

# MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

# To navigate the links in the worksheet: Click to go to the link. ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

**Red** text denotes developer information that has changed since the last measure evaluation review.

# **Brief Measure Information**

#### NQF #: 2286

**Corresponding Measures:** 

De.2. Measure Title: Functional Change: Change in Self Care Score

**Co.1.1. Measure Steward:** Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. and its successor in interest, UDSMR, LLC.

**De.3. Brief Description of Measure:** Change in Rasch derived values of self-care function from admission to discharge among adults receiving inpatient medical rehabilitation and discharged alive. The timeframe for the measure is 12 months. The measure includes the following 8 items: Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory.

**1b.1. Developer Rationale:** The new mandated quality measures for Inpatient Rehabilitation Facilities (GG items within the IRF-PAI v 20 to be used October 2019) do not adequately address the rehabilitative objectives or functional status of patients. The measures do not allow facilities to substantiate the quality of their restorative care program to CMS or payers. The emphasis on restoration or maintenance of function affected by the patient's illness or injury is paramount in the episode of care. The primary aim of inpatient rehabilitation is to increase function to return the patient to living in the community. Yet the current measures don't adequately capture function or functional improvement. The current quality indicator measures address facility level process, which, has been argued, is not applicable to the IRF as the overall prevalence is very low (less than 2% of patients affected per year) and often times, the presence of the quality indicator occurred in the acute care setting or prior to admission to acute or post-acute care (CAUTIs and incidence of new or worsened pressure ulcers).

The self-care measure is constructed by utilizing items from the FIM® instrument, which is presently used across the post-acute care continuum. Measures of effectiveness, efficiency, timeliness, resource use and safety are an integral part of the FIM® instrument. The FIM® instrument is already used in inpatient rehabilitation as it is embedded in the IRF-PAI, which is presently required to be completed for prospective payment but will no longer be required as of October 2019. Utilizing the change in self-care function measure as a quality indicator would not create any additional costs to IRFs, since IRFs are already transmitting the current IRF-PAI data to CMS for payment purposes. The change in self-care measure has demonstrated both reliability and validity as results indicated a high overall internal consistency, the ability to capture significant functional gains during rehabilitation, has high discriminative capabilities for rehabilitation patients, and predictive of change in self-care function outcomes and likelihood of patient discharge from inpatient rehabilitation to the community. It is imperative that any quality indicators used for the PAC setting take into

account the overriding goal of rehabilitation outcomes, which is to restore and improve function and increase functional independence among individuals receiving rehabilitation, and by doing so, allowing the patient the ability to return to a community setting upon discharge.

**S.4. Numerator Statement:** Average change in Rasch derived self-care score from admission to discharge at the facility level. Items at admission and discharge include: Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory. Average is calculated as: ((sum of change at the patient level for all items (Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory) / total number of patients)).

**S.6. Denominator Statement:** Facility adjusted expected change in Rasch derived self-care values, adjusted at the Case Mix Group (CMG) level.

**S.8. Denominator Exclusions:** National values used in the CMG-adjustment procedure will not include cases who died in the IRF or cases less than 18 years old. It is standard to exclude cases who died during rehabilitation as this is a highly atypical outcome, in addition, minors are excluded as well. The measure testing file includes further explanation regarding the exclusion criteria as well as references.

De.1. Measure Type: Outcome

S.17. Data Source: Instrument-Based Data, Other

S.20. Level of Analysis: Facility, Other

IF Endorsement Maintenance – Original Endorsement Date: Nov 04, 2015 Most Recent Endorsement Date: Nov 04, 2015

# **Preliminary Analysis: Maintenance of Endorsement**

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

# Criteria 1: Importance to Measure and Report

# 1a. <u>Evidence</u>

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

**<u>1a. Evidence.</u>** The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

#### **Evidence Summary**

• Brief background: this is a measure of functional status change assessing eight different self-care functions for patients 18+ as assessed by a clinician. The items that comprise the self-care measure include: Eating, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory.

- The primary aim of inpatient rehabilitation is to restore function, increase functional independence, and to discharge the patient back to home/the community setting or residence prior to the patient's acute admission and/or IRF stay.
- The measure is informed by the FIM instrument, a tool used to assess the patient's level of functional status at admission and discharge.
- The developer notes that through multiple peer-reviewed journal articles, scores on the FIM instrument have shown to be a significant predictor of patient outcomes in inpatient rehabilitation facilities.
- Low FIM scores at admission have been linked to increased risk of discharge to non-community settings and/or increased risk of being readmitted to an acute care hospital.

# Changes to evidence from last review

# $\Box$ The developer attests that there have been no changes in the evidence since the measure was last evaluated.

# $\boxtimes$ The developer provided updated evidence for this measure:

# Updates:

- Developer provides a logic model depicting the relationship between IRF admission, patient goals and rehab plan, treatment, discharge, and self-care change in function.
- Developer did not provide a healthcare structure, process, intervention, or service that can be deployed to improve performance on the measure. Presumably, the provision of rehabilitation services would lead to improvement in scores, but the developer did not offer evidence of this.
- Developer instead offered evidence that the self-care measure correlates to positive outcomes
  - Measure 2286 correlates statistically significantly to the FIM instrument (p<.001). The measure's self-care items:
    - Admission items was correlated to the admission FIM at .97
    - Discharge items was correlated to the discharge FIM at .98
    - Total change score was correlated to the total change FIM at .93
  - Developer concludes that the statistically significant correlations between the change in selfchange score measure and FIM indicate a high predictor of patient outcomes for in-patient rehabilitation facilities. The self-care measure was assessed to determine the predictive ability of the measure on patient outcomes.
    - The self-care items at admission were significantly predictive of:
      - patient discharge to the community, chi-square=50178.4, (df=8), p<.001, R2</li>
         =.15
      - patient length of stay (LOS), adjusted R2 =.15, p<.001
      - patient change in function (total functional change from admission to discharge), adjusted R2=.44, p<.001.
      - All self-care items were retained in the models above and were statistically significant (p<.001).

# Question for the Committee:

• The developer did not provide empirical evidence of a structure, process, intervention or service that can improve performance. Is there at least one thing that the provider can do to achieve a change in the measure results?

# Guidance from the Evidence Algorithm

Measure assesses outcome (box 1) YES -> relationship between outcome and at least one healthcare action (box 2) NO -> DOES NOT PASS

# Preliminary rating for evidence: □ Pass No Pass

# **RATIONALE:**

NQF's Evidence requirements indicate a developer must provide empirical evidence that there is at least one structure, process, intervention, or service that can improve performance. Therefore the preliminary analysis is rated as No Pass. However, if the developer can provide this evidence at the Committee measure evaluation meeting, and the Committee agrees it meets the criteria, the measure would be eligible for a Pass.

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

## Maintenance measures - increased emphasis on gap and variation

**<u>1b. Performance Gap.</u>** The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Developer analyzed mean change in self-care scores at facility level and then grouped facilities by performance quartile (not quartiles based on number of facilities).
- Quartile 1 (25th%): (n = 37), Mean 4.6, Standard Deviation 4.2
- Quartile 2 (25th-50th%): (n = 489), Mean 11.5, Standard Deviation 1.1
- Quartile 3 (50th-75th%): (n = 288), Mean 15.9, Standard Deviation 1.4
- Quartile 4 (75th%): (n = 22), Mean 23.3, Standard Deviation 4.02

#### Disparities

- The developer assessed disparities in performance for the following social risk factors: race, sex, and marital status. Across all three groups assessed, no differences in mean change in self-care score were evident. The change in total self-care score from admission to discharge by group was:
  - Race (all race and ethnic categories): eta2 < .001
  - Sex: eta2 < .001
  - Marital status: eta2 < .001

## Questions for the Committee:

- Is there a meaningful spread of performance between the entities evaluated by the measure developer?
- Is measure gap sufficient for the Committee to assume that there may be actionable differences and not just differences in population that account for the measure performance gaps, and thus represent evidence of structures, processes, interventions or services that improve performance?

# Preliminary rating for opportunity for improvement:

# **Committee Pre-evaluation Comments:**

# Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

**<u>1a. Evidence</u>**: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures — are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- More evidence needed to show relationship between outcome and at least one healthcare action.
- For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Provided in the analysis supplied by CMS. Does it apply directly or is it tangential? This applies directly. How does the structure, process, or outcome relate to desired outcomes? Unclear if the "outcome" is return to independence or something else. This is not clearly defined. For maintenance measures -are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? I found a large number of studies (~900) on a Pub Med Search including some from 2019 using the search strategy "fim score, inpatient rehabilitatation". An addition reference was also noted in Appendix C page 59 of the Competing Measures Memo of June 11, 2019: Citation: Fisher, Steve R., Middleton, Addie, Graham, James E., Ottenbacher, Kenneth J.. (2018). Same but different: FIM summary scores may mask variability in physical functioning profiles. Archives of Physical Medicine and Rehabilitation, 99(8), Pgs. 1479-1482, 1482.e1. Retrieved 12/6/2018, from REHABDATA database. The references in this Memo provided on page 13 are at least 10 years old. This is a disappointment from my perspective. For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure." The measure developers did not provide any evaluation or data regarding the point of view of patients who are evaluated using the patient reported outcomes within this particular measure.
- The argument for evidence to support measurement is circular high correlations between the FIM and the measure are not surprising since the FIM is the source of the measure data (as I understand it). I'd like to see some evidence for how the measure score relates to at least one structure or process of care within IRFs. The correlation to length of stay hints at this but it really depends on the direction of the association, which the developers do not report.

**<u>1b. Performance Gap</u>**: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Quality problems and opportunities for improvement were noted by the developer, showing a performance gap. Scores may help improve the quality. Disparities data was included.
- 4. 1b. Performance Gap: Was current performance data on the measure provided? Yes. How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Unclear. The most currently available data does not show significant change within deciles over a recent 2 year period suggesting that this measure may be "topped out". Disparities: Was data on the measure by population subgroups provided? Not that I could find, which is disappointing given the heterogeneity of this particular population and its various subpopulations. How does it demonstrate disparities in the care? Not provided. This was noted in the 2015 Standing Committee voting summary, though, on page 65 of the Memo: "The Committee inquired about the lack of information on disparities in measure performance; the developer indicated the data is available; however, due to the wealth of information they have, they were unsure how much and what data to submit. They agreed to provide additional information on this topic was included in the current measure summary data for either 2286 or 2633.
- Developers need to explain what the measure score means. Is lower score better or worse? What are the
  min and max scores? Can't interpret this or how wide the variation is without understanding the score to
  begin with. Likewise, the statistics provided for disparities need interpretation. For the time being, I cannot
  tell whether there's actually any evidence of performance gaps or disparities.

# Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

# Reliability

**<u>2a1. Specifications</u>** requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

<u>2a2. Reliability testing</u> demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

# Validity

**<u>2b2. Validity testing</u>** should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

# Complex measure evaluated by Scientific Methods Panel? $\boxtimes$ Yes $\square$ No

Evaluators: NQF Scientific Methods Panel

Methods Panel Review (Combined)

# **Methods Panel Evaluation Summary:**

This measure was reviewed by the Scientific Methods Panel and discussed on the call. A summary of the measure and the Panel discussion is provided below.

- **Reliability:** 1 high, 4 moderate, 1 low and 0 insufficient → measure passed SMP with moderate reliability ranking
  - o Testing included score-level and data element testing
  - Cronbach's alpha and Rasch analysis for 8-item FIM for data element level, score level used split-half ICCs for comparison of reliabilities across facilities.
  - SMP assessment of results:
    - Alpha (0.78) is good for a 4-item scale, but some concern over low item-total correlation for transfer to and from toilet (0.37), although probably ok
    - The Rasch person-reliability correlation was 0.89. The infit and outfit statistics were acceptable for the 4 items (all < 2.0).
    - Score level reliability across facilities was good (ICC=0.92)
  - Note for measure developer: why was it necessary to do a random sample of 30 facilities instead of using the full set of 855 facilities? This would have been more informative.
  - Note to measure developer: "A stronger method of reliability testing would include an analysis of within- facility score and between-facility score variation to understand the strength of the 'signal' represented in measure scores. Alternatively, adding bootstrapping to the ICC analysis would make the analysis more robust."
- Validity: 3 high, 1 moderate, 0 low and 2 insufficient  $\rightarrow$  measure passes with high validity
  - o Testing included score-level and data element testing
  - Measure developer employed construct validity, predictive validity for the item level analysis and criterion-referenced validity for the score-level. The developer evaluated construct,

criterion and predictive validity. Criterion validity focused on the relationship between the self-care items and the full FIM instrument, whereas predictive validity focused on patient outcomes (discharge to the community, LOS). The SMP considered the predictive validity analyses appropriate and compelling.

 Panelists noted that "Factor analysis identified two meaningful components that account for substantial total variance. All items were predictive of several relevant dependent variables. The results of the criterion-referenced validity testing indicated a very strong correlation between the self-care measure and the FIM Instrument."

#### Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

## Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability:	🗆 High	Moderate	□ Low	Insufficient
Preliminary rating for validity:	🛛 High	□ Moderate	🗆 Low	Insufficient

Combined Methods Panel Scientific Acceptability Evaluation

Measure Number: 2286

Measure Title: Functional Change: Change in Self-Care Score

#### Type of measure:

Process D Process: Appropriate Use	□ Structure	Efficiency	Cost/Resource Use
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□□ Outcome ⊠□ Outcome: PRO-PM □ Outcome: Intermediate Clinical Outcome □ Composite

#### Data Source:

🗆 Claims	🗵 Electr	onic Health Data		tronic Health Records	🗆 Mana	agement Data
🗆 Assessme	ent Data	🗆 Paper Medica	l Records	⊠□ Instrument-Bas	ed Data	□⊠ Registry Data
Enrollme	nt Data	□ Other				

#### Level of Analysis:

□ Clinician: Group/Practice □ Clinician: Individual ⊠ Facility □ Health Plan

□ Population: Community, County or City □ Population: Regional and State

□ Integrated Delivery System ⊠□ Other : Patient-patient level change in function, including aggregate

#### Measure is:

**New Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

**MP#2:** Average change in Rasch-scored FIM score from admission to discharge. 8 items from feeding and grooming to expression and memory.

Data source: Patient data from the FIM<sup>®</sup> instrument collected from inpatient rehabilitation facilities, long term acute care facilities, and skilled nursing facilities subscribing to the Uniform Data System for Medical Rehabilitation (UDSMR).

# **RELIABILITY: SPECIFICATIONS**

1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?  $\Box \boxtimes$  Yes  $\boxtimes \Box$  No

Submission document: "MIF\_xxxx" document, items S.1-S.22

**NOTE**: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.

# 2. Briefly summarize any concerns about the measure specifications.

## MP#6: None.

**MP#1:** Specs are not clear but this measure has been implemented for years and the measure is not in the public domain, so this may be less of an issue.

# **RELIABILITY: TESTING**

**Submission document:** "MIF\_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

- 3. Reliability testing level 🛛 🖾 Measure score 🖾 Data element 🗌 Neither
- 4. Reliability testing was conducted with the data source and level of analysis indicated for this measure □⊠ Yes □ No
- 5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical <u>VALIDITY</u> testing** of <u>patient-level data</u> conducted?

 $\Box$  Yes  $\Box$  No NA

6. Assess the method(s) used for reliability testing

**MP#6:** Rasch analysisappears to be an appropriate conversion for the analysis along with the Cronbach's alpha. ICC split half method for the facility analysis did not raise concerns.

## MP#2:

# a. Methods were appropriate. Cronbach's alpha and Rasch analysis for 8-item FIM, ICCs for comparison of reliabilities across facilities.

Submission document: Testing attachment, section 2a2.2 Methods used are appropriate.

**MP#1:** Cronbach's alpha (data element) and ICC (measure score) were used to evaluate reliability. However, based on the results provided, it does not appear that an evaluation of between and within facility score variation performed (i.e. signal-to-noise).

**MP#5:** The methods used were standard and generally acceptable. Cronbach's alpha was used to assess data element (instrument) reliability, and a split-half ICC test was conducted for reliability at the measure score level. It is not clear at all why a random sample of 30 facilities was needed for the ICC analysis, as no other measure developers using this method seem to have a problem with a large number of facilities in a data base. Analysis on the full set of 855 facilities would have been more informative, although the random sample results are worth something.

**MP#3:** The developer conducted reliability testing for both data element and measure score. For data element reliability, the developer reported internal consistency. For measure score reliability, the developer conducted split-half reliability testing based on a random sample of facilities. Both testing methods were appropriate, however, it is not obvious why split-half reliability testing could not be conducted with all facilities. At minimum, it will be useful for the developer to provide additional

descriptive information of the random sample. Volume information is particularly relevant, as it will directly impact reliability estimated.

# 7. Assess the results of reliability testing

MP#6: All resultssupported reliability at the item and facility level.

MP#2:

- a. Alpha (0.78) is good for a 4-item scale, but some concern over low item-total correlation for transfer to and from toilet (0.37), although probably ok
- b. The Rasch person-reliability correlation was 0.89. The infit and outfit statistics were acceptable for the 4 items (all < 2.0).
- c. Score level reliability across facilities was good (ICC=0.92)

Submission document: Testing attachment, section 2a2.3

**MP#4:** Testing sample is adequate. Moderate to high confidence results are reliable.

**MP#1:** Internal consistency and ICC facility-level correlations were results were positive however, this analysis does not provide strong evidence regarding the precision of the measure score results (only that scores are correlated across facilities). A stronger method of reliability testing would include an analysis of within- facility score and between-facility score variation to understand the strength of the 'signal' represented in risk-adjusted measure scores.

MP#3: Cronbach's alpha was 0.83 which is very good.

Measure score reliabliyt measured by ICC was 0.92 which is excellent.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

Submission document: Testing attachment, section 2a2.2

 $\Box \boxtimes \mathbf{Yes}$ 

 $\boxtimes \Box$  No

□ Not applicable (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

Submission document: Testing attachment, section 2a2.2

🛛 Yes

🗆 No

□ Not applicable (data element testing was not performed)

10. OVERALL RATING OF RELIABILITY (taking into account precision of specifications and <u>all</u> testing results):

□ High (NOTE: Can be HIGH <u>only if</u> score-level testing has been conducted)

□ ☑ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

**□ Low** (NOTE: Should rate <u>LOW</u> if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

□ **Insufficient** (NOTE: Should rate <u>INSUFFICIENT</u> if you believe you do not have the information you need to make a rating decision)

11. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability. Based

MP#2:

# a. Would be high were it not for low-ish item-total correlations on memory and dressing-lower extremity

**MP#6:** No concerns, analysis at the item and facility levels both supported reliability of the measure.

**MP#5**: As noted above, the statistical results of reliability testing look very good, but the use of a small random sample of facilities for the ICC analysis was strange.

**MP#1:** A stronger method of reliability testing would include an analysis of within- facility score and between-facility score variation to understand the strength of the 'signal' represented in measure scores. Alternatively, adding bootstrapping to the ICC analysis would make the analysis more robust.

**MP#3:** Comprehensive reliability testing was conducted, covering both data element and measure score. The results were very good. Moderate rating is partly due to split-half relability testing was only based on a small sample of facilities.

MP#4: Based on the results of testing.

# VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

MP#2: Death and under 18 exclusion ok and well-defended.

MP#6: No concerns

Submission document: Testing attachment, section 2b2.

MP#4: No concerns.

MP#1: None

MP#3: No concern.

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

MP#2: Highly-significant F statistic in comparing 4 quartiles on score change values

Submission document: Testing attachment, section 2b4.

MP#4: None

**MP#5**: The developers could show that the facilities could be arrayed from high to low (or vice-versa) in terms of measure score, and quartiles established based on that distribution. There are differences in score among the quartiles. This speaks to the issue of there being differences at all among facilities, but does not bear on the question of whether the differences are meaningful. That analysis would require some link to information on clinical significance to patients or caregivers of a given difference in the FIM score.

MP#1: None.

MP#3: No concern.

14. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified. NA

Submission document: Testing attachment, section 2b5. NA

MP#5: None

**MP#1:** N/A

MP#3: No concern.

## 15. Please describe any concerns you have regarding missing data.

MP#6: Missing data was eliminated by sampling method

MP#2:

a. Submitters report there is no missing data. with such a huge data source, this is hard to believe. Perhaps this is linked to the definition of denominator? Surely there is missing FIM data in IRFs?

Submission document: Testing attachment, section 2b6.

MP#4: No missing data.

MP#1: None

MP#3: No concern.

# 16. Risk Adjustment

16a. Risk-adjustment method $\Box$ None $\boxtimes$ Statistical model $\boxtimes \Box$ Stratification

16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?

 $\Box$  Yes  $\Box$  No  $\boxtimes \Box$  Not applicable

16c. Social risk adjustment:

16c.1 Are social risk factors included in risk model? 🛛 🖂 Yes 🔤 🖾 No 🗔 Not applicable

16c.2 Conceptual rationale for social risk factors included?

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ⊠□ Yes □⊠ No

# 16d. Risk adjustment summary:

- 16d.1 All of the risk-adjustment variables present at the start of care?  $\boxtimes$  Yes  $\Box$  No
- 16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ⊠□ Yes □ No NA

16d.3 Is the risk adjustment approach appropriately developed and assessed? oxtimes Yes  $\hfill\square$  No

- 16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
- MP#6: results indicated there were no differences in mobility score by race, sex or marital status

□⊠ Yes ⊠□ No

16d.5.Appropriate risk-adjustment strategy included in the measure?

# 16e. Assess the risk-adjustment approach

MP#4: Appropriate for measure

**MP#6:** Case Mix Group (CMG) through indirect standardization is appropriate and demonstrated statistical differences between impairment types.

**MP#5**: I think the risk adjustment method is probably much better than the results and description provided in the testing form. There are apparently adjustments made with a range of clinical and demographic variables, but the testing form only describes one example of stratification in any detail. The example given is stroke, implying not only stratification, but a selection of the subset of patients with stroke for measurement and analysis. While this is a perfectly acceptable example of use of the measure, the measure is not specified or tested for reliability for stroke only, so there is a "disconnect" between the reliability data and the information provided on risk adjustment. What should have been provided would be data on the full adjustment or standardization model for calculation of the scores at the facility level.

# MP#2:

Uses CMS case-mix group specifications. With functional outcomes of inpatient care one must control for differences in patient impairment types/conditions and for the severity within a given impairment type/condition. Stratification for patient impairment type/condition and risk adjusting data by CMG has been used extensively in prior, published research on patient functional outcomes of inpatient rehabilitation.

**MP#1:** Difficult to assess the approach without information about the performance of the model. The developer provides mean change in self care by CMG group. Model lacks social risk factors but developer

notes mobility scores did not vary by race, sex or marital status. CMG is a reasonable approach but lacks important social risk factors.

**MP#3:** Overall, the risk adjustment approach was acceptable.

# For cost/resource use measures ONLY:

- 17. Are the specifications in alignment with the stated measure intent?
  - ☑ Yes ☐ Somewhat ☐ No (If "Somewhat" or "No", please explain)
- 18. Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):

# **VALIDITY: TESTING**

- 19. Validity testing level:  $\Box \boxtimes$  Measure score  $\Box \boxtimes$  Data element  $\boxtimes \Box$  Both
- 20. Method of establishing validity of the measure score:
  - ☑□ Face validity Systematic assessment of perfomrance measure score
  - $\Box \boxtimes \ {\rm Empirical} \ {\rm validity}$
  - **⊠**□ N/A (score-level testing not conducted)

# 21. Assess the method(s) for establishing validity

**MP#6:** Construct validity, predictive validity for the item level analysis and criterion-referenced validity for the score-level were appropriate.

## MP#2:

a. To calculate the facility's adjusted expected change in Rasch derived values, indirect standardization was used which weights national CMG-specific values by facility-specific CMG proportions. CMG-adjustment derives the expected value based on the case mix and severity mix of each facility. The CMG classification system groups similarly impaired patients based on functional status at admission or patient severity. Patients within the same CMG are expected to have similar resource utilization needs and similar outcomes.

## Submission document: Testing attachment, section 2b2.2

**MP#4:** Used principal component analysis to establish validity of the instrument. High correlation with the FIM instrument.

**MP#1:** The developer evaluated construct, criterion and predictive validity. Criterion validity focused on the relationship between the self-care items and the full FIM instrument, whereas predictive validity focused on patient outcomes (discharge to the community, LOS). The predictive validity analyses were appropriate and compelling.

**MP#3:** Extensive validity tests were conducted, including construct validity, predictive validity, criterion validity, and others. All methods were appropriate.

# 22. Assess the results(s) for establishing validity

# MP#2: the full set of CMG analyses were not included in the submission. To illustrate the risk adjustment by CMG, stroke (the most common impairment) was presented and the results on FIM average change by CMG group were as predicted/expected.

**MP#6:** Regression models for predictive validity demonstrated significant results for DC to community, LOS and discharge disposition (home vs acute care facility). Stepwise regreassion demonstrated all items except for expression were predictive ability.

# Submission document: Testing attachment, section 2b2.3

**MP#4:** Appropriate test sample. Sufficient validity established.

**MP#1:** The predictive validity analysis showed a strong and significant relationship between the self-care items and outcomes (discharge to the community, LOS, change in function), providing evidence of the validity of the measures.

**MP#3:** Factor analysis identified two meaningful components that account for substantial total variance. All items were predictive of several relevant dependenat variables.

The results of the criterion-referenced validity testing indicated a very strong correlation between the selfcare measure and the FIM Instrument.

**MP#5**: As far as I can tell, the testing for validity was done only at the data element (instrument) level. I see no testing of measure score validity. The data element validity testing was reasonable and used multiple analytic methods.

# 23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

Submission document: Testing attachment, section 2b1.

🛛 Yes

🗆 No

□ Not applicable (score-level testing was not performed)

24. Was the method described and appropriate for assessing the accuracy of ALL critical data elements? *NOTE that data element validation from the literature is acceptable.* 

Submission document: Testing attachment, section 2b1.

🛛 Yes

🗆 No

- □ Not applicable (data element testing was not performed)
- 25. OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.
  - ⊠□ High (NOTE: Can be HIGH only if score-level testing has been conducted)

□ ☑ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

- □ **Low** (NOTE: Should rate LOW if you believe that there <u>are</u> threats to validity and/or relevant threats to validity were <u>not assessed OR</u> if testing methods/results are not adequate)
- ☑□ Insufficient (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level <u>is required</u>; if not conducted, should rate as INSUFFICIENT.)

# 26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.

MP#4: Subset of IRF-PAI tool.

MP#6: As noted above, all analysis supported validity of both the item level and facility level scores

**MP#5**: Testing of both measure score and data element validity showed good results, particularly measure score validity.

MP#2:

a. Overall rating for stroke impairment group would be moderate. Likely true of others, but data not provided.

**MP#1:** Very good predictive validity results, would have been helpful to see the full model results as well as to include other covariates included in the multivariable model of discharge to community and LOS to understand the unique contribution provided by the self care items and other covariates.

**MP#3:** Testing of both measure score and data element validity showed good results, particularly measure score validity.

# FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?

🗆 High

□ Moderate

- $\Box$  Low
- □ Insufficient

28. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION

# ADDITIONAL RECOMMENDATIONS

29. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

# **Committee Pre-evaluation Comments:**

# Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

**<u>2a1. Specifications</u>**: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- No concerns about reliability
- 5. 2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? No concern here. Which codes with descriptors, if any, are not provided? No concern here. Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? Not evaluated or adjusted for healthcare disparities (e.g. Social Determinants of Health, socio demographic differences, etc. What concerns do you have about the likelihood that this measure can be consistently implemented? Not evaluated or adjusted for healthcare disparities (e.g. Social Determinants of Health, socio demographic differences, etc.
- no concerns

**<u>2a2. Reliability testing</u>**: Do you have any concerns about the reliability of the measure?

- No
- 6. 2a2. Reliability Testing: Do you have any concerns about the reliability of the measure? Not at present.
- No concerns agree with SMP assessment of moderate reliability
- **<u>2b2. Validity testing</u>**: Do you have any concerns with the testing results?
- No
- 7. 2b1. Validity -Testing: Do you have any concerns with the testing results? There appears to be little change in 2633 measure over a two year period when compared with this measure (2286), which does show significant change over a 4 year period as previously noted. This raises concerns as it relates to the discussion on harmonization of competing measures.
- No concerns agree with SMP assessment of high validity

<u>Validity-Threats to Validity</u>: Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data). 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- (pass)
- 8. 2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) Not evaluated or adjusted for healthcare disparities (e.g. Social Determinants of Health, socio demographic differences, etc. 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? Not sure if these are cross-correlated with longitudinal improvement in functional status of patients ultimately discharged from an IRF to home or a different post-acute setting. 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? NA 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure? No concern noted by the Measure Developer.
- I agree that the measure can distinguish the best from the worse facilities but its ability to distinguish those in the middle 50% is more questionable. This has implications for how the performance scores are reported and acted upon. Although there is not currently any missing data because the FIM is required for payment, what do the developers say about potential for missing data once the FIM is dropped from the IRF-PAIas of Oct 2019?

<u>Other Threats to Validity</u>: Other Threats to Validity (Exclusions, Risk Adjustment). 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- No concerns
- 2b2. Exclusions: Are the exclusions consistent with the evidence? I am not clear on the purpose of this question. There are many exclusions but I am not certain these help or hinder the end-users of this measure. Are any patients or patient groups inappropriately excluded from the measure? None, although I am not certain the subpopulations excluded help or hinder the end-users of this measure. 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? Unclear and not well specified. How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Unclear and not well specified. Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? No concern here. Was the risk adjustment (case-mix adjustment) appropriately developed and tested? No concern here. Is an appropriate risk-adjustment strategy included in the measure? No concern here.
- no concerns

# Criterion 3. Feasibility

# Maintenance measures - no change in emphasis - implementation issues may be more prominent

**<u>3. Feasibility</u>** is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- FIM tool data is collected by healthcare personnel during the provision of care and all data elements are defined fields in electronic clinical data.
- The developer states the measure is publicly available for use free of charge.
- Facility-level and national benchmark reporting are available by the developer through a subscription; cost varies based on facility type and size.

## **Questions for the Committee:**

• Does the Committee feel that the measure developer has provided sufficient information to determine how feasible the collection of this data is?

Preliminary rating for feasibility: 🛛 High 🗌 Moderate 🗌 Low 🔲 Insufficient

# **Committee Pre-evaluation Comments: Criteria 3: Feasibility**

**<u>3. Feasibility</u>**: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- Data collection is not burdensome and data exists already in clinical data.
- 10. 3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Since the submission of these data are required for revenue cycle activities and subsequent billing to CMS, the data elements should be readily available in most/all electronic systems used in the IRF setting. Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? NA What are your concerns about how the data collection strategy can be put into operational use? None currently as the data structures are quite well standardized and specifications are regularly reviewed and updated.
- No concerns with current feasibility as the necessary data elements are already collected as part of standard care delivery. However, since developers note that FIM won't be required anymore after Oct 2019, what do they have to say about feasibility after that point? Will additional data collection be required to calculate the measure after October?

# Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

# 4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

<u>4a. Use</u> evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

**4a.1.** Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

 Current uses of the measure

 Publicly reported?
 ☑ Yes □ No

 Current use in an accountability program?
 ☑ Yes □ No □ UNCLEAR

OR

Planned use in an accountability program? 

Yes 
No

# Accountability program details

- CMS IRF-PAI (will no longer be required as of October 2019)
- Quality Improvement National IRF Benchmark Reports
- Quality Improvement Facility-level IRF Reports

**4a.2. Feedback on the measure by those being measured or others.** Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

## Feedback on the measure by those being measured or others

- Feedback was not solicited from those being measured.
- Measure developer notes that the FIM instrument has been in use for over 25 years and required in IRF-PAI since 2002.

# Additional Feedback: N/A

# Question for the Committee:

• Does the Committee have any concerns about the current or future use of this measure?

Preliminary rating for Use: 🛛 Pass 🗌 No Pass

# 4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

<u>4b. Usability</u> evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

**4b.1 Improvement.** Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

## Improvement results

- The developer did not offer year over year data to show improvement in self-care change scores amongst measured facilities over time.
- The developer instead showed that differences in average self-care change scores among differing facilities can be measured and rank ordered in terms of patient average change in self-care function from admission to discharge.
  - Statistically significant differences in mean change scores by quartile were determined, however standard deviation within the inner quartiles were small.
  - Mean change scores and standard deviation by quartile:
    - Quartile 1 (25th%): Mean 4.6, Standard Deviation 4.2
    - Quartile 2 (25th-50th%): Mean 11.5, Standard Deviation 1.1
    - Quartile 3 (50th-75th%): Mean 15.9, Standard Deviation 1.4
    - Quartile 4 (75th%): Mean 23.3, Standard Deviation 4.02

**4b2. Benefits vs. harms.** Benefits of the performance measure in facilitating progress toward achieving highquality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

# Unexpected findings (positive or negative) during implementation

- The developer examined impact of cognitive self-care items on predictive validity of the self-care measure.
- Expression and memory were statistically significant (p<.001) in predicting patient discharge to the community, length of stay, and change in function.
- Examining cognitive self-care items revealed a 23% predictive variance in explaining patient's change in overall function from admission to discharge.

# Potential harms: N/A

# Additional Feedback: N/A

# Questions for the Committee:

• How can the performance results be used to further the goal of high-quality, efficient healthcare?

Preliminary rating for Usability and use: 
High Moderate Low Insufficient

# **RATIONALE:**

- Developer did not offer an evaluation of changes in performance over time.
- The submission is therefore insufficient for Usability.
- Note: this is not a must-pass criterion.

# Committee Pre-evaluation Comments: Criteria 4: Usability and Use

**4a.** Use: 4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Results are publicly reported and used for accountability. Feedback has been obtained from appropriate users.
- 11. 4a1. Use Accountability and Transparency: How is the measure being publicly reported? By CMS for comparative purposes via Inpatient Rehabilitation Facility (IRF) Compare. https://www.medicare.gov/inpatientrehabilitationfacilitycompare/; These measures will no longer be in use in IRF-PAI as of October 2019. According to the Competing Measures Memo (page 7), "NQF's maintenance criteria require that maintenance measures be in use for continued endorsement. The developer's submission does not include information about the future uses of these measures." Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? Yes For maintenance measures - which accountability applications is the measure being used for? Public reporting and payment For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? NA
- No concerns about current use. I agree it would be helpful to see data on changes in scores over time. I
  also don't see anything on feedback from users but as this is a new area of interest for NQF I don't think its
  essential.

**4b. Usability**: 4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- Concern over the lack of data around changes in performance over time. Need more info on this.
- 12. 4b1. Usability Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? There appears to be little change in 2633 measure over a two year period when compared with this measure (2286), which does show significant change over a 4 year period as previously noted. This raises concerns as it relates to the discussion on harmonization of competing measures. Since there has been quite a significant change in 2286 over time, this measure appears to be an effective quality improvement measure. If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? It seems shortsighted to retire this measure from Inpatient Rehabilitation Facility (IRF) Compare. 4b2. Usability Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them. It seems shortsighted to retire this measure is showing significant improvement over time.
- Are the developers aware of any unintended negative consequences?

# Criterion 5: Related and Competing Measures

## **Related or competing measures**

- This measure is competing with one measure: 2633: Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients
- The Committee will need to compare both measures and attempt to reach a best-in-class decision. NQF staff will prepare additional materials to assist the Committee in this comparison.

## Harmonization

Measure 2286 consists of eight self-care items (six physical and two cognitive) which are rated on a 7-level scale, where clinicians rate the patient's lowest actual observed score for the past 24-hour period. Measure 2286 is similar to measure 2633 which includes seven self-care items, all of which are physical, and rates using a 6-level rating system. The rating system for measure 2633 allows for options to not assess each item while the 7-level rating system for measure 2286 does not allow for missing responses. The developer of measure 2286 believes that if clinicians use the 6-level rating system there is "less room to demonstrate change over time" thereby potentially leading to the patient exhibiting a higher level of function than truly exists. The developer also notes that because the 6-level rating system can omit data its predictive modeling would be less effective. Additionally, the measure specifications differ in that measure 2286 is intended for all patients ages 18 and older receiving post-acute care, while measure 2633 is intended for Medicare only, who receive care at an Inpatient Rehabilitation Facility.

# **Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures**

**<u>Related and Competing</u>**: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- Competing with 2633
- If so, are any specifications that are not harmonized? Yes. 2633 for Medicare only. Are there any additional steps needed for the measures to be harmonized? Yes but unclear what these could be since CMS has now retired 2286.

• Yes, competing with measure 2633. Will need to debate which is best-in-class with the committee. For my part, key considerations are feasibility and data collection burden after FIM no longer required starting Oct 2019 (presumably this changes does NOT affect 2633?) and applicability to Medicare-only vs all adult patients within an IRF.

# **Public and Member Comments**

# Comments and Member Support/Non-Support Submitted as of: June/13/2019

As a family caregiver, I have been following the conversation re self-care/mobility scores across the care continuum, including discharge to community. In the Fall 2017 report of the Patient Experience and Function Standing Committee, there appeared to be uncertainty aboutt the merits of Section GG vs FIMS. I've searched the Fall 2018 report and have had a hard time discerning whether of not this issue has been settled. In the event that the Standing Committee is still accepting comments on this issue, I urge that Section GG be selected. The Section GG 6pt scale clearly communicates the level to which a patient relies on personal assistance in a manner that the patient, clinician and family member can understand. Particularly in discharges to home, the family needs to appreciate the degree to which their loved one will be depending on their presence to perform self-care tasks.

Please note: Study examined how similar summary scores of physical functioning using the Functional Independence Measure (FIM) can represent different patient clinical profiles. Data were analyzed for 765,441 Medicare fee-for-service beneficiaries discharged from inpatient rehabilitation. Patients' scores on items of the FIM were used to quantify their level of independence on both self-care and mobility domains. Patients requiring "no physical assistance" at discharge from inpatient rehabilitation were identified by using a rule and score-based approach. In patients with FIM self-care and mobility summary scores suggesting no physical assistance needed, the study found that physical assistance was in fact needed frequently in bathroom-related activities (e.g., continence, toilet and tub transfers, hygiene, clothes management) and with stairs. It was not uncommon for actual performance to be lower than what may be suggested by a summary score of those domains. The authors conclude that further research is needed to create clinically meaningful descriptions of summary scores from combined performances on individual items of physical functioning. Citation: Fisher, Steve R., Middleton, Addie, Graham, James E., Ottenbacher, Kenneth J.. (2018). Same but different: FIM summary scores may mask variability in physical functioning profiles. Archives of Physical Medicine and Rehabilitation , 99(8), Pgs. 1479-1482, 1482.e1. Retrieved 12/6/2018, from REHABDATA database.

• While this is not an eCQM, we would encourage the measure steward to use a standard terminology such as LOINC for encoding the FIM instrument in their measure. Without this level of standardization, interoperability will be a perpetual challenge, and impact the ability to measure a patient's functional status across the continumm of care.

# 1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. *Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.* 

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF\_evidence\_attachment\_2286\_.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 2286

Measure Title: Functional Change: Change in Self Care Score

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:  $\ensuremath{\mathsf{N}}\xspace/\ensuremath{\mathsf{A}}\xspace$ 

Date of Submission: <u>4/8/2019</u>

**1a.1.This is a measure of**: (should be consistent with type of measure entered in De.1)

Outcome

Outcome: Functional Change; change in patient self-care score from admission to discharge

□ Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

 $\Box$  Process:

□ Appropriate use measure:

□ Structure:

□ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Inpatient rehabilitation facilities (IRFs) are one part of a multi-level post-acute care continuum. Inpatient rehabilitation is meant to provide intensive rehabilitation therapy for patients who, due to the complexity of their nursing, medical management and rehabilitation needs, require extensive rehabilitation therapy

utilizing a multidisciplinary team approach. The primary aim of inpatient rehabilitation is restore function, increase functional independence, and ideally, to discharge the patient back to home/the community setting or residence prior to the patient's acute admission and/or IRF stay. <u>1</u>:2. The FIM instrument is presently embedded in CMS's IRF-PAI, which is the instrument used in inpatient medical rehabilitation to assess the patient's level of functional status at admission and at discharge. Completion of the IRF-PAI is required by CMS as part of prospective payment for facility reimbursement of services provided to the patient. The FIM instrument includes 18 items, of which, eight items address patient ability to self-care. The self-care items have been extensively used for over 25 years as a component of the larger FIM instrument, in essence, the self-care measure is a measure within a larger measure. The self-care measure is to be administered within 24-36 hours of the patient's admission to the post acute facility and again on the day of patient discharge. Interim assessments can be performed for case management purposes (goal setting or altering the therapy) but are not required. The items that comprise the self-care measure include: Eating, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory; items are assessed by trained clinicians at the facility. Below is a flow chart depicting the methodology for patient assessment of the measure:



**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

## Measure is not derived by patient report, rather it is clinician assessed.

## \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

# 1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

As previously stated, the self-care measure items exist within a larger instrument, the FIM instrument, which has been widely used and extensively published upon. For these reasons, much of the rationale, feasibility, usability and validity of the self-care measure is referenced to the larger FIM instrument, which is, in essence, the foundation. The FIM® instrument has been demonstrated in hundreds of peer-reviewed journal articles

(see bibliography in Appendix) to be a significant predictor of patient outcomes of inpatient rehabilitation. Lower FIM<sup>®</sup> scores at admission to an IRF have been associated with an increased risk of being discharged to a non-community setting; in particular, several studies have found patients with a lower admission FIM<sup>®</sup> total had an increased odds of readmission to an acute care hospital <u>3,4</u>. Additionally, Tan et al. <u>4</u> found that admission FIM<sup>®</sup> total was a positive predictor functional gain (score at discharge from score at admission) and length of stay in an IRF <u>5'6</u>, <u>7'8</u>. Specific references included below.

The self-care measure was examined as a stand-alone measure, independent of the FIM instrument. The self-care measure items at admission, at discharge and the measure change score (difference in total score from admission to discharge) was compared to the total FIM Instrument scores at admission, discharge and change in FIM from admission to discharge score. As previously stated, the FIM Instrument is embedded in the IRF-PAI tool, which is used by IRFs throughout the country for reimbursement by CMS (mandated since 2002) and for patient level and facility level outcomes of care reporting, see udsmr.org for more information and for a list of references related to the FIM Instrument. The FIM Instrument has 18 items, 13 motor items and 5 cognitive items. Since the self-care measure includes both motor/physical items and cognitive items, the full 18-item FIM was used in the analysis.

The correlations between the self-care measure and the FIM Instrument were statistically significant (p<.001). The correlation between the admission self-care measure and the admission FIM was .97, between the discharge self-care measure and the discharge FIM was .98, and between the total change in self-care score and the total change in FIM score was .93.

The self-care measure, independently, was assessed to determine the predictive ability of the measure on patient outcomes. Predictive ability is of great importance in health care as it can be used to determine the relative influence, effect or contribution of a variable (such as level of function) upon another variable (like discharge to home or improvement in function) in order to detect which predictors have the strongest influence on outcomes. Predictive validity can be assessed using regression modeling. A R<sup>2</sup> value can be calculated which is interpreted as the proportion of variance accounted for, in essence, it explains how much of the variance in the dependent variable/outcome of interest (such as improvement in function), is accounted for by the independent variable/predictor (such as admission self-care score). The R<sup>2</sup> value is a number between 0 and 1 whereby a higher value indicate higher predictive validity. Regression modeling was performed to determine if the self care measure is predictive of patient outcomes such as: change in function (total change in functional status from admission to discharge), and likelihood of discharge to the community setting from inpatient facility, and total length of stay (LOS) in inpatient facility. Linear regression was used to determine functional change, whereas the change in self-care score was the independent variable, the R<sup>2</sup> value (proportion of change accounted for) and the Pearson correlation coefficient were examined. For discharge to community setting, logistic regression was used, admission self-care total was the independent variable and the dependent variable was dichotomized as discharge to the community (yes or no). The adjusted R<sup>2</sup> value was examined to determine the proportion of variance accounted for by the measure.

The self-care items at admission were significantly predictive of: patient discharge to the community, chi-square=50178.4, (df=8), p<.001. R2 =.15, patient length of stay (LOS), adjusted R2 =.15, p<.001, and patient change in function (total functional change from admission to discharge), adjusted R2=.44, p<.001. All self-care items were retained in the models above and were statistically significant (p<.001).

- 1. Medicare program; prospective payment system for inpatient rehabilitation facilities. Final rule. *Federal register.* Aug 7 2001;66(152):41315-41430.
- Medicare program; inpatient rehabilitation facility prospective payment system for federal fiscal year 2012; changes in size and square footage of inpatient rehabilitation units and inpatient psychiatric units. Final rule. *Federal register*. Aug 5 2011;76(151):47836-47915.
- **3.** Chung DM, Niewczyk P, Divita M, Markello S, Granger C. Predictors of discharge to acute care after inpatient rehabilitation in severely affected stroke patients. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* May 2012;91(5):387-392.

- **4.** Tan WH, Goldstein R, Gerrard P, et al. Outcomes and predictors in burn rehabilitation. *Journal of burn care & research : official publication of the American Burn Association.* Jan-Feb 2012;33(1):110-117.
- 5. Inouye M, Hashimoto H, Mio T, Sumino K. Influence of admission functional status on functional change after stroke rehabilitation. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* Feb 2001;80(2):121-125; quiz 126, 146.
- **6.** Leung AW, Cheng SK, Mak AK, Leung KK, Li LS, Lee TM. Functional gain in hemorrhagic stroke patients is predicted by functional level and cognitive abilities measured at hospital admission. *NeuroRehabilitation*. 2010;27(4):351-358.
- **7.** Franchignoni F, Tesio L, Martino MT, Benevolo E, Castagna M. Length of stay of stroke rehabilitation inpatients: prediction through the functional independence measure. *Annali dell'Istituto superiore di sanita*. 1998;34(4):463-467.
- 8. McClure JA, Salter K, Meyer M, Foley N, Kruger H, Teasell R. Predicting length of stay in patients admitted to stroke rehabilitation with high levels of functional independence. *Disability and rehabilitation*. 2011;33(23-24):2356-2361.

1a.3. SYSTEMATIC REVIEW(S) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the <u>systematic review of the body of evidence</u> that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

□ Clinical Practice Guideline recommendation (with evidence review)

□ US Preventive Services Task Force Recommendation

□ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

 $\Box$  Other

Source of Systematic Review: <ul> <li>Title</li> <li>Author</li> <li>Date</li> <li>Citation, including page number</li> <li>URL</li> </ul>	
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	
Grade assigned to the <b>evidence</b> associated with the recommendation with the definition of the grade	
Provide all other grades and definitions from the evidence grading system	
Grade assigned to the <b>recommendation</b> with definition of the grade	

Provide all other grades and definitions from the recommendation grading system	
Body of evidence:	
<ul> <li>Quantity – how many studies?</li> </ul>	
<ul> <li>Quality – what type of studies?</li> </ul>	
Estimates of benefit and consistency across studies	
What harms were identified?	
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	

# **1a.4 OTHER SOURCE OF EVIDENCE**

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

# 1a.4.3. Provide the citation(s) for the evidence.

# 1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

**1b.1. Briefly explain the rationale for this measure** (*e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure*)

<u>If a COMPOSITE</u> (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The new mandated quality measures for Inpatient Rehabilitation Facilities (GG items within the IRF-PAI v 20 to be used October 2019) do not adequately address the rehabilitative objectives or functional status of patients. The measures do not allow facilities to substantiate the quality of their restorative care program to CMS or payers. The emphasis on restoration or maintenance of function affected by the patient's illness or injury is paramount in the episode of care. The primary aim of inpatient rehabilitation is to increase function to return the patient to living in the community. Yet the current measures don't adequately capture function or functional improvement. The current quality indicator measures address facility level process, which, has been argued, is not applicable to the IRF as the overall prevalence is very low (less than 2% of patients affected per year) and often times, the presence of the quality indicator occurred in the acute care setting or prior to admission to acute or post-acute care (CAUTIs and incidence of new or worsened pressure ulcers).

The self-care measure is constructed by utilizing items from the FIM® instrument, which is presently used across the post-acute care continuum. Measures of effectiveness, efficiency, timeliness, resource use and safety are an integral part of the FIM® instrument. The FIM® instrument is already used in inpatient rehabilitation as it is embedded in the IRF-PAI, which is presently required to be completed for prospective payment but will no longer be required as of October 2019. Utilizing the change in self-care function measure as a quality indicator would not create any additional costs to IRFs, since IRFs are already transmitting the current IRF-PAI data to CMS for payment purposes. The change in self-care measure has demonstrated both reliability and validity as results indicated a high overall internal consistency, the ability to capture significant

functional gains during rehabilitation, has high discriminative capabilities for rehabilitation patients, and predictive of change in self-care function outcomes and likelihood of patient discharge from inpatient rehabilitation to the community. It is imperative that any quality indicators used for the PAC setting take into account the overriding goal of rehabilitation outcomes, which is to restore and improve function and increase functional independence among individuals receiving rehabilitation, and by doing so, allowing the patient the ability to return to a community setting upon discharge.

**1b.2.** Provide performance scores on the measure as specified (<u>current and over time</u>) at the specified level of analysis. (<u>This is required for maintenance of endorsement</u>. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Facility-level performance results are provided in the measure testing attachment.

Mean change in self-care scores at the facility level were computed and self-care change scores were grouped by quartile to determine if facilities can be 'ranked' in terms of patient outcomes (average change in self-care function from admission to discharge). There were 37 facilities in the 1st quartile (25th%) which includes mean self-care change scores less than 9.0, 489 facilities were in the 2nd quartile which includes mean self-care change scores of 9.0-13.0 (25th through 50th%), 288 facilities were in the 3rd quartile which includes mean self-care change scores of 13.1-18.9 (50th through 75th%) and 22 facilities were in the upper quartile (over 75th%) which includes mean self-care change scores 19.0 or greater. An ANOVA was conducted using the quartiles as constructed above to determine if there is a statistically significant difference between the selfcare change scores by quartile. The means and standard deviations are displayed in Table 5 below. There were statistically significant differences between the mean self-care change scores by quartile grouping, F=807723.87 (df=3), p=.000. The Eta2 = .83, Eta2 is the effect size, it is considered the most important outcome of empirical research because the effect size captures the practical significance of the research results15. Eta2 is interpreted as the proportion of variance accounted for in the dependent variable (mean self-care change) that is associated with the membership of different groups in the independent variable (quartile) and the value is interpreted similar to a correlation coefficient where as a value of .2 is considered a small effect, .5 a moderate effect and .8 is a large, strong effect15.

Quartile	Mean	N	Std. Deviation
25th%	4.5768	142637	4.23618
50th%	11.5356	103348	1.11252
75th%	15.8892	119853	1.40212
over 75th%	23.3347	123104	4.01989
Total	13.5434	488942	7.73567

Table 5: Mean Change in Self-Care by Quartile

**1b.3.** If no or limited performance data on the measure as specified is reported in **1b2**, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

Facility-level performance results are provided in the measure testing attachment and described above in 1b.2.

**1b.4.** Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (*This is* required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for

*improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.* 

Results of disparities analysis are included in the measure testing attachment.

There were no differences in mean change in self-care score (change in total self-care score from admission to discharge) by race (eta2 <.001 for all race/ethnic categories), sex (eta2 <.001) or marital status (eta2 <.01). This is consistent with the findings of other published research, references listed in the measure testing attachment.

# **1b.5.** If no or limited data on disparities from the measure as specified is reported in **1b.4**, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in **1b.4**

Results of disparities analysis are included in the measure testing attachment and described above in 1b.4.

# 2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. *Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.* 

**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

**De.5.** Subject/Topic Area (check all the areas that apply):

**De.6. Non-Condition Specific**(check all the areas that apply):

Care Coordination, Health and Functional Status : Change

**De.7. Target Population Category** (Check all the populations for which the measure is specified and tested if any):

Populations at Risk : Dual eligible beneficiaries, Populations at Risk : Individuals with multiple chronic conditions

**S.1. Measure-specific Web Page** (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

**S.2a.** <u>If this is an eMeasure</u>, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

## This is not an eMeasure Attachment:

**S.2b. Data Dictionary, Code Table, or Value Sets** (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: NQF\_Submission\_Self\_Care-635507770592714533.xlsx

**S.2c.** Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

## Attachment: IRFPAI\_V20\_2018.pdf

**S.2d.** Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

## Clinician

**S.3.1.** For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

# No

**S.3.2.** For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

No changes to the measure specifications since last endorsement.

**S.4. Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

<u>IF an OUTCOME MEASURE</u>, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Average change in rasch derived self-care score from admission to discharge at the facility level. Items at admission and discharge include: Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory. Average is calculated as: ((sum of change at the patient level for all items (Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory) / total number of patients)).

**S.5. Numerator Details** (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

<u>IF an OUTCOME MEASURE</u>, describe how the observed outcome is identified/counted. Calculation of the riskadjusted outcome should be described in the calculation algorithm (S.14).

For Inpatient Rehabilitation Facilities (IRFs) data collection currently occurs as required by the Centers for Medicare and Medicaid Services (CMS) reimbursement using the mandated payment document, the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). Embedded in the IRF-PAI is the FIM<sup>®</sup> Instrument. The FIM<sup>®</sup> Instrument is a criterion referenced tool with 18 items that measure patient physical and cognitive functional status and patient burden of care (level of dependence/need for helper assistance). Each item is rated on a scale of 1 (most dependent) to 7 (completely independent). For the purposes of this measure, a subset of 8 FIM<sup>®</sup> items has been tested and validated which comprise the self-care measure; those items are: Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory. Rasch analysis was performed on the 8 items and the difference in the rasch derived values (defined in S.2b) from admission to discharge reflect the change at the patient level. The numerator of the measure is the facility's average change.

While the IRF-PAI is specific to inpatient rehabilitation facilities, the measure can be used in all post-acute care venues. The FIM<sup>®</sup> instrument can be assessed in all venues of care and has been tested and validated for use in inpatient medical rehabilitation, long term acute care facilities (LTAC), skilled nursing facilities (SNF) and home health. At present, numerous LTACs and SNFs utilize the FIM<sup>®</sup> instrument (www.udsmr.org), thus the self-care measure is applicable for use in IRF, SNF, LTAC and other venues where patient functional change is anticipated.

**S.6. Denominator Statement** (Brief, narrative description of the target population being measured)

Facility adjusted expected change in rasch derived self-care values, adjusted at the Case Mix Group (CMG) level.

**S.7. Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection

items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

# <u>IF an OUTCOME MEASURE</u>, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

To calculate the facility adjusted expected self-care change in rasch derived values, indirect standardization is used, which weights national CMG-specific values by facility-specific CMG proportions. CMG-adjustment derives the expected value based on the case mix and severity mix of each facility. The case-mix group (CMG) classification system groups similarly impaired patients based on functional status at admission (in essence, patient severity). Patients within the same CMG are expected to have similar resource utilization needs and similar outcomes. There are three steps to classifying a patient into a CMG at admission:

- 1. Identify the patient's impairment group code (IGC).
- 2. Calculate the patient's weighted motor index score, calculated from 12 of the 13 motor FIM<sup>®</sup> items as indicated on the CMS IRF-PAI v. 20 instrument (attached).
- 3. Calculate the cognitive FIM<sup>®</sup> rating (as indicated on the CMS IRF\_PAI v. 20 instrument) and the patient age at admission. (This step is not required for all CMGs.)

See file uploaded in S.15 for calculations.

While CMGs are only present for patients admitted to an IRF, the same procedure can be used for patients receiving care at a LTAC facility and/or a SNF, with groupings specific to those venues of care.

# **S.8. Denominator Exclusions** (Brief narrative description of exclusions from the target population)

National values used in the CMG-adjustment procedure will not include cases who died in the IRF or cases less than 18 years old. It is standard to exclude cases who died during rehabilitation as this is a highly atypical outcome, in addition, minors are excluded as well. The measure testing file includes further explanation regarding the exclusion criteria as well as references.

**S.9. Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

Patient date of birth (DOB) and discharge setting are both variables collected in the IRF-PAI. Age can be calculated from DOB and patient date of admission (also collected in the IRF-PAI). In the variable discharge setting, there is a specific category for 'died' (code: 11). Date of birth, date of admission and discharge setting (including died as a category) are also assessed in the LTAC and SNF.

**S.10. Stratification Information** (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)

While the measure can be stratified by specific impairment type (using IGC), the CMG adjustment procedure allows for the measure to be complete, accurate, and valid for all patients within the facility, excluding cases who died and excluding patient under age 18 years.

**S.11. Risk Adjustment Type** (Select type. Provide specifications for risk stratification in measure testing attachment)

Stratification by risk category/subgroup

If other:

S.12. Type of score:

Ratio

If other:

**S.13. Interpretation of Score** (*Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score*)

# Better quality = Higher score

**S.14. Calculation Algorithm/Measure Logic** (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.*)

- 1. Target population: Inpatient rehabilitation facility patients, skilled nursing facility short term patients, long term acute care facility patients, and home health patients.
- 2. Exclusions: Age less than 18 and cases who died during the episode of care.
- 3. Cases meeting target process: All remaining cases.
- 4. Outcome: Ratio of facility level average self-care change (rasch derived values) to facility CMG adjusted expected self-care change.
- 5. Risk adjustment: CMG adjustment using indirect standardization of the proportion of cases at the facility by CMG, and CMG specific national average of rasch derived value of self-care change.

# **S.15. Sampling** (*If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.*)

<u>IF an instrument-based</u> performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

All patients aged 18 and older discharged alive are included in measure testing and assessment of outcomes. Self-care measure is clinician assessed, the measure is not patient reported or proxy reported.

**S.16. Survey/Patient-reported data** (*If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.*)

Specify calculation of response rates to be reported with performance measure results.

All self-care measure items at admission and discharge are required to be completed; values of 'not applicable' do not exist. The measure testing included complete data for all patients, whereby there were no missing values. Details on assessment instructions and item rating rules can be found on the CMS website under 'IRF-PAI Training Manual effective October 1, 2014 [ZIP, 2MB]' using the following link:

https://www.cms.gov/medicare/medicare-fee-for-service-payment/inpatientrehabfacpps/irfpai.html

**S.17. Data Source** (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

Instrument-Based Data, Other

**S.18. Data Source or Collection Instrument** (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

<u>IF instrument-based</u>, identify the specific instrument(s) and standard methods, modes, and languages of administration.

The collection instrument is the FIM Instrument, which is embedded in the CMS IRF-PAI instrument and can be found on page 2 using the following link: <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Final-IRF-PAI-Version-20-Effective-October-1-2018.pdf</u>

**S.19. Data Source or Collection Instrument** (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

Available in attached appendix at A.1

**S.20. Level of Analysis** (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

# Facility, Other

**S.21. Care Setting** (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Inpatient/Hospital, Post-Acute Care

If other:

**S.22.** <u>COMPOSITE Performance Measure</u> - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

For inpatient rehabilitation facilities, CMGs are used to create the adjusted expectation. CMGs are defined by: impairment group code, functional status at admission, and age at admission (for some CMGs). The FIM<sup>®</sup> instrument is divided into motor and cognitive items. Twelve of the 13 motor items are used to calculate a weighted motor index. CMS created this weighting methodology as a way of accounting for the effect of each FIM<sup>®</sup> motor item on the cost of providing care to a patient in an IRF. The patient's weighted admission FIM<sup>®</sup> motor rating is the sum of the weighted admission ratings for the 12 FIM<sup>®</sup> motor items. The following weights are used for each item:

- Eating: 0.6
- Grooming: 0.2
- Bathing: 0.9
- Dressing Upper Body: 0.2
- Dressing Lower Body: 1.4
- Toileting: 1.2
- Bladder Management: 0.5
- Bowel Management: 0.2
- Transfers: Bed, Chair, Wheelchair: 2.2
- Transfers: Toilet: 1.4
- Locomotion: Walk, Wheelchair: 1.6
- Locomotion: Stairs: 1.6

CMS chose not to include the item 'Transfers: Tub, Shower' in the weighted motor score because analysis performed by the RAND Corporation for CMS found that this particular motor item did not predict the cost of patient care as the other 12 items did predict patient resource utilization.

When calculating the weighted admission FIM<sup>®</sup> motor rating, a score of 0 for Transfers: Toilet is converted to a score of 0 for any other item at admission is converted to a score of 1.

While no such functional based grouping exists for LTAC facilities or SNFs, this same process can be utilized in these other venues to group similarly functioning patients to allow for the adjusted comparison.

For more details on CMG calculation, see 'CMG Version 3.00 [ZIP, 9.02mb]' at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/CMG.html

# 2. Validity – See attached Measure Testing Submission Form

NQF2286\_Fall2018\_testing\_attachment\_v7.1\_Final.docx

# 2.1 For maintenance of endorsement

*Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing* 

attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

# 2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

# 2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number: 2286

Measure Title: Functional Change: Change in Self-Care

Date of Submission: 1/7/2019

Type of Measure:

	□ Composite – STOP – use composite testing form
Intermediate Clinical Outcome	□ Cost/resource
Process (including Appropriate Use)	Efficiency
□ Structure	

# 1. DATA/SAMPLE USED FOR <u>ALL</u> TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. <u>If there are differences by aspect of testing</u>, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

**1.1. What type of data was used for testing**? (Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for <u>all</u> the sources of data specified and intended for measure implementation. **If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.**)

Measure Specified to Use Data From: (must be consistent with data sources entered in S.17)	Measure Tested with Data From:
□ abstracted from paper record	□ abstracted from paper record
claims	□ claims
⊠ registry	⊠ registry
⊠ abstracted from electronic health record	☑ abstracted from electronic health record
eMeasure (HQMF) implemented in EHRs	□ eMeasure (HQMF) implemented in EHRs
🗆 other:	□ other:

**1.2. If an existing dataset was used, identify the specific dataset** (the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

Patient data from the FIM<sup>®</sup> instrument collected from inpatient rehabilitation facilities, long term acute care facilities, and skilled nursing facilities subscribing to the Uniform Data System for Medical Rehabilitation (UDSMR). The UDSMR maintains the largest non-governmental database for medical rehabilitation outcomes, whereby ~75% of all US inpatient rehabilitation facilities submit patient level data to include in facility level and national benchmarking reports. UDSMR is a not-for-profit organization affiliated with the University at Buffalo, located in Amherst, New York.

# 1.3. What are the dates of the data used in testing?

Patients discharged between 10/1/2016 to 9/30/2017 were included in the updated testing.

**1.4. What levels of analysis were tested**? (testing must be provided for <u>all</u> the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan)

Measure Specified to Measure Performance of: (must be consistent with levels entered in item S.20)	Measure Tested at Level of:
🗆 individual clinician	🗆 individual clinician
□ group/practice	□ group/practice
⊠ hospital/facility/agency	☑ hospital/facility/agency
🗆 health plan	🗆 health plan
☑ other: patient level change in function	☑ other: patient level, aggregate

**1.5.** How many and which <u>measured entities</u> were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample)

All patients discharged from inpatient rehabilitation facilities (IRFs) in the U.S. between 10/1/2016 to 9/30/2017 (N=488,942, missing=0) were included in the updated aggregate testing. There were 855 facilities included, of which 76% were units within an acute care hospital and 24% were free-standing facilities. Every state in the U.S. was represented.

For the facility level analysis, a random sample of 30 facilities from the 855 total included facilities, were selected. A random sample was necessary as it would not be feasible to perform the analysis on all 855 facilities. The random sample included 7 freestanding IRFs and 23 units. Selection criteria for the random sampling were as follows: facilities must have had at least 100 cases discharged in the time period of reference and each facility contained complete patient records, meaning all items at admission and discharge were completed for each patient (no missing data). For the analysis, each of the 30 facilities were randomly split into two datasets, and the rasch-converted average change scores at the facility level were calculated, results were compared across the facilities (ICC).

To ensure the facilities selected in the random sample were representative of an average IRF, facilities with fewer than 100 patients discharged per year were excluded from selection, as this is not typical for the large majority of IRFs throughout the country and these facilities are outliers and likely differ in vast ways from the majority of IRFs. The number of facilities in the database that had less than 100 patients discharge in the one year time frame was 36, which is ~4% of the total number of facilities. Of the 36 facilities that were excluded from selection in the random sample, the average number of patients discharged per year was 74, with a

median of 81, the range was 11 to 99. In contrast, of the 819 facilities eligible for selection in the random sample, the average number of patients discharged per year was 594, with a median of 413.

**1.6.** How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample)

All patients discharged from 855 facilities in the U.S. between 10/1/2016 to 9/30/2017 (N=488,942, missing=0) were included in the updated aggregate testing. Patient admission and discharge data were used. All patients age 18 and over were included, the mean age of the total sample was 69.1 years (S.D.= 15.5), 51% were female and 49% were male. All race/ethnicities were included and the distribution was as follows: 76.5% Caucasian (n=374,527), 12% African American (n=59,197), 6% Hispanic/Latino (n=28,321), 2% Asian (n=9,420), .5% Hawaiian/Pacific Islander (n=3,020), .5% American Indian/Alaskan (n=2,471), and 2.5% other race/ethnicity not specified (n=11,986). All payment sources were included and the distribution was as follows: 72.7% Medicare (n=355,424), 14.7% commercial health insurance (n=71,980), 6.5% Medicaid (n=31,717), 2.8% other payment source (Workers Compensation, no-fault auto, employer) (n=13,686), 1.7% unknown/payment source not specified (n=8,344), 1% un-reimbursed/no-pay (n=4,746), .3% Veterans benefits (n=1,545), .3% self-pay/private pay (n=1,500). All impairments/conditions were included, the distribution of sample conditions/impairments displayed in Table 1 below.

Impairment Type	Frequency	Percent
Stroke	115607	23.6
Brain Dysfunction	55943	11.4
Neurologic Conditions	67436	13.8
Spinal Cord Dysfunction	28527	5.8
Amputation	15202	3.1
Arthritis	1877	.4
Pain Syndromes	1444	.3
Orthopedic Conditions	107219	21.9
Cardiac Disorders	22654	4.6
Pulmonary Disorders	7638	1.6
Burns	646	.1
Congenital Deformities	163	.0
Other Disabling Impairments	4421	.9
Major Multiple Trauma	14915	3.1
Debility	42571	8.7
Medically Complex Conditions	2679	.5
Total	488942	100.0

#### Table 1: Distribution of Sample by Impairment Type

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

N/A

**1.8 What were the social risk factors that were available and analyzed**? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient

(e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

The social risk variables available in the dataset include: race, sex and marital status.

## 2a2. RELIABILITY TESTING

<u>Note</u>: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.

2a2.1. What level of reliability testing was conducted? (may be one or both levels)

Critical data elements used in the measure (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☑ Performance measure score (e.g., signal-to-noise analysis)

**2a2.2. For each level checked above, describe the method of reliability testing and what it tests** (*describe the steps*—*do not just name a method; what type of error does it test; what statistical analysis was used*)

SPSS version 22 was used to compute Cronbach's alpha to determine the internal consistency of the measure and to perform inter-item correlations.

Rasch analysis allows for the conversion of ordinal-level data into interval-level data. Ordinal measures do not inherently act as interval measures, where the difference between one score is equidistance compared to the difference between another two scores, i.e. the difference between a 15 and a 16 in our measure may not reflect the same difference between a 56 and a 57, in terms of difficulty. If the data fit the Rasch model, a result of the analysis is the conversion of the raw ordinal scores to a Rasch derived interval score. This allows for a more precise estimation of differences in functional status both between patients and across facilities. Rasch analysis was conducted to test the psychometric properties of the self-care measure and to determine the measure reliability at both the person and item level. Rasch analysis was also used to determine the fit of each item within the measure (8 items: Eating, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, and Memory) through infit and outfit statistics and item specific correlations. Winsteps 3.73 was used for the analysis.

To assess the measure reliability across facilities, an Intraclass Correlation Coefficient (ICC) using the split-half method was computed. The ICC analyses were previously suggested by the NQF PFCC committee staff. For the facility level analysis, a random sample of 30 facilities from the 855 included facilities, were selected. A random sample was necessary as it would not be feasible to perform the analysis on all 855 facilities. The random sample included 7 freestanding IRFs and 23 units. Selection criteria for the random sampling were as follows: facilities must have had at least 100 cases discharged in the time period of reference, each facility contained complete patient records, meaning all items at admission and discharge were completed for each patient (no missing data). For the analysis, each of the 30 facilities were randomly split into two datasets, and the rasch-derived average change score at the facility level was calculated, results were compared across the facilities (ICC).

**2a2.3.** For each level of testing checked above, what were the statistical results from reliability testing? (e.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis)

Cronbach's alpha= .83 (8 items) and was statistically significant (p<.05) indicating a reliable measure. Interitem correlations ranged from .79 (expression and memory) to .21 (memory and dressing lower), all items were significantly correlated (p<.001). Results of the Rasch analysis are as follows: The person-reliability correlation was 0.89. The infit and outfit statistics were acceptable for all items (less than 2.0).

An intra-class correlation coefficient (ICC) using the split-half method was used to assess the score level reliability across facilities. Results of ICC was 0.917, p <.001, demonstrating very high consistency among

facilities for the measure. Rasch-converted average range in scores for the measure by facility was 9.2 to 21.2. Table 2 below shows the average range in the self-care measure by facility, from lowest to highest value.

Table 2: Average Rasch-derived Self-Care Scores by Facility

FacilityScoreFacility 39.164435Facility 89.313398Facility 1311.8082Facility 2811.82017Facility 2811.82017Facility 1912.56429Facility 1912.56429Facility 1013.71142Facility 713.82861Facility 514.05408Facility 514.05408Facility 214.0993Facility 1015.23045Facility 1215.86657Facility 1215.86657Facility 1215.86657Facility 2316.08963Facility 2416.58076Facility 1516.65991Facility 1516.65991Facility 3017.00802Facility 1117.30545Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 2720.00859Facility 2620.28757Facility 2221.22518	0	
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Facility 713.82861Facility 514.05408Facility 214.0993Facility 2514.41253Facility 2514.41253Facility 915.03005Facility 1615.23045Facility 1215.86657Facility 1215.86657Facility 2316.08963Facility 2416.58076Facility 1516.65991Facility 116.79333Facility 3017.00802Facility 1117.30545Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 2720.00859Facility 2620.28757	Facility 14	13.54962
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Facility 1215.86657Facility 1715.9689Facility 2316.08963Facility 2416.58076Facility 1516.65991Facility 116.79333Facility 3017.00802Facility 1117.30545Facility 1817.3578Facility 2917.73805Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 9	15.03005
Facility 1715.9689Facility 2316.08963Facility 2416.58076Facility 1516.65991Facility 116.79333Facility 117.00802Facility 3017.00802Facility 1117.30545Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 2720.00859Facility 2620.28757	Facility 16	15.23045
Facility 2316.08963Facility 2416.58076Facility 1516.65991Facility 116.79333Facility 3017.00802Facility 1117.30545Facility 1817.3578Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 2720.00859Facility 2620.28757	Facility 12	15.86657
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Facility 1516.65991Facility 116.79333Facility 3017.00802Facility 1117.30545Facility 1817.3578Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 23	16.08963
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Facility 3017.00802Facility 1117.30545Facility 1817.3578Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 15	16.65991
Facility 1117.30545Facility 1817.3578Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 1	16.79333
Facility 1817.3578Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 30	17.00802
Facility 2917.73805Facility 2018.91Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 11	17.30545
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Facility 2119.99345Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 29	17.73805
Facility 620.00255Facility 2720.00859Facility 2620.28757	Facility 20	18.91
Facility 2720.00859Facility 2620.28757	Facility 21	19.99345
Facility 26 20.28757	Facility 6	20.00255
	Facility 27	20.00859
Facility 22 21.22518	Facility 26	20.28757
	Facility 22	21.22518

# **2a2.4 What is your interpretation of the results in terms of demonstrating reliability**? (i.e., what do the results mean and what are the norms for the test conducted?)

The results of the reliability analysis for the self-care measure were statistically significant; the Cronbach's alpha indicated high internal consistency, thus a very stable measure. Inter item correlations were all statistically significant demonstrating very high consistency among items within the measure. The self-care measure is reliable and internally stable.

The facility-level intra-class correlation coefficient (ICC) was statistically significant demonstrating consistency among facilities in terms of ratings and outcome scores for the measure. Clearly there are differences in patient outcomes between facilities as illustrated in the table above, whereby the average patient self-care
measure score (higher is better in terms of average patient self-care function and facility performance) for Facility 3 is 9.2 vs 15.9 for Facility 12 vs 21.2 for Facility 22.

#### **2b1. VALIDITY TESTING**

**2b1.1. What level of validity testing was conducted**? (may be one or both levels)

Critical data elements (data element validity must address ALL critical data elements)

### ⊠ Performance measure score

⊠ Empirical validity testing

Systematic assessment of face validity of <u>performance measure score</u> as an indicator of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

**2b1.2.** For each level of testing checked above, describe the method of validity testing and what it tests (describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)

Construct validity is defined as the degree to which a test or instrument actually measures what it is intended the measure, the 'construct' of interest. For the current purpose, construct validity was assessed using SPSS to determine how well the self-care measure is able to capture the functional ability of a person to perform tasks of caring for self independently. Factor analysis using principal component analysis was used.

Predictive validity refers to the extent to which a score on an assessment predicts a future event, occurrence or performance. Predictive validity is of great importance as it can be used to determine the relative influence, effect or contribution of a variable (such as level of function) upon another variable (like discharge to home or improvement in function) in order to detect which predictors have the strongest influence on outcomes. Predictive validity can be assessed using regression modeling. A  $R^2$  value can be calculated which is interpreted as the proportion of variance accounted for, in essence, it explains how much of the variance in the dependent variable/outcome of interest (such as improvement in function), is accounted for by the independent variable/predictor (such as admission self-care score). The R<sup>2</sup> value is a number between 0 and 1 whereby a higher value indicate higher predictive validity. Regression modeling was performed to determine if the self care measure is predictive of patient outcomes such as: change in function (total change in functional status from admission to discharge), and likelihood of discharge to the community setting from inpatient facility, and total length of stay (LOS) in inpatient facility. Linear regression was used to determine functional change, whereas the change in self-care score was the independent variable, the R<sup>2</sup> value (proportion of change accounted for) and the Pearson correlation coefficient were examined. For discharge to community setting, logistic regression was used, admission self-care total was the independent variable and the dependent variable was dichotomized as discharge to the community (yes or no). The adjusted R<sup>2</sup> value was examined to determine the proportion of variance accounted for by the measure.

Criterion-referenced validity was assessed by comparing the self-care measure at admission, at discharge and the measure change score (difference in total score from admission to discharge) to the total FIM Instrument scores at admission, discharge and change in FIM from admission to discharge score. The FIM Instrument is embedded in the IRF-PAI tool, which is used by IRFs throughout the country for reimbursement by CMS (mandated since 2002) and for patient level and facility level outcomes of care reporting, see udsmr.org for more information and for a list of references related to the FIM Instrument. The FIM Instrument has 18 items, 13 motor items and 5 cognitive items. Since the self-care measure includes both motor/physical items and cognitive items, the full 18-item FIM was used in the analysis.

**2b1.3.** What were the statistical results from validity testing? (e.g., correlation; t-test)

**Construct Validity** 

Factor analysis using principal component analysis resulted in 2 components identified in the measure, cumulatively accounting for 63.8% of the total explained variance. Component 1 included: eating (.68), grooming (.72), dressing upper (.77), dressing lower (.68), toileting (.71), and bowel (.59), eigenvalue=3.78, contributing 47.3% of the explained variance. Component 2 included: expression (.61) and memory (.63), eigenvalue=1.32, contributing 16.5% of the explained variance.

## **Predictive Validity**

Regression models were used to determine the predictive ability of the self-care measure items on patient outcomes. Specific patient outcomes included: patient discharge from inpatient facility to a community setting/home, total length of stay (LOS) in inpatient facility, and patient functional change from admission to inpatient facility to discharge. The first set of models included all 8 items of the self-care measure. In light of the results of the factor analysis, in that 2 components were identified, in essence, two constructs are measured by the self-care measure, a physical aspect of self care (6 motor items) and a cognitive aspect of self-care (2 cognitive items), a second set of regression models were performed to determine the extent of the cognitive items ability to predict patient outcomes, in essence, how much do the 2 cognitive items contribute to the predictive ability of the self-care measure. Results of the regression models are as follows:

**Full model (all 8 items) regression results:** The self-care items at admission were significantly predictive of: patient discharge to the community, chi-square=50178.4, (df=8), p<.001. R2 =.15, patient length of stay (LOS), adjusted R2 =.15, p<.001, and patient change in function (total functional change from admission to discharge), adjusted R2=.44, p<.001. All items were retained in the models above and were statistically significant (p<.001).

**Stepwise regression model results:** To examine the impact of the cognitive items on the predictive validity of the self-care measure, stepwise regression models were performed to determine the contribution of each individual item within the measure on the outcomes, the results are as follows: In predicting likelihood of patient discharge to the community: expression and memory were retained and statistically significant predictors (p<.001) in the model (in addition to all of the other self-care items, each item was significantly predictive of the outcome). In predicting LOS: expression was retained and statistically significant (p<.001), in addition to all 6 motor/physical items, however, memory was not retained in this model and did not contribute in predicting patient LOS in the inpatient facility. In predicting patient change in function (total functional change from admission to discharge): expression and memory were retained and statistically significant (p<.001) predictors of functional change in the model in addition to each of the 6 motor/physical items. It is noteworthy to mention that expression was the first item retained in the model predicting patient change in function, with a contributing adjusted R2 = .23 for this item alone, thus the expression item predicted 23% of the variance in explaining patient change in overall function from admission to discharge from an inpatient facility.

## **Criterion-referenced Validity**

The correlations between the self-care measure and the FIM Instrument were statistically significant (p<.001). The correlation between the admission self-care measure and the admission FIM was .97, between the discharge self-care measure and the discharge FIM was .98, and between the total change in self-care score and the total change in FIM score was .93.

## **2b1.4. What is your interpretation of the results in terms of demonstrating validity**? (i.e., what do the results mean and what are the norms for the test conducted?)

The results show the self-care measure is valid; the measure demonstrated construct, discriminant and predictive validity in all of the analyses. The r-square values in each of the regression models were moderate to strong, meaning the self-care measure was able to account for a significant percent of variance explained in the dependent variables. Overall, results of the principal components factor analysis were the self-care items cumulatively accounted for 63.8% of the total explained variance overall, which is strong and robust considering the very small number (8 items) of total items in the measure.

The results of the criterion-referenced validity testing indicated a very strong correlation between the self-care measure and the FIM Instrument which is the 'gold standard' measure for patient function.

## **2b2. EXCLUSIONS ANALYSIS**

## NA $\Box$ no exclusions – skip to section <u>2b4</u>

**2b2.1.** Describe the method of testing exclusions and what it tests (describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used)

Patients that had expired in the inpatient rehabilitation facility (an unanticipated, very low frequency outcome) and patients under age 18 years were excluded from the analyses; both criteria are consistent exclusions in published literature examining rehabilitation outcomes.<sup>3-8</sup>

**2b2.2. What were the statistical results from testing exclusions**? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Frequency of occurrence was less than 5% of total sample for each exclusion criteria (<1% died during inpatient stay and 4% of patients were under 18 years of age), findings are consistent with other published studies examining outcomes of inpatient medical rehabilitation using UDSMR data from earlier years. <sup>5-7</sup>

**2b2.3.** What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e.*, the value outweighs the burden of increased data collection and analysis. <u>Note</u>: *If patient preference is an exclusion*, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion)

Criteria for patient admission to inpatient rehabilitation includes patient ability to participate in three hours of intensive rehabilitation therapy per day every day (3 hrs per day at a minimum of 5 days per week) and a high likelihood for the patient to be discharged from the inpatient facility to their home or a community-based living setting (retirement community, assisted living, family member's home)<sup>9</sup>. Considering the aforementioned admission criteria, the 'typical' patient treated in inpatient rehabilitation tends to be medically stable and has functional limitations but shows some level of physical conditioning or functional abilities that indicate the individual would be able to withstand the three hours a day rigorous therapy requirement. Therefore, patients that are at increased risk for death in the near future (medically unstable/in critical condition, those requiring intensive 24 hour medical care, those with severe cognitive deficits (late stage dementia/Alzheimer's disease), patients with severe debility/highly deconditioned) do not tend to receive care in an inpatient rehabilitation facility and are more likely to be admitted to a skilled nursing facility, subacute facility, long-term acute care and/or Hospice care, so the small number of patients that do expire during an inpatient stay are extreme outliers and not representative of the larger population of patients that receive care at an inpatient rehabilitation facility.

Persons younger than age 18 requiring care at an inpatient rehabilitation facility may be treated at an adult facility or may receive care at one of many specialized pediatric facilities located throughout the country. Specialized pediatric inpatient rehabilitation facilities often provide a number of additional patient services such as educational coordination (in-hospital education/tutoring may be provided for school-age children) and developmental-related therapeutic services may be provided. Considering there may be a large difference in minors treated at a pediatric facility compared to those treated at a non-pediatric facility, and data are not available to UDSMR from the pediatric facilities for comparison, any results from persons under 18 years in the present dataset are not generalizable to the larger pediatric population and may be biased with a number of confounding variables. Thus, to control for possible bias, persons under 18 years of age were excluded from the present analyses.

### 2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

#### If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section <u>2b5</u>.

2b3.1. What method of controlling for differences in case mix is used?

□ No risk adjustment or stratification

 $\boxtimes$  Statistical risk model with <u>1</u> risk factor

 $\boxtimes$ Stratification by <u>1</u>risk category

## $\Box$ Other,

**2b3.1.1** If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

The Case Mix Group (CMG) specifications, definitions, codes and algorithm can be accessed on the Centers for Medicare and Medicaid Services (CMS) website under the CMG version 3.00.<sup>10</sup> CMG version 3.00 can be accessed using the following link: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/CMG.html</u>.

2b3.2. If an outcome or resource use component measure is <u>not risk adjusted or stratified</u>, provide <u>rationale</u> <u>and analyses</u> to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

## N/A

**2b3.3a.** Describe the conceptual/clinical <u>and</u> statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g.*, *potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

Outcomes, in terms of change in function, would lack meaning if *all* patients were aggregated, considering the many different conditions that patients are admitted to an inpatient rehabilitation facility for treatment. There are vast differences in patient conditions (stroke vs spinal cord injury vs knee replacement) in addition to a range of severity of within each condition (ex. for spinal cord injury there is a large difference in functional impairment between a patient with quadriplegia vs a patient with central cord syndrome), therefore, when examining functional outcomes of inpatient care it is imperative to control for these difference both between patient impairment types/conditions and to control for the severity within a given impairment type/condition. Stratification for patient impairment type/condition and risk adjusting data by CMG has been used extensively in prior, published research on patient functional outcomes of inpatient rehabilitation.<sup>11, 12</sup> CMG adjustment is a standard and expected procedure<sup>10, 12</sup>.

Data was first stratified by impairment type, which is the specific, primary condition/reason a person is admitted to inpatient rehabilitation. The impairment types are listed in Table 1, previously displayed.

Next, the data was adjusted by Case Mix Group (CMG) through indirect standardization.

CMG is a proxy for severity of condition, just as two conditions are very different in terms of physical, psychological, physiological, cognitive and quality of life impact, there can be a large difference in severity within the same condition, for instance, a stroke can be very mild where no limitations in physical or cognitive functioning occur or a stroke can be very severe, whereby if death does not occur the result may include major cognitive impairment, loss of ability to control facilities, loss of speech, inability to swallow, walk or dress self.

To calculate the facility's adjusted expected change in Rasch derived values, indirect standardization was used which weights national CMG-specific values by facility-specific CMG proportions. CMG-adjustment derives the expected value based on the case mix and severity mix of each facility. The CMG classification system groups similarly impaired patients based on functional status at admission or patient severity<sup>10</sup>. Patients within the

same CMG are expected to have similar resource utilization needs and similar outcomes. There are three steps to classifying a patient into a CMG at admission:

- 1. Identify the patient's impairment group code (IGC).
- Calculate the patient's weighted motor index score, calculated from 12 of the 13 motor FIM<sup>®</sup> items.
- 3. Calculate the cognitive FIM<sup>®</sup> rating and the age at admission (this step is not required for all CMGs, see specifications on CMS website for more details). <sup>10</sup>

**2b3.3b.** How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

Published literature

□ Internal data analysis

□ Other (please describe)

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Published literature was used to determine appropriate risk factors to adjust for in the dataset<sup>1-12</sup>.

**2b3.4b.** Describe the analyses and interpretation resulting in the decision to select social risk factors (*e.g.* prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.) Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.

There were no differences in mean change in self-care score (change in total self-care score from admission to discharge) by race (eta<sup>2</sup> <.001 for all race/ethnic categories), sex (eta<sup>2</sup> <.001) or marital status (eta<sup>2</sup> <.01). This is consistent with the findings of other published research.<sup>1, 2</sup>

**2b3.5.** Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model <u>or</u> stratification approach (describe the steps—do not just name a method; what statistical analysis was used)

CMG adjustment is a standard procedure<sup>4, 5</sup>. Stratification for patient impairment type/condition and risk adjusting data by CMG has been used extensively in prior, published research on patient functional outcomes of inpatient rehabilitation<sup>4-12</sup>.

*Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.* 

## If stratified, skip to <u>2b3.9</u>

## **2b3.6.** Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R-squared):

Due to constraints in space/size the full CMG analysis is not included in the present testing submission. However, to illustrate the risk adjustment by CMG, one impairment type was selected and presented below. Considering stroke was the most frequently occurring impairment in the dataset (23.6% of patients (n=115,607) had stroke as their admission condition), stroke was selected and the data was stratified by impairment and only cases with stroke were included in the CMG risk adjustment analysis. An ANOVA was conducted to determine if there were significant differences in mean self-care change by CMG within the stroke subset. CMG for stroke includes 10 categories, ranging from 101 to 110, whereby CMG 101 is the least severe and CMG 110 is the most severe. A statistically significant difference was found in mean self-care change by CMG, F=506.81 (df=9), p=.000. The mean and standard deviation in total self-care change (total selfcare score from admission to discharge) by CMG for patients with stroke is displayed in Table 3 below.

Table 3: Mean Self-Care Change Score by CMG for Patients with Stroke

		Self-Care
CMG		Change
101.00	Mean	9.4289
	Ν	5457
	Std. Dev	4.34985
102.00	Mean	10.5473
	Ν	7427
	Std. Devi	4.65968
103.00	Mean	11.2080
	Ν	2166
	Std. Dev	5.65422
104.00	Mean	11.4230
	Ν	12900
	Std. Dev	5.40449
105.00	Mean	12.5457
	Ν	11049
	Std. Dev	6.11665
106.00	Mean	13.6125
	Ν	10414
	Std. Dev	6.53985
107.00	Mean	14.3717
	Ν	10072
	Std. Dev	7.26532
108.00	Mean	11.9042
	Ν	8441
	Std. Dev	8.24727
109.00	Mean	14.9599
	Ν	9037
	Std. Dev	7.62084
110.00	Mean	13.5984
	Ν	38644
	Std. Dev	8.89982
Total	Mean	12.8010
	Ν	115607
	Std. Dev	7.57249

**2b3.7.** Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

N/A

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

N/A

2b3.9. Results of Risk Stratification Analysis:

An ANOVA was conducted to determine if there were significant differences in mean self-care change by impairment type. A statistically significant difference was found in mean self-care change by impairment type, F=393.46 (df=15), p=.000. The mean and standard deviation in total self-care change (total self-care score from admission to discharge) by impairment type is displayed in Table 4 below.

Impairment Type	Mean	Ν	Std. Dev.
Stroke	12.8010	115607	7.57249
Brain Dysfunction	13.3019	55943	8.44882
Neurologic Conditions	14.4555	67436	8.09448
Spinal Cord Dysfunction	13.0328	28527	7.72998
Amputation	11.8729	15202	7.14697
Arthritis	14.9680	1877	7.50906
Pain Syndromes	13.8878	1444	7.64093
Orthopaedic Conditions	14.4137	107219	7.16719
Cardiac Disorders	13.1641	22654	7.61212
Pulmonary Disorders	12.4235	7638	7.52597
Burns	14.7446	646	8.39849
Congenital Deformities	13.2089	163	7.37188
Other Disabling Impairments	13.1393	4421	7.45821
Major Multiple Trauma	15.5560	14915	7.87043
Debility	13.0292	42571	7.76859
Medically Complex Conditions	10.3513	2679	6.93673
Total	13.5434	488942	7.73567

Table 4: Mean Change in Self-Care by Impairment Type

**2b3.10.** What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.e., what do the results mean and what are the norms for the test conducted)

There are statistically significant differences in mean self-care change by impairment type and by CMG; the self-care measure is able to discriminate in functional ability both between different functional impairments and within the same type of functional impairment.

**2b3.11. Optional Additional Testing for Risk Adjustment** (*not required*, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed)

## 2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

**2b4.1.** Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps*—*do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b*).

Mean change in self-care scores at the facility level were computed and self-care change scores were grouped by quartile to determine if facilities can be 'ranked' in terms of patient outcomes (average change in self-care function from admission to discharge).

**2b4.2.** What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g.,

## number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined)

There were 37 facilities in the 1<sup>st</sup> quartile (25<sup>th</sup>%) which includes mean self-care change scores less than 9.0, 489 facilities were in the 2<sup>nd</sup> quartile which includes mean self-care change scores of 9.0-13.0 (25<sup>th</sup> through 50<sup>th</sup>%), 288 facilities were in the 3<sup>rd</sup> quartile which includes mean self-care change scores of 13.1-18.9 (50<sup>th</sup> through 75<sup>th</sup>%) and 22 facilities were in the upper quartile (over 75<sup>th</sup>%) which includes mean self-care change scores 19.0 or greater. An ANOVA was conducted using the quartiles as constructed above to determine if there is a statistically significant difference between the self-care change scores by quartile. The means and standard deviations are displayed in Table 5 below. There were statistically significant differences between the mean self-care change scores by quartile grouping, F=807723.87 (df=3), p=.000. The Eta<sup>2</sup> = .83, Eta<sup>2</sup> is the effect size, it is considered the most important outcome of empirical research because the effect size captures the practical significance of the research results<sup>15</sup>. Eta<sup>2</sup> is interpreted as the proportion of variance accounted for in the dependent variable (mean self-care change) that is associated with the membership of different groups in the independent variable (quartile) and the value is interpreted similar to a correlation coefficient where as a value of .2 is considered a small effect, .5 a moderate effect and .8 is a large, strong effect<sup>15</sup>.

Quartile	Mean	Ν	Std. Deviation
25th%	4.5768	142637	4.23618
50th%	11.5356	103348	1.11252
75th%	15.8892	119853	1.40212
over 75th%/upper quartile	23.3347	123104	4.01989
Total	13.5434	488942	7.73567

Table 5: Mean	Change	in Self-Care	by Quartile
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# **2b4.3.** What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.e., what do the results mean in terms of statistical and meaningful differences?)

Difference in average self-care change scores between facilities can be determined and rank ordered in terms of patient average change in self-care function from admission to discharge. From the above mentioned results, clearly 'top performing' facilities, in terms of patient change in function, can be identified, in addition to facilities that are at the lowest quartile. There were statistically significant differences in mean change scores by quartile and the standard deviations within the quartiles were small, indicating some variability within groups but small enough so the scores are fully contained within the quartile and no not extend into another category. The Eta<sup>2</sup> value is very strong, which is further evidence that the differences in mean scores are true differences and not a result of the very large sample size; a very large sample can often can lead to small, negligible differences detected as statistically significant but when examining the actual values, the differences are not clinically relevant or meaningful (for instance a difference in self-care change of 6.2 and 6.4, may be statistically significant due to the very large sample size but both values are, in essence, a 6, so the difference is not clinically relevant or meaningful in any way).

## 2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

## If only one set of specifications, this section can be skipped.

<u>Note</u>: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of

specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

**2b5.1.** Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps*—*do not just name a method; what statistical analysis was used*)

**2b5.2.** What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.e., what do the results mean and what are the norms for the test conducted)

## 2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

**2b6.1.** Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*).

There were no missing data in the dataset. The items in the self-care measure were selected from the FIM instrument, which is embedded in the IRF-PAI instrument<sup>13</sup>, used by inpatient rehabilitation facilities for prospective payment by CMS. The instructions for rating the specific items can be found in the IRF-PAI Training Manual<sup>14</sup>, effective 10/1/2014, and can be accessed using the following link:

https://www.cms.gov/medicare/medicare-fee-for-service-payment/inpatientrehabfacpps/irfpai.html. In brief, the item rating rules state that a code of 0 may be used for some items at admission (eating, grooming, dressing upper, dressing lower, and toileting) if the activity did not occur. It is stated that use of this code should be rare and that a code of 0 translates to a 1 (most dependent) in facility level reports and aggregate patient data reports. A code of 0 may not be used for bowel management, expression and memory items and a code of 0 may not be used for any items at discharge. All items are to be rated at both admission and discharge and there are no options for 'not applicable' or 'do not apply' or 'missing data' codes.

**2b6.2.** What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each)

## No missing data in dataset/analyses.

**2b6.3.** What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias? (i.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; <u>if no empirical analysis</u>, provide rationale for the selected approach for missing data)

## No missing data in dataset/analyses.

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## 3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

**3a. Byproduct of Care Processes** 

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

## 3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

## **3b. Electronic Sources**

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

**3b.1.** To what extent are the specified data elements available electronically in defined fields (*i.e.*, data elements that are needed to compute the performance measure score are in defined, computer-readable fields) Update this field for maintenance of endorsement.

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

**3b.2.** If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For <u>maintenance of endorsement</u>, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

No plans to develop an eMeasure at this time.

**3b.3.** If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

## Attachment:

## **3c. Data Collection Strategy**

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. <u>Required for maintenance of endorsement.</u> Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

<u>IF instrument-based</u>, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

No difficulties in data collection or use, no missing data.

**3c.2.** Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (*e.g.,* value/code set, risk model, programming code, algorithm).

Measure is publicly available for use free of change. Facility-level and national benchmark reporting available by UDSMR through a subscription, cost vary based on facility type and size. National reporting may be available free of charge if CMS elects to provide.

## 4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of highquality, efficient healthcare for individuals or populations.

## 4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

## 4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting	Payment Program
Regulatory and Accreditation	CMS IRF-PAI
Programs	cms.gov
	Quality Improvement (external benchmarking to organizations)
	National IRF Benchmark Reports
	udsmr.org
	Quality Improvement (Internal to the specific organization)
	Facility-level IRF Reports
	udsmr.org

## 4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Completion of the IRF-PAI is required by all IRFs throughout the country for all patients in which the IRF requests payment reimbursement from the Inpatient Rehabilitation Facility Prospective Payment System through the Centers for Medicare and Medicaid Services.

FIM<sup>®</sup> outcomes are currently benchmarked for all UDSMR subscribing facilities, with internal and external benchmarking options. UDSMR has 875 current enrolled IRFs which is roughly 80% of all IRF in the U.S. In addition, there are SNFs and LTAC facilities that subscribe to UDSMR and utilize the FIM<sup>®</sup> instrument to track patient functional outcomes (SNF = 152 and LTAC = 7).

**4a1.2.** If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?) As described above in 4a1.1, completion of the IRF-PAI is required by all IRFs throughout the country for all patients in which the IRF requests payment reimbursement from the Inpatient Rehabilitation Facility Prospective Payment System through the Centers for Medicare and Medicaid Services.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

As described above in 4a1.1, completion of the IRF-PAI is required by all IRFs throughout the country for all patients in which the IRF requests payment reimbursement from the Inpatient Rehabilitation Facility Prospective Payment System through the Centers for Medicare and Medicaid Services.

## 4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

## How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Facilities subscribing to UDSMR primarily do so because of the national benchmarking reports and services that UDSMR provides. Patient outcomes are currently benchmarked for all UDSMR subscribing facilities, with facility level and national benchmark reporting provided on a quarterly basis. UDSMR maintains the world's largest government-independent repository of rehabilitation outcomes and IRF-PAI data. The repository contains data from over 1,400 rehabilitation facilities worldwide, 875 of which are IRFs in the United States, that use UDSMR's outcomes reporting, credentialing, auditing, training, and consulting services. UDSMR works with subscribing facilities and healthcare providers to document and improve patient functional outcomes, facility-level quality processes, and delivery of care in a uniform, standardized way.

For more than 30 years, UDSMR has been a national leader in medical rehabilitation outcomes reporting and has provided aggregate summary information to many well-known and well-regarded organizations, including the Medicare Payment Advisory Commission (MedPAC), the Centers for Medicare and Medicaid Services (CMS), the American Hospital Association (AHA), and the American Medical Rehabilitation Providers Association (AMRPA).

## 4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

Patient level outcomes are currently benchmarked for all UDSMR subscribing facilities, with facility level and national benchmark reporting provided on a quarterly basis. UDSMR works with subscribing facilities and healthcare providers to document and improve patient functional outcomes, facility-level quality processes, and delivery of care in a uniform, standardized way. UDSMR provides assistance to subscribing facilities on coding and assessment education and support. Training for facility providers on patient assessment and functional outcomes documentation of the functional measures. Custom reports, facility quality improvement information and report interpretation is provided by request at no charge.

## 4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

## Describe how feedback was obtained.

Feedback from users was not solicited. The items in the measure are not new and have been in use for over two decades in post acute rehabilitation.

## 4a2.2.2. Summarize the feedback obtained from those being measured.

Feedback was not solicited. The measure is clinician assessed and collected routinely as part of clinical care. Patients are not questioned and do not provide any responses for the items within the measures. The items in the measure are not new and have been in use for over two decades in post acute rehabilitation.

## 4a2.2.3. Summarize the feedback obtained from other users

Feedback from other users was not solicited.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

No modifications were made to the measure. No negative feedback was received.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Difference in average self-care change scores between facilities can be determined and rank ordered in terms of patient average change in self-care function from admission to discharge. Top performing facilities, in terms of patient change in self-care function, can be identified, in addition to facilities that are at the lowest quartile. There were statistically significant differences in mean change scores by quartile and the standard deviations within the quartiles were small, indicating some variability within groups but small enough so the scores are fully contained within the quartile and do not extend into another category.

## 4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

### No unexpected/unanticipated findings related to the self-care measure.

### 4b2.2. Please explain any unexpected benefits from implementation of this measure.

CMS recently included new functional items in the IRF-PAI (GG items) which are similar to the items in measure #2286, except none of the new GG items measure cognitive function. In light of this, we examined the impact of the cognitive items of the self-care measure on the predictive validity of the self-care measure as a whole using stepwise regression. Regression models were performed to determine the contribution of each individual item within the measure on patient outcomes, the results are as follows: In predicting likelihood of patient discharge to the community: expression and memory were retained and statistically significant predictors (p<.001) in the model (in addition to all of the other self-care items, each item was significantly predictive of the outcome). In predicting inpatient length of stay: expression was retained and statistically significant (p<.001), in addition to all 6 motor/physical items, however, memory was not retained in this model and did not contribute in predicting patient LOS in the inpatient facility. In predicting patient change in function (total functional change from admission to discharge): expression and memory were retained and statistically significant (p<.001) predictors of functional change in the model in addition to each of the 6 motor/physical items. It was unexpected to find that the expression item was the first item retained in the model predicting patient change in function, with a contributing adjusted R2 value of .23 for this item alone, thus the expression item predicted 23% of the variance in explaining patient change in overall function from admission to discharge from an inpatient facility. These results clearly support the inclusion of the two cognitive items within the self-care measure and provide evidence that patient self-care includes both physical and cognitive function; the physical aspect is well accepted but the cognitive aspect appears to be less understood, however the results demonstrate the importance of cognitive items when assessing a patient's self-care functional status and change in function from admission to discharge.

## 5. Comparison to Related or Competing Measures

If a measure meets the above criteria <u>and</u> there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

## 5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

## 5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

## 5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures; **OR** 

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

## 5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

Measure 2286 includes 8 self-care items (6 physical and 2 cognitive) rated on a 7 level scale, clinicians rate the patient's lowest actual observed score over the past 24 hour period (if patient is independent with toileting while awake but needs assistance in the middle of the night the rating would be the lowest/middle of the night score for the item), all items are to be rated at admission and at discharge, there are no codes for missing/do not apply. Measure 2633 includes 7 self-care items all of which are physical items, and uses a 6 level rating scale (1-6) which includes options for not assessing each item, thus allows for missing responses (ex. not applicable/ patient refused/ not attempted due to safety). For measure 2633, the patient's usual performance is used as the basis of the score whereby if a patient were independent in toileting during the day but needed assistance in the middle of the night the score would be independent as there would be more frequent independent episodes throughout the day opposed to a single instance over night. The two measures use different rating scales and different assessment rules and when trying to determine a patient's actual level of function, a 6 level scale is less sensitive than a 7 level scale as there is less 'room' to demonstrate change over time captured in the 6 level rating scale. Additionally, if clinicians are using the patient's functional level to determine patient discharge setting, using patient 'usual performance' may portray a higher level of function than truly exists for the patient, whereby if it is believed the patient is independent in certain items but does in fact need assistance at certain times of day or in some instances, and there are not provisions in place to provide the care, the patient is at risk for a fall or readmission to inpatient care if a caregiver or attendant is not with the patient to provide the assistance (such as in the example of toileting used previously). Furthermore, the inclusion of multiple 'missing' options for each item to be allowed for use at admission and at discharge lends the possibility for data that is not able to be interpreted, if an item is not rated at admission because the patient refused but is rated at discharge, of what value is this information? It is unknown if the patient would have been rated the exact same at admission, thus no change actually occurred from admission to discharge, of if there were an improvement, it would not be captured, or if there was a decline in function, this too is unknown, so if an item is not applicable (or not safe for administration at admission) than it lends question as to why it is included in the measure at all and if it is applicable, allowing missing values adds to the

clinical data collection burden without any benefit to the patient as any other values collected cannot be interpreted directly when an item was missing at another point in time (an admission rating but no discharge rating or vice versa). Predictive models at the measure level require complete data so even if one value is missing for one item the entire case is dropped from the analytical model so the facility level outcome data would be impacted by the missing values as well as the patient level outcomes data.

### **5b. Competing Measures**

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); **OR** 

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Measure #2286 is similar to CMS Measure #2633, except Measure #2286 is intended for all patients ages 18 and older receiving post acute care (at an IRF, SNF or LTAC facility) and Measure #2233 is intended for use among Medicare patients only (of which the majority is persons aged 65 and older) receiving care at an IRF. Furthermore, Measure #2286 includes both physical and cognitive functional items whereas Measure #2633 includes only physical items and does not include any items specific to cognitive self-care function. Measure 2286 includes 8 self-care items (6 physical and 2 cognitive) rated on a 7 level scale, clinicians rate the patient's lowest actual observed score over the past 24 hour period (if patient is independent with toileting while awake but needs assistance in the middle of the night the rating would be the lowest/middle of the night score for the item), all items are to be rated at admission and at discharge, there are no codes for missing/do not apply. Measure 2633 includes 7 self-care items all of which are physical items, and uses a 6 level rating scale (1-6) which includes options for not assessing each item, thus allows for missing responses (ex. not applicable/ patient refused/ not attempted due to safety). For measure 2633, the patient's usual performance is used as the basis of the score whereby if a patient were independent in toileting during the day but needed assistance in the middle of the night the score would be independent as there would be more frequent independent. episodes throughout the day opposed to a single instance over night. The two measures use different rating scales and different assessment rules and when trying to determine a patient's actual level of function, a 6 level scale is less sensitive than a 7 level scale as there is less 'room' to demonstrate change over time captured in the 6 level rating scale. Additionally, if clinicians are using the patient's functional level to determine patient discharge setting, using patient 'usual performance' may portray a higher level of function than truly exists for the patient, whereby if it is believed the patient is independent in certain items but does in fact need assistance at certain times of day or in some instances, and there are not provisions in place to provide the care, the patient is at risk for a fall or readmission to inpatient care if a caregiver or attendant is not with the patient to provide the assistance (such as in the example of toileting used previously). Furthermore, the inclusion of multiple 'missing' options for each item to be allowed for use at admission and at discharge lends the possibility for data that is not able to be interpreted, if an item is not rated at admission because the patient refused but is rated at discharge, of what value is this information? It is unknown if the patient would have been rated the exact same at admission, thus no change actually occurred from admission to discharge, of if there were an improvement, it would not be captured, or if there was a decline in function, this too is unknown, so if an item is not applicable (or not safe for administration at admission) than it lends question as to why it is included in the measure at all and if it is applicable, allowing missing values adds to the clinical data collection burden without any benefit to the patient as any other values collected cannot be interpreted directly when an item was missing at another point in time (an admission rating but no discharge rating or vice versa). Predictive models at the measure level require complete data so even if one value is missing for one item the entire case is dropped from the analytical model so the facility level outcome data would be impacted by the missing values as well as the patient level outcomes data.

## Appendix

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment Attachment: Appendix-636824836707822691.pdf

## **Contact Information**

**Co.1 Measure Steward (Intellectual Property Owner):** Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. and its successor in interest, UDSMR, LLC.

Co.2 Point of Contact: Paulette, Niewczyk, pniewczyk@udsmr.org, 716-817-7868-

**Co.3 Measure Developer if different from Measure Steward:** Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. and its successor in interest, UDSMR, LLC.

Co.4 Point of Contact: Paulette, Niewczyk, pniewczyk@udsmr.org, 716-817-7868-

## **Additional Information**

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Margaret DiVita, PhD, UDSMR assisted with the measure testing.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2014

Ad.3 Month and Year of most recent revision: 04, 2019

Ad.4 What is your frequency for review/update of this measure? Unknown, new measure

Ad.5 When is the next scheduled review/update for this measure? 04, 2019

**Ad.6 Copyright statement:** © 2014 Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. All rights reserved.

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: