

Measure Evaluation Report

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

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**Project No.:
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Submitted To:

Centers for Medicare & Medicaid Services

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ECONOMETRICA, INC.

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Chapter 1. Total Falls Measure Evaluation Report

Project Title:

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Econometrica, Inc., to develop quality measures for the PACE program: Total Falls, Falls With Injury, Pressure Ulcers, Pressure Ulcer Prevention, and 30-Day All-Cause Hospital Readmissions. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The contract number is HHSM-500-2013-13006I/HHSM-500-T0002.

The current health care system does not consistently deliver high-quality care for every participant at every opportunity, resulting in gaps in the quality of care provided. One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. The purpose of this project is to develop, implement, and align measures for PACE.

Date: Information included is current as of May 15, 2015.

Measure Name: Total Falls

Measure Set (or Setting): PACE program sites. The target population is all participants in the PACE site census during the month, regardless of their location. That is, participants who were living at home, in long-term care, emergency rooms, hospitals, or otherwise away from home are to be included.

Measure Contractor: Econometrica, Inc.

1. Evidence, Performance Gap, and Priority (Impact)—Importance to Measure and Report

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1a. Evidence to Support the Measure Focus/Measure Intent	Pass	
1b. Performance Gap	Pass	
1c. High Priority (previously referred to as High Impact)	Pass	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1d. Explicit Logic (Composite Measures only)	NA	

Summary Rating for Importance: Pass

Brief Statement of Conclusions That Support the Summary Rating:

1.a. Measure Focus

The patient fall rate is an individual health care outcome with structures and processes of care that can positively impact this rate. Seven peer-reviewed articles on patient falls in hospitals were reviewed.

Structural factors related to falls include: characteristics of the nursing workforce, nurse staffing levels, Magnet status (a status awarded by the American Nurses Credentialing Center (ANCC) based on organization and delivery of nursing care within a health care facility), nursing turnover, and nursing work environment.

Process factors include: fall risk assessment, frequency of risk assessment, how recent the last risk assessment was conducted, and implementation of prevention protocols.

Strengths: All seven studies examined patient fall rates and nursing characteristics/nurse staffing at the unit level (as opposed to the hospital level). Most studies used a conceptual framework to guide the testing of the relationships between staffing and fall rates. Most studies used nursing care hours, nursing skill mix, fall rates, and rates of falls with injury as specified by the National Quality Forum (NQF) or similar to NQF.

Weaknesses: Some studies failed to use a hierarchical model of analysis (i.e., patients and nurses nested in units and, in turn, units nested in hospitals). Some studies only examined one aspect of the nursing workforce, such as examining only staffing, rather than examining multiple aspects such as staffing, experience, education, and certification. Generally, studies were cross-sectional and observational rather than experimental. Process measures (fall risk assessment and prevention protocol implementation) associated with patient fall rates were not included in any of the studies.

Results

- Six studies found a significant indirect relationship between some aspect of inpatient nurse staffing and fall rates (Duffield et al., 2010; Dunton, Gajewski, Klaus, & Pierson, 2007; Dunton, Gajewski, Taunton, & Moore, 2004; Lake, Shang, Klaus, & Dunton, 2010; Potter, Barr, McSweeney, & Sledge, 2003; Whitman, Kim, Davidson, Wolf, & Wang, 2002). For example, higher total nursing hours per patient day or higher proportion of hours provided by registered nurses was related to lower fall rates.
- The evidence on fall prevention activities (processes) is mixed. Oliver, Hopper, and Seed (2000) found through a systematic literature review and meta-analysis that fall prevention activities may have reduced fall rates by up to 25 percent. More recently, Miake-Lye,

Hempel, Ganz, and Shekelle (2013) found that fall prevention strategies reduced falls by up to 30 percent, although an optimal prevention bundle was not identified.

Reference List

- Duffield, C., Diers, D., O'Brien-Pallas, L., Aisbett, C., Roche, M., King, M., & Aisbett, K. (2010). Nursing staffing, nursing workload, the work environment and patient outcomes. *Applied Nursing Research*. <http://dx.doi.org/10.1016/j.apnr.2009.12.004>.
- Dunton, N., Gajewski, B., Klaus, S., & Pierson, B. (2007). The relationships of nursing workforce characteristics to patient outcomes. *The Online Journal of Issues in Nursing*, 12(3). Retrieved from <http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume122007/No3Sept07/NursingWorkforceCharacteristics.aspx>.
- Dunton, N., Gajewski, B., Taunton, R. L., & Moore, J. (2004). Nurse staffing and patient falls on acute care hospital units. *Nursing Outlook*, 52(1), 53–59.
- Lake, E. T., Shang, J., Klaus, S., & Dunton, N. E. (2010). Patient falls: Association with hospital Magnet status and nursing unit staffing. *Research in Nursing & Health*, 33(5), 413–425.
- Miake-Lye, I. M., Hempel, S., Ganz, D., & Shekelle, P. (2013). Inpatient fall prevention programs as a patient safety strategy: A systematic review. *Annals of Internal Medicine*, 158(5), 390–396.
- Oliver, D., Hopper, A., & Seed, P. (2000). Do hospital fall preventions work? A systematic review. *Journal of the American Geriatrics Society*, 48(12), 1679–1689.
- Potter, P., Barr, N., McSweeney, M., & Sledge, J. (2003). Identifying nurse staffing and patient outcome relationships: A guide for change in care delivery. *Nursing Economics*, 21(4), 158–166.
- Whitman, G. R., Kim, Y., Davidson, L. J., Wolf, G. A., & Wang, S. L. (2002). The impact of staffing on patient outcomes across specialty units. *The Journal of Nursing Administration*, 32(12), 633–639.

1.b. Performance Gap

Because falls data from PACE sites have not yet been collected, the evidence currently available is primarily from hospital-based studies. Those data do show considerable variation in patient fall rates.

- Bouldin et al. (2013) examined fall rates on medical, surgical, and medical-surgical units. Fall rates were highest on medical units (4.03 falls per 1,000 patient days (PD)) and lowest on surgical units (2.56 falls per 1,000 PD).
- He et al. (2012) identified trends in fall rates by hospital unit type. The analysis showed that fall rates remained stable or declined for most unit types between 2004 and 2009.

Rates for surgical units, however, increased over time, from 2.74 falls/1,000 PD to 3.19/1,000 PD in 2008, decreasing to 2.89/1,000 PD in 2009.

- Lake et al. (2010) found that fall rates were 5 percent lower in hospitals that had achieved ANCC Nursing Magnet status than in non-Magnet hospitals.

Reference List

Bouldin, E. L., Andresen, E. M., **Dunton, N. E.**, Simon, M., Waters, T. M., Liu, M., ... Shorr, R. I. (2013). Falls among adult patients hospitalized in the United States: Prevalence and trends. *Journal of Patient Safety*, 9(1), 13–17.

He, J., Dunton, N., & Staggs, V. (2012). Unit-level time trends in inpatient fall rates of US hospitals. *Medical Care*, 50, 801–807.

Lake, E. T., Shang, J., Klaus, S., & Dunton, N. E. (2010). Patient falls: Association with hospital Magnet status and nursing unit staffing. *Research in Nursing & Health*, 33(5), 413–425.

1.c. High Priority

Fall rates are an important safety concern in acute care and long-term care settings. There is evidence that falls are one of the most common adverse patient events in hospitals and a source of significant injury or disability. Several national health care improvement organizations, including the National Quality Strategy and the CMS Partnership for Patients and Hospital-Acquired Condition (HAC) Reduction Program, have identified patient falls as a patient safety concern.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

NOTE: Section 2, Scientific Acceptability, will be updated with the results from the content validity testing. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a. Reliability		
2a1. Precisely Specified		
2a2. Reliability Testing		
Cost and Resource Use Measure-Specific Sub-Criteria		
2a3. Construction Logic		
2a4. Clinical Logic		
2a5. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2a6. Adjustments for Comparability—Risk Adjustment		
2a7. Adjustments for Comparability—Costing Method		
2a8. Adjustment for Comparability—Scoring		
2b. Validity		

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2b1. Specifications	Moderate	
2b2. Validity Testing	Moderate	
2b3. Exclusions		
2b4. Risk Adjustment		
2b5. Meaningful		
2b6. Comparable Results		
2b7. Missing Data (eMeasures, Composite Measures, and PRO-PMs)		
Cost and Resource Use Measure-Specific Sub-Criteria		
2b8. Construction Logic		
2b9. Clinical Logic		
2b10. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2b11. Adjustments for Comparability—Risk Adjustment		
2b12. Adjustments for Comparability—Costing Method		
2b13. Adjustment for Comparability—Scoring		
2b14. Significant Differences in Performance		
2b15. Comparability of Multiple Data Sources		
2c. Disparities		
2c1. Disparities Identified		
2d. Empirical Analysis (Composite Measures Only)		
2d1. Quality Construct		
2d2. Aggregation and Weighting Rules		
2e. eMeasure-Specific Sub-Criteria		
2e1. HQMF Specifications		
2e2. Data Types		
2e3. Data Element Validity		
2e4. Comparability Analysis		

Summary Rating for Scientific Acceptability of Measure Properties:

Brief Statement of Conclusions That Support the Summary Rating:

Validity Testing Results:

Content validity was assessed using a panel of experts to: (1) quantify experts' degree of agreement regarding the content of the measure instructions (i.e., PACE Measure Instructions) and (2) obtain experts' narrative comments on the measure instructions. The findings were used to evaluate the content validity of developed quality measures and improve each measure's instructions. Thirteen experts (9 TEP experts and 4 academic experts) provided their evaluation on content validity and narrative feedback on measure instructions. Some of them reviewed all quality measure instructions (falls, pressure ulcers, and readmissions); others reviewed one or two instructions based on their specialty.

Content validity of the measure instructions was analyzed by calculating item-level content validity indices (I-CVIs). Experts rated each component's content validity using a 4-point scale: 1=very low (major modification needed), 2=low (some modification needed), 3=high (no modification needed but could be improved with minor changes), and 4=very high (no modification needed). I-CVI is computed for each item by counting the number of experts giving a rating of three or four (thus dichotomizing the ordinal scale into high vs. low valid) and dividing the number by the total number of experts (Polit, Beck, & Owen, 2007). Polit et al. (2007) suggested that items with good content validity should have an I-CVI of .78 or higher from three or more experts' review. Based on this, we used .78 as a cut-off point to determine good, acceptable content validity. Another evaluation criterion was based on Lynn (1986). Lynn (1986) argued that the disagreement is accepted only if "six or more experts" are rated as 1 (very low) or 2 (low).

Twelve experts, including 10 TEP experts and 2 academic experts, independently evaluated content validity of the total falls/falls with injury measure instructions.

Content validity was systematically assessed using expert review. Table 1 below displays I-CVIs for the total falls/falls with injury measure instructions. The findings showed good, acceptable content validity for the measure descriptions, definitions, measure calculations, and inclusion/exclusion criteria, for which the I-CVIs were all greater than .78. The I-CVI of the overall capacity to measure and capture what the indicator of total falls was .67 (8 out of 12). This low content validity of the total falls measure might be related to the underreporting issue of fall events, that is, patients may be reluctant to report to healthcare providers when they have no or only minor injuries after a fall event. However, there were still 8 experts who rated high or very high for the total falls indicator with regard to the overall capability to measure.

Low content validity about data sources (I-CVI/Ave = .76) might also be related to the underreporting issue. Falls occurring at home and without injuries may not be fully captured by current data sources, e.g., clinical records. However, this I-CVI value is close to .78.

Experts showed low content validity about clarity of measure instruction (I-CVI = .75) and denominator's definition (I-CVI = .70). The total falls/falls with injury measure instructions were revised accordingly to address the issue prior to our pilot data collection.

Overall, experts reported good content validity regarding the overall applicability of the total fall and falls with injury measures to the PACE sites and participants (I-CVI=.92) and highly agreed upon the overall usefulness of the measures for internal quality improvement purposes and for comparison of PACE sites. Our expert review supported using the measure of "total falls (or falls with injury) per 1,000 participant days" rather than the measure of "the proportion of participants with total falls or falls with injury" (I-CVI = .90 vs. .56).

Table 1. I-CVIs for Data Elements in the Total Falls/Falls with Injury Measure Instructions

Total Falls/Falls with Injury Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Measure Description	.75 (6/8)	1.0 (5/5)	1.0 (6/6)	.92
Definitions:	.91 (10/11)	.88 (7/8)	1.0 (10/10)	.93
• Numerator				
• Denominator	.70 (7/10)	.88 (7/8)	.90 (9/10)	.83
• Injury level:	1.0 (9/9)			
○ None				
○ Minor	.89 (8/9)	1.0 (6/6)	1.0 (9/9)	.93
○ Moderate	.89 (8/9)			
○ Major	.78 (7/9)			
Measure Calculation	1.0 (6/6)	1.0 (5/5)	.86 (6/7)	.95
Inclusion Criteria:				
• All PACE participant falls occurring in any location; <i>Participants who were in long-term care, emergency rooms, hospitals, or otherwise away from home</i> will be to be included for this fall data collection. Programs will document the fall's location so they can assess where most falls occur.	.92 (10/11)	.80 (8/10)	.70 (7/10)	.81
• Participants who fall (or sink) back to a bed, chair, or toilet are only counted as falls <i>if they result in injury</i> .	.83 (10/12)	.80 (8/10)	.90 (9/10)	.84
• Participants who are assisted to the floor by a care provider (<i>assisted fall</i>) are to be included in the count of falls.	.91 (10/11)	.90 (9/10)	1.0 (10/10)	.94
Exclusion Criteria:				
• Falls by staff, visitors, or others who were not PACE participants.	1.0 (11/11)	1.0 (4/4)	1.0 (2/2)	.97
• Falls in which the PACE participant fell or sank back onto a bed, chair, or toilet without incurring an injury.	.91 (10/11)	1.0 (9/9)	1.0 (9/9)	.97
Data Sources	.80 (8/10)	.67 (4/6)	.80 (4/5)	.76
Overall clarity of the Data Collection Guidelines	.64 (7/11)			
Overall capability to measure/capture what the indicator of “total falls” intends to measure	.67 (8/12)			
Overall capability to measure/capture what the indicator of “injury falls” intends to measure	.82 (9/11)			
Overall applicability of the indicator to the PACE participants and PACE sites	.92 (11/12)			
Overall usefulness of the indicator for internal quality improvement purposes	.91 (10/11)			
Overall usefulness of the indicator for comparison of PACE sites	.90 (9/10)			

Total Falls/Falls with Injury Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Total falls per 1,000 participant days Injury falls per 1,000 participant days	.90 (9/10)			
No. participants with falls / No. participants No. participants with injury falls / No. participants	.56 (5/9)			

Note. I-CVI, item-level content validity index; I-CVI/ave, average of I-CVIs.

Each parenthesis indicates the number of experts who rated the data element as three or four divided by the total number of experts who responded.

References:

Polit, D. F., Beck, C. T., & Owen, S. V. (2007). Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health*, 30, 459-467.

Lynn, M. (1986). Determination and quantification of content validity. *Nursing Research*, 35, 381-385.

3. Feasibility

NOTE: Section 3, Feasibility, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3a. Data Are a Byproduct of Care		
3b. Electronic Sources		
3c. Data Collection Strategy		
3d. eMeasure Feasibility Assessment Summary		For data elements that score low on current feasibility, indicate the anticipated feasibility score in three to five years based on a projection of the maturation of the electronic health record, or maturation of its use.
3d1. Data Availability		
3d2. Data Accuracy		
3d3. Data Standards		
3d4. Workflow		

Summary Rating for Feasibility/eMeasure Feasibility:

Brief Statement of Conclusions That Support the Summary Rating:

4. Usability and Use

NOTE: Section 4, Usability and Use, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
4a. Accountability and Transparency		
4b. Improvement		
4c. Benefits		
4d. Measure Deconstruction (Cost and Resource Use Measure Only)		

Summary Rating for Usability:

Brief Statement of Conclusions That Support the Summary Rating:

5. Comparison to Related or Competing Measures

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
5a. Related Measure	High	
5b. Competing Measure	NA	

Summary Rating for Harmonization: High

Rationale for Rating/Comments:

The PACE total fall rate measure was developed with the intent to be harmonized with NQF-endorsed fall rate measure 0141. The PACE measure has some differences from related measure 0266 (see Table 1-1).

The PACE total fall measure is largely harmonized with NQF-endorsed measure 0141. The numerators are the same for each measure, and the denominators are conceptually similar. The denominators differ because measure 0141 is an acute inpatient measure and the PACE measure is an ambulatory measure. Both denominators reflect the concept of exposure to an adverse event. The denominator of measure 0141 is inpatient days and the sum of short-stay patient hours divided by 24. The PACE total fall rate denominator is participant days, calculated as the sum of participants enrolled in a PACE site each day of the month.

The PACE fall rate measure differs from NQF-endorsed measure 0226 both in the numerator description of falls and in the patient population captured in the denominator. Measure 0141 is more detailed than NQF measure 0266; thus, we chose to align our specifications to measure 0141 and not 0266.

Table 1-1. Comparison of Fall Rate Measures

	PACE Total Fall Rate	Measure 1	Measure 3
NQF Number	NA	0141	0266
Measure Title	Total Fall Rate for PACE Participants	Patient Fall Rate	Patient Fall
Measure Description	<ul style="list-style-type: none"> Total falls by PACE participants per 1,000 participant days. 	<ul style="list-style-type: none"> Total Fall Rate: Total falls per 1,000 patient days. (Total number of falls/patient days) \times 1,000. All documented falls, with or without injury, experienced by patients on eligible acute care inpatient unit types in a calendar month. 	<ul style="list-style-type: none"> Percentage of ambulatory surgery center (ASC) admissions experiencing a fall within the ASC.
Fall Definition	A sudden, unanticipated descent in which a participant comes to rest on the floor or some other surface, person, or object, regardless of injury, assistance, or location. Calculation: Total falls \times 1,000 \div participant days.	A sudden, unintentional descent, with or without injury to the patient, that results in the patient coming to rest on the floor, on or against some other surface (e.g., a counter), on another person, or on an object (e.g., a trash can).	A sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object. (Source: National Center for Patient Safety)
Numerator Statement	<p>Participants in the PACE program who experienced a fall during the month.</p> <ul style="list-style-type: none"> Falls occurring in any location a PACE participant might be are to be counted. Location of the fall will be documented so that programs can assess where most falls are occurring. Participants who fall (or sink) back to a bed, chair, or toilet are not counted as falls Participants who are assisted to the floor by a care provider (assisted fall) are to be included in the count of falls. 	<p>Total number of patient falls (with or without injury to the patient and whether or not assisted by a staff member) by eligible reporting hospital unit during the calendar month \times 1,000.</p> <ul style="list-style-type: none"> Eligible unit types: adult critical care, adult step-down, adult medical, adult surgical, adult medical-surgical combined, critical access, adult rehabilitation inpatient. 	ASC admissions experiencing a fall in the ASC.

	PACE Total Fall Rate	Measure 1	Measure 3
Denominator Statement	<p>Total number of participant-days in the month</p> <ul style="list-style-type: none"> Total number of PACE participant days during the calendar month. This is calculated as the sum of days each PACE participant was in the program during the month. This represents participants' exposure to the risk of falling. 	<p>Patient days by hospital unit during the calendar month.</p> <ul style="list-style-type: none"> Inpatients, short-stay patients, observation patients, and same-day surgery patients who receive care on eligible inpatient units for all or part of a day. 	All ASC admissions.
Exclusions	Falls by persons not enrolled in PACE.	Falls by: visitors, students, staff members, patients on units not eligible for reporting, and patients from eligible reporting unit not on unit at time of the fall.	ASC admissions experiencing a fall outside the ASC.
Risk Adjustment	Yes, risk stratification, by 3 site characteristics: site age, number of participants, and geographic location.	Yes, by unit type.	No.

	PACE Total Fall Rate	Measure 1	Measure 3
Reliability/ Validity	<ul style="list-style-type: none"> No data available at this time. 	<ul style="list-style-type: none"> Site coordinator interview to identify core processes and key personnel in data collection. Evidence: No difference between hospital type and limited differences by hospital size and teaching status. Video review of fall scenarios to assess consistency, sensitivity, and specificity. Evidence: A high rate of agreement of 85% on the classification of falls between raters and a group of experts and a 91% sensitivity agreement in identifying falls. Examine threats to validity (under-reporting issue). Evidence: There is substantial evidence that fall reporting is quite complete based on survey results that 93% of site coordinators said staff would submit a report on falls without injury most or all of the time and 92% of direct care providers said they would file an incident report on fall scenarios. 	<ul style="list-style-type: none"> Retrospective chart auditing with a convenience sample of 22 ASCs. Evidence: Zero error rates for the numerator and denominator. A questionnaire to rate characteristics of the measure. Evidence: A high level of agreement.
Actual/ Planned Use	<p>Quality improvement (internal to the specific organization with peer benchmarking).</p> <p>Public reporting is planned by CMS for some time in the future.</p>	<p>Quality improvement (internal to the specific organization & external benchmarking): About one-third of hospitals (1,634) nationwide are reporting on this measure.</p> <p>Public reporting: It is reported publicly in Colorado Hospital Report Card and Massachusetts Public Reporting—Patient Care Link, Norton Healthcare, and through Leapfrog on 39 States.</p>	<p>Quality improvement (internal to the specific organization & external benchmarking).</p> <p>Public reporting: The public report of ASC quality data from 1,373 ASCs is available on the ASC Quality Collaboration Web site (www.ascquality.org). CMS will use this measure for public reporting.</p>
Care Setting	PACE site	Hospital/acute care facility Post-acute/long-term care facility Inpatient rehabilitation facility	Ambulatory care: Ambulatory surgery center (ASC)
Target Population	PACE participants	Adult acute care inpatients and adult rehabilitation patients	Ambulatory surgery center patients

	PACE Total Fall Rate	Measure 1	Measure 3
Level of Analysis	Site	Facility; unit	Facility
Data Source	Clinical records	Electronic clinical data, other, paper medical records	Paper records
Measure Type	Outcome	Outcome	Outcome
Measure Developer/ Steward	Econometrica	American Nurses Association	Ambulatory Surgical Center Association

Preliminary Recommendation for Endorsement

Based on the individual rating of each of the five major criteria, provide an initial recommendation for endorsement based on the overall suitability of this measure.

Criteria	High	Medium	Low	Insufficient
1. Importance to Measure and Report	X			
2a. Overall Reliability				
2b. Overall Validity				
2c. Disparities of Care				
3. Feasibility				
4. Usability and Use				
5. Comparison to Related or Competing Measures	X			

Recommendation:

Explanation:

Chapter 2. Falls With Injury Measure Evaluation Report

Project Title:

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Econometrica, Inc., to develop quality measures for the PACE program: Total Falls, Falls With Injury, Pressure Ulcers, Pressure Ulcer Prevention, and 30-Day All-Cause Hospital Readmissions. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The contract number is HHSM-500-2013-13006I/HHSM-500-T0002.

The current health care system does not consistently deliver high-quality care for every participant at every opportunity, resulting in gaps in the quality of care provided. One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. The purpose of this project is to develop, implement, and align measures for PACE.

Date: Information included is current as of May 15, 2015.

Measure Name: Falls With Injury

Measure Set (or Setting): PACE program sites. The target population is all participants in the PACE site census during the month, regardless of their location. That is, participants who were living at home, in long-term care, emergency rooms, hospitals, or otherwise away from home are to be included.

Measure Contractor: Econometrica, Inc.

1. Evidence, Performance Gap, and Priority (Impact)—Importance to Measure and Report

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1a. Evidence to Support the Measure Focus/Measure Intent	Pass	
1b. Performance Gap	Pass	
1c. High Priority (previously referred to as High Impact)	Pass	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1d. Explicit Logic (Composite Measures only)	NA	

Summary Rating for Importance: Pass

Brief Statement of Conclusions That Support the Summary Rating:

1.a. Measure Focus

The falls with injury rate is an individual health care outcome. The elements of structure and process of care have been known to be related to the outcome of the falls with injury rate. Eighteen peer-reviewed articles were reviewed with regard to structural and process factors related to falls with injury in hospital settings.

Structural factors related to falls with injury include: characteristics of the nursing workforce, nurse staffing levels, Magnet status (a status awarded by the American Nurses Credentialing Center based on organization and delivery of nursing care within a health care facility), nursing turnover, and nursing work environment.

Process factors include: fall risk assessment; frequency and how recent the last risk assessment was; implementation of prevention protocols, including the removal of tripping hazards, slick surfaces, and hard edges; and adding additional lighting.

Strengths: All seven studies examined patient fall rates and nursing characteristics/nurse staffing at the unit level (as opposed to the hospital level). Most studies used a conceptual framework to guide the testing of the relationships between staffing and fall rates. Most studies used nursing care hours, nursing skill mix, fall rates, and fall with injury rates as specified by the National Quality Forum (NQF) or similar to NQF.

Weaknesses: Some studies failed to use a hierarchical model of analysis (i.e., patients and nurses nested in units and, in turn, units nested in hospitals). Some studies only examined one aspect of the nursing workforce, such as examining only staffing, rather than examining multiple aspects such as staffing, experience, education, and certification. Generally, studies were cross-sectional and observational rather than experimental. Process measures (fall risk assessment and prevention protocol implementation) associated with patient fall rates were not included in any of the studies.

Results:

- Six studies found a significant indirect relationship between some aspect of inpatient nurse staffing and fall rates (Duffield et al., 2010; Dunton, Gajewski, Klaus, & Pierson, 2007; Dunton, Gajewski, Taunton, & Moore, 2004; Lake, Shang, Klaus, & Dunton, 2010; Potter, Barr, McSweeney, & Sledge, 2003; Whitman, Kim, Davidson, Wolf, & Wang, 2002). For example, higher total nursing hours per patient day or higher proportion of hours provided by registered nurses was related to lower fall rates.

- The evidence on fall prevention activities (processes) is mixed. Oliver, Hopper, and Seed (2000) found through a systematic literature review and meta-analysis that fall prevention activities may have reduced fall rates by up to 25 percent. More recently, Miake-Lye, Hempel, Ganz, and Shekelle (2013) found that fall prevention strategies reduced falls by up to 30 percent, although an optimal prevention bundle was not identified.

Reference List

- Duffield, C., Diers, D., O'Brien-Pallas, L., Aisbett, C., Roche, M., King, M., & Aisbett, K. (2010). Nursing staffing, nursing workload, the work environment and patient outcomes. *Applied Nursing Research*. <http://dx.doi.org/10.1016/j.apnr.2009.12.004>.
- Dunton, N., Gajewski, B., Klaus, S., & Pierson, B. (2007). The relationships of nursing workforce characteristics to patient outcomes. *The Online Journal of Issues in Nursing*, 12(3). Retrieved from <http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume122007/No3Sept07/NursingWorkforceCharacteristics.aspx>
- Dunton, N., Gajewski, B., Taunton, R. L., & Moore, J. (2004). Nurse staffing and patient falls on acute care hospital units. *Nursing Outlook*, 52(1), 53–59.
- Lake, E. T., Shang, J., Klaus, S., & Dunton, N. E. (2010). Patient falls: Association with hospital Magnet status and nursing unit staffing. *Research in Nursing & Health*, 33(5), 413–425.
- Miake-Lye, I. M., Hempel, S., Ganz, D., & Shekelle, P. (2013). Inpatient fall prevention programs as a patient safety strategy: A systematic review. *Annals of Internal Medicine*, 158(5), 390–396.
- Oliver D., Hopper A., & Seed, P. (2000). Do hospital fall preventions work? A systematic review. *Journal of the American Geriatrics Society*, 48(12), 1679–1689.
- Potter, P., Barr, N., McSweeney, M., & Sledge, J. (2003). Identifying nurse staffing and patient outcome relationships: A guide for change in care delivery. *Nursing Economic\$,* 21(4), 158–166.
- Whitman, G. R., Kim, Y., Davidson, L. J., Wolf, G. A., & Wang, S. L. (2002). The impact of staffing on patient outcomes across specialty units. *The Journal of Nursing Administration*, 32(12), 633–639.

1.b. Performance Gap

There are performance gaps in the falls with injury rate. Bouldin et al. (2013) report that falls with injury rates in acute inpatient units varied by unit type and over time (see Table 2-1). In this study, falls with injury were measured if patients had an injury level of minor or greater. He et al. (2012) found the same results. All unit types experienced decreases in fall rates between 2004 and 2009, except for surgical units. Surgical units experienced an increase in fall rates over the period.

Table 2-1. Falls With Injury Rate, 2008. Falls With Injury × 1000/Total Patient Days

	Percentiles				
Unit Type	10th	25th	50th	75th	90th
Medical	0.26	0.59	0.96	1.36	1.79
Surgical	0.08	0.31	0.57	0.88	1.24
Medical/Surgical	0.17	0.49	0.83	1.21	1.36

Reference List

Bouldin, E. L., Andresen, E. M., **Dunton, N. E.**, Simon, M., Waters, T. M., Liu, M., ... Shorr, R. I. (2013). Falls among adult patients hospitalized in the United States: Prevalence and trends. *Journal of Patient Safety*, 9(1), 13–17.

He, J., Dunton, N., & Staggs, V. (2012). Unit-level time trends in inpatient fall rates of US hospitals. *Medical Care*, 50, 801–807.

1.c. High Priority

Fall rates are an important safety concern in acute care and long-term care settings. There is evidence that falls are one of the most common adverse patient events in hospitals and a source of significant injury, disability, and/or death. Several national health care improvement organizations, including the National Quality Strategy and the CMS Partnership for Patients and Hospital-Acquired Condition (HAC) Reduction Program, have identified patient falls as a patient safety concern.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

NOTE: Section 2, Scientific Acceptability, will be updated with the results from the content validity testing. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a. Reliability		
2a1. Precisely Specified		
2a2. Reliability Testing		
Cost and Resource Use Measure-Specific Sub-Criteria		
2a3. Construction Logic		
2a4. Clinical Logic		
2a5. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2a6. Adjustments for Comparability—Risk Adjustment		
2a7. Adjustments for Comparability—Costing Method		
2a8. Adjustment for Comparability—Scoring		
2b. Validity		
2b1. Specifications	Moderate	
2b2. Validity Testing	Moderate	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2b3. Exclusions		
2b4. Risk Adjustment		
2b5. Meaningful		
2b6. Comparable Results		
2b7. Missing Data (eMeasures, Composite Measures, and PRO-PMs)		
Cost and Resource Use Measure-Specific Sub-Criteria		
2b8. Construction Logic		
2b9. Clinical Logic		
2b10. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2b11. Adjustments for Comparability—Risk Adjustment		
2b12. Adjustments for Comparability—Costing Method		
2b13. Adjustment for Comparability—Scoring		
2b14. Significant Differences in Performance		
2b15. Comparability of Multiple Data Sources		
2c. Disparities		
2c1. Disparities Identified		
2d. Empirical Analysis (Composite Measures Only)		
2d1. Quality Construct		
2d2. Aggregation and Weighting Rules		
2e. eMeasure-Specific Sub-Criteria		
2e1. HQMF Specifications		
2e2. Data Types		
2e3. Data Element Validity		
2e4. Comparability Analysis		

Summary Rating for Scientific Acceptability of Measure Properties:

Brief Statement of Conclusions That Support the Summary Rating:

Validity Testing Results:

Content validity was assessed using a panel of experts to: (1) quantify experts' degree of agreement regarding the content of the measure instructions (i.e., PACE Measure Instructions) and (2) obtain experts' narrative comments on the measure instructions. The findings were used to evaluate the content validity of developed quality measures and improve each measure's instructions. Thirteen experts (9 TEP experts and 4 academic experts) provided their evaluation on content validity and narrative feedback on measure instructions. Some of them reviewed all quality measure instructions (falls, pressure ulcers, and readmissions); others reviewed one or two instructions based on their specialty.

Content validity of the measure instructions was analyzed by calculating item-level content validity indices (I-CVIs). Experts rated each component's content validity using a 4-point scale: 1=very low (major modification needed), 2=low (some modification needed), 3=high (no modification needed but could be improved with minor changes), and 4=very high (no modification needed). I-CVI is computed for each item by counting the number of experts giving a rating of three or four (thus dichotomizing the ordinal scale into high vs. low valid) and dividing the number by the total number of experts (Polit, Beck, & Owen, 2007). Polit et al. (2007) suggested that items with good content validity should have an I-CVI of .78 or higher from three or more experts' review. Based on this, we used .78 as a cut-off point to determine good, acceptable content validity. Another evaluation criterion was based on Lynn (1986). Lynn (1986) argued that the disagreement is accepted only if "six or more experts" are rated as 1 (very low) or 2 (low).

Twelve experts, including 10 TEP experts and 2 academic experts, independently evaluated content validity of the total falls/falls with injury measure instructions.

Content validity was systematically assessed using expert review. Table 2 below displays I-CVIs for the total falls/falls with injury measure instructions. The findings showed good, acceptable content validity for the measure descriptions, definitions, measure calculations, and inclusion/exclusion criteria, for which the I-CVIs were all greater than .78. The experts reported that there was good content validity on the overall capacity to measure and capture what the indicator of falls with injury intends to measure (I-CVI=.82).

Low content validity about data sources (I-CVI/Ave = .76) might be relevant to the underreporting issue. Falls occurring at home and without injuries may not be fully captured by current data sources, e.g., clinical records. However, this I-CVI value is close to .78.

Experts showed low content validity about clarity of measure instruction (I-CVI = .75) and denominator's definition (I-CVI = .70). The total falls/falls with injury measure instructions were revised accordingly to address the issue prior to our pilot data collection.

Overall, experts reported good content validity regarding the overall applicability of the total fall and falls with injury measures to the PACE sites and participants (I-CVI=.92) and highly agreed upon the overall usefulness of the measures for internal quality improvement purposes and for comparison of PACE sites. Our expert review supported using the measure of "total falls (or falls with injury) per 1,000 participant days" rather than the measure of "the proportion of participants with total falls or falls with injury" (I-CVI = .90 vs. .56). Table 2 displays a summary of I-CVIs for each data element used in the total falls/falls with injury measure instructions.

Table 2. I-CVIs for Data Elements in the Total Falls/Falls with Injury Measure Instructions

Total Falls/Falls with Injury Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Measure Description	.75 (6/8)	1.0 (5/5)	1.0 (6/6)	.92
Definitions:				
• Numerator	.91 (10/11)	.88 (7/8)	1.0 (10/10)	.93
• Denominator	.70 (7/10)	.88 (7/8)	.90 (9/10)	.83
• Injury level:	1.0 (9/9)	1.0 (6/6)	1.0 (9/9)	.93
o None				
o Minor	.89 (8/9)			
o Moderate	.89 (8/9)			
o Major	.78 (7/9)			
Measure Calculation	1.0 (6/6)	1.0 (5/5)	.86 (6/7)	.95
Inclusion Criteria:				
• All PACE participant falls occurring in any location; <i>Participants who were in long-term care, emergency rooms, hospitals, or otherwise away from home</i> will be to be included for this fall data collection. Programs will document the fall's location so they can assess where most falls occur.	.92 (10/11)	.80 (8/10)	.70 (7/10)	.81
• Participants who fall (or sink) back to a bed, chair, or toilet are only counted as falls <i>if they result in injury</i> .	.83 (10/12)	.80 (8/10)	.90 (9/10)	.84
• Participants who are assisted to the floor by a care provider (<i>assisted fall</i>) are to be included in the count of falls.	.91 (10/11)	.90 (9/10)	1.0 (10/10)	.94
Exclusion Criteria:				
• Falls by staff, visitors, or others who were not PACE participants.	1.0 (11/11)	1.0 (4/4)	1.0 (2/2)	.97
• Falls in which the PACE participant fell or sank back onto a bed, chair, or toilet without incurring an injury.	.91 (10/11)	1.0 (9/9)	1.0 (9/9)	.97
Data Sources	.80 (8/10)	.67 (4/6)	.80 (4/5)	.76
Overall clarity of the Data Collection Guidelines	.64 (7/11)			
Overall capability to measure/capture what the indicator of “total falls” intends to measure	.67 (8/12)			
Overall capability to measure/capture what the indicator of “injury falls” intends to measure	.82 (9/11)			
Overall applicability of the indicator to the PACE participants and PACE sites	.92 (11/12)			
Overall usefulness of the indicator for internal quality improvement purposes	.91 (10/11)			
Overall usefulness of the indicator for comparison of PACE sites	.90 (9/10)			

Total Falls/Falls with Injury Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Total falls per 1,000 participant days Injury falls per 1,000 participant days	.90 (9/10)			
No. participants with falls / No. participants No. participants with injury falls / No. participants	.56 (5/9)			

Note. I-CVI, item-level content validity index; I-CVI/ave, average of I-CVIs. Each parenthesis indicates the number of experts who rated the data element as three or four divided by the total number of experts who responded.

References:

Polit, D. F., Beck, C. T., & Owen, S. V. (2007). Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health*, 30, 459-467.

Lynn, M. (1986). Determination and quantification of content validity. *Nursing Research*, 35, 381-385.

3. Feasibility

NOTE: Section 3, Feasibility, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3a. Data Are a Byproduct of Care		
3b. Electronic Sources		
3c. Data Collection Strategy		
3d. eMeasure Feasibility Assessment Summary		For data elements that score low on current feasibility, indicate the anticipated feasibility score in three to five years based on a projection of the maturation of the electronic health record, or maturation of its use.
3d1. Data Availability		
3d2. Data Accuracy		
3d3. Data Standards		
3d4. Workflow		

Summary Rating for Feasibility/eMeasure Feasibility:

Brief Statement of Conclusions That Support the Summary Rating:

4. Usability and Use

NOTE: Section 4, Usability and Use, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
4a. Accountability and Transparency		
4b. Improvement		
4c. Benefits		
4d. Measure Deconstruction (Cost and Resource Use Measure Only)		

Summary Rating for Usability:

Brief Statement of Conclusions That Support the Summary Rating:

5. Comparison to Related or Competing Measures

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
5a. Related Measure	High	
5b. Competing Measure	NA	

Summary Rating for Harmonization: High

Rationale for Rating/Comments:

The PACE falls with injury rate measure was developed to be harmonized with NQF-endorsed fall rate measure 0202. The PACE measure has some differences from related measure 0674 (see Table 2-2).

The PACE falls with injury measure is largely harmonized with NQF-endorsed measure 0202. The numerators are the same for each measure, and the denominators are conceptually similar. The denominators differ because 0202 is an acute inpatient measure and the PACE measure is an ambulatory measure. Both denominators reflect the concept of exposure to an adverse event. The denominator of measure 0202 is inpatient days and the sum of short-stay patients hours divided by 24. The PACE falls with injury rate denominator is participant days, calculated as the sum of participants enrolled in a PACE site each day of the month.

The PACE falls with injury rate measure differs from NQF-endorsed measure 0674 in several ways, as described in Table 2-2.

Table 2-2. Comparison of Falls With Injury Rate Measures

	PACE Falls With Injury Rate	Measure 1	Measure 2
NQF Number	NA	0202	0674
Measure Title	Falls With Injury Rate for PACE Participants	Falls With Injury	Percent of Long-Term Care Residents Experiencing One or More Falls With Major Injury (Long Stay)

	PACE Falls With Injury Rate	Measure 1	Measure 2
Measure Description	<ul style="list-style-type: none"> Falls with injury by PACE participants per 1,000 participant days. 	<ul style="list-style-type: none"> Falls with injury rate: Falls with injury per 1,000 patient days. (Total number of falls with injury/patient days) \times 1,000 All documented patient falls with an injury level of minor or greater on eligible acute care inpatient unit types in a calendar month. 	<ul style="list-style-type: none"> Percent of long-stay nursing facility residents experiencing one or more falls with major injury (as defined in the MDS 3.0—bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematoma) in the last year (12-month period).
Falls With Injury Definition	<p>A sudden, unanticipated descent in which a participant comes to rest on the floor or some other surface, person, or object, regardless of injury, assistance or location. Calculation: Total falls \times 1,000 \div participant days.</p> <p>Fall Injury Classifications:</p> <ul style="list-style-type: none"> None = 1 Minor (Level I reporting) = 2 Moderate (Level II reporting, injury required hospitalization of 5 days or more) = 3 Major (Level II reporting, permanent loss of function) = 4 Death = 5 DK = 99 	<p>A sudden, unintentional descent, with or without injury to the patient, that results in the patient coming to rest on the floor, on or against some other surface (e.g., a counter), on another person, or on an object (e.g., a trash can).</p>	<p>No definition reported.</p>

	PACE Falls With Injury Rate	Measure 1	Measure 2
Numerator Statement	<p>Participants in the PACE program who experienced an injurious fall during the month.</p> <ul style="list-style-type: none"> Falls occurring in any location a PACE participant might be are to be counted. Location of the fall will be documented so that programs can assess where most falls are occurring. Participants who fall (or sink) back to a bed, chair, or toilet are not counted as falls. Participants who are assisted to the floor by a care provider (assisted fall) are to be included in the count of falls. 	<p>Total number of patient falls of injury level minor or greater (whether or not assisted by a staff member) by eligible reporting hospital unit during the calendar month $\times 1,000$.</p> <ul style="list-style-type: none"> Eligible unit types: adult critical care, adult step-down, adult medical, adult surgical, adult medical-surgical combined, critical access, adult rehabilitation inpatient. 	<p>The number of long-stay nursing facility residents experiencing one or more falls resulting in major injury (J1900c = 1 or 2) on any non-admission MDS assessment in the last 12 months, which may be annual, quarterly, significant change, significant correction, or discharge assessment.</p>
Denominator Statement	<p>Total number of participant-days in the month.</p> <ul style="list-style-type: none"> Total number of PACE participant days during the calendar month. This is calculated as the sum of days each PACE participant was in the program during the month. This represents participants' exposure to the risk of falling. 	<p>Patient days by hospital unit during the calendar month.</p> <ul style="list-style-type: none"> Inpatients, short-stay patients, observation patients, and same-day surgery patients who receive care on eligible inpatient units for all or part of a day. 	<p>The total number of long-stay residents in the nursing facility who were assessed during the selected time window and who did not meet the exclusion criteria.</p>
Exclusions	<p>Falls by persons not enrolled in PACE.</p>	<p>Falls by: visitors, students, staff members, patients on units not eligible for reporting, and patients from eligible reporting unit not on unit at time of the fall.</p>	<p>Residents with MDS admission assessments (OBRA or a 5-day PPS assessment) from the current quarter are excluded. Also excluded are residents for whom data from the relevant section of the MDS are missing. Residents must be present for at least 100 days to be included in long-stay measures.</p>

	PACE Falls With Injury Rate	Measure 1	Measure 2
Risk Adjustment	Yes, risk stratification by 3 site characteristics: site age, number of participants, and geographic location.	Yes, by unit type.	No.
Reliability/ Validity	<ul style="list-style-type: none"> No data available at this time. 	<ul style="list-style-type: none"> Site coordinator interview to identify core processes and key personnel in data collection. Evidence: No difference between hospital type and limited differences by hospital size and teaching status. Online written fall injury scenario survey to determine inter-rater reliability and construct validity. Evidence: An intraclass correlation coefficient (ICC) was 0.85 for 13 scenarios, and confirmatory factor analysis results confirm the 2-factor structure that is appropriate for predicting severity of falls with injury. Patient days (denominator) reliability test. Evidence: High agreement between patient days computed using the multiple census data collected for the study (gold standard) and patient days as routinely reported to NDNQI (ICC=0.97). 	Not available.
Actual/ Planned Use	<p>Quality improvement (internal to the specific organization with peer benchmarking).</p> <p>Public reporting is planned by CMS for some time in the future.</p>	<p>Quality improvement (internal to the specific organization & external benchmarking): About one-third of hospitals (1,634) nationwide are reporting on this measure.</p> <p>Public reporting: It is reported publicly in Colorado Hospital Report Card and Massachusetts Public Reporting—Patient Care Link, Norton Healthcare, and through Leapfrog on 39 States.</p>	<p>Quality improvement (internal to the specific organization & external benchmarking).</p> <p>Public reporting: No specific information.</p>

	PACE Falls With Injury Rate	Measure 1	Measure 2
Care Setting	PACE site	Hospital/acute care facility Post-acute/long-term care facility Inpatient rehabilitation facility	Nursing home (NH)/skilled nursing facility (SNF)
Target Population	PACE participants	Adult acute care inpatients and adult rehabilitation patients.	Long-stay residents
Level of Analysis	Site	Facility; unit	Facility
Data Source	Clinical records	Electronic clinical data, other, paper medical records	Electronic clinical data
Measure Type	Outcome	Outcome	Outcome
Measure Developer/Steward	Econometrica	American Nurses Association	CMS

Preliminary Recommendation for Endorsement

Based on the individual rating of each of the five major criteria, provide an initial recommendation for endorsement based on the overall suitability of this measure.

Criteria	High	Medium	Low	Insufficient
1. Importance to Measure and Report	X			
2a. Overall Reliability				
2b. Overall Validity				
2c. Disparities of Care				
3. Feasibility				
4. Usability and Use				
5. Comparison to Related or Competing Measures	X			

Recommendation:

Explanation:

Chapter 3. Pressure Ulcers Acquired While Enrolled in PACE Measure Evaluation Report

Project Title:

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Econometrica, Inc., to develop quality measures for the PACE program: Total Falls, Falls With Injury, Pressure Ulcers, Pressure Ulcer Prevention, and 30-Day All-Cause Hospital Readmissions. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The contract number is HHSM-500-2013-13006I/HHSM-500-T0002.

The current health care system does not consistently deliver high-quality care for every participant at every opportunity, resulting in gaps in the quality of care provided. One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. The purpose of this project is to develop, implement, and align measures for PACE.

Date: Information included is current as of May 15, 2015.

Measure Name: Pressure Ulcers Acquired While Enrolled in PACE

Measure Set (or Setting): PACE program sites. The target population is all participants in the PACE site census during the month, regardless of their location. That is, participants who were living at home, in long-term care, emergency rooms, hospitals, or otherwise away from home are to be included.

Measure Contractor: Econometrica, Inc.

1. Evidence, Performance Gap, and Priority (Impact)—Importance to Measure and Report

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1a. Evidence to Support the Measure Focus/Measure Intent	Pass	
1b. Performance Gap	Pass	
1c. High Priority (previously referred to as High Impact)	Pass	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1d. Explicit Logic (Composite Measures only)		

Summary Rating for Importance: Pass

Brief Statement of Conclusions That Support the Summary Rating:

1.a. Measure Focus

The PACE-acquired pressure ulcer rate is an outcome measure. While it has not been measured in PACE settings, pressure ulcer rates are collected and reported by CMS for hospitals, nursing homes, and home care. The Leapfrog Group also reports pressure ulcer rates for hospitals.

Recommendations from clinical practice guidelines on pressure ulcers include the identification of individuals at risk and early implementation of interventions to prevent pressure ulcer occurrence. In most at-risk participants, interventions to reduce pressure, friction, and shear, and to mitigate other risk factors (immobility, incontinence, impaired nutrition, etc.), will decrease pressure ulcer development and the worsening of existing pressure ulcers. Pressure ulcer prevention requires multidisciplinary effort and administrative support.

In other settings, pressure ulcer rates have been related to structural characteristics of the setting, such as hospital unit type, staff turnover rates, nurse staffing levels, and registered nurse specialty certification.

Pressure ulcer rates also have been linked to process factors: risk assessment, risk status, and implementation of a prevention plan.

Reference List

Park, S. H., Boyle, D. K., Bergquist-Beringer, S., Staggs, V. S., & Dunton, N. (2014). Concurrent and lagged effects of registered nurse turnover and staffing on unit-acquired pressure ulcers. *Health Services Research*, 49, 1205–1225.

WOCN Guidelines Task Force. (2010). *Guideline for prevention and management of pressure ulcers*. Mount Laurel, NJ: Wound Ostomy and Continence Nurses Society.

1.b. Performance Gap

Pressure ulcer data have not yet been collected across PACE sites. Thus, evidence currently available is primarily from hospital- or nursing home-based studies. It is estimated that there are approximately 2.5 million pressure ulcers in acute care hospitals in the United States (Sherve, 2010), or a nationwide hospital-associated pressure ulcer (HAPU) incidence rate of 4.5 percent (Lyder et al., 2012). In a study of the National Medicare Patient Safety Monitoring System, the researchers observed variance by patient characteristics and States across the nation (Lyder et al., 2012). Specifically, patients that were older, nonwhite, and with chronic conditions (e.g., congestive heart failure and cerebrovascular disease) were more likely to develop HAPU, and the highest HAPU incidence rates were observed in the Northeast and Missouri (4.6 percent and 5.9 percent, respectively). In another study using data from a national quality indicators database,

researchers observed variance in pressure ulcers by unit types (Bergquist-Beringer, Dong, He, & Dunton, 2013). Critical care units had the highest rates (8.1 percent) relative to step-down units (3.7 percent), medical units (3.1 percent), surgical units (2.4 percent), and medical-surgical combined units (2.6 percent). The researchers also reported that the frequency of interventions to prevent pressure ulcers also varied among at-risk patients. For example, the researchers reported that only 56.3 percent of at-risk patients received nutrition support. Other studies of pressure ulcers in U.S. acute care hospitals indicated that the occurrence of pressure ulcers during hospitalization was related to hospital characteristics (e.g., bed size, teaching status, and Magnet status), nursing resources, and work conditions (Park, Boyle, Bergquist-Beringer, Staggs, & Dunton, 2014; Choi, Bergquist-Beringer, & Staggs, 2013).

Researchers have also studied pressure ulcers among nursing home residents. Park-Lee and Caffrey (2009) report that about 11 percent of the 1.5 million U.S. nursing residents in 2004 developed at least one pressure ulcer. They also found that only 35 percent of residents with stage II or higher pressure ulcers received wound care by specially trained professionals or staff.

There are performance gaps in pressure ulcers. In 2004, pressure ulcer rates in U.S. nursing homes ranged from 2 percent to 28 percent (Park-Lee & Caffrey, 2009). In 2010, a study using data obtained from acute care hospital units found that HAPU rates differed by unit type (Bergquist-Beringer, Dong, He, & Dunton, 2013).

Table 3-1. Hospital-Acquired Pressure Ulcer Rates by Unit Type

Unit Type	Rate
Critical Care	8.1%
Step Down	3.7%
Medical	3.1%
Surgical	2.4%
Medical/Surgical	2.6%

Reference List

- Bergquist-Beringer, S., Dong, L., He, J., & Dunton, N. (2013). Pressure ulcers and prevention among acute care hospitals in the United States. *The Joint Commission Journal on Quality and Patient Safety*, 39, 404–414.
- Choi, J., Bergquist-Beringer, S., & Staggs, V. S. (2013). Linking RN workgroup job satisfaction to pressure ulcers among older adults on acute care hospital units. *Research in Nursing & Health*, 36(2), 181–190.
- Lyder, C. H., Wang, Y., Metersky, M., Curry, M., Kliman, R., Verzier, N. R., & Hunt, D. R. (2012). Hospital-acquired pressure ulcers: Results from the national Medicare Patient Safety Monitoring System study. *Journal of the American Geriatrics Society*, 60(9), 1603–1608.
- Park, S. H., Boyle, D. K., Bergquist-Beringer, S., Staggs, V. S., & Dunton, N. E. (2014). Concurrent and lagged effects of registered nurse turnover and staffing on unit-acquired pressure ulcers. *Health Services Research*, 49(4), 1205–1225.

- Park-Lee, E., & Caffrey, C. (2009) Pressure ulcers among nursing home residents: United States, 2004. *NCHS Data Brief, 14*. Retrieved from <http://www.cdc.gov/nchs/data/databriefs/db14.pdf>.
- Shreve, J., Van Den Bos, J., Gray, T., Halford, M., Rustagi, K., & Ziemkiewicz, E. (2010). *The economic measurement of medical errors*. Sponsored by Society of Actuaries' Health Section. Milliman Inc.

1.c. High Priority

Pressure ulcer rates are an important safety concern in acute care and long-term care settings. There are an estimated 2.5 million pressure ulcers per year in acute care hospitals in the United States, with a cost of \$9.1 billion to \$11.6 billion (Reddy, Gill, & Ronchon, 2006; Shreve, Van Den Bos, Gray, Halford, Rustagi, & Ziemkiewicz, 2010; Institute for Healthcare Improvement, 2014). In addition to increasing health care resource consumption and costs, pressure ulcers also cause pain to the patient, prolong hospital stays, and place patients at risk for other adverse events (Gorecki et al., 2009; Lyder et al., 2012; National Pressure Ulcer Advisory Panel (NPUAP) & European Pressure Ulcer Advisory Panel (EPUAP), 2009). The occurrence of pressure ulcers is considered a serious consequence of substandard quality of care.

The prevention of pressure ulcers has become the focus of national policy and patient safety initiatives. The National Quality Forum (NQF) (2008) considers HAPUs of stages III and IV “largely preventable, grave errors” (p. 1). On October 1, 2008, CMS stopped reimbursing hospitals for costs of treating stage III and IV HAPUs (CMS, 2007; Stone et al., 2010). Additionally, CMS is planning to implement the Hospital-Acquired Condition (HAC) Reduction Program in the near future, under which hospitals will be penalized for excess rates of HAPUs and other HACs (CMS, 2014). National health care stakeholders, including the National Quality Strategy and the CMS Partnership for Patients and HAC Reduction Program, have identified pressure ulcers as a patient safety concern.

Reference List

- CMS. (2014). *Fact sheets: CMS proposals to improve quality of care during hospital inpatient stays*. Retrieved August 24, 2014, from <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-04-30-2.html>.
- CMS. (2007). *FY 2008 inpatient prospective payment system final rule*. Retrieved from <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2007-Fact-sheets-items/2007-08-012.html>.
- Gorecki, C., Brown, J. M., Nelson, E. A., Briggs, M., Schoonhoven, L., Dealey, C., ... Nixon, J. (2009). Impact of pressure ulcers on quality of life in older patients: A systematic review. *Journal of the American Geriatrics Society*. 57(7), 1175–1183.
- He, J., Staggs, V., Bergquist-Beringer, S., & Dunton, N. (2013). Unit-level time trends and seasonality in the rate of hospital acquired pressure ulcers in US acute care hospitals. *Research in Nursing & Health*, 36, 171–180. doi: 10.1002/nur.21527.

- Institute for Healthcare Improvement. (2014). *Protecting 5 million lives from harm: Overview*. Cambridge, MA. Retrieved September 27, 2014, from <http://www.ihl.org/engage/Initiatives/completed/5MillionLivesCampaign/Pages/default.aspx>.
- Lyder, C. H. (2002). Pressure ulcer prevention and management. *Annual Review of Nursing Research*, 20, 35–61.
- Lyder, C. H., Wang, Y., Metersky, M., Curry, M., Kliman, R., Verzier, N. R., & Hunt, D. R. (2012). Hospital-acquired pressure ulcers: Results from the national Medicare Patient Safety Monitoring System study. *Journal of the American Geriatrics Society*, 60(9), 1603–1608.
- NPUAP/EPUAP. (2009). *Prevention and treatment of pressure ulcers: Clinical practice guideline*. Washington, DC: NPUAP.
- NQF. (2008). *Serious reportable events*. Retrieved from <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=57355>.
- Reddy, M., Gill, S. S., & Rochon, P. (2006). Preventing pressure ulcers: A systematic review. *The Journal of the American Medical Association*, 296(8), 974–984.
- Shreve, J., Van Den Bos, J., Gray, T., Halford, M., Rustagi, K., & Ziemkiewicz, E. (2010). *The economic measurement of medical errors*. Sponsored by the Society of Actuaries' Health Section. Milliman Inc.
- Stone, P. W., Glied, S. A., McNair, P. D., Matthes, N., Cohen, B., Landers, T. F., & Larson, E. L. (2010). CMS changes in reimbursement for HAIs. *Medical Care*, 48, 433–439. doi: 10.1097/MLR.0b013e3181d5fb3f.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

NOTE: Section 2, Scientific Acceptability, will be updated with the results from the content validity testing. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a. Reliability		
2a1. Precisely Specified		
2a2. Reliability Testing		
Cost and Resource Use Measure-Specific Sub-Criteria		
2a3. Construction Logic		
2a4. Clinical Logic		
2a5. Adjustments for Comparability—Inclusion/Exclusion Criteria		

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a6. Adjustments for Comparability—Risk Adjustment		
2a7. Adjustments for Comparability—Costing Method		
2a8. Adjustment for Comparability—Scoring		
2b. Validity		
2b1. Specifications	Moderate	
2b2. Validity Testing	Moderate	
2b3. Exclusions		
2b4. Risk Adjustment		
2b5. Meaningful		
2b6. Comparable Results		
2b7. Missing Data (eMeasures, Composite Measures, and PRO-PMs)		
Cost and Resource Use Measure-Specific Sub-Criteria		
2b8. Construction Logic		
2b9. Clinical Logic		
2b10. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2b11. Adjustments for Comparability—Risk Adjustment		
2b12. Adjustments for Comparability—Costing Method		
2b13. Adjustment for Comparability—Scoring		
2b14. Significant Differences in Performance		
2b15. Comparability of Multiple Data Sources		
2c. Disparities		
2c1. Disparities Identified		
2d. Empirical Analysis (Composite Measures Only)		
2d1. Quality Construct		
2d2. Aggregation and Weighting Rules		
2e. eMeasure-Specific Sub-Criteria		
2e1. HQMF Specifications		
2e2. Data Types		
2e3. Data Element Validity		
2e4. Comparability Analysis		

Summary Rating for Scientific Acceptability of Measure Properties:

Brief Statement of Conclusions That Support the Summary Rating:

Validity Testing Results:

Content validity was assessed using a panel of experts to: (1) quantify experts' degree of agreement regarding the content of the measure instructions (i.e., PACE Measure Instructions) and (2) obtain experts' narrative comments on the measure instructions. The findings were used to evaluate the content validity of developed quality measures and improve each measure's instructions. Thirteen experts (9 TEP experts and 4 academic experts) provided their evaluation on content validity and narrative feedback on measure instructions. Some of them reviewed all quality measure instructions (falls, pressure ulcers, and readmissions); others reviewed one or two instructions based on their specialty.

Content validity of the measure instructions was analyzed by calculating item-level content validity indices (I-CVIs). Experts rated each component's content validity using a 4-point scale: 1=very low (major modification needed), 2=low (some modification needed), 3=high (no modification needed but could be improved with minor changes), and 4=very high (no modification needed). I-CVI is computed for each item by counting the number of experts giving a rating of three or four (thus dichotomizing the ordinal scale into high vs. low valid) and dividing the number by the total number of experts (Polit, Beck, & Owen, 2007). Polit et al. (2007) suggested that items with good content validity should have an I-CVI of .78 or higher from three or more experts' review. Based on this, we used .78 as a cut-off point to determine good, acceptable content validity. Another evaluation criterion was based on Lynn (1986). Lynn (1986) argued that the disagreement is accepted only if "six or more experts" are rated as 1 (very low) or 2 (low).

Eight experts, including 7 TEP experts and 1 academic expert, independently evaluated content validity of the pressure ulcer (PU) and PU prevention measure instructions.

Content validity was systematically assessed using expert review. Table 3 below displays I-CVIs for the PU and PU prevention measure instructions. The findings showed good content validity for measure description and PU stages (except deep tissue injuries), presenting I-CVIs greater than .78. Due to concern about the difficulty in accurately identifying deep tissue injuries, this element of deep tissue injuries was removed in the final measure instructions.

Furthermore, there was good content validity (agreement) on the overall usefulness of the PU/PU prevention measures for internal quality improvement purposes and for comparison between PACE sites (I-CVIs = .88).

The PU definitions of numerator and denominator, PU prevention definitions, measure calculations, and inclusion/exclusion criteria had I-CVIs less than .78. Although their I-CVIs were less than .78, there were only two or four disagreements on content validity for those components. However, to improve content validity and address the input provided by the experts, we made multiple revisions on the PU and PU prevention instructions. Specifically, denominators for PU rates were revised to improve clarity. We also clarified PUs present on enrollment in PACE and PACE-acquired PUs. In the revised instructions, we provided three ways to measure PU rates (i.e., PU prevalence rate, PACE-acquired PU rate, and PACE-acquired PU Stage II and above rate) to clearly differentiate PACE-acquired PUs from PUs present on enrollment.

Table 3. I-CVIs for Data Elements in the PU and PU Prevention Measure Instructions

PU Rates Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Measure Description	1.0 (6/6)	.80 (4/5)	.88 (7/8)	.89
Pressure Ulcer Rate Definitions:				
• Numerator	.44 (4/9)	.75 (6/8)	.88 (7/8)	.69
• Denominator	.57 (4/7)	.75 (6/8)	.88 (7/8)	.73
• Pressure Ulcer Stages:	1.0 (7/7)	.75 (6/8)	.88 (7/8)	.88
○ Stage II				
○ Stage III	1.0 (7/7)	.71 (5/7)	.88 (7/8)	.86
○ Stage IV	1.0 (7/7)	.75 (6/8)	.88 (7/8)	.88
○ Deep tissue injuries	.83 (5/6)	.63 (5/8)	.86 (6/7)	.77
○ Unstageable	1.0 (7/7)	.63 (5/8)	.88 (7/8)	.84
Pressure Ulcer Prevention Rate Definitions:				
• Days Since Last Pressure Ulcer Risk Assessment Conducted	.43 (3/7)	.50 (4/8)	.43 (3/7)	.45
• Pressure Ulcer Prevention Included in Plan of Care	.75 (6/8)	.50 (4/8)	.75 (6/8)	.67
• Pressure Ulcer Prevention Implemented	.75 (6/8)	.63 (5/8)	.63 (5/8)	.67
Measure Calculations:				
• Pressure Ulcer Rate Calculation	.38 (3/8)	.38 (3/8)	.86 (6/7)	.54
• Pressure Ulcer Risk Assessment Calculation	.50 (4/8)	.50 (4/8)	.71 (5/7)	.57
• Pressure Ulcer Prevention Plan of Care Calculation	.50 (4/8)	.38 (3/8)	.88 (7/8)	.59
• Pressure Ulcer Prevention Implemented Calculation	.63 (5/8)	.75 (6/8)	.75 (6/8)	.71
Inclusion Criteria:				
• PACE participants who have a new or previously documented PU.	.63 (5/8)	.88 (7/8)	.75 (6/8)	.75
• PACE participants who have a closed PU that reopened at the same site are counted as having a new PU.	.75 (6/8)	.75 (6/8)	.88 (7/8)	.79

PU Rates Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Exclusion Criteria:				
<ul style="list-style-type: none"> Persons not enrolled in the PACE program 	1.0 (8/8)	1.0 (8/8)	1.0 (8/8)	1.0
<ul style="list-style-type: none"> Newly enrolled PACE participants who had the current PUs present on enrollment. 	.75 (6/8)	.71 (5/7)	.75 (6/8)	.74
<ul style="list-style-type: none"> Participants who declined to participate in the PU assessment or for whom it would be inappropriate to assess due to medical conditions. 	.63 (5/8)	.57 (4/7)	.75 (6/8)	.65
Data Sources	.60 (3/5)	.29 (2/7)	1.0 (2/2)	.63
Overall clarity of the Data Collection Guidelines	.50 (4/8)			
Overall capability to measure/capture what the indicator of “pressure ulcer prevalence rates” intends to measure	.50 (4/8)			
Overall capability to measure/capture what the indicator of “pressure ulcer prevention rates” intends to measure	.50 (4/8)			
Overall applicability of the indicator to the PACE participants and PACE sites	.71 (5/7)			
Overall usefulness of the indicator for internal quality improvement purposes	.88 (7/8)			
Overall usefulness of the indicator for comparison between PACE sites	.88 (7/8)			
Participants with one or more documented PUs of stage II, III, IV, or unstageable × 1,000 / Number of PACE participants whose medical records were reviewed for PUs	.43 (3/7)			
Number of participants with one or more documented PUs of stage II, III, IV, or unstageable / Number of PACE participants	.63 (5/8)			

Note. I-CVI, item-level content validity index; I-CVI/ave, average of I-CVIs.

Each parenthesis indicates the number of experts who rated the data element as three or four divided by the total number of experts who responded.

References:

Polit, D. F., Beck, C. T., & Owen, S. V. (2007). Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health*. 30, 459-467.

Lynn, M. (1986). Determination and quantification of content validity. *Nursing Research*, 35, 381-385.

3. Feasibility

NOTE: Section 3, Feasibility, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3a. Data Are a Byproduct of Care		
3b. Electronic Sources		
3c. Data Collection Strategy		
3d. eMeasure Feasibility Assessment Summary		For data elements that score low on current feasibility, indicate the anticipated feasibility score in three to five years based on a projection of the maturation of the electronic health record, or maturation of its use.
3d1. Data Availability		
3d2. Data Accuracy		
3d3. Data Standards		
3d4. Workflow		

Summary Rating for Feasibility/eMeasure Feasibility:

Brief Statement of Conclusions That Support the Summary Rating:

4. Usability and Use

NOTE: Section 4, Usability and Use, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
4a. Accountability and Transparency		
4b. Improvement		
4c. Benefits		
4d. Measure Deconstruction (Cost and Resource Use Measure Only)		

Summary Rating for Usability:

Brief Statement of Conclusions That Support the Summary Rating:

5. Comparison to Related or Competing Measures

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
5a. Related Measure	Moderate	The NQF should convene the measure stewards to determine if greater harmonization is attainable.
5b. Competing Measure		

Summary Rating for Harmonization: Moderate

Rationale for Rating/Comments:

A search of the NQF Quality Positioning System found three endorsed pressure ulcer measures. Pressure Ulcers Acquired While Enrolled in PACE differs in several ways from the three NQF-endorsed rates, and they differ from one another as well.

- Although the definition of pressure ulcers is not found in the measure specifications on the NQF Web site, it is likely that all use the definition of the Wound Ostomy and Continence Nurses Society.
- The settings differ: PACE programs, long-term care facilities, acute care hospitals, and pediatric hospitals.
- Each of the measures relies on a different data source: medical records, discharge data, prevalence study, Minimum Data Set.
- Exclusion criteria differ across measures.

All but one of the NQF-endorsed measures are based on periodic assessments or surveys. The PACE measure is intended to be collected monthly and will provide more accurate representations of true performance. Differences in the denominator and exclusions seem reasonable given the populations being measured.

Table 3-2. Comparison of the PACE Pressure Ulcer Rate With NQF-Endorsed Pressure Ulcer Rates

	PACE Pressure Ulcer Rate	Measure 2	Measure 3	Measure 4
NQF Number	NA	0679	0201	0337
Measure Title	Pressure Ulcers Acquired While Enrolled In PACE	Percent of High Risk Residents With Pressure Ulcers (Long Stay)	Pressure Ulcer Prevalence (Hospital Acquired)	Pediatric Pressure Ulcer Rate (PDI 2)

	PACE Pressure Ulcer Rate	Measure 2	Measure 3	Measure 4
Measure Description	Participants with one or more documented pressure ulcers $\times 1,000 \div$ number of PACE participants whose medical records were reviewed for pressure ulcers.	The measure reports the percentage of all long-stay residents in a nursing facility with an annual, quarterly, significant change or significant correction MDS assessment during the selected quarter (3-month period) who were identified as high risk and who have one or more stage II–IV pressure ulcer(s). High-risk populations are those who are comatose, impaired in bed mobility or transfer, or suffering from malnutrition.	The total number of patients that have hospital-acquired (nosocomial) category/stage II or greater pressure ulcers on the day of the prevalence measurement episode.	Percent of discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9-CM code of pressure ulcer in any secondary diagnosis field and ICD-9-CM code of pressure ulcer stage III or IV (or unstageable) in any secondary diagnosis field.

	PACE Pressure Ulcer Rate	Measure 2	Measure 3	Measure 4
Numerator Statement	The total number of participants that have a documented pressure ulcer of stage II, III, IV, or unstageable during the month \times 1,000.	The number of long-stay residents who have been assessed with an OBRA, PPS, or discharge MDS 3.0 assessment during the selected time window and who are defined as high risk with one or more stage II–IV pressure ulcer(s). High-risk populations are those who are comatose, impaired in bed mobility or transfer, or suffering from malnutrition. Stage I ulcers are not included in this measure because recent studies have identified difficulties in objectively measuring them across different populations.	Patients that have at least one category/stage II or greater hospital-acquired pressure ulcer on the day of the prevalence measurement episode.	Discharges among cases meeting the inclusion and exclusion rules for the denominator with ICD-9-CM code of pressure ulcer in any secondary diagnosis field and ICD-9-CM code of pressure ulcer stage III or IV (or unstageable) in any secondary diagnosis field.
Denominator Statement	Number of PACE participants whose medical records were reviewed for evidence of pressure ulcers.	All long-stay residents with a selected target assessment who meet the definition of high risk, except those with exclusions.	All patients surveyed for the measurement episode.	All surgical and medical discharges under age 18 defined by specific DRGs or MS-DRGs.
Inclusion Criteria	PACE participants who have a new or previously documented pressure ulcer acquired after enrollment in PACE.	None listed.	None listed.	None listed.

	PACE Pressure Ulcer Rate	Measure 2	Measure 3	Measure 4
Exclusions	<ul style="list-style-type: none"> Persons not enrolled in the PACE program. Pressure ulcers present on admission to PACE. Pressure ulcers developed while participant was in a hospital, nursing home, rehabilitation facility, or other domiciled setting. 	<p>A long-stay resident is excluded from the denominator if the MDS assessment in the current quarter is an OBRA admission assessment, a 5-day PPS assessment, or a readmission/return PPS assessment or if a resident did not meet the pressure ulcer conditions for the numerator AND any stage II, III, or IV item is missing (M0300B1 = - OR M0300C1 = - OR M0300D1 = -). The OBRA admission assessment and two PPS assessment types are excluded because pressure ulcers identified on them reflect care received in the previous setting and do not reflect the quality of care provided in the nursing home.</p> <p>Nursing homes with fewer than 30 residents in the sample are excluded from public reporting because of small sample size.</p>	<ul style="list-style-type: none"> Patients who refuse to be assessed. Patients who are off the unit at the time of the prevalence measurement, i.e., surgery, x-ray, physical therapy, etc. Patients who are medically unstable at the time of the measurement for whom assessment would be contraindicated at the time of measurement, i.e., unstable blood pressure, uncontrolled pain, or fracture awaiting repair. Patients who are actively dying for whom pressure ulcer prevention is no longer a treatment goal. 	<p>Patients:</p> <ul style="list-style-type: none"> Neonates. Length of stay of less than 5 days. With preexisting condition of pressure ulcer (see Numerator) (principal diagnosis or secondary diagnosis present on admission). With an MDC 9 (Skin, Subcutaneous Tissue, and Breast). With an ICD-9-CM procedure code for debridement or pedicle graft before or on the same day as the major operating room procedure (surgical cases only). With an ICD-9-CM procedure code of debridement or pedicle graft as the only major operating room procedure (surgical cases only). Transfer from a hospital (different facility). Transfer from a skilled nursing facility (SNF) or intermediate care facility (ICF). Transfer from another health care facility. MDC 14 (pregnancy, childbirth, and puerperium). With missing discharge gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing), or principal diagnosis (DX1=missing).

	PACE Pressure Ulcer Rate	Measure 2	Measure 3	Measure 4
Risk Adjustment	Yes, risk stratification by PACE site age, number of enrollees, and geographic location.	Yes	Yes	Yes
Actual/Planned Use	Planned for eventual public reporting.	Used by CMS in Nursing Home Compare and in payment systems that promote quality of care.	In Joint Commission reviews of acute care facilities.	Reported in Patient Safety Indicators.
Care Setting	PACE sites	Long-term care	Acute care hospitals	Acute care hospitals
Target Population	PACE enrollees	Residents	Patients	Patients
Level of Analysis	PACE site	Long-term care facility	Hospital	Hospital
Data Source	Clinical records	MDS	Prevalence study combined with medical record review	Discharge data
Measure Type	Outcome	Outcome	Outcome	Outcome
Measure Developer/Steward	Econometrica	CMS	The Joint Commission	Agency for Healthcare Research and Quality

Preliminary Recommendation for Endorsement

Based on the individual rating of each of the five major criteria, provide an initial recommendation for endorsement based on the overall suitability of this measure.

Criteria	High	Medium	Low	Insufficient
1. Importance to Measure and Report				
2a. Overall Reliability				
2b. Overall Validity				
2c. Disparities of Care				
3. Feasibility				
4. Usability and Use				
5. Comparison to Related or Competing Measures				

Recommendation:

Explanation:

Chapter 4. Pressure Ulcer Prevention Measure Evaluation Report

Project Title:

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Econometrica, Inc., to develop quality measures for the PACE program: Total Falls, Falls With Injury, Pressure Ulcers, Pressure Ulcer Prevention, and 30-Day All-Cause Hospital Readmissions. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The contract number is HHSM-500-2013-13006I/HHSM-500-T0002.

The current health care system does not consistently deliver high-quality care for every participant at every opportunity, resulting in gaps in the quality of care provided. One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. The purpose of this project is to develop, implement, and align measures for PACE.

Date: Information included is current as of May 15, 2015.

Measure Name: Pressure Ulcer Prevention

Measure Set (or Setting): PACE program sites. The target population is all participants in the PACE site census during the month, regardless of their location. That is, participants who were living at home, in long-term care, emergency rooms, hospitals, or otherwise away from home are to be included.

Measure Contractor: Econometrica, Inc.

1. Evidence, Performance Gap, and Priority (Impact)—Importance to Measure and Report

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1a. Evidence to Support the Measure Focus/Measure Intent	Pass	
1b. Performance Gap	Pass	
1c. High Priority (previously referred to as High Impact)	Pass	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1d. Explicit Logic (Composite Measures only)		

Summary Rating for Importance: Pass

Brief Statement of Conclusions That Support the Summary Rating:

1.a. Measure Focus

The PACE pressure ulcer prevention rates are process measures. While it has not been measured in PACE settings, a highly harmonized measure has been used in home health care.

Recommendations from clinical practice guidelines on pressure ulcers include the identification of individuals at risk and early implementation of interventions to prevent pressure ulcer occurrence (WOCN, 2010). In most at-risk participants, interventions to reduce pressure, friction, and shear, and to mitigate other risk factors (immobility, incontinence, impaired nutrition, etc.), will decrease pressure ulcer development and the worsening of existing pressure ulcers. Common prevention activities include regular turning of participants who spend long hours in bed, use of pressure reduction surfaces, moisture management, nutritional support, and frequent assessment. Pressure ulcer prevention requires multidisciplinary effort and administrative support.

Despite tremendous efforts in pressure ulcer prevention and management, systematic reviews of pressure ulcer literature suggest that not all interventions are effective and that accurate measures of pressure ulcers are needed to effectively prevent pressure ulcers (Chou et al., 2013; Reddy, Gill, & Rochon, 2006).

Reference List

- Chou, R., Dana, T., Bougatsos, C., Blazina, I., Starmer, A. J., Reitel, K., & Buckley, D. I. (2013). Pressure ulcer risk assessment and prevention: A systematic comparative effectiveness review. *Annals of Internal Medicine*, 159(1), 28–38.
- Reddy, M., Gill, S. S., & Rochon, P. A. (2006). Preventing pressure ulcers: A systematic review. *The Journal of the American Medical Association*, 296(8), 974–984.
- WOCN Guidelines Task Force. (2010). *Guideline for prevention and management of pressure ulcers*. Mount Laurel, NJ: Wound Ostomy and Continence Nurses Society.

1.b. Performance Gap

Information on the performance gap is not yet available for PACE sites and not readily accessible for home health care. Research has found that the frequency of interventions to prevent pressure ulcers varied among at-risk patients (Bergquist-Beringer, Dong, He, & Dunton, 2013). For example, the researchers reported that only 56.3 percent of at-risk patients received nutrition support. Other studies of pressure ulcers in U.S. acute care hospitals indicated that the occurrence of pressure ulcers during hospitalization was related to hospital characteristics (e.g.,

bed size, teaching status, and Magnet status), nursing resources, and work conditions (Choi, Bergquist-Beringer, & Staggs, 2013; Park, Boyle, Bergquist-Beringer, Staggs, & Dunton, 2014).

A review of the literature about pressure ulcer prevention in long-term care settings found the following:

- Recommended pressure ulcer prevention practices were followed in fewer than half of the appropriate instances in Veterans Health Administration (VHA) nursing homes (Salbia et al., 2003). There was a significant range (29 percent to 51 percent) in adherence to recommendations across VHA nursing homes, as well as significant room for improvement in care practices.
- An analysis of data for 16 long-term care facilities in Missouri found that valid and reliable pressure ulcer risk-assessment tools were seriously underused and that evidence-based guidelines for pressure ulcer prevention were rarely followed (Wipke-Tevis et al., 2004).

Reference List

- Bergquist-Beringer, S., Dong, L., He, J., & Dunton, N. (2013). Pressure ulcers and prevention among acute care hospitals in the United States. *The Joint Commission Journal on Quality and Patient Safety*, 39, 404–414.
- Choi, J., Bergquist-Beringer, S., & Staggs, V. S. (2013). Linking RN workgroup job satisfaction to pressure ulcers among older adults on acute care hospital units. *Research in Nursing & Health*, 36(2), 181–190.
- Park, S. H., Boyle, D. K., Bergquist-Beringer, S., Staggs, V. S., & Dunton, N. (2014). Concurrent and lagged effects of registered nurse turnover and staffing on unit-acquired pressure ulcers. *Health Services Research*, 49, 1205–1225.
- Saliba, D., Rubenstein, L. V., Simon, B., Hickey, E., Ferrell, B., Czarnowski, E., & Berlowitz, D. (2003). Adherence to pressure ulcer prevention guidelines: Implications for nursing home quality. *Journal of the American Geriatrics Society*, 51(1), 56–62. doi: 10.1034/j.1601-5215.2002.511010.
- Wipke-Tevis, D. D., Williams, D. A., Rantz, M. J., Popejoy, L. L., Madsen, R. W., Petroski, G. F., & Vogelsmeier, A. A. (2004). Nursing home quality and pressure ulcer prevention and management practices. *Journal of the American Geriatrics Society*, 52(4), 583–588. doi: 10.1111/j.1532-5415.2004.52166.

1.c. High Priority

The dire and costly implications of pressure ulcers make pressure ulcer prevention an important safety concern in all health care settings. While pressure ulcer prevention rates are routinely available for quality improvements in a few instances, such as home health care, VHA facilities, and hospitals participating in the National Database of Nursing Quality Indicators®, performance measurement of pressure ulcer prevention rates is not available for most health care settings in the United States. In addition, they have not been used in accountability or pay-for-performance programs.

Preventing pressure ulcers has been identified as a national priority by national health care organizations including CMS, the Partnership for Patients, the Joint Commission, the Institute for Healthcare Improvement (IHI), and the National Quality Forum (NQF).

Reference List

Bergquist-Beringer, S., Dong, L., He, J., & Dunton, N. (2013). Pressure ulcers and prevention among acute care hospitals in the United States. *The Joint Commission Journal on Quality and Patient Safety*, 39, 404–414.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

NOTE: Section 2, Scientific Acceptability, is updated with the results from the content validity testing. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a. Reliability		
2a1. Precisely Specified		
2a2. Reliability Testing		
Cost and Resource Use Measure-Specific Sub-Criteria		
2a3. Construction Logic		
2a4. Clinical Logic		
2a5. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2a6. Adjustments for Comparability—Risk Adjustment		
2a7. Adjustments for Comparability—Costing Method		
2a8. Adjustment for Comparability—Scoring		
2b. Validity		
2b1. Specifications	Moderate	
2b2. Validity Testing	Moderate	
2b3. Exclusions		
2b4. Risk Adjustment		
2b5. Meaningful		
2b6. Comparable Results		
2b7. Missing Data (eMeasures, Composite Measures, and PRO-PMs)		
Cost and Resource Use Measure-Specific Sub-Criteria		
2b8. Construction Logic		
2b9. Clinical Logic		
2b10. Adjustments for Comparability—Inclusion/Exclusion Criteria		

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2b11. Adjustments for Comparability—Risk Adjustment		
2b12. Adjustments for Comparability—Costing Method		
2b13. Adjustment for Comparability—Scoring		
2b14. Significant Differences in Performance		
2b15. Comparability of Multiple Data Sources		
2c. Disparities		
2c1. Disparities Identified		
2d. Empirical Analysis (Composite Measures Only)		
2d1. Quality Construct		
2d2. Aggregation and Weighting Rules		
2e. eMeasure-Specific Sub-Criteria		
2e1. HQMF Specifications		
2e2. Data Types		
2e3. Data Element Validity		
2e4. Comparability Analysis		

Summary Rating for Scientific Acceptability of Measure Properties:

Brief Statement of Conclusions That Support the Summary Rating:

Validity Testing Results:

Content validity was assessed using a panel of experts to: (1) quantify experts' degree of agreement regarding the content of the measure instructions (i.e., PACE Measure Instructions) and (2) obtain experts' narrative comments on the measure instructions. The findings were used to evaluate the content validity of developed quality measures and improve each measure's instructions. Thirteen experts (9 TEP experts and 4 academic experts) provided their evaluation on content validity and narrative feedback on measure instructions. Some of them reviewed all quality measure instructions (falls, pressure ulcers, and readmissions); others reviewed one or two instructions based on their specialty.

Content validity of the measure instructions was analyzed by calculating item-level content validity indices (I-CVIs). Experts rated each component's content validity using a 4-point scale: 1=very low (major modification needed), 2=low (some modification needed), 3=high (no modification needed but could be improved with minor changes), and 4=very high (no modification needed). I-CVI is computed for each item by counting the number of experts giving a rating of three or four (thus dichotomizing the ordinal scale into high vs. low valid) and dividing the number by the total number of experts (Polit, Beck, & Owen, 2007). Polit et al. (2007) suggested that items with good content validity should have an I-CVI of .78 or higher from three or more experts' review. Based on this, we used .78 as a cut-off point to determine good, acceptable content validity. Another evaluation criterion was based on Lynn (1986).

Lynn (1986) argued that the disagreement is accepted only if “six or more experts” are rated as 1 (very low) or 2 (low).

Eight experts, including 7 TEP experts and 1 academic expert, independently evaluated content validity of the pressure ulcer (PU) and PU prevention measure instructions.

Content validity was systematically assessed using expert review. Table 4 below displays I-CVIs for the PU and PU prevention measure instructions. The findings showed good content validity for measure description and PU stages (except deep tissue injuries), presenting I-CVIs greater than .78. Due to concern about the difficulty in accurately identifying deep tissue injuries, this element of deep tissue injuries was removed in the final measure instructions.

Furthermore, there was good content validity (agreement) on the overall usefulness of the PU/PU prevention measures for internal quality improvement purposes and for comparison between PACE sites (I-CVIs = .88).

The PU definitions of numerator and denominator, PU prevention definitions, measure calculations, and inclusion/exclusion criteria had I-CVIs less than .78. Although their I-CVIs were less than .78, there were only two or four disagreements on content validity for those components. However, to improve content validity and address the input provided by the experts, we made multiple revisions on the PU and PU prevention instructions. Specifically, denominators for PU prevention rates were revised to improve clarity. In the revised instructions, PU prevention measures were revised to improve clarity, capability to measure, and applicability.

Table 4. I-CVIs for Data Elements in the PU and PU Prevention Measure Instructions

PU Rates Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Measure Description	1.0 (6/6)	.80 (4/5)	.88 (7/8)	.89
Pressure Ulcer Rate Definitions:				
• Numerator	.44 (4/9)	.75 (6/8)	.88 (7/8)	.69
• Denominator	.57 (4/7)	.75 (6/8)	.88 (7/8)	.73
• Pressure Ulcer Stages:				
○ Stage II	1.0 (7/7)	.75 (6/8)	.88 (7/8)	.88
○ Stage III	1.0 (7/7)	.71 (5/7)	.88 (7/8)	.86
○ Stage IV	1.0 (7/7)	.75 (6/8)	.88 (7/8)	.88

PU Rates Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
○ Deep tissue injuries	.83 (5/6)	.63 (5/8)	.86 (6/7)	.77
○ Unstageable	1.0 (7/7)	.63 (5/8)	.88 (7/8)	.84
Pressure Ulcer Prevention Rate Definitions:				
• Days Since Last Pressure Ulcer Risk Assessment Conducted	.43 (3/7)	.50 (4/8)	.43 (3/7)	.45
• Pressure Ulcer Prevention Included in Plan of Care	.75 (6/8)	.50 (4/8)	.75 (6/8)	.67
• Pressure Ulcer Prevention Implemented	.75 (6/8)	.63 (5/8)	.63 (5/8)	.67
Measure Calculations:				
• Pressure Ulcer Rate Calculation	.38 (3/8)	.38 (3/8)	.86 (6/7)	.54
• Pressure Ulcer Risk Assessment Calculation	.50 (4/8)	.50 (4/8)	.71 (5/7)	.57
• Pressure Ulcer Prevention Plan of Care Calculation	.50 (4/8)	.38 (3/8)	.88 (7/8)	.59
• Pressure Ulcer Prevention Implemented Calculation	.63 (5/8)	.75 (6/8)	.75 (6/8)	.71
Inclusion Criteria:				
• PACE participants who have a new or previously documented PU.	.63 (5/8)	.88 (7/8)	.75 (6/8)	.75
• PACE participants who have a closed PU that reopened at the same site are counted as having a new PU.	.75 (6/8)	.75 (6/8)	.88 (7/8)	.79
Exclusion Criteria:				
• Persons not enrolled in the PACE program	1.0 (8/8)	1.0 (8/8)	1.0 (8/8)	1.0
• Newly enrolled PACE participants who had the current PUs present on enrollment.	.75 (6/8)	.71 (5/7)	.75 (6/8)	.74

PU Rates Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
<ul style="list-style-type: none"> Participants who declined to participate in the PU assessment or for whom it would be inappropriate to assess due to medical conditions. 	.63 (5/8)	.57 (4/7)	.75 (6/8)	.65
Data Sources	.60 (3/5)	.29 (2/7)	1.0 (2/2)	.63
Overall clarity of the Data Collection Guidelines	.50 (4/8)			
Overall capability to measure/capture what the indicator of “pressure ulcer prevalence rates” intends to measure	.50 (4/8)			
Overall capability to measure/capture what the indicator of “pressure ulcer prevention rates” intends to measure	.50 (4/8)			
Overall applicability of the indicator to the PACE participants and PACE sites	.71 (5/7)			
Overall usefulness of the indicator for internal quality improvement purposes	.88 (7/8)			
Overall usefulness of the indicator for comparison between PACE sites	.88 (7/8)			
Participants with one or more documented PUs of stage II, III, IV, or unstageable $\times 1,000$ / Number of PACE participants whose medical records were reviewed for PUs	.43 (3/7)			
Number of participants with one or more documented PUs of stage II, III, IV, or unstageable / Number of PACE participants	.63 (5/8)			

Note. I-CVI, item-level content validity index; I-CVI/ave, average of I-CVIs.

Each parenthesis indicates the number of experts who rated the data element as three or four divided by the total number of experts who responded.

References:

Polit, D. F., Beck, C. T., & Owen, S. V. (2007). Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health*, 30, 459-467.

Lynn, M. (1986). Determination and quantification of content validity. *Nursing Research*, 35, 381-385.

3. Feasibility

NOTE: Section 3, Feasibility, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3a. Data Are a Byproduct of Care		
3b. Electronic Sources		
3c. Data Collection Strategy		
3d. eMeasure Feasibility Assessment Summary		For data elements that score low on current feasibility, indicate the anticipated feasibility score in three to five years based on a projection of the maturation of the electronic health record, or maturation of its use.
3d1. Data Availability		
3d2. Data Accuracy		
3d3. Data Standards		
3d4. Workflow		

Summary Rating for Feasibility/eMeasure Feasibility:

Brief Statement of Conclusions That Support the Summary Rating:

4. Usability and Use

NOTE: Section 4, Usability and Use, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
4a. Accountability and Transparency		
4b. Improvement		
4c. Benefits		
4d. Measure Deconstruction (Cost and Resource Use Measure Only)		

Summary Rating for Usability:

Brief Statement of Conclusions That Support the Summary Rating:

5. Comparison to Related or Competing Measures

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
5a. Related Measure	High	
5b. Competing Measure		

Summary Rating for Harmonization: High

Rationale for Rating/Comments:

CMS has a pressure ulcer prevention and care measure for home health populations endorsed by NQF. The PACE pressure ulcer prevention measure was harmonized with that measure.

Table 4-1. Comparison of the PACE Pressure Ulcer Rate With NQF-Endorsed Pressure Ulcer Rates

	PACE Pressure Ulcer Prevention	Measure 2
NQF Number	NA	0538
Measure Title	PACE Pressure Ulcer Prevention	Pressure Ulcer Prevention & Care
Measure Description	<p>Pressure Ulcer Risk Assessment Conducted: Percentage of PACE participants who were assessed for risk of developing pressure ulcers at start/resumption of care.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Percentage of PACE participants at risk of pressure ulcers for whom the clinician-ordered plan of care included interventions to prevent pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: Percentage of PACE participants for whom the clinician-ordered plan of care had been implemented.</p>	<p>Pressure Ulcer Risk Assessment Conducted: Percentage of home health episodes of care in which the patient was assessed for risk of developing pressure ulcers at start/resumption of care.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Percentage of home health episodes of care in which the physician-ordered plan of care included interventions to prevent pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: Percentage of home health episodes of care during which interventions to prevent pressure ulcers were included in the physician-ordered plan of care and implemented.</p>

	PACE Pressure Ulcer Prevention	Measure 2
Numerator Statement	<p>Pressure Ulcer Risk Assessment Conducted: PACE participants who were assessed for risk of developing pressure ulcers at start/resumption of care.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: PACE participants at risk of pressure ulcers for whom the clinician-ordered plan of care included interventions to prevent pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: PACE participants for whom the clinician-ordered plan of care had been implemented.</p>	<p>Pressure Ulcer Risk Assessment Conducted: Percentage of home health episodes of care in which the patient was assessed for risk of developing pressure ulcers at start/resumption of care.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Percentage of home health episodes of care in which the physician-ordered plan of care included interventions to prevent pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: Percentage of home health episodes of care during which interventions to prevent pressure ulcers were included in the physician-ordered plan of care and implemented.</p>
Denominator Statement	<p>Pressure Ulcer Risk Assessment Conducted: Number of PACE participants.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Number of PACE participants determined to be at risk for pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: Number of PACE participants at risk for pressure ulcers who had a clinician-ordered plan of care for the prevention of pressure ulcers.</p>	<p>Pressure Ulcer Risk Assessment Conducted: Number of home health episodes of care ending during the reporting period, other than those covered by generic exclusions.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Number of home health episodes of care ending during the reporting period, other than those covered by generic exclusions.</p> <p>Pressure Ulcer Prevention Implemented: Number of home health episodes of care ending during the reporting period, other than those covered by generic or measure-specific exclusions.</p>
Exclusions	Persons not enrolled in the PACE program.	<p>Pressure Ulcer Risk Assessment Conducted: No measure-specific exclusions.</p> <p>Pressure Ulcer Prevention Included in Plan of Care: Episodes in which the patient is not assessed to be at risk for pressure ulcers.</p> <p>Pressure Ulcer Prevention Implemented: Number of home health episodes in which the patient was not assessed to be at risk for pressure ulcers, or the home health episode ended in transfer to an inpatient facility or death.</p>
Risk Adjustment	No	No
Actual/Planned Use	Quality improvement	Quality improvement
Care Setting	PACE sites	Home health agencies
Target Population	PACE enrollees	Patients

	PACE Pressure Ulcer Prevention	Measure 2
Level of Analysis	PACE site	Home health agency
Data Source	Clinical records	Clinical records
Measure Type	Process	Process
Measure Developer/ Steward	Econometrica	CMS

Preliminary Recommendation for Endorsement

Based on the individual rating of each of the five major criteria, provide an initial recommendation for endorsement based on the overall suitability of this measure.

Criteria	High	Medium	Low	Insufficient
1. Importance to Measure and Report				
2a. Overall Reliability				
2b. Overall Validity				
2c. Disparities of Care				
3. Feasibility				
4. Usability and Use				
5. Comparison to Related or Competing Measures				

Recommendation:

Explanation:

Chapter 5. 30-Day All-Cause Readmissions Measure Evaluation Report

Project Title:

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Econometrica, Inc., to develop quality measures for the PACE program: Total Falls, Falls With Injury, Pressure Ulcers, Pressure Ulcer Prevention, and 30-Day All-Cause Hospital Readmissions. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The contract number is HHSM-500-2013-13006I/HHSM-500-T0002.

The current health care system does not consistently deliver high-quality care for every participant at every opportunity, resulting in gaps in the quality of care provided. One way that CMS will carry out its obligation to drive improvement in the health care system is through the development and use of quality measures and related activities. The purpose of this project is to develop, implement, and align measures for PACE.

Date: Information included is current as of May 15, 2015.

Measure Name: 30-Day All-Cause Hospital Readmissions

Measure Set (or Setting): PACE program sites. The target population is all participants in the PACE site census during the month, regardless of their location. That is, participants who were living at home, in long-term care, emergency rooms, hospitals, or otherwise away from home are to be included.

Measure Contractor: Econometrica, Inc.

1. Evidence, Performance Gap, and Priority (Impact)—Importance to Measure and Report

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1a. Evidence to Support the Measure Focus/Measure Intent	Pass	
1b. Performance Gap	Pass	
1c. High Priority (previously referred to as High Impact)	Pass	

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
1d. Explicit Logic (Composite Measures only)	NA	

Summary Rating for Importance: Pass

Brief Statement of Conclusions That Support the Summary Rating:

1.a. Measure Focus

Hospital readmissions are a serious problem in the U.S. health care system, and their prevention has become a national policy focus. Hospital readmissions are thought to reflect poorer levels of care coordination in non-acute settings and lower use of other types of appropriate residential care. They may result from patient frailty, premature discharge, and lack of appropriate care supports for returning home. Readmission rates for individuals that receive care in the PACE program are unknown but are a useful indicator of the ability of the PACE program to coordinate care and keep patients in the community, which is a primary objective of this program.

The Institute for Healthcare Improvement and The Commonwealth Fund conducted a review of published literature to identify the structures and processes that resulted in a reduction in readmissions. There is evidence of four interventions that are directly related to this reduction: effective support during transitions, enhanced patient education and self-management capabilities, team management that is multidisciplinary, and end-of-life planning that is patient-centered (Boutwell, 2009).

Reference List

Boutwell, A. H. S. (2009). *Effective interventions to reduce rehospitalizations: A survey of the published evidence*. Cambridge, MA: Institute for Healthcare Improvement.

1.b. Performance Gap

A systematic literature review found that a median of 27 percent of readmissions were judged to be avoidable, ranging from 5 percent to 79 percent (Van Walraven, Bennett, Jennings, Austin, & Forster, 2011). Among Medicare patients, 20 percent of those discharged from a hospital are readmitted within 30 days (Jenks, Williams, & Coleman, 2009). A recent study found that 40 percent of large hospitals and 28 percent of small hospitals would be highly penalized by CMS' Hospital Readmissions Reduction Program (HRRP) (Joynt & Jha, 2013). Additionally, 47 percent of small hospitals—compared with 24 percent of large hospitals—will receive no payment reduction. Major teaching hospitals (44 percent) were more likely to be penalized than nonteaching hospitals (33 percent). Reduced hospital readmissions lower the cost of participant health care. Reduced readmissions also lower the risk of hospital-based infections and other adverse events for PACE participants. However, little is known about readmission rates for PACE participants, and there is no steward measure of readmission for PACE participants.

Reference List

Jencks, S. F., Williams, M. V., Coleman, E. A. (2009). Rehospitalizations among patients in the Medicare Fee-for-Service Program. *The New England Journal of Medicine*, 360, 1418–1428.

Joynt, K., & Jha, A. (2013). Characteristics of hospitals receiving penalties under the Hospital Readmissions Reduction Program. *The Journal of the American Medical Association*, 309(4), 342–343.

Van Walraven, C., Bennett, C., Jennings, A., Austin, P. C., & Forster, A. J. (2011). Proportion of hospital readmissions deemed to be avoidable: A systematic review. *Canadian Medical Association Journal*.

1.c. High Priority

Several national health care organizations, including the National Quality Strategy and the CMS HRRP and Partnership for Patients, have identified hospital readmissions as an issue reflecting resource use. The total cost of readmissions is more than \$15 billion per year (MedCAP, 2007).

Reference List

Medicare Payment Advisory Commission (MedCAP). (2007). *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: Medicare Payment Advisory Commission.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

NOTE: Section 2, Scientific Acceptability, is updated with the results from the content validity testing. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2a. Reliability		
2a1. Precisely Specified		
2a2. Reliability Testing		
Cost and Resource Use Measure-Specific Sub-Criteria		
2a3. Construction Logic		
2a4. Clinical Logic		
2a5. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2a6. Adjustments for Comparability—Risk Adjustment		
2a7. Adjustments for Comparability—Costing Method		
2a8. Adjustment for Comparability—Scoring		
2b. Validity		
2b1. Specifications		
2b2. Validity Testing		
2b3. Exclusions		
2b4. Risk Adjustment		
2b5. Meaningful		
2b6. Comparable Results		

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
2b7. Missing Data (eMeasures, Composite Measures, and PRO-PMs)		
Cost and Resource Use Measure-Specific Sub-Criteria		
2b8. Construction Logic		
2b9. Clinical Logic		
2b10. Adjustments for Comparability—Inclusion/Exclusion Criteria		
2b11. Adjustments for Comparability—Risk Adjustment		
2b12. Adjustments for Comparability—Costing Method		
2b13. Adjustment for Comparability—Scoring		
2b14. Significant Differences in Performance		
2b15. Comparability of Multiple Data Sources		
2c. Disparities		
2c1. Disparities Identified		
2d. Empirical Analysis (Composite Measures Only)		
2d1. Quality Construct		
2d2. Aggregation and Weighting Rules		
2e. eMeasure-Specific Sub-Criteria		
2e1. HQMF Specifications		
2e2. Data Types		
2e3. Data Element Validity		
2e4. Comparability Analysis		

Summary Rating for Scientific Acceptability of Measure Properties:

Brief Statement of Conclusions That Support the Summary Rating:

3. Feasibility

NOTE: Section 3, Feasibility, will be updated once data from the testing phase is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3a. Data Are a Byproduct of Care		
3b. Electronic Sources		
3c. Data Collection Strategy		

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
3d. eMeasure Feasibility Assessment Summary		For data elements that score low on current feasibility, indicate the anticipated feasibility score in three to five years based on a projection of the maturation of the electronic health record, or maturation of its use.
3d1. Data Availability		
3d2. Data Accuracy		
3d3. Data Standards		
3d4. Workflow		

Summary Rating for Feasibility/eMeasure Feasibility:

Brief Statement of Conclusions That Support the Summary Rating:

Validity Testing Results:

Content validity was assessed using a panel of experts to: (1) quantify experts' degree of agreement regarding the content of the measure instructions (i.e., PACE Measure Instructions) and (2) obtain experts' narrative comments on the measure instructions. The findings were used to evaluate the content validity of developed quality measures and improve each measure's instructions. Thirteen experts (9 TEP experts and 4 academic experts) provided their evaluation on content validity and narrative feedback on measure instructions. Some of them reviewed all quality measure instructions (falls, pressure ulcers, and readmissions); others reviewed one or two instructions based on their specialty.

Content validity of the measure instructions was analyzed by calculating item-level content validity indices (I-CVIs). Experts rated each component's content validity using a 4-point scale: 1=very low (major modification needed), 2=low (some modification needed), 3=high (no modification needed but could be improved with minor changes), and 4=very high (no modification needed). I-CVI is computed for each item by counting the number of experts giving a rating of three or four (thus dichotomizing the ordinal scale into high vs. low valid) and dividing the number by the total number of experts (Polit, Beck, & Owen, 2007). Polit et al. (2007) suggested that items with good content validity should have an I-CVI of .78 or higher from three or more experts' review. Based on this, we used .78 as a cut-off point to determine good, acceptable content validity. Another evaluation criterion was based on Lynn (1986). Lynn (1986) argued that the disagreement is accepted only if "six or more experts" are rated as 1 (very low) or 2 (low).

Nine experts, including 7 TEP experts and 2 academic experts, independently evaluated content validity of the 30-day all-cause readmission measure instructions.

Content validity was systematically assessed using expert review. Table 5 below displays I-CVIs for the readmission measure instructions. The findings showed good content validity for measure description, definitions, measure calculations, inclusion/exclusion criteria, and data sources, with I-CVIs greater than .78. Experts reported good content validity regarding the overall applicability of the readmission measure to the PACE sites and participants and the

overall capability to measure and capture what this indicator intends to measure (I-CVIs = .89). Although there was low content validity regarding the overall usefulness of the readmission indicator for internal quality improvement purpose (I-CVI = .67), only three experts disagreed on this. This low value of I-CVI might reflect current concerns that 30-day readmissions may be more relevant to hospital's quality outcomes rather than those at PACE sites. However, experts agreed that the readmission measure could be useful for comparison among PACE sites (I-CVI = .78).

Based on experts' evaluation on content validity and narrative comments, the instructions were revised to improve clarity. The descriptions about index hospital discharges and index discharge time window were clarified in the revised instructions.

Table 5. I-CVIs for Data Elements in the 30-day All-cause Readmission Measure Instructions

30-day Readmission Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
Measure Description	1.0 (6/6)	1.0 (6/6)	1.0 (5/5)	1.0
Definitions:				
• Numerator	.78 (7/9)	1.0 (9/9)	.89 (8/9)	.89
• Denominator	.78 (7/9)	1.0 (9/9)	.89 (8/9)	.90
Measure Calculation	.86 (6/7)	1.0 (8/8)	.83 (5/6)	.90
Inclusion Criteria:				
• PACE Participants' unplanned readmissions for any cause within 30 days of the index discharge.	1.0 (9/9)	1.0 (9/9)	1.0 (8/8)	1.0
Exclusion Criteria :				
• A planned readmission, which is determined by the needs of the treatment plan rather than an emergent condition. Examples of planned readmissions include, but are not limited to, regular chemotherapy sessions, elective surgery, and semi-elective procedures, such as removal of tumors.	1.0 (9/9)	1.0 (9/9)	1.0 (8/8)	1.0
• Initial admission with a discharge of death	1.0 (9/9)	1.0 (8/8)	1.0 (8/8)	1.0
• Admission to one acute hospital directly after discharge from another acute hospital (i.e., hospital-to-hospital transfer).	1.0 (9/9)	1.0 (9/9)	1.0 (7/7)	1.0
• Readmitted to a prospective payment system-exempt cancer hospital.	.86 (6/7)	.88 (7/8)	.88 (7/8)	.87
• Index discharge was against medical advice (American Medical Association).	1.0 (9/9)	1.0 (9/9)	1.0 (8/8)	1.0

30-day Readmission Data Element	Clarity I-CVI	Capability to Measure I-CVI	Applicability I-CVI	Overall I-CVI/Ave
• Readmitted for primary psychiatric diagnoses.	.89 (8/9)	.88 (7/8)	1.0 (8/8)	.92
• Readmitted for medical treatment of cancer.	.89 (8/9)	.88 (7/8)	1.0 (8/8)	.92
Data Sources	.88 (7/8)	1.0 (7/7)	.75 (3/4)	.88
Overall clarity of the Data Collection Guidelines	.75 (6/8)			
Overall capability to measure/capture what the indicator of “30-day all-cause readmission” intends to measure	.89 (8/9)			
Overall applicability of the indicator to the PACE participants and PACE sites	.89 (8/9)			
Overall usefulness of the indicator for internal quality improvement purposes	.67 (6/9)			
Overall usefulness of the indicator for comparison between PACE sites	.78 (7/9)			

Note. I-CVI, item-level content validity index; I-CVI/ave, average of I-CVIs.

Each parenthesis indicates the number of experts who rated the data element as three or four divided by the total number of experts who responded.

References:

Polit, D. F., Beck, C. T., & Owen, S. V. (2007). Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health*, 30, 459-467.

Lynn, M. (1986). Determination and quantification of content validity. *Nursing Research*, 35, 381-385.

4. Usability and Use

NOTE: Section 4, Usability and Use, will be updated once data from the testing is available and analyzed. Testing of this measure runs through mid-July 2015.

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
4a. Accountability and Transparency		
4b. Improvement		
4c. Benefits		
4d. Measure Deconstruction (Cost and Resource Use Measure Only)		

Summary Rating for Usability:

Brief Statement of Conclusions That Support the Summary Rating:

5. Comparison to Related or Competing Measures

Sub-Criteria	Anticipated NQF Rating	Rating Improvement Plan (if Low/Moderate)
5a. Related Measure	Moderate	
5b. Competing Measure	NA	

Summary Rating for Harmonization: Moderate

Rationale for Rating/Comments:

The National Quality Forum (NQF) has endorsed 42 readmission-related measures. This discussion is limited to 30-day all-cause readmission measures. Table 5-1 presents information on 12 readmission measures for which CMS is the measure steward. All 12 measures are defined as readmission to a hospital within 30 days after an index discharge. All are based on Medicare claims data and are risk adjusted or risk standardized.

The PACE readmission measure will share many defining elements with the CMS measures. An index discharge will be identified, and unplanned readmissions within 30 days will be captured. The PACE measure will not be risk adjusted, as there are only small numbers of participants per program and data from only a small number of the Nation's hospitals. Rather, data will be stratified by a set number of variables, such as number of participants, age of PACE site, and geographic location of PACE site, to provide detail on the PACE programs for comparison, which may be informative and useful for quality improvement efforts by each PACE site. Finally, the data source will be PACE clinician records, which may include hospital discharge records if there is active care coordination between PACE sites and local hospitals.

Table 5-1. PACE Readmissions and NQF-Endorsed 30-Day All-Cause Readmissions Measures for Which CMS Is the Steward

	PACE Readmission Rate	Measure 2	Measure 3	Measure 4	Measure 5
NQF Number	NA	2504	2502 (2501 is a companion measure for long- term care hospitals)	0505 Companion measures for: <ul style="list-style-type: none"> • Vascular Procedures (2513) • Pneumonia (2015) • PCI (0695) • COPD (1891) • CABG (2515) • HF (0330) • Total Hip/Knee (1551) 	1789
Measure Title	PACE 30-Day All-Cause Hospital Readmission Rate	30-Day Rehospitalizations for Medicare Fee- for-Service Beneficiaries	All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities (IRFs)	Hospital 30- Day All-Cause Risk- Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization	Hospital- Wide All- Cause Unplanned Readmission Measure
Numerator Statement	Number of inpatient discharges by PACE participants that were followed by an unplanned readmission for any cause within 30 days of the index discharge.	Number of rehospitalizations within 30 days of discharge from an acute care hospital (PPS or CAH).	Risk-adjusted estimate of the number of unplanned readmissions that occurred within 30 days from discharge. This estimate includes risk adjustment for patient characteristics and a statistical estimate of the facility effect beyond patient mix.	Inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index AMI admission.	Inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from an eligible index admission.

	PACE Readmission Rate	Measure 2	Measure 3	Measure 4	Measure 5
Denominator Statement	Number of PACE participant hospital discharges for the month.	Medicare FFS beneficiaries, prorated based on the number of days of FFS eligibility in the time period (quarter or year).	Number of readmissions that would be expected for that patient population at the average IRF. The measure includes all IRF stays in the measurement period that are observed in national Medicare FFS data and do not fall into an excluded category.	Currently publicly reported by CMS for those 65 years and older who are either Medicare FFS beneficiaries admitted to non-Federal hospitals or patients admitted to VA hospitals.	Currently publicly reported by CMS for those 65 years and older who are Medicare FFS beneficiaries admitted to non-Federal hospitals.
Risk Adjustment	Yes, risk stratified by PACE site age, geographic location, and number of participants.	Yes	Yes	Yes	Yes
Use	Quality improvement and accountability	Public accountability	Public accountability	Public accountability	Public accountability
Care Setting	PACE site	Acute care general hospital	Inpatient rehabilitation facility	Acute care general hospital	Acute care general hospital
Target Population	PACE enrollees	Patients	Patients	Patients	Patients
Level of Analysis	PACE site	Hospital	Rehabilitation facility	Hospital	Hospital
Data Source	Clinical records	Discharge data	Discharge data	Discharge data	Discharge data
Measure Type	Outcome	Outcome	Outcome	Outcome	Outcome
Measure Developer/Steward	Econometrica	CMS	CMS	CMS	CMS

Preliminary Recommendation for Endorsement

Based on the individual rating of each of the five major criteria, provide an initial recommendation for endorsement based on the overall suitability of this measure.

Criteria	High	Medium	Low	Insufficient
1. Importance to Measure and Report	X			
2a. Overall Reliability				
2b. Overall Validity				
2c. Disparities of Care				
3. Feasibility				
4. Usability and Use				
5. Comparison to Related or Competing Measures	X			

Recommendation:

Explanation: