on the systematic evidence review that is conducted by the Beers Criteria Expert Panel. The complete evidence tables for the systematic review can be accessed on the American Geriatrics Society's website here: http://geriatricscareonline.org/toc/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CL001 NCQA recognizes that some of the medications that are most attributable to adverse drug events in older adults that result in ED visits and hospitalizations are not included in the Beers Criteria as medications to be generally avoided (e.g., warfarin, antidiabetics and oral antiplatelets - although some oral antiplatelets are in fact included in the Beers Criteria and this measure: Dipyridamole, Ticlopidine). These other high-risk medications should be addressed in separate quality measures that focus on safe prescribing and

2950: Use of Opioids from Multiple Providers in Persons without Cancer
appropriate monitoring, rather than this measure which focuses on medications that should be generally avoided. We agree with the need for such quality measures to improve safe prescribing of anticoagulants, antidiabetics, and opioids and have current work underway at NCQA to explore development of measures in these areas. Of note, the Pharmacy Quality Alliance has several measures addressing opioid prescribing that are currently being considered for NQF endorsement as part of this Patient Safety project. NCQA supports the endorsement of these measures and has plans to adapt them for health plan reporting in the near future. In terms of the way this measure is currently specified to include a number of different medications, we believe that creating separate quality measures or indicators for all the specific medications in the Beers Criteria, or for each drug-disease interaction, would be burdensome for measurement and reporting by health plans. Plans can look at medications on an individual basis to see where improvements and interventions are needed, however we do not think this level of detail would be desirable for national reporting by health plans. As a measure of potentially inappropriate medication use, NCQA does not expect this measure's performance to ever reach 0% (i.e., no prescribing of high-risk medications). There will always be cases where the benefits of prescribing a high-risk medication may outweigh the risks for certain patients. Clinicians should take into account various factors when considering the risk-benefit ratio of prescribing a high-risk medication to an individual. A companion paper to the Beers Criteria was published by the American Geriatrics Society Workgroup on Improving Use of the Beers Criteria in 2015. The paper specifically states "the AGS 2015 Beers Criteria are reasonable to use for performance measurement across large groups of patients and providers but should not be used to judge care for any individual" (Steinman et al., 2015, JAGS). We believe measuring this concept of potentially inappropriate medication use among elderly at the health plan (i.e., population) level is an important and useful medication safety measure that health plans can use to identify high-risk medication prescribing. **Committee Response:** The Committee agrees with the developer response and maintains their decision to recommend this measure for continued endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer
Submission | Specifications
Description: The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer

Numerator Statement: Any member in the denominator with opioid prescription claims where the MED is greater than 120mg for 90 consecutive days or longer* AND who received opioid prescriptions from 4 or more prescribers AND 4 or more pharmacies.

*MED calculation is included in S.6 Numerator Details

Denominator Statement: Any member with two or more prescription claims for opioids filled on at least two separate days, for which the sum of the days supply is greater than or equal to 15.

Exclusions: Any member with a diagnosis for Cancer or a Prescription Drug Hierarchical Condition Category (RxHCC) 8, 9, 10, or 11 for Payment Year 2015; or RxHCC 15, 16, 17, 18, or 19 for Payment Year 2016 (see list in S.11 and S.2b); or a hospice indicator (Medicare Part D) from the enrollment database.

Adjustment/Stratification: N/A

Level of Analysis: Health Plan, Population: National, Population: State

Setting of Care: Other, Pharmacy

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **0-H;17-M; 1-L; 0-I**; 1b. Performance Gap: **10-H; 6-M; 0-L; 0-I**

<u>Rationale</u>:

- The benefits for high dose opioids for chronic pain are not established and the risks for serious harms related to opioid therapy increase at higher opioid dosage. The use of multiple prescribers and pharmacies are associated with increased risks for opioid overdose. The risk for overdose increases with the number of prescribers and pharmacies.
- The measure's performance was tested in three different health plan data sources – the Medicare population (mean was 3.03 per 1,000 and the median was 2.89 per 1,000), one commercial heath plan (mean rate 1.45 per 1,000), and the Medicaid population (mean was 2.68 per 1,000 and the median was 2.38 per 1,000).

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: **11-H; 5-M; 0-L;0-I** 2b. Validity: **16-M; 2-L; 0-I**

<u>Rationale</u>:

- The measure was tested at the score level. The developer used several data sets for reliability testing:
- For Medicare testing, the analysis included a convenience sample of over 700 Medicare Part D prescription drug plans (comprising a total of 7,067,445 individuals aged 18 and older)
- Testing was also conducted in one Commercial health plan (comprising a total of 209,191 individuals age 18 and older)
- For Medicaid testing, the analysis included 8 state-based prescription drug plans covering 6 states (comprising a total of 1,437,410 individuals age 18 and older)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons without Cancer
• The mean reliability score across all plans is 0.9208. • The developer assessed the face validity (only) of the measure using a technical expert panel from the Pharmacy Quality Alliance (PQA). 83.3 percent strongly agreed that the measure results reflected quality of care. Five PQA member organizations also tested the measure using their own data, and all strongly agreed that the measure reflected the quality of care provided for their populations.
3. Feasibility: 15-H; 2-M; 0-L; 0-I *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • All data elements are defined in field in electronic claims • Pilot test sites indicated the measure was feasible and results were able to be reported efficiently and accurately.
4. Usability and Use: 10-H; 9-M; 1-L; 0-I *(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 being used in the Medicare Part D Overutilization Monitoring System to monitor the utilization of opioids for members with the Medicare drug benefit. • Although no unintended negative consequences to individuals or populations were identified during testing, , concerns have been raised that prescribing changes such as dose reduction (without offering or arranging evidence-based treatment for patients with opioid use disorder) might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (1,2) or interference with appropriate pain treatment.(3) Data indicate that if access to prescription opioids is limited, some users of opioid analgesics will transition to heroin or other illicitly obtained opioids, leading to increased overdose death coincident with prescribing restrictions.(
5. Related and Competing Measures • Measure 2950: Use of Opioids from Multiple Providers in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies. • Measure 2940: Use of Opioids at high Dosage in Persons without Cancer- The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer. • These measures are also being considered for endorsement. The Committee determined that they are related but not competing.
Steering Committee Recommendation for Endorsement: **18-Y; 0-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities

Submission | Specifications

Description: Percentage of patient-months for which medication reconciliation* was performed and documented by an eligible professional.**

* "Medication reconciliation" is defined as the process of creating the most accurate list of all home medications that the patient is taking, including name, indication, dosage, frequency, and route, by comparing the most recent medication list in the dialysis medical record to one or more external list(s) of medications obtained from a patient or caregiver (including patient-/caregiver-provided "brown bag" information), pharmacotherapy information network (e.g., Surescripts), hospital, or other provider.

** For the purposes of medication reconciliation, "eligible professional" is defined as: physician, RN, ARNP, PA, pharmacist, or pharmacy technician.

Numerator Statement: Number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period.

The medication reconciliation MUST:

• Include the name or other unique identifier of the eligible professional;

AND

• Include the date of the reconciliation;

AND

• Address ALL known home medications (prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements, and medical marijuana);

AND

• Address for EACH home medication: Medication name(1), indication(2), dosage(2), frequency(2), route of administration(2), start and end date (if applicable)(2), discontinuation date (if applicable)(2), reason medication was stopped or discontinued (if applicable)(2), and identification of individual who authorized stoppage or discontinuation of medication (if applicable)(2);

AND

• List any allergies, intolerances, or adverse drug events experienced by the patient.

_____

1. For patients in a clinical trial, it is acknowledged that it may be unknown as to whether the patient is receiving the therapeutic agent or a placebo.

2. "Unknown" is an acceptable response for this field.

Denominator Statement: Total number of patient-months for all patients permanently assigned to a dialysis facility during the reporting period.

Exclusions: In-center patients who receive < 7 hemodialysis treatments in the facility during the reporting month.

Adjustment/Stratification: N/A

Level of Analysis: Facility

2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities

Setting of Care: Ambulatory Care: Dialysis Facility

Type of Measure: Process

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

Measure Steward: Kidney Care Quality Alliance

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **0-H; 14-M; 4-L; 1-I** 1b. Performance Gap: **7-H; 10-M; 1-L; 2-I**

<u>Rationale</u>:

- The developer conducted a literature review which shows evidence to support the high incidence of medication-related problems in dialysis patients as well as evidence that supports their economic impact.
- Performance scores over time are not available. However, the measure was tested using data from three Kidney Quality Alliance member dialysis organizations, each with the capacity to provide retrospective analysis from a data warehouse repository. The mean performance score obtained from these organizations was 52.62% with a median score of 48.18%.

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: **9-H; 10-M; 0-L; 0-I** 2b. Validity: **0-H; 17-M; 2-L; 0-I**

<u>Rationale</u>:

- The developer tested the measure at the score level using beta-binomial testing. The mean reliability score is 0.9935.
- There was a systematic assessment of face validity by experts. Two groups of field experts in the field of ESRD / dialysis care.
    - 88.9% of the 9-member panel agreed it is highly likely or likely that the measure score provides an accurate reflection of medication reconciliation quality.
    - 77.8% of the panel agreed it is highly likely or likely that the measure can be used to distinguish good from poor quality.

3. Feasibility: 6-H; 11-M; 1-L; 2-I

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

<u>Rationale</u>:

- All data elements are defined in fields in electronic health records.
- This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

4. Usability and Use: 5-H; 12-M; 3-L; 0-I

(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>:

2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities

- Variants of the measure are currently in use member dialysis organizations for internal quality improvement, prompting the developer to develop this measure to standardize the specifications and definitions for accountability purposes.
- The developer suggests the measure be used in accountability programs in the future.

5. Related and Competing Measures

Related measures:

- 0097: Medication Reconciliation Post-Discharge- The percentage of discharges for patients 18 years of age and older for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record by a prescribing practitioner, clinical pharmacist or registered nurse.
- 0554: Medication Reconciliation Post-Discharge (MRP)- The percentage of discharges during the first 11 months of the measurement year (e.g., January 1–December 1) for patients 66 years of age and older for whom medications were reconciled on or within 30 days of discharge.
- 2456: Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient-This measure assesses the actual quality of the medication reconciliation process by identifying errors in admission and discharge medication orders due to problems with the medication reconciliation process. The target population is any hospitalized adult patient. The time frame is the hospitalization period.
- This measure is harmonized with existing NQF-endorsed medication reconciliation measures in that all similarly specify that the medication reconciliation must address ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency, and route. This measure, however, is unique among the currently endorsed medication reconciliation measures in that the level of analysis is the dialysis facility. The KCQA measure also moves beyond a single "check/box", specifying multiple components that must be met to be counted as a "success".

Steering Committee Recommendation for Endorsement: **17-Y; 2-N**

6. Public and Member Comment

Comments:

This measure received 2 comments. One comment expressed that medication reconciliation as a quality measure becomes too burdensome for providers without actually demonstrating that meaningful reconciliation has taken place. Another comment noted that the measure may not be harmonized with existing measures.

Developer Response:

KCQA agrees that medication reconciliation is a critical domain for patient safety and shares RPA's belief that, ideally, a systematic approach to medication management would optimize care. We note that the publication referenced in RPA's comment (Pai, 2013) suggests that the optimal model for such a systematic approach to medication management therapy (MTM) services for ESRD patients should be structured around the dialysis facility and provided by a pharmacist; the authors acknowledge that most dialysis facilities do not have ready access to a pharmacist. Recognizing this, the KCQA measure specifications permit medication reconciliation by appropriate, qualified professionals.

2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities
We disagree that NQF 2988 will be a "paper chase," and note that during testing in 5,292 facilities, approximately 4.5% of facilities scored 0 on the measure over the 6-month period for which data were examined. We believe it is a crucial first step towards improving medication management processes in the ESRD population that will improve patient safety. Going forward, we look forward to continuing to work with RPA, a KCQA member, and other members to improve medication management and this measure. **Committee Response:** The Committee agrees with the developer response and maintains their decision to recommend this measure for continued endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2993: Potentially Harmful Drug-Disease Interactions in the Elderly
Submission | Specifications
Description: The percentage of patients 65 years of age and older who have evidence of an underlying disease, condition or health concern and who are dispensed an ambulatory prescription for a potentially harmful medication, concurrent with or after the diagnosis. Four rates are reported for this measure: -Rate 1: The percentage of those with a history of falls that received a potentially harmful medication -Rate 2: The percentage of those with dementia that received a potentially harmful medication -Rate 3: The percentage of those with chronic kidney disease that received a potentially harmful medication -Rate 4: Total rate A lower rate represents better performance for all rates. **Numerator Statement**: Numerator 1: Patients with a history of falls who received at least one potentially harmful medication from Table DDE-A or Table DDE-B Numerator 2: Patients with a diagnosis of dementia who received at least one potentially harmful medication from Table DDE-D Numerator 3: Patients with chronic kidney disease who received at least one potentially harmful medication from Table DDE-E Numerator 4: The sum of the three numerators **Denominator Statement**: All patients ages 65 years of age and older with a history of falls, dementia or chronic kidney disease in the measurement year or the year prior to the measurement year. **Exclusions**: The following are exclusions for the condition-specific rates and total rate: For those who meet denominator criteria for the history of falls rate (Rate 1): exclude those with a diagnosis of psychosis, schizophrenia, bipolar disorder or seizure disorder.

2993: Potentially Harmful Drug-Disease Interactions in the Elderly

For those who meet denominator criteria for those with dementia rate (Rate 2): exclude those with a diagnosis of psychosis, schizophrenia or bipolar disorder.

Adjustment/Stratification: N/A

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Pharmacy

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Pharmacy

Measure Steward: National Committee for Quality Assurance

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **13-H; 7-M; 0-L; 0-I**; 1b. Performance Gap: **17-H; 3-M; 0-L; 0-I**

<u>Rationale</u>:

- The developer provides evidence based on the AGS Beers Criteria recommendations against the use of potentially harmful medications in older adults with specific conditions.
- The developer provided data extracted from HEDIS data collection for Medicare Advantage Health Plans (including both HMO and PPO plans). The performance data is summarized at the health plan level. The data demonstrates variation in all four rates of the measure.
- For 2014, 48.0 percent of individuals with a history of falls received at least one high-risk medication. Among individuals with dementia, 48.5 percent received at least one high-risk medication and among those with chronic kidney disease, 9.6 percent received at least one high-risk medication.

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: **9-H; 8-M; 3-L;0-I** 2b. Validity: **7-H; 9-M; 4-L;0-I**

<u>Rationale</u>:

- The developer tested the measure at the score level using beta-binomial testing. Strong reliability is demonstrated since majority of variance is due to signal and not to noise. The reliability rates for each condition are:
    - Rate 1 (History of Falls)-0.96565
    - Rate 2 (Dementia)-0.97552
    - Rate 3 (Chronic Kidney Disease)-0.95273
    - Rate 4 (Total)-0.98571
- There was both an assessment of face validity and also of construct validity by correlations of this measure with other measures of medication safety. The developers found Pearson correlation coefficients:
    - Rate 1 (History of Falls)-0.694
    - Rate 2 (Dementia)-0.585
    - Rate 3 (Chronic Kidney Disease)-0.480
    - Rate 4 (Total)-0.386

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▪ Coefficients with absolute value of less than 0.3 are generally considered indicative of weak associations whereas absolute values of 0.3 or higher denote moderate to strong associations.
3. Feasibility: 12-H; 5-M; 3-L; 0-I *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score) • ALL data elements are in defined fields in a combination of electronic sources.
4. Usability and Use: 11-H; 7-M; 2-L; 0-I *(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 several accountability programs.
5. Related and Competing Measures • 0022: Use of High-Risk Medications in the Elderly (DAE)- There are two rates for this measure: the percentage of patients 65 years of age and older who received at least one high-risk medication. The percentage of patients 65 years of age and older who received at least two prescriptions for the same high-risk medication. For both rates a lower rate represents better performance. • This measure is not completely harmonized with 0022. They both have a similar focus (measuring potentially inappropriate medication use in the elderly) and reporting level (health plan), however they have different target populations. This measure targets patients with a specific condition or disease that can experience adverse effects when combined with certain medications that are recommended to be avoided for that condition. NQF 0022 targets a larger population of all older adults and assesses use of high-risk medications that have been recommended to be avoided in all older adults.
Steering Committee Recommendation for Endorsement: **17-Y; 3-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3001: PACE Participant Fall Rate
Submission | Specifications
Description: The quarterly incidence rate of falls amongst PACE participants per 1,000 participant days. **Numerator Statement**: Falls experienced by Participants in the PACE program during the month.

3001: PACE Participant Fall Rate

Denominator Statement: The denominator represents exposure of PACE participants to the risk of falling.

Exclusions: Exclude persons who were not enrolled as PACE participants, or who were not in their home location.

Adjustment/Stratification: N/A

Level of Analysis: Facility

Setting of Care: Other: PACE programs provide services to participants who live in their own homes (or in home-like settings) in the community. Participants attend PACE centers regularly (e.g., 3 days per week) for a variety of activities and support services.

Type of Measure: Outcome

Data Source: Electronic Clinical Data: Electronic Health Record, Management Data, Paper Medical Records

Measure Steward: Center for Medicare and Medicaid Services

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **16-Y; 3-N**; 1b. Performance Gap: **2-H; 15-M; 1-L; 1-I**

<u>Rationale</u>:

- The developer provides the structural and process factors that influence fall rates and cites several studies that find an indirect relationship between inpatient staffing and fall rates. The developer also calls out two studies that found, through a systematic review and meta-analysis, that fall prevention activities can reduce falls by up to 30 percent.
- The Committee agreed that there were ways that providers could reduce the incidence of falls. The Committee also recognized the importance of falls an important measure of quality, but was concerned that the evidence presented for this measure did not include some of the literature describing fall prevention in the home, rather it focused on fall prevention in hospitals. Notably, this measure not only includes falls where the patient reaches the floor but also falls that are assisted.
- The developers collected data from a sample of 50 sites which were randomly selected out of a total of 114 PACE sites. A total of 34 of these sites submitted data from January –March 2015 for the fall rate. One site was excluded. They found a mean fall rate of 4.27 per 1,000 participant day (n=33). The mean rate appears to be higher that the rates obtained from primarily hospital-based studies provided by the developer after a review of the literature.
- The developers examined fall rates based on two demographic variables, age and gender, to that the potential so socio-demographic adjustment could be assessed. Both PACE-site mean participant age and mean proportion of males had very weak correlations with total fall rates ($r = 0.08$ and $r = -0.14$, respectively).
- Several studies have demonstrated a difference in falls rates for specific populations. Disparities have been identified according to age, gender, disability, and race/ethnicity. Hospitalization for hip fractures due to falls is significantly higher for females than for males. However, fatality rates due to falls are higher for men than for women, and higher for Caucasians compared to African-Americans. Among community-dwelling older women, age-adjusted fall rates are not different between African-Americans and Caucasians.

3001: PACE Participant Fall Rate

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: **0-H; 17-M; 1-L;1-I** 2b. Validity: **15-M; 4-L; 0-I**

Rationale:

- The committee agreed that the specifications of this metric were clear.
- Reliability data using a signal-to-noise analysis demonstrated that it was reliable with score of 0.83 across 33 PACE sites.
- Content validity was assessed with a group of experts which demonstrated that experts agreed that this was a valid measure of quality.
- There were also several exclusions to this measure, including falling into a chair, toilet or bed that were not included. There were some concerns by the Committee that these falls were also clinically significant and should be included. Given these definitions there was concern about the precision of measuring falls, particularly in the home setting where monitoring may vary. For these reasons, there was a concern about under-reporting.

3. Feasibility: 0-H; 14-M; 5-L; 0-I

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

Rationale:

- This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score) Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Some data elements are in defined fields in a combination of electronic sources.
- Some PACE Organizations do not use electronic medical records. All organizations will abstract data manually for this measure from either their electronic or paper charts.
- After collecting data from PACE sites for feasibility and reliability testing, a post-data collection survey was conducted, to ask PACE sites about data that they did not have available, data collection burden, and other issues.
- Some sites reported a fairly high data collection burden, however, this was balanced by the fact that over half of the sites stated that the data were very easy to obtain. Although there is a perceived data collection burden, this is outweighed by the usefulness of the data and comparative benchmarks.
- Because of the high reported ease of obtaining the data, we anticipate that the perceived data collection burden will decrease as sites become more familiar with the data collection and submission process.
- No fees or licensing requirements to use any aspect of the measure as specified, were reported.
- The committee did not have any major concerns about feasibility.

4. Usability and Use: 0-H; 14-M; 3-L; 0-I

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

Rationale:

- CMS is considering the use of the PACE Participant Fall Rate in accountability applications within the next two years.

3001: PACE Participant Fall Rate
• The Committee discussed the impact of public reporting this metric in the future and potential issues that may arise regarding its usability and feasibility in practice
5. Related and Competing Measures • There are two related measures in the portfolio: 0141: Patient Fall Rate and 0266: Patient Fall which measure falls in different settings. • There was also concern that because NQF has endorsed several fall measures that vary in definition those future efforts should focus on ensuring that fall definitions are harmonized across measures.
Steering Committee Recommendation for Endorsement: **17-Y; 1-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3003: PACE- Participants Falls with Injury
Submission | Specifications
Description: The quarterly incidence rate of falls with injury amongst PACE participants per 1,000 participant days. **Numerator Statement**: Falls with injury experienced by participants in the PACE program during the month. **Denominator Statement**: The denominator represents exposure of PACE participants to the risk of falling. **Exclusions**: Exclude persons who were not enrolled as PACE participants, or who were not in their home location. **Adjustment/Stratification**: N/A **Level of Analysis: Facility** **Setting of Care: Other: PACE programs provide services to participants who live in their own homes (or in home-like settings) in the community. Participants attend PACE centers regularly (e.g., 3 days per week) for a variety of activities and support services.** **Type of Measure**: Outcome **Data Source**: Electronic Clinical Data: Electronic Health Record, Management Data, Paper Medical Records **Measure Steward**: Center for Medicare and Medicaid Services
STEERING COMMITTEE MEETING 07/27-07/28/2016 **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **18-Y;1-N** 1b. Performance Gap: **6-H; 12-M; 1-L; 0-I** Rationale:

3003: PACE- Participants Falls with Injury

- The developers reviewed eight peer-reviewed articles on patient falls in hospitals and summarized the strengths and weaknesses of those studies. Overall, these studies found a significant indirect relationship between some aspect of inpatient nursing staffing and fall rates. Two studies found the evidence on fall prevention activities (processes) is mixed. One study found through a systematic literature review and meta-analysis that fall prevention activities may have reduced fall rates by up to 25 percent. Another study found that fall prevention strategies reduced falls up to 30 percent, although an optimal prevention bundle was not identified.
- The developers found a 1.78 mean participant falls with injury rate (n=33). They concluded that there are performance gaps in falls with injury and cited a study that reported falls with injury rates in acute inpatient units varied by unit type and over time.
- The committee agreed that there were one or more ways that providers can impact falls rates with injury as an outcome. However, there was concern by the committee that the literature provided by the developer solely includes studies from inpatient studies, particularly when it comes to preventing falls with injury.

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: **10-H; 9-M; 0-L;0-I** 2b. Validity: **16-M; 3-L; 0-I**

Rationale:

- The committee agreed that the specifications for this metric were clear.
- Reliability testing was done at 33 PACE sites and demonstrate a signal-to-noise ratio of 0.88.
- Content experts reviewed the validity of the measure and agreed that falls with injury was a valid measure of quality.
- The committee did not have concerns about the scientific acceptability of this measure.

3. Feasibility: 6-H; 11-M; 2-L; 0-I

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

Rationale:

- This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score) Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Some data elements are in defined fields in a combination of electronic sources.
- Some PACE Organizations do not use electronic medical records. All organizations will abstract data manually for this measure from either their electronic or paper charts.
- After collecting data from PACE sites for feasibility and reliability testing, a post-data collection survey was conducted, to ask PACE sites about data that they did not have available, data collection burden, and other issues.
- Some sites reported a fairly high data collection burden, however, this was balanced by the fact that over half of the sites stated that the data were very easy to obtain. Although there is a perceived data collection burden, this is outweighed by the usefulness of the data and comparative benchmarks.
- Because of the high reported ease of obtaining the data, we anticipate that the perceived data collection burden will decrease as sites become more familiar with the data collection and submission process.

3003: PACE- Participants Falls with Injury
• No fees or licensing requirements to use any aspect of the measure as specified, were reported. • The committee did not have concerns about the feasibility of this measure.
4. Usability and Use: 6-H; 10-M; 3-L; 0-I *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • CMS is considering the use of the PACE Participant Fall Rate in accountability applications within the next two years. • There were no concerns about the usability of this metric.
5. Related and Competing Measures • There are measures that are related to this that measure the same concept but do it in different (i.e. non-PACE settings), specifically 0202: Falls with injury and 0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay). • There was concern that there was overlap with measure 3001 specifically this metric is a subset of the 3001 (falls in PACE settings).
Steering Committee Recommendation for Endorsement: **18-Y; 1-N**
6. Public and Member Comment **Comment:** This measure received 1 comment. The commenter provided additional references that relevant to the measure and requested the measure include data on the urgency of the task. **Developer Response:** The developer believes that this situation (i.e., urgency) is common across all care settings and this issue is not unique to the PACE setting. We sought to harmonize our measure with existing NQF-endorsed measures, which do not capture this information at this time. In addition, we are concerned that collecting this data would be challenging and therefore could negatively impact the reliability and validity of the measure if included. **Committee Response:** The Committee agrees with the developer response and maintains their decision to recommend this measure for continued endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

Submission | Specifications

Description: This measure is for the risk-adjusted Standardized Infection Ratio (SIR) for all Surgical Site Infections (SSI) following breast procedures conducted at ambulatory surgery centers (ASCs) among adult patients (ages 18 - 108 years) and reported to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The measure compares the reported number of surgical site infections observed at an ASC with a predicted value based on nationally aggregated data. The measure was developed collaboratively by the CDC, the Ambulatory Surgery Center Quality Collaboration (ASC QC), and the Colorado Department of Public Health and Environment. CDC is the measure steward.

Numerator Statement: Surgical site infections (SSIs) during the 30-day (superficial SSI) and 90-day (deep and organ/space SSI) postoperative periods following breast procedures in Ambulatory Surgery Centers.

Denominator Statement: Breast procedures, as specified by the operative codes that comprise the breast procedure category of the NHSN Patient Safety Component Protocol, performed at ambulatory surgery centers.

Exclusions: Hospital inpatients and hospital outpatient department patients, pediatric patients and very elderly patients, and brain-dead patients whose organs are being removed for donor purposes

Adjustment/Stratification: N/A

Level of Analysis: Facility

Setting of Care: Ambulatory Care: Ambulatory Surgery Center (ASC)

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper Medical Records

Measure Steward: Surveillance Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **19-Y; 0-N**; 1b. Performance Gap: **7-H; 12-M; 0-L; 0-I**

Rationale:

- The overall body of evidence on the incidence, outcomes, and prevention of SSIs in the ambulatory surgical center (ASC) patient population is sparse but the available data suggest risks for SSIs following some breast procedures in some settings may be as high as 30%. In the current literature, the rates of SSI in ambulatory surgery centers is relatively low—however, aggregate numbers of infections can still cause a substantial burden, as those often result in post-surgical visits and morbidity.
- ASCs have been shown to have a lower SSI rate than inpatient settings. Though estimates of risk for breast procedures specifically vary from 1% to over 30% (and rate varies from 3 SSI to 28 SSI per 1000 procedures) depending on breast procedure type, sample population, and definition of SSI, it is clear that breast procedure-related SSIs are a large burden to outpatient healthcare facilities, and provide much room for benefit. There is little data on the number or proportion of preventable SSI specifically following breast procedures conducted in ASCs.
- The developer summarized an exploratory analysis of NHSN data that showed that out of 67,150 ambulatory surgical center (ASC) procedures reported to NHSN from 2010-2013, 30,787 (45.9%) were breast procedures.

3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

- Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating a risk of SSI of 0.25%. This was the highest volume and SSI risk among all outpatient ASC procedures reported in the timeframe.
- Numerous individual studies and systematic reviews provide strong evidence that measurement and feedback of surgical site infections leads to lower SSI rates in the long term.
- Data on disparities in surgical site infections in ASCs, as well as in hospitals, are sparse. No studies or reviews were found specifically on disparities surrounding SSI in any healthcare facility. However, it has been extensively documented that surgical site infections lead to an excess cost burden as well as excess hospital stay for patients. These additional costs may cause disparities in care for SSI, which are reflective of disparities in access to health care in general.

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: **13-M, 1-L, 2-I** 2b. Validity: **17-M; 1-L; 1-I**

Rationale:

- This measure calculates a Standardized Infection Ratio (SIR) for Surgical Site Infections (SSI) following breast procedures conducted at ambulatory surgery centers (ASCs) among adult patients (ages 18 - 108 years)
- The measure is reported as an observed-to-expected ratio, which compares the reported number of surgical infections observed at an ASC with a predicted value based on nationally-aggregated data.
- The developer assessed data element reliability on procedures reported from selected ASCs in Colorado from January to December 2014..
- To demonstrate validity of the measure score, the developer conducted a face validity assessment using a formal consensus process.
- The developer reports that there was high level of agreement among the respondents regarding the validity of the measure, with 9/11 (81.8%) agreeing that the measure appears to measure what it is intended to, giving a 5/5 rating response.
- The measure is risk adjusted using a statistical model with two factors: categorical ASA classification, and ordinal age categories.

3. Feasibility: 3-H; 16-M; 1-L; 0-I

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

Rationale:

- Data for this measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score) and abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Some data elements are in defined fields in a combination of electronic sources.

4. Usability and Use: 12-H; 7-M; 0-L; 0-I

3025: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure
(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 in use in several programs.
5. Related and Competing Measures • This measure directly competes with [NQF # and Title] [Description]. [Summarize the related/competing measure issue here, and the disposition of it] OR • No related or competing measures noted.
Steering Committee Recommendation for Endorsement: **12-Yes, 4-N** Rationale •
6. Public and Member Comment •
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate
Submission | Specifications
Description: Prevalence of PACE participants on the PACE organization census with pressure ulcers/injuries in a quarter, expressed as persons with 1 or more pressure ulcers/injuries divided by the number of participants on the PACE organization's census for at least one day during the quarter. This is a rate-based measure of skin breakdown due to pressure or pressure combined with sheer. The rate will be calculated quarterly. The target population is participants on a PACE organizations census for at least one day during the quarter. **Numerator Statement**: The total number of participants enrolled during the quarter that have at least one documented PU (of any stage) acquired while a PACE participant. **Denominator Statement**: Number of participants on a PACE organization's census during the quarter. **Exclusions**: Exclude persons who were not on the PACE census for at least one day during the quarter. Exclude participants who lived outside their home/assisted living setting for every day of the quarter. **Adjustment/Stratification**: N/A **Level of Analysis: Facility** **Setting of Care: Other: PACE programs provide services to participants who live in their own homes (or in home-like settings) in the community. Participants attend PACE centers regularly (e.g., 3 days per week) for a variety of activities and support services.**

3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate

Type of Measure: Outcome
Data Source: Electronic Clinical Data, Management Data, Paper Medical Records

Measure Steward: Center for Medicare and Medicaid Services

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **16-Y;0-N** 1b. Performance Gap: **2-H; 11-M; 3-L; 0-I;**

Rationale:

- Pressure ulcers are an important outcome, particularly in the frail older adult population cared for in PACE programs.
- The committee agreed that there were ways to prevent pressure ulcers, as an outcome, in this population of frail older adults who are cared for in PACE organizations.
- The developers collected data from a sample of 50 sites which were randomly selected out of a total of 114 PACE sites. A total of 29 of these sites submitted data from January-February 2015 for the fall rate. One site was excluded.
- The developers found a mean pressure related injury rate of 1.85 among every 100 participants (n=28) and a mean of 0.81 per 100 participations for stage 3 or above. Their testing showed some evidence of variation in pressure injury rates by academic affiliation and with metropolitan status, however due to small sample size, none of the differences were statistically significant.
- The literature selected by the developer seem to indicate that there is a performance gap in pressure ulcer related injury rates. However, there was considerable discussion on the performance gap, and despite a demonstrated performance gap by the developer the committee did not reach consensus on performance gap

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: **2-H; 11-M; 3-L;0-I** 2b. Validity: **2-H, 11-M, 2-L, 0-I**

Rationale:

- There were specifications provided by the developer that were somewhat confusing to the committee.
- The reliability data was provided as a signal-to-noise analysis. Mean reliability scores were 0.73 for all ulcers and 0.83 for stage 3 and 4 ulcers.
- A total of 8 academic experts completed content validity testing. As shown in Table 2 above, the majority of items on the content validity testing survey had good validity as indicated by an I-CVI of greater than 0.78 (16 of 20 items or 75%). In addition, none of the items was disagreed upon by 6 or more experts
- There were concerns by the committee over the validity of the assessment of the pressure ulcers, particularly because a high percentage of them were “unknown” states.
- There were also concerns that the reliability was poorer for lower stage ulcers, particularly stage 1 and 2 than stage 3 and 4 (deeper ulcers). The committee was identified several issues with the specifications of the measure, that were somewhat confusing. As a result, the measure failed on

3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate
reliability and was recommended that the developer clarify the specifications for re-review at a later time. • In response to the Committee' concerns, the developer revised the reliability specifications to more clearly define the inclusion and exclusion criteria. The measure was also updated to only capture pressure ulcers stage 3+. The median reliability at these stages was much higher at .92.
3. Feasibility: 3-H, 10-M, 3-L-0-I *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score, and/or, Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry) • Some data elements are in defined fields in electronic sources • Some PACE Organizations do not use electronic medical records. All organizations will abstract data manually for this measure from either their electronic or paper charts. • Overall, the data collection time was reasonable, around 4 hours with less than an hour for data submission when the developer conducted a survey with PACE organizations to collect information on their experiences with data collection. • There is a perceived data collection burden, however, this is outweighed by the usefulness of the data for quality improvement and distinguishing PACE sites based on their quality of care. • Because of the high reported ease of obtaining the data, the developer anticipates that the perceived data collection burden will decrease as sites become more familiar with the data collection and submission process. • No fees or licensing requirements to use any aspect of the measure as specified, were reported. • The Committee discussed this criteria during the post-comment call on October 25,2016 and had no concerns.
4. Usability and Use: 3-H; 10-M; 3-L; 0-I *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The developer is evaluating its use in upcoming PACE quality programs. • The developer is considering the use of the PACE-Acquired Pressure Ulcer/Injury Prevalence Rate in accountability applications within the next two years. • The Committee discussed this criteria during the post-comment call on October 25,2016 and had no concerns.
5. Related and Competing Measures • There are several related measures that measure pressure ulcers in different settings. However, no metrics specifically report the outcome of pressure ulcers in PACE organizations so no measures are directly competing. • 0201: Pressure ulcer prevalence (hospital acquired) • 0538: Pressure Ulcer Prevention and Care

3000: PACE-Acquired Pressure Ulcer-Injury Prevalence Rate
• 0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) • 0679: Percent of High Risk Residents with Pressure Ulcers (Long Stay) measure issue here, and the disposition of it]
Steering Committee Recommendation for Endorsement: **Y-12**; **N-4** Rationale •
6. Public and Member Comment •
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
Rationale for deferral

Measure Recommended for Trial Use

2983: Potassium Sample Hemolysis in the Emergency Department

Submission | Specifications

Description: Percentage of laboratory potassium samples drawn in the emergency department (ED) with hemolysis.

Numerator Statement: ED Potassium Samples with Hemolysis

Denominator Statement: All ED patients getting a lab potassium sample

Exclusions: None

Adjustment/Stratification: N/A

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility, Other

Type of Measure: Intermediate Clinical Outcome

Data Source: Electronic Clinical Data: Laboratory

Measure Steward: Cleveland Clinic

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **6-H;11-M; 1-L; 2-I**; 1b. Performance Gap: **3-H; 16-M; 0-L; 0-I;**

Rationale:

- The developer provided a number of studies that demonstrate that hemolysis is preventable by using appropriate blood draw techniques. The evidence is weak to moderate and several studies provided are rated as insufficient evidence.
- The developer presented results from a study conducted at the Cleveland Clinic between June 2013 and October 2015. The percentage of hemolysis in Cleveland Clinic's emergency department decreased over time with about 13% hemolysis rate in June-2013 and a 2% rate in October 2015.

2. Scientific Acceptability of Measure Properties: As this e-measure is a candidate for eMeasure Approval for Trial Use, testing for the measure will be submitted at a later time.

(2b1. specifications consistent w/evidence)

Trial Measure Specifications: H-X; **M-X**; **L-X**; **I-X**

The measure may be considered for endorsement after sufficient data to assess reliability and validity have been submitted to NQF, within three years of approval.

Rationale:

- This measure has not yet been tested; for this reason, it is being considered for Trial Use Approval.

3. Feasibility: 11-H; 7-M; 0-L; 0-I

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

Rationale:

2983: Potassium Sample Hemolysis in the Emergency Department
• There are multiple ways to collect this data. The developer collected data from both the ONC certified EMR Epic (Epic 14) and the ONC certified Laboratory information systems • ALL data elements are in defined fields in electronic health records (EHRs). • This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)
4. Usability and Use: 4-H; 13-M; 0-L; 0-I *(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 not currently in use. • Panned use includes: Public Reporting, Public Health/Disease Surveillance, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), and Quality Improvement (Internal to the specific organization)
5. Related and Competing Measures • N/A
Steering Committee Recommendation for eMeasure Approval for Trial Use: **19-Y; 0-N**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Not Recommended

3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission
Submission
Description: This measure determines the proportion of Pediatric Intensive Care Unit (PICU) patients for whom an initial risk assessment for development of an immobility-related pressure ulcer is performed. The assessment is to be performed within the first 24 hours of admission to the PICU with the use of a standardized, validated pressure ulcer risk assessment tool designated as appropriate by the institution. The results of the assessment must be documented in the patient's chart upon completion. **Numerator Statement**: Number of PICU patients for whom an assessment of immobility-related pressure ulcer risk using a standardized pressure ulcer risk assessment tool was documented within 24 hours of admission. **Denominator Statement**: All patients admitted to the PICU for at least 24 hours during a monthly or quarterly reporting period. **Exclusions**: none **Adjustment/Stratification**: N/A **Level of Analysis: Facility, Integrated Delivery System**

3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data: Electronic Health Record, Other, Paper Medical Records

Measure Steward: Pediatric Consultants, LLC

STEERING COMMITTEE MEETING 07/27-07/28/2016

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

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

1a. Evidence: **0-H; 6-M; 9-L; 4-I** 1b. Performance Gap: **H-X**; **M-X**; **L-X**; **I-X; ;** Evidence Exception: **Y-X; N-X**

<u>Rationale</u>:

- The developers state that there are currently no clinical guidelines for pressure ulcer prevention and treatment in the pediatric population. Assessment tools are limited, so the Braden Q Scale was adapted from the Braden Scale of be used in this population.
- The developer proposed that the early identification of patients at risk for pressure ulcer is a key step in preventing them in critically ill and injured children which has been shown to reduce morbidity and mortality rates as well as healthcare costs.
- There was concern by the committee that despite being an important area of focus that there was insufficient evidence to demonstrate a link between assessment and outcomes. There was no systematic review of the evidence nor any grading provided by the developer.
- This measure was tested as an eMeasure at one site, Lurie Children's Hospital. Electronic output was provided for a reporting period of 01 Jan – 31 March 2015 and included 106 unique patients representing 109 events. Overall (N=106), clinical performance was high with 94% of patients meeting the measure.
- Reasons for not meeting the measure including having a pressure ulcer assessment performed outside of the 24-hour window (N=4) and not having a pressure ulcer assessment performed at all (N=3). Looking across age groups, of the children aged 0 - <6 (N=66), 92% met the measure, of the children aged 6 - <13 (N=16), 94% met the measure, of the children aged 13 - <19 (N=20), 95% met the measure, and of PICU patients 19 and older (N=4), 100% met the measure.
- The committee also mentioned that studies in pediatric populations are harder to do, and high-grade evidence is more difficult to attain than for other populations. It was also pointed out that there was a performance gap, and that despite not having evidence linking this process to outcomes, clinicians felt that not assessing for pressure ulcers placed children at risk. However, the committee felt that the assessment required to implement this – the Braden Q scale – may overburden providers given that there are 28 questions. This would be a threat to the feasibility of implementation of the measure. Ultimately, for these reasons the committee did not pass the measure on evidence and there was no further discussion of the measure.

2. Scientific Acceptability of Measure Properties: The measure [does/does not] meet the Scientific Acceptability criteria

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

2a. Reliability: **H-X**; **M-X**; **L-X**; **I-X** 2b. Validity: **H-X**; **M-X**; **L-X**; **I-X**

3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission
Rationale: • This measure assesses the proportion of PICU patients for whom an initial risk assessment for development of an immobility-related pressure ulcer has been performed within 24 hours of admission. • The measure is specified at the hospital facility or integrated delivery system level of analysis, and is meant to be reported on a monthly or quarterly basis. • The denominator includes all patients admitted to the PICU for at least 24 hours during the reporting period. • The numerator includes patients from the denominator population who have been assessed for risk of pressure ulcers using a standardized, validated tool. • The measure defines a standardized, validated pressure ulcer risk assessment tool as "a validated assessment tool that is applied in a standardized fashion to each patient admitted to the PICU for at least 24 hours." • The developer notes that, currently, the Braden Q is the only validated immobility-related pressure ulcer risk assessment tool available for critically ill and injured children; however, the measure allows for the use of other validated risk assessment tools, if available. • To demonstrate reliability, the developer performed data element testing at one hospital site with 288 pediatric beds (including 40 PICU beds) and approximately 11,291 pediatric admissions annually. • The developer reported that inter-rater reliability was 100% for all critical data elements, and 100% for overall clinical performance of the measure. • Because this measure failed on evidence, scientific acceptability was not discussed.
3. Feasibility: H-X; M-X; L-X; I-X *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The committee felt that the assessment required to implement this – the Braden Q scale – may overburden providers given that there are 28 questions.
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)* Rationale: • Use and usability of this metric was not discussed by the committee.
5. Related and Competing Measures • There are two related measures, one outcome and one process measure: 0337: Pressure Ulcer Rate (PDI 2) and 0539: Pressure Ulcer Prevention Implemented during Short Term Episodes of Care
Steering Committee Recommendation for Endorsement: **Y-X**; **N-X** Rationale: • The Committee did not vote on the suitability for the endorsement because the measure did not pass on evidence.

3005: Initial Risk Assessment for Immobility-Related Pressure Ulcer within 24 Hours of PICU Admission
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3006: Initial Baseline Screen of Nutritional Status for Every Patient within 24 Hours of PICU Admission
Submission
Description: The measure will determine the percentage of pediatric intensive care unit (PICU) patients for whom an initial nutritional status screening was performed. The screening is to be performed within the first 24 hours of admission to the PICU with the use of a standardized nutrition-screening tool. The results of the screening must be documented in the patient's chart upon completion. **Numerator Statement**: Number of PICU patients for whom a screening of nutritional status was documented with use of a standardized nutrition screening tool within 24 hours of admission to the PICU. **Denominator Statement**: All patients admitted to the PICU for at least 24 hours during a monthly or quarterly reporting period. **Exclusions**: Patients who have already had a documented nutrition screening or assessment in the previous 48 hours. **Adjustment/Stratification**: N/A **Level of Analysis: Facility, Integrated Delivery System** **Setting of Care: Hospital/Acute Care Facility** **Type of Measure**: Process **Data Source**: Electronic Clinical Data: Electronic Health Record, Other **Measure Steward**: Pediatric Consultants, LLC
STEERING COMMITTEE MEETING 07/27-07/28/2016 **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **2-H; 8-M; 7-L; 3-I** 1b. Performance Gap: **0-H; 10-M; 9-L; 1-I;** <u>Rationale</u>: • The developers provide evidence based on clinical guidelines from the American Society for Parenteral and Eternal Nutrition. The guideline states "children admitted with critical illnesses should undergo nutrition screening to identify those with existing malnutrition or those who are nutritionally at-risk." • The developers cite a systematic review and studies published after the systematic review that demonstrate the that the majority of children present to the PICU with indices of malnutrition and that

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throughout PICU stay, negative energy and protein balances are common among patients and correlate with decreasing anthropometric changes. • At the time of publication of this clinical guideline, there were no validated nutritional status screening tools in use in PICUs, and for that reason, the clinical guideline does not present estimates of benefit of nutritional screening. • The eMeasure also demonstrated good clinical performance across age groups with 92% of screens performed for children 0 - <6, 96% of screens performed for children 6 - <13, and 88% of screens performed for children 13 - <19 meeting the measure. Only 67% of screens performed on patients 19 years or older met the measure due to the low sample size (N=3) in this age group. • Reasons for not meeting the measure included not meeting the denominator criteria by having a nutrition screen more than 48 hours prior to PICU admission (N=8), not having the screen performed in the PICU (n=2), and meeting the denominator exclusion criteria by having a nutrition screen performed between 24 hours and 48 hours of PICU admission (N=5). • There was concern that while nutritional status assessment in PICUs may be important, there was insufficient evidence linking this process measure to outcomes. Based upon the discussion the committee was not able to reach consensus on the evidence for the measure. • In addition, the committee did not reach consensus on measurement gap.
2. Scientific Acceptability of Measure Properties: The measure [does/does not] meet the Scientific Acceptability criteria (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: **7-M; 8-L;4-I** 2b. Validity: **H-X**; **M-X**; **L-X**; **I-X** Rationale: • To demonstrate reliability, the developer performed data element testing at one hospital site (Ann and Robert H. Lurie Children's Hospital) with 288 pediatric beds (including 40 PICU beds) and approximately 11,291 pediatric admissions annually. • The testing involved implementation of the eMeasure to compute scores automatically, and manual chart review of the same patients by a trained chart abstracter; inter-rater reliability was then assessed. • The developer reported that inter-rater reliability was conducted on five patient charts. • Agreement was 100% for all critical data elements, and 100% for overall clinical performance of the measure. • Because the developer presented reliability results at the data element level in a single facility, and there was no testing at the measure score level, the committee voted that the measure did not pass on reliability, and there was no additional discussion about this measure. • There was no vote on validity because the measure failed on reliability.
3. Feasibility: H-X; M-X; L-X; I-X *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • There was concern that there is no broadly used tool across institutions, and there was no validated instrument for this process. There was also concern that this was already, to some degree required by the Joint Commission.

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• There was no committee discussion or vote on feasibility because it failed on reliability.
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)* Rationale: • This measure is being submitted for endorsement for use in public and private health plans, Medicaid, and CHIPRA to assess the quality of care related to the prevention of pressure ulcers for children in the PICU for public reporting and quality improvement. • The developer sees this measure becoming a part of an American Board of Pediatrics (ABP) Maintenance of Certification (MOC) Performance Improvement Module (PIM). • The developer also foresees this measure being tested as a discrete module in the Virtual Pediatric System (VPS) pending receipt of funding from AHRQ. • There was no committee discussion on usability and use because it failed on reliability.
5. Related and Competing Measures • There are no related and competing measures.
Steering Committee Recommendation for Endorsement: **Y-X**; **N-X** Rationale: • The Committee did not vote on the suitability for the endorsement because the measure did not pass on reliability.
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals