**TO:** Consensus Standards Approval Committee (CSAC)

**FR:** Marcia Wilson, Helen Burstin and Sarah Sampsel

**RE:** Person- and Family-Centered Care Phase 2 CSAC Review and Approval (CARE and FIM IRF Measures)

**DA:** September 1, 2015

**CSAC ACTION REQUIRED**

**The CSAC is being asked to reconsider the remaining competing Inpatient Rehabilitation Facility (IRF) measures under Person- and Family-Centered Care Phase 2 (PFCC-2) in a broader policy context, as requested by the Board of Directors. It is recommended that the measures be endorsed with special update requirements for the following four measures from both measure stewards. (**See Appendices A, B and C for additional measure level detail.)

- Approval of endorsement for the following four measures:
  - 2633: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (CMS)
  - 2634: IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (CMS)
  - 2286: Functional Change: Change in Self Care Score (UDSMR)
  - 2321: Functional Change: Change in Mobility Score (UDSMR)
- Endorsement with conditions for specific updates from each measure developer to address concerns raised during the measure reviews by the Standing Committee and CSAC.

**BACKGROUND**

The Board of Directors reviewed the recommendations of the CSAC and the rationale for non-approval of two of the measures. The Board provided greater policy context including the importance of the IMPACT Act enacted in 2014 and the need for aligned measures that can be used to assess care across settings. The Board therefore directed NQF staff to return the four competing IRF measures in question back to the CSAC for further consideration. (See Appendix B for a side by side comparison of the competing measures.). In addition, the Board expressed concerns regarding measures derived from proprietary versus non-proprietary instruments, and the desirability of having measures that help assess quality improvement from the patient's perspective as he/she moves among multiple sites of care

As was true at the June CSAC meeting, there were extensive public comments made during the Board meeting. The FIM tool proponents primarily focused on concerns around the sensitivity of the CARE tool measures, the burden of having to report on two sets of measures for the same setting and the concerns about having to use a new tool (CARE) after providers have built considerable infrastructure (e.g., staff training, software) to collect data with the FIM Instrument. The CARE tool proponents supported measures developed from the CARE tool because they recognize the importance of all providers moving to just one tool and they supported the CMS' decision to use the CARE tool across multiple settings. Additionally, proponents supported the use of a non-proprietary assessment tool generally.

**CONSENSUS PROCESS TO DATE:**

These four measures were recommended for endorsement by the Standing Committee after considerable public comment, member voting and additional information provided by measure developers. (Appendix C provides themes from the public comments.) The Standing Committee was unable to select a best-in-class for either set of competing measures (#2633 versus 2286 and #2634 versus 2321). The two UDSMR measures (#2286 and 2321) were recommended for endorsement with 71% of councils approving. The councils were unable to reach consensus for the two CMS measures (#2633 and 2634) with only 56% of councils approving the measures.

The CSAC voted to recommend the two UDSMR measures, while the two CARE tool measures only received 56% approval (below the required 60% threshold for CSAC approval). Based on the rationale provided by CSAC members, the CMS IRF measures were not approved largely due to competing measure concerns.

**CSAC CONSIDERATIONS:**

Approval of endorsement for the following four measures with conditions for specific updates:

- 2633: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (CMS)
- 2634: IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (CMS)
- 2286: Functional Change: Change in Self Care Score (UDSMR)
- 2321: Functional Change: Change in Mobility Score (UDSMR)

Update Requirements:

| UDSMR | CMS |
|---|---|
| • Provide information about how the inclusion or exclusion of cognitive items impacts the overall assessment of the patient.<br>• Provide updated measure level testing for reliability and validity given that all the measures are new. There is particular interest in measure performance/scientific acceptability across care settings beyond IRF.<br>• Provide information about costs associated with use of the FIM Instrument, respective software and tools; and costs of ongoing training in order to accurately use the FIM Instrument. | • Provide information about how the inclusion or exclusion of cognitive items impacts the overall assessment of the patient.<br>• Provide updated measure level testing for reliability and validity given that all the measures are new and will be implemented in 2016.<br>• Provide data on comparison of the competing measure results to gain an understanding of which scale is more reliable, valid and feasible.<br>• Provide a summary of qualitative data gathered during rule-making process including perceived benefits from the field for instruments that cut across settings. |

If the CSAC agrees to endorsement of the four measures with these conditions, NQF staff will work with the developers to establish firm deadlines for submission of the required information and incorporate the findings into the Standing Committee work plan for future phases of work.

**Should the CSAC choose not to approve the above recommendation, the following two options are available:**

- Vote to uphold the original recommendation, which would mean the two Inpatient Rehabilitation Facility measures using the CARE tool, 2633 and 2634, would not be endorsed.

- Vote to reverse the original recommendation, and vote for measures 2633 and 2634 as "best in class" and deny endorsement to the pair of competing measures, 2286 and 2321, which use the FIM assessment tool.

**Appendix A: Additional Measure Level Detail for Four Candidate Consensus Standards**

| Measure | Steward | Committee Recommendation and Member Votes for Approval | Type of Measure | Measure* Setting of Care - Level of Analysis | Assessment tool Used | Standing Committee History/Considerations |
|---|---|---|---|---|---|---|
| **2286: Functional Change: Change in Self Care Score (new)** | UDSMR | Committee: Recommended<br>% Councils Approving: 71%<br>% CSAC Approving (original vote): 100% | Outcome | IRF – Facility | FIM® Instrument | Measure recommended at In-Person Meeting; while additional information not required, the Committee requested disparities data (data for race, age, payer); intra-class co-efficient at the facility level; and mean fit statistics. |
| **2321: Functional Change: Change in Mobility Score (Uniform Data System for Medical Rehabilitation) (new)** | UDSMR | Committee: Recommended<br>% Councils Approving: 71%<br>% CSAC Approving (original vote): 100% | Outcome | IRF – Facility | FIM® Instrument | Measure recommended at In-Person Meeting; while additional information not required, the Committee requested disparities data (data for race, age, payer); intra-class co-efficient at the facility level; and mean fit statistics. |
| **2633: Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (new)** | CMS | Committee: Recommended<br>% Councils Approving: 57%<br>% CSAC Approving (original vote): 56% | Outcome | IRF – Facility | CARE Item Set | Consensus Not Reached on Reliability and Validity at In-Person Meeting. Additional information was provided on reliability, validity and performance at the facility level and the Committee subsequently recommended the measure for endorsement. |

| Measure | Steward | Committee Recommendation and Member Votes for Approval | Type of Measure | Measure* Setting of Care - Level of Analysis | Assessment tool Used | Standing Committee History/Considerations |
|---|---|---|---|---|---|---|
| **2634: Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation** | CMS | Committee: Recommended<br>% Councils Approving: 57%<br>% CSAC Approving (original vote): 56% | Outcome | IRF– Facility | CARE Item Set | Measure recommended at In-Person Meeting. No additional information requested from the developer for clarification of NQF criteria. |

*Note: While the assessment tools (or item sets) used to calculate these measures may be used in more than one setting, the Standing Committee evaluated and recommended endorsement based on the MEASURE submission form and information provided in the measure description, evidence, rationale, etc. As with the measures submitted for specific settings utilizing the CARE Item Set, UDSMR has been advised to prepare new measure submissions for settings of care beyond IRFs for the FIM tool.

**Appendix B: Side By Side Comparisons of the Competing Measures**

**Measure Focus: Self-Care**
**Target Population: Inpatient Rehabilitation Facilities**

| | 2633: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients | 2286: Functional Change: Change in Self-Care Score |
|---|---|---|
| **Steward** | CMS | UDSMR |
| **Brief Description** | This measure estimates the risk-adjusted mean change in self-care score between admission and discharge for Inpatient Rehabilitation Facility (IRF) Medicare patients. | Change in rasch derived values of self-care function from admission to discharge among adult patients treated at an inpatient rehabilitation facility who were 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. |
| **Measure Type** | Outcome | Outcome |
| **Measure Data Source/tool** | Electronic Clinical Data Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). CARE tool | Electronic/ FIM® Instrument |
| **Reporting Level** | Facility | Facility |
| **Care Setting** | Post Acute/Long Term Care Facility : Inpatient Rehabilitation Facility | Inpatient Rehab (per measure description); FIM used in broader settings: Home Health, Post Acute/Long Term Care Facility : Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing |

| | 2633: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients | 2286: Functional Change: Change in Self-Care Score |
|---|---|---|
| | | Facility |
| **Time Window** | 12 months | 12 months |
| **Numerator** | This measure estimates the risk-adjusted change in self-care score between admission and discharge among Inpatient Rehabilitation Facility (IRF) Medicare patients age 21 or older. The change in self-care score is calculated as the difference between the discharge self-care score and the admission self-care score.<br><br>The 7 self-care items are:<br>GG 0130A. Eating<br>GG 0130B. Oral hygiene<br>GG 0130C. Toilet hygiene<br>GG 0130D. Shower/bathe self<br>GG 0130E. Upper body dressing<br>GG 0130F. Lower body dressing<br>GG 0130G. Putting on/taking off footwear | Average change in rasch derived self-care functional score from admission to discharge at the facility level, including items: 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<br>• Feeding,<br>• Grooming,<br>• Dressing Upper Body,<br>• Dressing Lower Body,<br>• Toileting,<br>• Bowel,<br>• Expression,<br>• and Memory) / total number of patients). |
| **Denominator** | The denominator is Inpatient Rehabilitation Facility Medicare patients, age 21 and older, Medicare beneficiaries who have complete stays. | Facility adjusted expected change in rasch derived values, adjusted at the Case Mix Group level. 18 and older; alive at discharge |

**Measure Focus: Mobility**
**Target Population: Inpatient Rehabilitation Facilities**

| | 2321 Functional Change: Change in Mobility Score | 2634 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients |
|---|---|---|
| Steward | UDSMR | CMS |
| Brief Description | Change in rasch derived values of mobility function from admission to discharge among adult inpatient rehabilitation facility patients aged 18 years and older who were discharged alive. The timeframe for the measure is 12 months. The measure includes the following 4 mobility FIM® items: Transfer Bed/Chair/Wheelchair, Transfer Toilet, Locomotion and Stairs. | This measure estimates the mean risk-adjusted mean change in mobility score between admission and discharge for Inpatient Rehabilitation Facility (IRF) Medicare patients. |
| Measure Type | Outcome | Outcome |
| Measure Data Source/tool | Electronic Clinical Data : Electronic Health Record FIM® Instrument | Electronic Clinical Data Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). CARE tool |
| Reporting Level | Facility | Facility |
| Care Setting | Inpatient Rehab (per measure description); FIM used in broader settings: Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility | Post Acute/Long Term Care Facility : Inpatient Rehabilitation Facility |
| Time Window | 12 months | 12 months |

| | 2321 Functional Change: Change in Mobility Score | 2634 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients |
|---|---|---|
| **Numerator** | Average change in rasch derived mobility functional score from admission to discharge at the facility level. Includes the following FIM items:<br>• Transfer Bed/Chair/Wheelchair,<br>• Transfer Toilet,<br>• Locomotion and<br>• Stairs. | This measure estimates the risk-adjusted change in mobility score between admission and discharge among Inpatient Rehabilitation Facility (IRF) patients age 21 and older. The change in mobility score is calculated as the difference between the discharge mobility score and the admission mobility score.<br>The 15 mobility items are:<br>GG 0170A. Roll left and right<br>GG 0170B. Sit to lying<br>GG 0170C. Lying to sitting on side of bed<br>GG 0170D. Sit to stand<br>GG 0170E. Chair/bed-to-chair transfer<br>GG 0170F. Toilet transfer<br>GG 0170G. Car transfer<br>GG 0170I. Walk 10 feet<br>GG 0170J. Walk 50 feet with 2 turns<br>GG 0170K. Walk 150 feet<br>GG 0170L. Walking 10 feet on uneven surfaces<br>GG 1070M. 1 step<br>GG 0170N. 4 steps<br>GG 0170O. 12 steps<br>GG 0170P. Pick up object |
| **Denominator** | Facility adjusted adjusted expected change in rasch derived values, adjusted at the Case Mix Group level. 18 and older; alive at discharge | Inpatient Rehabilitation Facility patients included in this measure are at least 21 years of age, Medicare beneficiaries, are not independent with all of the mobility activities at the time of admission, and have complete stays. |

**Appendix C: Themes from Public Comment**

In addition to the two sets of competing measures, the CSAC also voted on eight additional measures. Out of these twelve measures, three were derived from the FIM® Instrument for use in an Inpatient Rehabilitation Facility and nine were derived from the CARE tool for use in different settings including Inpatient Rehabilitation Facility. There were a number of comments received during the Public Comment period on the June 9th CSAC call. Many of the comments covered issues that had previously been raised either by the Standing Committee during measure evaluation or during the Public Comment period, and can be summarized as follows:

1. **Sensitivity of the CARE tool:** The overarching concern from the provider community is that the CARE tool is not sensitive enough to assess improvement in patients, and with this lack of sensitivity at the patient level there was question about impact on the overall measure. The Standing Committee conducted a detailed review of data at both the scale/item level and subsequently at various facility levels for each of the measures, regardless of the assessment tool used. They did not perceive a concern with the sensitivity testing conducted at the CARE item set. CMS and their measure development contractors re-iterated substantial testing at both levels of analysis (item and facility) that indicated the ability to discriminate between facilities. Additional measures based on the CARE Item Set, but developed by the American Health Care Association (AHCA), were supported by data that demonstrated sensitivity at both the item and facility levels. The measure developers have provided detailed responses on this issue in the attached memos. CMS response is located at this link and AHCA response can be found at the following link.
2. **Measurement Burden**: As indicated above, having multiple measures with the same focus and designed for the same care settings is expected to cause substantial burden on facility staff; this was a consideration by the Standing Committee and is part of the rationale for inability to reach consensus regarding harmonization or determination of best in class measures. The discussion around burden of measurement centered around the collection of the following assessment tools/item sets:
    a. The FIM System® is a an outcomes management program for skilled nursing facilities, sub-acute facilities, long-term care hospitals, Veterans Administration programs, international rehabilitation hospitals, and other related venues of care. While the FIM® has been collected for some time, the measures submitted for this project (#2286, 2287 and 2321) are considered new for endorsement. It should also be noted that the measures submitted, while potentially applicable for additional settings, were only considered for IRFs. The measure submission forms, including measure titles, descriptions, rationale and evidence provided were specific to IRFs, thus the Committee was directed to only consider that setting.
    b. CARE Item Set: As a part of the Medicare Post-Acute Care Payment Reform Demonstration (PAC-PRD), a standardized patient assessment tool was developed for use at acute hospital discharge and at post-acute care admission and discharge. This tool was named the Continuity Assessment Record and Evaluation (CARE) Item Set. Data collected using the CARE Item Set served as a major source of information in the demonstration. The CARE Item Set measures the health and functional status of Medicare beneficiaries at acute discharge, and measures changes in severity and other outcomes for Medicare post-acute care patients. The CARE Item Set is designed to standardize assessment of patients' medical, functional, cognitive, and social support status across acute and post-acute settings,

including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and home health agencies (HHAs). The goal was to standardize the items used in each of the existing assessment tools while posing minimal administrative burden to providers. Nine (9) measures were submitted to this project, and are based on data derived from use of the CARE tool.

3. **Measure Gaps**: The Standing Committee and public comments expressed the need and interest in measures that focus on patient stabilization, when improvement is not the goal of treatment; and also for measures more directly related to patient goals versus treatment goals.