Technical Expert Panel Summary/Expert Input Report (Second Convening)

Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data

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Charlayne Van, COR
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1. Introduction and Overview

1.1 Introduction

The RAND Corporation, on behalf of the Centers for Medicare & Medicaid Services (CMS), convened a Technical Expert Panel (TEP) on January 5 and 6, 2017 to seek expert input on the development of Post-Acute Care (PAC) cross-setting standardized patient assessment data with a focus on Home Health Agencies (HHAs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Skilled Nursing Facilities (SNFs). The January 2017 meeting convened this TEP for a second time in-person in Baltimore, Maryland.The first TEP meeting, held in April 2016, is summarized in the report: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/RAND-IMPACT-TEP-Report-Final-Rev.pdf. A critical component of RAND's work on the development and maintenance of PAC cross-setting standardized patient assessment data is stakeholder involvement, of which the TEP is one component. The development and selection of data elements are guided by a consensus-based process involving expert input from PAC health care professionals across the country.

This report provides a summary of the TEP proceedings from the January 2017 meeting, detailing key issues of standardized patient assessment data development and the TEP's discussion around those issues. In this chapter, we provide background information on the larger project, describe the process used to identify TEP members and the process of the TEP meeting, and outline the organization of the remainder of this report.

1.2 Background

The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act of 2014) requires CMS to develop, implement, and maintain standardized patient assessment data elements for PAC settings to facilitate care coordination, interoperability, and improve Medicare beneficiary outcomes.[1] The types of providers covered by the IMPACT Act of 2014 include HHAs, IRFs, LTCHs, and SNFs.

Existing PAC assessment instruments by setting include the: Outcome and Assessment Information Set (OASIS) for HHAs; Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs; LTCH CARE Data Set (LCDS) for LTCHs; and Minimum Data Set (MDS) for SNFs. With few exceptions, the data elements used in these assessments are not

[1] https://www.govtrack.us/congress/bills/113/hr4994

currently standardized or interoperable. While each assessment instrument collects data elements pertaining to similar concepts, the individual items — questions and response options — vary by assessment instrument.. As a result, comparisons across the assessment instruments are not always possible. Implementation of a core set of standardized assessment items across PAC settings for the currently used assessment instruments will enable fuller comparability of PAC assessment data and has important implications for Medicare beneficiaries, families, providers, and policymakers alike.

CMS has contracted with the RAND Corporation (contract no. HHSM-500-2013-13014I) to develop standardized assessment data elements for PAC settings that meet the requirements of the IMPACT Act of 2014. Standardized assessment items will contribute to assessment data comparability across PAC providers, data exchange and interoperability, care coordination, payment analysis, and longitudinal outcome analysis. The categories and domains in the IMPACT Act that guide data item standardization within this contract include: cognition and mental status; medication reconciliation; care preferences; pain (medical condition); and impairments in hearing, vision, and continence. As part of its data element development efforts, CMS requires that contractors convene groups of stakeholders and experts who contribute direction and thoughtful input on the development of this work. As a part of this process, RAND convened a set of advisors to assist in identifying data elements that could be standardized across all four PAC assessment instruments. In addition to convening the TEP, RAND conducted literature reviews, focus groups, and case studies to inform its work. These activities are reported on elsewhere.

The objective of the January 2017 TEP meeting was to review and comment on candidate standardized patient assessment data elements for selected categories and domains named in the IMPACT Act of 2014, to consider and discuss possible future direction of standardized assessment data in those categories and domains, and to identify optimal directions for pilot testing of candidate data elements.

1.3 Organization of the Report

This TEP summary report describes the process of convening the TEP in 2016 and provides details about the structure and content of the January 2017 TEP meeting (Section 2), then summarizes the feedback obtained from TEP members during discussions and from the ratings that were obtained from participants after each day of the meeting in Sections 3 through 9. The summaries address the topics of Cognitive Function and Mental Status; Behavioral Signs and Symptoms; Observational Assessments for Patients Who Are Unable to Communicate: Cognition, Mood, and Pain; Medication Reconciliation; Special Services, Treatments, and Interventions; Care Preferences; and PROMIS Profile Score for health-related quality of life. Each section offers the background and rationale for the importance of assessing the topic in

PAC settings, reports on the TEP's discussion, and summarizes the ratings given by the TEP on potential assessment data elements.

2. About The Technical Expert Panel (TEP) Meeting

2.1 TEP Nomination Process

To support RAND's work for CMS, a call soliciting for technical experts was posted on the CMS Measure Management Public Comment webpage on February 8, 2016, in order to find individuals who would be able to add input on the development and testing of standardized patient assessment data elements for use in PAC. The TEP solicitation included a call for participants with a diverse range of perspectives and areas of expertise within the four PAC settings as outlined in the IMPACT Act of 2014: HHAs, IRFs, LTCHs, and SNFs.

Individuals who were nominated or self-nominated were instructed to complete the nomination form, which asked for the individual's current title/professional role, credentials, organizational affiliation and/or employer, role (recent PAC patient, family member of PAC patient, advocate, other consumer, provider or staff, administrator, regulator, purchaser, researcher, and/or organizational employee), and the PAC settings in which they have experience (HHA, IRF, LTCH, or SNF). Additionally, they were asked to include a short biographical statement and, for applicants other than consumers and family caregivers, a curriculum vitae.

The nomination period closed on February 19, 2016. RAND received 117 nominations. Nominees came from 94 different organizations from across 34 states, and they represented a variety of disciplines, experience, and reported expertise across the spectrum of PAC.

2.2 TEP Selection Process

After the close of the nomination period, RAND finalized the TEP composition by selecting 17 nominees who offered a diverse range of clinical, research, consumer, and administrative expertise in the subject areas to be discussed at the TEP (cognitive status, medication reconciliation, care preferences, pain, hearing and vision, and continence), including expertise in one or more PAC settings. Nominees were invited to participate in the TEP based on their content expertise, experience in PAC, and disciplinary perspective. The TEP was constructed purposefully to balance representation of individual disciplines, experience, and PAC settings. The membership also reflected geographic and organizational diversity, as well as the variety of organization types that may have an interest in the topic. Two of the selected nominees were not available to attend the first meeting of the TEP in April 2016. In addition, a consumer representative, who is an advocate for people with disabilities, participated in the TEP. The process resulted in a 16-member panel that convened for the April 2016 meeting (that roster is available in the report of that meeting: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/RAND-IMPACT-TEP-Report-Final-Rev.pdf.

When the TEP was reconvened for a second meeting (January 2017), five of the original members were not able to attend, three due to prior commitments and two due to last-minuteconflicts. To maintain the balance of PAC setting and disciplinary perspectives, we invited three additional panelists, noted in the table below with asterisks. Two of the three additional panelists were nominated in the original call for participants, but were not invited at that time because their skills and experience overlapped with other members. The other additional panelist was referred by a TEP member who was unable to attend. Table 1 provides the list of TEP members present at the January 2017 meeting; brief biographies of each member are available in Appendix A. Table 1.

	Name, Credentials, Professional Role	Organizational Affiliation, City, State	PAC setting(s)	Role/Area of Expertise
1	**Susan Battaglia, RN-BC, RAC-C** Director of Case Mix Management	**Tara Cares**; NGNA; AANAC Orchard Park, NY	SNF	Patient assessment, workforce, QI
2	**Janet Brown, MA CCC-SLP*** Director, Health Care Services in Speech Language Pathology	American Speech-Language-Hearing Association Rockville, MD	HH, IRF, LTCH, SNF	Hearing and vision assessment
3	**Judy Elmore, BS** Vice President, Ancillary Operations	Covenant Healthcare Aliso Viejo, CA	HH, SNF	Administrator: Workforce, QI, Health Information Technology
4	**Janet Herbold, PT, MPH, CHC** Senior Administrator and Corporate Compliance Officer	Burke Rehabilitation Hospital White Plains, NY	IRF	Provider/Administrator patient assessment, care transitions
5	**Kathleen Lawrence, MSN, RN, CWOCN** Wound Ostomy Continence Program Manager	Rutland Area Visiting Nurse and Hospice Rutland, VT	HH, IRF, LTCH, SNF	Provider: care preferences, pain, workforce
6	**Natalie Leland, PhD, OTR/L, BCG, FAOTA** Assistant Professor	University of Southern California; Los Angeles, CA	IRF, SNF	Care preferences, QI, HIT
7	**Cheryl Phillips, MD*** Senior VP Public Policy and Health Services	Leading Age Washington, DC	SNF, IRF, HH	Administrator: QI, performance measurement, patient assessment process
8	**Marc Rothman, MD** Senior VP & Chief Medical Officer	Kindred Healthcare; Louisville, KY	HH, IRF, LTCH, SNF	Provider: QI, workforce, care transitions
9	**Chloe Slocum, MD** Physical Medicine and Rehabilitation Physician	Spaulding Rehabilitation Hospital, Sandwich, MA	HH, IRF	Provider: pain assessment, performance measurement, medication reconciliation

10	**Peter W. Thomas, JD** Principal	Powers Pyles Sutter & Verville PC; Washington, DC	HH, IRF, LTCH, SNF	Consumer
11	**Barbara Thomsen, CDM, CFPP, RAC-CT** MDS/Case Mix Audit Specialist and Quality Assurance	Hawkeye Care Centers, Norwalk, IA	HH, IRF, LTCH, SNF	Provider: patient assessment, performance measurement
12	**John Votto, DO, FCCP*** President & CEO	Hospital for Special Care, Inc. New Britain, CT	LTCH	Administrator: patient assessment, performance measurement
13	**Michael Wasserman, MD, CMP** Director, Nursing Home QIN-QIO	Woodland Hills, CA	HH, LTCH, SNF	Provider: QI, care transitions
14	**Kathleen Witcoskie, RN** Vice President	Visiting Nurse Association of American Health Systems Shamokin, PA	HH, LTCH, SNF	Research/ academic: QI, health care disparities

*Denotes a member of the TEP who was not present at the April 2016 convening.

2.3 In-Person TEP Meeting

TEP members were asked to review meeting materials (TEP Notebook) sent two weeks in advance of the in-person meeting. The TEP Notebook was organized by topic into chapters. Each chapter included:

- Summary of main points of the chapter
- Background and rationale for including content area in standardized assessment
- Preliminary results of Alpha 1 field testing (if applicable)
- Description of data elements under consideration for standardized assessment
- Reflection and discussion questions for TEP members

The two-day, in-person meeting took place in Baltimore, Maryland, on January 5th and 6th, 2017 (see Appendix B for meeting agenda). For data elements previously reviewed by the TEP that had gone through Alpha 1 Feasibility testing, RAND was interested in feedback on the acceptability of any changes being proposed to the data elements, as well as the continued feedback on suitability of these data elements for cross-setting standardization in PAC. For data elements new to the TEP, RAND requested feedback and discussion on the following key topics:

- **Potential for improving quality**, which includes consideration of the data element's ability to improve care transitions through meaningful exchange of data between providers; improve person-centered care and care planning; be used for quality comparisons; and support clinical decision-making and care coordination;
- **Validity**, which includes consideration of the data element's proven or likely inter-rater reliability (i.e., consensus in ratings by two or more assessors) and validity (i.e., whether it captures the patient attribute being assessed);
- **Feasibility for use in PAC**, which includes consideration of the data element's potential to be standardized and made interoperable across settings; clinical appropriateness; and relevance to the work flow across settings;
- **Utility for describing case mix**, which includes whether the data element could be used with different payment models, and whether it measures differences in patient severity levels related to resource needs.

The meeting was audio recorded and transcribed for the purpose of summarizing TEP proceedings in this report.

2.4 Rating Worksheet

RAND created two online rating forms ("rating sheets") for the TEP to complete electronically, one for each day of discussion. The web-based format was intended to facilitate TEP members' completion of the forms, allow ample space for written-in feedback, and facilitate data entry and analysis. After each day of the TEP meeting, a unique link to the rating forms was emailed to each TEP member. The rating forms included separate sections for each of the following discussion topics: Cognitive Status; Behavioral Signs and Symptoms; Observational Assessments; Medication Reconciliation; Care Preferences; and the PROMIS Profile Items. As an example, Appendix C contains a screen shot of some of the questions from the Behavioral Signs and Symptoms rating sheet.

RAND developed the rating sheets to obtain individual TEP participants' assessments and concerns regarding potential data elements. The rating sheets instructed TEP participants to evaluate the potential data elements on a scale from *excellent* to *poor* on each of the following dimensions:

- Validity
- Reliability
- Feasibility
- Utility for case mix
- Potential for improving quality

In addition to assessing data elements according to the above rating dimensions, TEP members were asked to rate data elements based on their cross-setting applicability (i.e., to what extent each data element is applicable across the four PAC settings), on a scale of *not applicable* to *highly applicable*. Rating sheets also included some questions that were specific to certain

topics, such as Cognition. Write-in space was provided on the rating sheets for TEP members to add comments to supplement their ratings.

TEP members were advised to complete their rating sheets as soon as possible, and all of the TEP members submitted their forms. However, not all TEP members provided ratings for each data element.

The subsequent sections of this report includes descriptive summaries of the ratings for data elements by discussion topic.

3. Cognitive Function and Mental Status: Cognition

3.1 Background and Rationale

Patients and residents in PAC settings are at risk for a number of cognitive impairments that can affect one's ability to recover from treatment and impact nearly every aspect of one's life. Conducting cognitive assessments is critically important in order to: (1) screen for cognitive impairment, (2) rate severity of disorder, and (3) develop a care plan and monitor progression. Cognitive impairments cover multiple subdomains (e.g., memory, reasoning, orientation, calculation, language, knowledge), which may be challenging to assess in some PAC settings. However, as is true for all assessments, care must be taken not to over-burden patients or residents and staff.

A summary of Year 1 Progress, including feedback received during the public comment period in August/September 2016 and the results of the Alpha 1 phase of feasibility testing, was presented to the TEP. Data elements being proposed for consideration in the Alpha 2 phase of feasibility testing were then presented, with time for discussion among the panel. These data elements were chosen to address gaps in assessment of executive function, capacity to perform everyday activities, patient judgment and safety, and differentiation of mild cognitive impairment from intact cognition. The data elements included a subset of items from the Developing Outpatient Therapy Payment Alternatives (DOTPA) Continuity Assessment Record and Evaluation (CARE) tool; the Menu Task; the Performance Assessment of Self-Care Skills (PASS) Medication Management Task; brief screeners of attention, auditory comprehension, and executive function; the Fall-Related Impulsive Behavior Scale (FIBS); and self-reported cognition and anxiety items from the PROMIS® item library. Images of these data elements can be found in Appendix D1.

Due to the volume of data elements under consideration for cognitive status and mental function, discussion of data elements related to cognition spanned several time slots of the TEP meeting. This section of the report summarizes the feedback received on performance or interview-based potential data elements for patients/residents who are able to communicate. Section 5 of this report, "Observational Assessments," summarizes feedback on the potential data elements for patients/residents who are unable to communicate.

3.2 Summary of TEP Discussion for Cognition

TEP members had a robust discussion regarding the importance of staying focused on the purpose and limitations of the charge they were given (i.e. to identify the best candidate items to supplement existing standardized assessment of PAC patient/resident cognition); amid so many high-quality data elements and given the complexity of cognitive function, members discussed

the need to be practical and mindful of the goals of standardized assessment, including keeping in mind what will be done with the data collected. They cautioned against trying to do too much because of potential patient/resident and clinician burden, and sought to narrow down or better focus the scope of what should be assessed with these items (e.g., executive function vs. functional assessment vs. cognitive function). TEP members stressed the need for the chosen data elements to address the gaps in what is currently being assessed so that providers may be aware of issues or behavior that could threaten patient safety, such as impulsivity which could lead to falls. One person mentioned the need to choose data elements that can identify patients/residents with mild cognitive impairment, as they might be the most likely to be discharged, whereas another questioned whether such information is useful if there is no course of treatment to offer. Others commented on the fact that patients/residents in PAC settings can have divergent needs: some might be undergoing treatment in order to be discharged to their home or a home-like setting, whereas other PAC patients/residents may not be candidates for discharge from higher-intensity care settings.

Many expressed concern over the burden of assessment on both providers and patients/residents. There was agreement that the selection of items to supplement the Brief Interview of Mental Status (BIMS) and the Confusion Assessment Method (CAM), for cross-setting assessment, should be strategic, with a goal of adding only a small number of data elements that returned new (non-duplicative), reliable, and necessary (e.g. useful for care planning and care transitions), information about patients/residents. Many were concerned that patients/residents might simply refuse to participate if too many questions overwhelmed them, or if assessments were conducted too frequently, particularly among those without cognitive impairment. Such burnout could affect the validity of assessments as well, one person commented. Panelists also stressed the importance of avoiding overlap, whether from other IMPACT Act of 2014–related efforts being implemented (e.g., function measure) or from setting-specific assessment tools with similar data elements already included. Some expressed the wish that procedures be developed to allow providers to skip data elements that seem less relevant to a particular patient's situation (e.g., patients who are not expected to be discharged home might be exempt from assessments of cognition that focus on independent management of medication or safety and judgment items).

Some TEP members generally questioned the use of data elements that rely on assessor observation and judgment (e.g., the DOTPA CARE tool items), and the reliability of such instruments that might yield different results from different assessors. A preference for performance-based (functional) tasks was expressed. Regardless of the type of assessment – of cognition and other areas – some TEP members reminded the group that basic hearing and vision impairments could be a confounding factor in a patient's performance, especially if not previously known or documented.

A presenter responded to these concerns by advising the TEP to consider which items pose the least amount of burden, are most likely to identify safe discharge, are able to help indicate the

next treatment setting, and focus on assessing executive function. She went on to reiterate that once the possible data elements have been evaluated, then decisions could be made on how to integrate with what already exists, and what "skip patterns" might allow for tailoring to certain situations, among other implementation concerns.

Specific comments on the data elements presented appear below. In addition to the in-person discussion, the TEP members rated the data elements' validity, reliability, feasibility, utility for case mix, and potential for improving quality (with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5); aggregate (i.e., overall) scores of these ratings are provided. (See Section 2.4 for more detail on ratings). The majority of the Cognition data elements received overall scores of 3 or above, which fall into the mid to high range of possible scores.

The TEP also evaluated the cross-setting applicability of the data elements (i.e., to what extent each data element is applicable across the four PAC settings), with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5. For cognition, TEP members were also asked to rate the importance of the data elements, with a scale from not important to very important, and to rank the data elements in order of priority from 1 to 7, where 1 is the *highest priority* and 7 is the *lowest priority*. In addition, the panel was asked whether the value of each data element exceeds the burden of administration to both patient/resident and clinician. Highlights of these ratings are also shown below.

DOTPA CARE Tool Items

One participant commented on this data element's history, mentioning that it both fills a gap by assessing functional performance and helps determine the level of assistance that may be needed at the next site of care. Because this data element is completed based on staff observation, this commenter suggested it should be paired with a performance-based measure, such as the PASS Medication Management Task. The participant also explained that the data elements were intended to be completed following a performance-based assessment to serve as a summary of the patient's/resident's performance. A different panelist commented that a shorter version of the DOTPA could help clinicians assess what steps are necessary in the next 24 hours to address patient functioning.

Another TEP member had difficulty seeing the utility of this assessment after doing functional screening, and there was some concern about the reliability of assessments conducted by different assessors.

In the TEP members' ratings, the DOTPA received an overall score of 3.1, which indicates that it was somewhat supported by the TEP. However, compared with other data elements, it was not highly recommended. In fact, it received the third-lowest overall rating of all of the Cognition data elements.

The Menu Task

Considerable discussion surrounded the cultural component of the food options listed in the example for this data element. One TEP member expressed strong concern over the ethnic and cultural sensitivity of the foods chosen and inquired whether the types of foods and meal schedules had been tested among diverse populations. Another questioned the use of the word "healthy," which can mean different things to different cultural groups.

One of the task's developers was able to speak to the cultural concern, saying that the food choices could be adjusted to be more relevant to any given population, and that the development team has begun testing the task with an African American population recently, with other populations to be tested soon. She went on to say that the task's development team is validating the task against other cognition measures, and she urged the TEP to focus on the process of the task and its purpose in screening for issues with a patient's executive functioning, rather than the food content in the example. The TEP member most concerned about the cultural sensitivity of the test questioned whether there might be too many cultural settings against which to fully test this type of task.

A different TEP member expressed support for this data element, stating that, despite the task's limitations, the cultural concerns could be managed. Another acknowledged that, even after addressing cultural issues, one would want to be able to compare results across populations.

Another TEP member raised a concern about the reading level necessary to complete this task, and pointed out that basic vision impairment could be a confounding factor.

The TEP members' ratings showed that the TEP panelists were largely unsupportive of the Menu Task. The data element received the least favorable rating by the TEP, with an overall rating of 2.5, and also received the lowest cross-setting applicability score, with a score of 2.6. Furthermore, the ratings of value for the Menu Task were the lowest, with 85 percent of TEP members indicating its value did not outweigh its burden of administration.

PASS Medication Management Task

TEP members generally agreed that this data element would be a useful addition to the existing cognitive assessments, although one person questioned whether the task would be relevant in care settings where patients do not manage their own medications. At least one person mentioned that shortening the tool would be a good idea, to reduce the overall burden of assessment and to help focus assessment on functional aspects of cognition. One member saw clinical relevance in PASS and preferred it to the Menu Task. Another commented that patients/residents would find this task relevant if they were preparing to be discharged.

In their ratings, the TEP showed support for the PASS. The data element received an overall rating of 3.7, and it was rated highest in terms of prioritization and importance in assessing cognition.

Brief Screeners

The initial comments on the brief screeners were positive with TEP members commenting that brief screens, as opposed to long assessments, would be less burdensome and allow for later in-depth assessment of patients/residents who might have problems passing one or more of the screening tasks. The presenter confirmed the testing has occurred in the legacy measures from which these items were drawn, though little data were available yet about the collections of items as stand-alones themselves. Several TEP members expressed support for the objectivity and clarity of the questions in the brief screeners, citing that they leave little room for misinterpretation and that they can be translated easily into other languages. One member thought these would be particularly useful for patients/residents experiencing delirium, and felt the burden of using them for screening to be very low.

In contrast, one TEP member expressed concern about the validity of the brief screeners because their performance characteristics are based on the larger assessments from which they were drawn. Another agreed, citing that they have not been validated outside their use in the larger assessment, and therefore may not be able to reliably differentiate, for example, cognitive impairment from language impairment. A RAND team leader responded that the validity would be tested with the national Beta sample if the screeners were chosen and performed well in Alpha 2 feasibility testing. One TEP member reiterated concerns about the validity, reliability, and feasibility, as well as whether the screeners could address the level of supervision needed. This person questioned whether the screeners have practical applicability beyond identifying cognitive deficiencies.

Another panelist questioned how the data gathered would be used, and whether the screeners would be applicable across all settings (particularly home health). One participant believed the screeners would be useful in a home health setting as a way to quickly ascertain level of cognitive function, but would not be useful for transferring information across care settings.

In the TEP members' ratings, the brief screeners as a whole received an overall rating of 3.7, which is indicative of "good." Ratings of the individual screeners were very close to the overall score; the highest rated screener, Attention – Auditory Comprehension, received a score of 3.9, and the lowest rated, Executive Function – Convergent Thinking, received a score of 3.6.

FIBS – Fall-Related Impulsive Behavior Scale

TEP members commented on being intrigued or curious about this data element, and generally thought it would be potentially clinically useful. One TEP member thought the FIBS could be promising in the home health context, with some adjustment to the wording to make it more applicable to that setting. Others expressed the importance of assessing impulsivity in PAC settings and felt that the FIBS would be useful in identifying individuals at risk of falls and other negative outcomes. TEP members generally agreed that the assessment burden for this data

element would be relatively low, highlighting that the FIBS is brief and appears simple to administer.

Results from the TEP members' ratings further demonstrated their support of the FIBS. This data element received the highest overall rating out of all the Cognition data elements considered, with an overall rating of 4.0. It also received the highest rating in terms of cross-setting applicability, with a score of 4.4.

PROMIS Cognitive Function

One TEP member expressed concern about whether a self-reported measure of cognition would yield a meaningful assessment of actual cognitive function, and therefore whether the time and energy that would be used to complete this assessment would be worthwhile. Another questioned whether patients/residents would only report what they thought the assessor wanted to hear, or what they thought might best serve them, in terms of staying at a facility versus being able to go home. In contrast, one member commented favorably about the patient-centered approach of this data element. When asked about the potential use of a proxy respondent (such as a caregiver) as the source of information for this data element, several TEP members were uncomfortable with the idea, raising concerns that it could be a source of bias. In home health, in particular, a proxy might not always be available, either.

In the TEP members' ratings, the PROMIS Cognition received an overall score of 3.0. This rating was the second-lowest rated data element after that of the Menu Task, indicating that the data element was not very well-regarded by the TEP.

PROMIS Anxiety

As with the other data elements in the Cognition assessment category, TEP members were interested in shortening the item list from its current quantity of 29. A researcher from the PROMIS development team reiterated that the advantage of the item bank is that the list of items can be shaped to suit the focus needed without compromising the reliability and validity of the data element. Some questioned the value of including items to which a majority of patients/residents would reply "yes," such as those that ask about worry. Clarification was offered that these items do not prompt a yes/no response but rather inquire about frequency. While the TEP panelists generally concurred with the importance of assessing anxiety in PAC patients/residents, some commented that they would like to see that there is evidence of predictive value in these items (e.g., that the collection of symptoms and behaviors in the item bank correspond to a physician diagnosis of anxiety) before asking patients/residents about it.

One commenter suggested focusing item selection on those that correlate with participation in routine medical care or care planning. Items with this focus might be: "I felt something awful would happen"; "My worries overwhelmed me"; or "I found it hard to focus on anything other than my anxiety."

Although the TEP discussed concerns about the PROMIS Anxiety, the ratings demonstrated some support for this data element. In particular, the PROMIS Anxiety received an overall rating of 3.5, or “good.”

3.3 Summary of TEP Recommendations for Cognition

Aside from the larger questions regarding how to narrow the choices presented and the burden of assessment on providers and patients/residents, TEP members found a lot to like among the cognition data elements. Generally, the panel felt that the data elements addressed gaps in assessment of executive function, capacity to perform everyday activities, patient judgment and safety, and differentiation of mild cognitive impairment from intact cognition. The least favored option was the Menu Task, as there were questions about its applicability across setting and cultural groups. Reviews of the DOTPA CARE Tool items were mixed, though some said they might like it better if it could be shortened a bit. Both the PASS Medication Management Task and the FIBS were seen as relevant to both clinicians and patients/residents, and the brief screeners were praised for their brevity and simplicity. Feedback on the PROMIS Cognition items related more generally to the utility and validity of self-assessment of cognition, which some called into question. There was general support for the importance of assessing anxiety across PAC settings and agreement that the PROMIS Anxiety item bank represented a good resource for this purpose.

4. Cognitive Function and Mental Status: Behavioral Signs and Symptoms

4.1 Background and Rationale

Behavioral disturbances—a patient or resident's disruptive or dangerous physical or verbal behaviors directed either at themselves or caregivers, often signaling distress or unmet or unrecognized needs—strain the time and resources of PAC providers, disrupt care, and result in poorer patient outcomes. Patients/residents with these behaviors may require more case management time, may have poorer quality of life and interpersonal relationships, and may be at risk for injury, isolation, and inactivity. These symptoms can also disrupt the institutional or home environment and affect the safety and privacy of other patients/residents and caregivers. Exposure to aggressive behaviors can also have a negative effect on staff job satisfaction. Assessment and documentation of behavioral disturbances can help inform care planning, staffing, interventions, and patient transitions.

A summary of Year 1 Progress, including feedback received during the public comment period in August/September 2016 and the results of the Alpha 1 phase of feasibility testing, was presented to the TEP. Data elements being proposed for consideration in the Alpha 2 phase of feasibility testing were then presented, with time for discussion among the panel. The Behavioral Signs and Symptoms data element included three items: Impact on Resident, Impact on Others, and Rejection of Care. Images of the data element can be found in Appendix D2.

4.2 Summary of TEP Discussion for Behavioral Signs and Symptoms

TEP members generally agreed that behavioral assessment is important to undertake. The simplicity of the items was appreciated, and the incorporation of the patient's goals of care in the Rejection of Care item instructions was viewed as a good attempt to consider a patient's care choices (e.g. refusal of care in light of their goals and preferences) before labeling a behavior as refusal of care.

But several members questioned whether the items presented too much room for misinterpretation or miscoding, including possible biased answers. Commenters discussed whether a patient's cognitive status would affect a provider's perception of their refusal of care, whether right to refuse care would be confused with rejection of care, and how a patient's goals would be factored into the data element rating. TEP members discussed the difficulty with patients/residents who do not follow their own care plans. Gathering data on care rejection could also affect risk adjustment, one panelist stated. The issue of whether noncompliance could be addressed with the Rejection of Care item was also raised.

Some TEP members asked about the administration of these items, and whether their use would be applicable across all four PAC settings. The presenter clarified that the provider would be filling out these items, but that information could be obtained from informal caregivers as well. Some questioned whether the look back period of 7 days would be sufficient for providers in the home health setting to observe or gather sufficient information to complete these items during their more limited, less frequent visits (relative to other PAC settings).

Discussants also considered two data elements from the OASIS-C2, M1740 and M1745, both of which assess the frequency of behavioral symptoms and were covered in the TEP Notebook but not formally presented at the meeting. For the M1740 data element, one TEP member thought it would be quick to collect (and therefore a low burden to providers), as behaviors like kicking are perhaps not very common in a PAC setting, but not everyone on the panel agreed with that statement. Others pointed out that patients/residents with Alzheimer's disease can exhibit these behaviors, many of whom use antipsychotic medications to control difficult behaviors in the home setting. One TEP member thought the cognitive portion of the M1740 data element should be left off, as it is assessed elsewhere.

Although panelists thought it would be valuable to assess whether problem behaviors were exhibited, several questioned the utility of coding the frequency of such behaviors as specified in the Rejection of Care item and the M1745 data element. One TEP member wondered how useful such information would be, clinically. Another saw the benefit of knowing whether the behavior happened once versus five times within the 7-day look back period, but was not sure that documenting the difference between 1 and 2 times, or 3 and 4 times, was useful.

TEP members rated the items' overall validity, reliability, feasibility, utility for case mix, and potential for improving quality (with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5), as well as their cross-setting applicability of the data elements (with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5). (See Section 2.4 for more detail on ratings.) Although the TEP expressed some concern regarding the Behavioral Signs and Symptoms data element during their discussion, the panel rated all of the items favorably, with overall scores in the "very good" range. The Impact on Resident item received the highest overall rating, with a score of 4.2, followed by Impact on Others with a score of 4.1, and Rejection of Care – Presence & Frequency with a score of 4.0. All items received the same rating in terms of cross-setting applicability: a score of 4.4, which indicates that the TEP considers them to be applicable.

4.3 Summary of TEP Discussion and Recommendations for Behavioral Signs and Symptoms

Two items, Impact on Resident and Impact on Others, were well received, garnering relatively high scores on the rating sheets and little discussion among the panel. Although the Rejection of Care item did not score poorly on the rating sheets, there were noteworthy concerns

over whether assessors can accurately assess rejection of care while considering a patient's goals and patient cognition, whether gathering data on incremental instances of this behavior is clinically useful, and whether this type of assessment is applicable to the home health setting.

5. Observational Assessments for Patients/Residents Who Are Unable to Communicate: Cognition, Mood, and Pain

5.1 Background and Rationale

Patients or residents in PAC settings may be experiencing impairments in cognition or mood, or may be experiencing pain, but may find themselves unable to communicate their needs easily to providers. As established in the Cognition section of this report (Section 3) and in the Pain section of the TEP Notebook, it is important for patients/residents experiencing cognitive impairment or pain to undergo screening to detect presence and severity, so that a care plan can be created and progress can be monitored. RAND's research, feedback from the TEP and other expert advisors, and comments received during the August/September 2016 public comment period identified the need for standardized assessment data elements to have the capacity to include and assess those patients/residents who have are unable to complete interview-based assessments. The data elements in this section provide protocols for administering cognition, mood, and pain assessments that are otherwise administered through interviews through observation.

A summary of Year 1 Progress, including feedback received during the 2016 public comment period and the results of the Alpha 1 phase of feasibility testing, was presented to the TEP. Data elements being proposed for consideration in the Alpha 2 phase of feasibility testing were then presented, with time for discussion among the panel. These included a cognition data element, MDS Staff Assessment for Mental Status; a mood data element, Staff Assessment of Patient/Resident Mood (PHQ-9-OV©); and two data elements for pain: the Frequency of Pain – Observational Assessment and Pain Relief – Observational Assessment. Images of these data elements can be found in Appendix D3.

5.2 Summary of TEP Discussion for Observational Assessments

The Observational Assessments portion of the TEP meeting began with clarifications of the circumstances under which these tools would be used, followed by discussion of how best to test these data elements in the Alpha 2 phase of feasibility testing. It was established that, for patients/residents with limited communication abilities, purely observational assessments may not be required as interview assessment can be conducted with the use of pictures or other nonverbal cues to accommodate patient abilities.

Comments on each data element are included below, as are brief summaries of the rating sheet results. (See Section 2.4 for more detail on ratings.) TEP members rated the data elements' overall validity, reliability, feasibility, utility for case mix, and potential for improving quality

(with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5), as well as their cross-setting applicability of the data elements (with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5). In general, the Observational data elements were rated favorably (i.e., overall ratings in the 3 and 4 range).

MDS 3.0 Staff Assessment of Mental Status

The observational MDS 3.0 Staff Assessment of Mental Status would be used only when the BIMS cannot be completed, either because verbal or nonverbal responses cannot be understood or because the patient refuses to continue (even if cognitively intact). In discussion of this data element, one TEP member questioned the usefulness of whether the patient can recall the names of staff versus knowing that the facility staff are staff. This commenter was also concerned that the "new situations only" phrasing of the coding instructions for "Modified Independence" would be overlooked, and suggested clarifying that the salient point is about judgment or decisions in a new situation. Another person added that cognitive skills for daily decision making overlaps with executive function, and that clarifying the meaning of modified independence would help distinguish the two.

One commenter questioned whether it wouldn't be better to stick with administering the BIMS if it's possible to use pictures or other nonverbal communication to complete that assessment, instead of introducing an additional, less sensitive assessment. A panelist suggested that, if BIMS cannot be completed due to impaired consciousness, a specialist such as a speech-language pathologist would be a good person to consult to assess the underlying reason and administer an alternate assessment. Another member of the panel pointed out that the reason the patient cannot communicate is not being captured with this instrument, and stated—with some agreement among the panel—that it would be useful to document whether the root of the problem is with communication or understanding.

As with other data elements under discussion, a TEP member suggested that changes in wording would be needed in order to make the MDS 3.0 Staff Assessment of Mental Status applicable to the home health setting.

Of all the ratings of the Observational Assessment data elements, the MDS 3.0 Staff Assessment of Mental Status data element received the lowest overall rating, with a score of 3.3.

Staff Assessment of Patient/Resident Mood (PHQ-9-OV)

The discussion on the PHQ-9-OV began with revisiting the testing of a "gateway" version of the PHQ's nine questions, which would start with the PHQ-2 and proceed with the remaining seven questions if indicated. The presenter clarified that the PHQ-9-OV would not implement the gateway version but would include ratings on all nine symptoms.

A TEP member mentioned that some of the symptoms on the PHQ-9-OV could be symptoms of physical co-morbidities, side effects of medications, or issues other than mood. The presenter acknowledged that this criticism would also apply to the interview-based version as well.

A comment was made that, in the home health setting, this observational assessment could be especially subject to misinterpretation if based on reports from caregivers. A similar concern was raised for the SNF setting, in which families might be interviewed for this assessment. For the IRF setting, a comment was made that the average total length of stay is 16 days, and so the look back period for this data element – 14 days – might be too long to be useful in this setting, as the patient will be asked to reflect on their mood in prior care settings. The presenter clarified that, in the case of mood, *whether* or not the patient had been experiencing signs and symptoms of depression was more important than *where* those symptoms occurred.

Although concerns were raised about this data element, the PHQ-9-OV received an overall score of 3.96.

Observational Assessments of Pain or Distress

The presenter began this portion of the discussion with a review of previous iterations of this item and how concerns have been addressed. The changes were well received, and one TEP member commented that the change in look back period from 14 days to 3 days was helpful in making this more applicable across settings. This commenter also appreciated the aspect of assessing relief from pain and thought it would be helpful, clinically, because it would prompt the clinician to see if a pain intervention was successful.

The timing of pain assessment was the subject of some debate. One panelist liked that the assessment was to be done twice daily, and pointed out that the words “morning” and “evening” might be interpreted differently in different settings, which might have nursing care only in one or the other, but not both. Another commenter agreed that there is value in having two, distinctly separate assessment times, but facilities might have different daily rhythms and it might be better to tie timing to care activities—or simply to advise assessing at different times of day—to ensure comparability across settings. Providers in the SNF setting, in particular, might bristle at the morning/night wording, one person said. That panelist went on to say that this assessment might be seen in SNFs as an additional time burden, if interpreted as a direction to visit the patient at two specific times during the day in order to complete this item.

One last commenter pointed out that it will be important consider how best to work with family members as collateral sources of information on this observational assessment.

In the TEP members’ ratings, the Observational Assessment data elements for pain were both rated favorably. The Frequency of Pain – Observational Assessment was rated highest of the Observational assessments, with an overall rating of 4.2, and Pain Relief – Observational Assessment received the second-highest overall rating, with a score of 4.0. The Frequency of Pain – Observational Assessment also received the highest cross-setting applicability rating, with a score of 4.1.

5.3 Summary of TEP Discussion and Recommendations for Observational Assessments

Once the TEP members digested logistics of how the observational assessments would work, they received them well. Panelists offered some suggestions for minor modifications to the assessments and for descriptions of the assessment process in training materials and user guides. The greatest concern seemed to be with timing—whether the assessment would be most useful, clinically, to be administered upon admission or discharge, and defining the intervals of assessment (for pain). Unlike other assessments, the issue of burden did not seem to be of great concern for these data elements.

6. Medication Reconciliation

6.1 Background and Rationale

Approximately 75 percent of medication errors during transitions in care are preventable, and Medication Reconciliation (MR)—the process of obtaining multiple medication lists and reconciling any discrepancies—is a cost-effective way to promote patient safety by reducing errors and resulting adverse drug events. The OASIS-C2, which became effective January 1, 2017, has three data elements that address drug regimen review (also called DRR, which specifies the end-goal of therapeutic effectiveness and minimizing errors), assuming that MR was completed. These DRR items will also be rolled out in the LTCH setting in April 2018 and in the IRF and SNF settings in October 2018. For the standardized data set, RAND is evaluating additional data elements that address an active MR process to assess the act of comparing lists and reconciling discrepancies and also to focus on high-risk medications, appropriateness of medications, and communication of the reconciled list to the patient and pharmacy at care transitions.

A summary of Year 1 Progress, including feedback received during last year's TEP convening and qualitative and quantitative data from nurses who participated in the Alpha 1 phase of feasibility testing, was presented to the TEP. The RAND presenter also led a detailed discussion of the steps of the MR process, as well as the refined data elements being proposed for consideration in the Alpha 2 phase of feasibility testing that would correspond with each of the five MR steps. Images of these data elements can be found in Appendix D4.

6.2 Summary of TEP Discussion for Medication Reconciliation

Because the MR data elements are at a more formative stage than those discussed in some of the other assessment categories and domains, much of the discussion from TEP members centered on questions to clarify the intended process and the clinical utility of the items. As with the other topics, TEP members rated the data elements' overall validity, reliability, feasibility, utility for case mix, and potential for improving quality (with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5), as well as their cross-setting applicability of the data elements (with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5). (See Section 2.4 for more detail on ratings.) The majority of the data elements received overall scores of 3 or above.

MR Step 1

The TEP began discussions with MR Step 1, as framed in the TEP notebook and presentation, "Obtain a current list of medications from various sources." Commenters

questioned whether system-level electronic health records (EHRs) would have an accurate list of a patient's medications, and whether assessors could unwittingly be perpetuating an erroneous list across care transitions (e.g., through simple cut-and-paste errors). Others wondered whether providers in the home health setting would have access to lists from the previous care setting, or if a provider can be certain, in the case of multiple medication lists, whether all have been collected.

Some TEP members questioned whether the provider conducting the assessment would be qualified to perform MR, to which the presenter clarified that Step 1 can be completed by anyone on the care team by consulting lists of medications, and that a full-scale MR is not called for in the MR assessment. Some applauded this focus on documentation of whether MR was done, which prevents a reliance on clinical judgment, because documentation is critical for care transitions. One TEP member questioned whether having an audit-type data element asking whether MR was done is useful for quality of care, stating that the value of MR is not in knowing whether it was done, but rather how it was done. While TEP members did not feel any steps were missing, they felt that gathering information on the quality with which it was done was important.

One TEP member was particularly concerned that this Step 1 data element was of low value with little bearing on quality of care, and that many assessors would be tempted to just "check the box" to complete the assessment, and move on. Others agreed. Another suggested that, if the purpose is to address transition of care, the physician would likely need to be consulted to check the medications against the EHR. Additionally, this commenter suggested consulting the Meaningful Use guidelines that outline a two-step process, which could relevant to developing this data element.

Ratings questions for the Step 1 data elements focused on the number of information sources used to obtain medication lists (item B1) and whether there is documentation that medication reconciliation was completed within three days of admission/discharge/Resumption of Care (ROC)/Start of Care (SOC) (item B2). The Step 1 items received the lowest overall ratings of all of the Medication Reconciliation items, with scores of 2.7 and 3.3, respectively. Furthermore, item B1 received the lowest cross-setting applicability rating, with a score of 3.3.

MR Step 2

The MR Step 2 data elements focused on assessing whether the patient/resident is taking any specific types of medications (item B3), whether the patient's medication list(s) include an indication for each high-risk medication identified (item B4), and whether the patient has any medication discrepancies involving any of the high-risk medications (item B5). Consensus emerged that the focus on documenting indications for listed medications would be clinically relevant and would be a useful step toward any adjustments that may need to be made to a patient's prescriptions. This sentiment is in agreement with a TEP suggestion during the April 2016 meeting that this may be the most critical data element for a MR assessment. One

additional question that arose was whether the correct indication was noted. The presenter clarified that asking about whether an indication has been noted is the first step to improving quality of care and reducing adverse drug events. This is supported by the Alpha 1 testing results, which suggested that for many patients/residents, no indication was noted at all on the patient's/resident's information sources.

While TEP members agreed that an attempt to identify high-risk medications among a patient's/resident's list would be useful, some were concerned about whether the providers tasked with this aspect of assessment would have the training to execute this function. One person suggested that looking for ways to simplify the task for interprofessional teams would be helpful.

In contrast, little consensus was reached regarding the classes of high-risk medications that should be listed in the item set. Some TEP members were inclined to list all medications on the Beers Criteria, and one member felt passionately that if a medication meets the Beers Criteria it should be listed because it is a well-accepted list that forces providers to consider prescribing practices. Others disagreed, saying the Beers Criteria was too inclusive and that the list of drug classes should be shorter. One person suggested that the list should be limited to drug classes posing the highest risk for an emergency department visit, such as anticoagulants or insulin. Another commented that there is a tendency to add to, but not subtract from, lists like these. One person suggested drug classes used infrequently, such as hypnotics (used in the Section N list of medications in the MDS), should be culled. The presenter commented that the list was being considered in consultation with researchers from the Centers for Disease Control and Prevention (CDC).

The Step 2 items received the highest overall ratings of all the Medication Reconciliation data elements. Item B3 (whether the patient/resident is taking any specific types of medications) received an overall rating of 4.0; item B4 (whether the patient's medication list(s) include an indication for each high-risk medication identified) received an overall rating of 3.7; and item B5 (whether the patient has any medication discrepancies involving any of the high-risk medications) received an overall rating of 3.8. Additionally, item B3 received the highest cross-setting applicability rating, with a score of 4.4.

MR Step 3

For MR Step 3, "Adjudicate and derive a list of medications," several TEP members questioned the ability of providers to complete item B8 (contacting a physician about all of the patient's high-risk discrepancies) within the 24-hour time frame. One person cast serious doubt on whether home health providers, in particular, could realistically do this. Another thought that the 24-hour period would encourage assessors to just "check the box" to say it was done.

The Step 3 data elements received good scores overall from the TEP panel. Item B6 (whether the patient's high-risk discrepancies were addressed immediately after admission/discharge/SOC/ROC) received an overall rating of 3.6; item B7 (whether the patient's

high-risk discrepancies were addressed by involving the patient/resident or patient's/resident's family/formal caregiver) received an overall rating of 3.5; item B8 (whether the patient's physician (or physician-designee) was contacted about all of the patient's high-risk discrepancies) received an overall rating of 3.7; and item B9 (whether the physician [or physician-designee] prescribed/recommended actions in response to all of the patient's high-risk discrepancies were carried out) received an overall rating of 3.4.

MR Steps 4 and 5

MR Steps 4 and 5, "Communicate the correct medication list/Interprofessional team notifies pharmacy," generated little discussion. One TEP member suggested that the current wording doesn't speak to whether the provider has communicated the medication list to the next site of care and suggested using the term "care team."

As with other data elements in the Medication Reconciliation cluster, the Step 4 and 5 data elements received good overall ratings from the TEP. Item B10 (whether the reconciled medication list was communicated to the patient/resident or patient's/resident's family/formal caregiver) received an overall rating of 3.7; item B11 (whether the reconciled medication list was communicated to all of the patient's/resident's primary care providers responsible for the patient's/resident's care following admission/discharge/SOC/ROC) received an overall rating of 3.6; and item B12 (whether the reconciled medication list was communicated to the patient's/resident's pharmacy that will be filling most of the medications following admission/discharge/SOC/ROC) received an overall rating of 3.6.

6.3 Summary of TEP Discussion and Recommendations for Medication Reconciliation

Members of the TEP generally agreed that conducting MR among the population of patients/residents who use post-acute care is a worthy objective. But there was significant disagreement about whether the data elements could capture the quality of MR. In particular, the discussion and written comments on the rating sheets focused on: (1) whether all of the lists that should be obtained were indeed obtained, (2) whether the indication noted was the correct one, (3) the vagueness of knowing whether *all* primary care providers were notified of the final reconciled medication list, and (4) the difficulty of a 24-hour turn-around time for home health settings. The discussion closed with an understanding that asking about the objective steps of MR defined by the Joint Commission was the first step in improving the quality of care and assisting with care transitions. There was also disagreement about the extent to which the Beers Criteria should be included in high-risk medications. Some of these concerns were resolved during the question-and-answer period of the TEP.

7. Special Services, Treatments, and Interventions (SSTIs)

7.1 Background and Rationale

Special services, treatments, and interventions (SSTIs) can have a profound effect on an individual's health status, self-image, and quality of life. Assessing patients/residents for use of SSTIs in PAC settings provides important information about the severity of a patient's illness and risk of complications and adverse health outcomes. These data may also provide information regarding resource use intensity. Patients/residents in a PAC setting who receive any of these services utilize more resources than patients/residents who do not receive them, due to the intensity and quantity of nursing care required to deliver the service, treatment, or intervention. Given that the resource intensity associated with some SSTIs is significantly higher (e.g., Total Parenteral Nutrition, Hemodialysis, and Ventilator in LTCHs), assessment will also help to ensure this higher level of complexity in care is documented for reimbursement purposes. The resource intensity associated with certain treatments may also dictate discharge options at times of care transitions, as the availability of more intensive nursing care may vary between types of settings. For example, some PAC facilities may not be equipped to handle patients/residents with certain treatments, such as ventilators. In addition, receipt of any one of these services usually indicates a higher level of patient acuity and, therefore, the patient would be likely to require more intense nursing care overall, not just during the delivery of the special service, treatment, or intervention. Therefore, these services, treatments, and interventions may be useful as payment adjustment variables. Finally, documentation of SSTIs can facilitate appropriate patient-centered care when the patient/resident transfers between settings.

A summary of Year 1 Progress, including feedback received during the public comment period in August/September 2016, was presented to the TEP. Data elements currently being used in the LCDS, OASIS, and the MDS were reviewed, and the presenter asked the panel to discuss whether other SSTIs should be added and at what level of detail these items should be collected to support care planning, clinical decision making, care coordination, and resource use and patient complexity documentation. Images of these data elements can be found in Appendix D5.

7.2 Summary of TEP Discussion for SSTIs

The SSTI discussion segment of the TEP meeting differed from the other categories and domains because they were not included in the feasibility or national testing activities associated with this effort. Rather they are considered to have adequate testing data on the basis of prior PAC PRD [CMS's Post-Acute Care Payment Reform Demonstration] experience and extant public comment and stakeholder input. As such, these data elements were not rated by TEP

members, and the discussion consisted more of general feedback on whether the right SSTIs were listed in the data elements, and whether the right level of detail was represented.

On the whole, the TEP members agreed that the level of detail for the items currently under consideration would be helpful clinically, both to document patients'/residents' needs, complexity and resource use, but also to facilitate care planning and safe and resource-appropriate transitions across settings and PAC providers.

Panel input was solicited to identify additional SSTIs for a cross-setting assessment. One panel member mentioned that a resource-intensive condition that can be relevant during transitions between settings is vesicocutaneous fistula. A panelist suggested that transfusions might be common enough to include, although another pointed out that SNFs already collect that information in the current version of the MDS. One TEP member suggested peritoneal dialysis as a candidate for inclusion, in addition to hemodialysis. There was some also discussion of whether certain types of oral chemotherapy should be included (e.g., tamoxifen); it was agreed that clear guidance in the assessment manuals would be important for such an item to be assessed accurately and comparably across settings.

Others mentioned considering specialized equipment, such as equipment for wound care, bariatric beds, special "enclosed" beds used for patients/residents with traumatic brain injury, or restraints for behavioral accommodations, which can represent greater resources for a PAC facility to have on hand and safely administer. Another panel member raised the issue of identifying conditions that create staffing issues, or intensive treatments that require frequent monitoring with lab work. Others noted that specific diagnoses might be better captured within different sections of the assessment instruments. Some mentioned that an "other" text box could be a useful way to pass along key information or patient safety concerns to the next setting, and several agreed that including examples or prompts for things to write in could help cue the assessor.

7.3 Summary of TEP Discussion and Recommendations for SSTIs

TEP members seemed to agree that the items presented assessed useful clinical information for cross-setting assessment of clinical complexity, resource use, and care transitions, and that there may be some more SSTIs to consider in addition to the data elements that were submitted for public comment. The panel did not raise concerns about additional burden during the SSTI discussion.

8. Care Preferences

8.1 Background and Rationale

The assessment of patient care preferences and goals for care is critical to assuring patient-centered and preference-concordant care through the course of a PAC episode and beyond. In addition to clinical guidelines, information about patient preferences and goals provides important direction for developing a care plan, selecting treatment options, and tailoring interventions. Understanding patient goals can also help to establish or reset both patient and provider expectations in the context of the current clinical condition. Improved understanding of patient/resident preferences and goals through a systematic assessment process can also strengthen the patient-provider relationship and build trust.

Preferences for health care address how much and what type of health care intervention a patient (and his or her caregiver) prefers. For example, a patient may prefer alternative approaches to pain management over pharmacologic intervention. Patients/residents receiving rehabilitation services may also have variable preferences for involvement in their health care or for the provision of information about their health care. In PAC settings, preferences for care might also involve preferences regarding daily routine and lifestyle, such as a preference for a private room or the ability to choose meal times.

Goals of care, which are intertwined with preferences, reflect the outcomes of care and encompass the patient's (and caregiver's) aspirations for care, health, and functioning. Short-term goals for PAC might be to return to home, or to restore/regain function of a limb, or to walk without caregiver assistance. Longer-term goals might relate to a patient's/resident's social context and could include things such as attending a child's wedding, being present for the birth of a grandchild, being able to travel, or being able to care for a pet.

A summary of Year 1 Progress, including feedback received during the public comment period in August/September 2016 and the results of the Alpha 1 phase of feasibility testing, was presented to the TEP. Data elements being proposed for consideration in the Alpha 2 phase of feasibility testing were then presented, with time for discussion among the panel. These data elements included Advance Directive and Goals of Care (which had two possible assessment approaches). Images of these data elements can be found in Appendix D6.

8.2 Summary of TEP Discussion for Care Preferences

Advance Directive

Discussion of the Advance Directive data element opened with an observation of how differently it is structured, in comparison to the steps presented with the MR assessment

category. Some suggested that the transactional question of whether an advance directive has been created (and where it is located) should be separated from probing questions that might spur a richer discussion of the nuances of a patient's preferences in the context of advanced illness. Further, another commented that the question of whether the patient has an advance directive should be separated from the question asking whether it is included in the medical record, because sometimes one exists but is not accessible.

Some conversation among the TEP centered on the difference between care preferences that might be expressed at the end of life versus preferences that might be expressed about day-to-day concerns. A TEP member wondered how an assessment might capture elements of discussions on these different types of preferences, in a person-centered way.

Although this data element is meant to be conducted by reviewing a patient/resident's chart, several TEP members brought patient-provider conversations regarding end-of-life preferences into the panel discussion. One TEP member brought up physician orders for comfort care and posed the question of whether categories of treatment restriction such as "no antibiotics" or "no feeding tubes" would be good to add to the standardized assessments. This panelist felt adding these categories might help patients/residents – as well as providers -- feel more comfortable with choosing those options. Others expressed concern over trying to document too much all at once, or offering too many options to patients/residents, who might not really understand the difference between a "do not resuscitate" and a "do not intubate" order.

Two suggestions were offered for restructuring this data element. The first involved adding a fourth, more open-ended question asking whether there has been conversation regarding the advance directive, to complement the first three more transactional questions. Another TEP member liked the idea of a fourth question that would ask whether the advance directive has been shared with the primary care team, family members, or other people important to the care of the patient/resident. A second suggestion involved making the data element into one question, "Have you had a conversation regarding the following items?" and then list the three items with Yes/No checkboxes.

For the third item in the Advance Directive data element, which addresses whether there is a health care proxy for the patient, one TEP member found this information particularly salient for providers to know, because often there is no proxy. The topic of a health care proxy prompted an offshoot discussion over whether it is important to use language that conveys legal authority versus referring to a designee. Some made the point that professional ethics require physicians to follow the patient's preferences regardless of the legal language used. One TEP member noted that physicians and nurses are not bound by the same oath, and that, in practice, some nurses may not feel comfortable following a "do not resuscitate" order that is in the medical record if it does not carry legal authority.

As with the other topics, TEP members rated the data elements' overall validity, reliability, feasibility, utility for case mix, and potential for improving quality (with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5), as well as their cross-setting applicability

of the data elements (with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5). In addition, TEP members were asked whether the data element was an improvement from Alpha 1. (See Section 2.4 for more detail on ratings.) The Advance Directives data element received the highest overall rating of the Care Preferences data elements, with a score of 4.0, and it was the only data element or item in this domain to receive an overall rating above 3. All TEP members who answered whether the data element was an improvement from Alpha 1 responded in the affirmative. The Advance Directives data element also received the highest cross-setting applicability rating, with a score of 4.5.

Goals of Care

The discussion of the Goals of Care data elements began with a review of how the data element was structured for the August/September 2016 public comment period and the Alpha 1 phase of feasibility testing. Although feedback from the public comment process—all of which was unprompted, suggesting the importance of this domain— was positive, the Alpha 1 testing showed little variation in the responses, indicating changes were needed. The presenter showed two variations on the Alpha 1 data element that were created in response to the testing data. One variation, "Drilling Down" focuses on the importance of goals and making them actionable; the other, "Pushing to Priorities" focuses on tradeoffs that might have to be made in order to meet one's stated care goals (e.g., quality versus quantity of life).

Overall, TEP members found the attempt at creating these data elements laudable, but full of challenges. The value of having conversations on patient goals was undisputed, but TEP members conveyed much concern over whether the assessment time would be the appropriate point to start such a conversation, and whether such conversations would be better conducted with a provider at a later time, when there is a more appropriate setting for care planning. One suggested that the stark contrast in choices would be a lot for someone to process, particularly in the midst of a battery of assessments—and especially so for a patient/resident with a language impairment. Another TEP member suggested that simply prompting the conversation and noting the need for a follow-up would be a step in the right direction. There was strong agreement that conversations regarding goals were too important to rush through, and that it would not be a good idea to collect information during the assessment that has no "home" in the medical record.

There was some disagreement concerning when a Goals of Care data element ought to be administered. Significant concern was raised about adding this to an already lengthy admission assessment, though one TEP member very strongly noted that if cuts were going to be made to save time, this wasn't the section from which to cut. Some thought conducting the assessment at discharge would help to minimize the burden at admission. It seemed logical to some that the information from that assessment would follow the patient to the next point of care. Others thought the most effective time to administer would be at admission so the care facility could address the wishes of the patient in a timely manner. The issue of burden was also raised for conducting this in a home health setting.

Some flagged wording choices as being problematic, such as use of the terms “getting fit” and doing “light housework,” which were unlikely to apply to a PAC patient who has deficiencies in their activities of daily living. Additionally, questions were raised as to whether patients/residents would rate questions such as “How important is it to you to take care of your body” in any way other than “very important”; this concern had also been raised of the version of the data element used during Alpha 1 testing.

Others pointed out that not all patients/residents in PAC settings are at the end of their life, and therefore the dichotomies presented in “Pushing to Priorities” might not be salient to some patients’/residents’ situations. Additionally, several members noted that clinicians must be very careful in making assumptions about what constitutes high quality of life for another person, or presuming what their treatment decisions should be. Younger, disabled patients/residents, for example, would likely be more interested in getting the treatment they need and getting home, as opposed to engaging in an end-of life preferences contemplation.

The TEP members appreciated the depth and breadth of the Goals of Care items, and suggested it would be useful to offer the questions to their patients/residents in a booklet form to consider at their own pace. Many agreed that quiet time for careful consideration, paired with a measured conversation with a qualified clinician, would be the best course for setting actionable goals.

In addition to the discussion, TEP members submitted ratings for the Goals of Care data elements, as described above for Advance Directives. TEP members were also asked whether there was value in using either of the subscales, in addition to the Expansion into Subareas of Goals of Care data element. Overall, the Goals of Care data elements received relatively poor ratings. The Expansion into Subareas of Goals of Care data element received an overall rating of 2.5; for the Health Outcomes and Tradeoffs Scale, Subscale 1 received a score of 2.6, whereas Subscale 2 received a slightly lower score of 2.4. The TEP did not perceive improvements to this data element from the version tested in Alpha 1, nor did they perceive value to using either of the Health Outcomes and Tradeoffs subscales. For cross-setting applicability, the Expansion into Subareas of Goals of Care, Health Outcomes and Tradeoffs Scale Subscale 1, and Health Outcomes and Tradeoffs Scale Subscale 2 received ratings of 2.6, 2.8, and 2.4, respectively.

8.3 Summary of TEP Discussion and Recommendations for Care Preferences

The intent to document care preferences among patients in PAC settings was well received among the TEP, and the panel fully supported the idea of encouraging patients/residents and providers to have meaningful conversations about care preferences. However participants had many reservations regarding whether the questions developed belonged in a standardized assessment. Some of the TEP members appreciated the procedural tack taken in questions 1 and 3 of the Advance Directives data element, but thought adding a question asking whether the

patient has discussed advance directives with a provider might prompt a richer discussion later. For the Goals of Care data elements, TEP members questioned what would be done with the data, and whether the time at which the assessments would be conducted would be an inopportune time to raise contemplative questions on care planning. Lastly, some concerns over wording choices were raised for the Goals of Care data elements, in which patients/residents might be asked to choose among options that have no bearing on their situation.

9. PROMIS® Profile Items

9.1 Background and Rationale

Health-related quality of life (HRQOL) is generally considered to describe the ways in which a medical condition and/or therapy affect a patient. It serves as an important indicator along with traditional measures (e.g., survival, tumor response) to capture the burden of disease or illness.

Assessing HRQOL through patient-reported outcomes (PROs) has the potential to improve quality of care by improving clinicians' abilities to monitor symptoms and treatment effectiveness, and by engaging patients/residents in their care through better patient-physician communication. The.

A set of Profile instruments consisting of 29, 43, and 57 items have been developed as part of the National Institute of Health (NIH) -supported Patient-Reported Outcomes Measurement Information System (PROMIS; http://www.healthmeasures.net/explore-measurement-systems/promis) initiative to assess overall HRQOL by including items from eight of the major PROMIS domains: Depression, Anxiety, Physical Function, Pain Interference, Pain Intensity, Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities.

Due to the broad use of the PROMIS profile assessments, the concept of developing a PROMIS profile specific to PAC settings could be useful for care planning and care transitions. The proposed PROMIS profile assessment for PAC covers the same content and follows the same administration format as the PROMIS-29. For this profile assessment, items from the Anxiety, Physical Function, Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities item banks would be used, but items currently in use in PAC assessments to assess depression and pain would also be used.

Images of Physical Function, Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities data elements can be found in Appendix D7.

9.2 Summary of TEP Discussion for PROMIS Profile Items

The segment of the TEP meeting on the PROMIS Profile Items began with an overview of the PROMIS item bank library and the ability to select subsets of items from a number of different domains to build a customized PROMIS profile. In addition to the presenter, two researchers from the NIH PROMIS team were on hand to answer questions and join the discussion.

After the overview, several members of the TEP noted that they understood the context of PROMIS significantly better than they did during the discussion of the Cognition and Anxiety items that had taken place the previous day. One TEP member raised concerns about developing

a profile score that is different from those already established, and, in particular, about using significantly fewer items to represent each domain.

Another TEP member asked about the performance of these items on those with limited communication or language abilities. This TEP member also asked about whether, psychometrically, a profile could be administered in writing, and other TEP members indicated interest in this as well.

One participant questioned how much meaning could be gleaned from these types of questions for a patient population that is moving between settings of care; this person could see how a PROMIS Profile could be useful in working with a care coordinator in a home health setting. Similarly, a TEP member pointed out the SNF facilities have two types of patients, those in transitional care (i.e. patients who will return home) and residents (i.e. patients who will transition from receiving post-acute care to receiving long-term care services), and that a PROMIS Profile would be relevant to the residents. Again, the issue of administration came up: would this be a paper-and-pencil assessment that could be left with the patient to complete, or would they be delivered as an interview, with the assessor reading through the questions?

There was some discussion of the types of questions to add, and whether there was duplication with other assessments. One TEP member pointed out that this has never been used in a PAC setting, and that several of the questions cover ground, such as on physical functioning and depression, already explored with other assessment tools. Another participant supported the idea of adding a question on sleep, although it was pointed out that there is a sleep question in the PHQ-9 (if all nine questions are administered). One panelist suggested having only one or two questions per domain, to be used to flag an aspect of a patient's/resident's care that might not be obvious for that particular setting, and was particularly supportive of including items in the profile from the Social Support domain.

The issue of burden was raised by one participant who stated that data on many of the things addressed in the proposed PROMIS Profile is already being collected in the SNF setting, and that the data is not being used. This person went on to ask whether items in other assessments will be replaced by quality of life items.

Although TEP members acknowledged the importance of quality of life, several questioned its role in the PAC setting and whether it is measurable there. A participant suggested this would be more relevant to a primary care setting, and that it might be useful to transmit such information to the primary care provider after administering the Profile assessment at discharge. One person raised the issue that therapists may have outcomes that are particularly short-term oriented, so front-line providers may find it difficult to gather enough data to follow up on the outcomes of a quality of life assessment and connect evidence with the bigger picture. Another was concerned that the Profile could be lumping things together, confounding results. For instance, if a patient in a PAC is not sleeping well, is that because of an injury that person sustained, necessitating care in the PAC, or is it because of the PAC setting itself? For

rehabilitation patients, a TEP member cautioned against developing interventions for an issue that was not present before their injury.

Some discussion concerned using the Profile as a composite measure, which brought out some strong feelings regarding the use of the resultant score. If the data element is to be administered at admission and discharge, the difference between the scores might be used as a indication of improvement, one participant noted. Another TEP member continued with concern that a composite score might be used for payment. Many agreed that the meaning of the composite score should be clear before it starts to be collected.

One participant suggested, along the lines of the discussion on presuming what a patient's/resident's goals of care should be (see Section 8.2), that the science of assessing quality of life is in its infancy and, therefore, using the Profile for this purpose is perhaps premature. To this, a panelist suggested that the Profile could take the place of the Goals of Care data element in the Care Preferences assessment category. Another commented that patients/residents in PAC settings may be more concerned with big picture questions of whether they can get back to enjoying their previous lifestyle, such as playing golf, than on discrete medical issues, such as the range of motion of their arm.

As with the other topics, TEP members evaluated the proposed PROMIS Profile assessment on the basis of its overall validity, reliability, feasibility, utility for case mix, and potential for improving quality (with a scale from *poor* to *excellent*, where *poor* equals 1 and *excellent* equals 5), as well as its cross-setting applicability (with a scale of *not applicable* to *highly applicable*, where *not applicable* equals 1 and *highly applicable* equals 5). (See Section 2.4 for more detail on ratings.) The PROMIS Profile assessment was not rated very favorably by the TEP, with an overall score of 2.68. The Ability to Participate in Social Roles domain received the lowest rating in terms of cross-setting applicability (a score of 2.4), whereas the Physical Function, Fatigue, and Sleep Disturbance domains received ratings of 3.1, 3.1, and 3.3, respectively.

9.3 Summary of TEP Discussion and Recommendations for PROMIS Profile Items

The TEP panel, while in agreement about the importance of quality of life for PAC patients/residents, had a number of concerns with using a PROMIS Profile score to assess quality of life, and generally seemed to struggle with the utility of using the proposed PROMIS Profile items, as currently constructed, in PAC settings. Suggestions were made for including, and excluding, certain types of items, and nearly every domain in the profile was acknowledged as important by at least one panelist during the discussion, but no clear consensus was reached on what the final Profile might constitute. The concerns raised by the TEP members were, in many ways, a function of the novelty of the use of a profile score in this setting. Because no data are available to document the utility of such a score in PAC, the TEP had more questions than

answers, and were skeptical about the feasibility and value implementing this type of assessment in PAC settings in a standardized fashion.

10. Conclusion and Summary of Findings from the TEP

The TEP engaged expert stakeholders in an effort to guide RAND and CMS's work and obtain consensus on the development and maintenance of cross-setting standardized patient assessment for PAC facilities, in support of the IMPACT Act of 2014. The TEP helped narrow the list of data elements under consideration through their discussion on the extent to which potential data elements would be feasible, clinically useful, and broadly applicable to patients/residents across the four PAC settings.

The key findings from the TEP meeting are listed below.

Cognitive Status

- TEP members generally felt that the presented Cognition data elements helped address gaps in assessment of executive function, capacity to perform everyday activities, patient judgment and safety, and differentiation of mild cognitive impairment from intact cognition.
- The panel expressed less support for the Menu Task and the PROMIS Cognition data elements than the others, due to concerns about cultural sensitivity, setting applicability, and the utility of self-reporting cognitive status.
- The DOTPA CARE Tool items received mixed reviews; many liked its focus on assessing cognitive function, but some raised concerns over its length and reliability.
- Both the PASS Medication Management Task and the FIBS were seen as relevant to both clinicians and patients/residents.
- The brief screeners were praised for their brevity and simplicity, though some had reservations about their validity.
- The PROMIS Anxiety data element was seen as relevant and feasible for PAC use.
- The panel urged consideration of the overall burden of assessment on providers and patients/residents, as well as minimizing overlap of what is being assessed, in the final determination of standardized data elements.

Behavioral Signs & Symptoms

- In terms of clinical relevance, all three items within the Behavioral Signs and Symptoms data element—Impact on Resident, Impact on Others, and Rejection of Care—were received well by the TEP.
- All three items were scored highly by the TEP, both overall and in terms of cross-setting applicability.
- Despite the high score, concerns were raised regarding the Rejection of Care item: whether patient goals and cognition would be adequately taken into account, and whether this type of assessment is applicable to the home health setting.
- TEP members also questioned the usefulness of gathering data on incremental instances of behavior within the 7-day look back period.

Observational Assessments for Patients/Residents Who Are Unable to Communicate: Cognition, Mood, and Pain

- The members of the TEP agreed that observational versions of assessments for cognition, mood, and pain are important to offer for patients/residents who cannot complete interview-based assessments.
- Some minor modifications and suggestions for describing the assessment process in training materials and user guides were offered.
- The timing of these assessments (i.e., whether they should be administered upon admission or discharge) and how to define the intervals of assessment (for pain) was a concern for the panel.
- The issue of burden did not seem to be of great concern for the Observational data elements.

Medication Reconciliation

- TEP members generally agreed that conducting MR among the population of PAC patients/residents who use post-acute care is a worthy objective.
- There was significant disagreement about whether the data elements could capture the quality of medication reconciliation.
- There was general disagreement about the extent to which the Beers Criteria should be included in high-risk medications.
- TEP members made some suggestions for minor rewording of the Steps 4 and 5 data element so that it addresses the care team as a whole, instead of specifying "all primary care providers."
- Next steps for the MR team include: confirming the extent to which it is important to understand how many lists were obtained; revisiting the high-risk medication classes; and reconsidering the 24 hour time frame for the B2 item.

Care Preferences

- The TEP praised the intent to document care preferences among patients/residents in PAC settings, but had many reservations regarding whether a standardized assessment could do so in a meaningful way.
- For the Advance Directives data element, some TEP members found it useful to have some task-oriented questions asking whether an advance directive exists, but also thought adding a question about whether the patient has had a conversation about advance directives might prompt subsequent discussion.
- Many of the TEP members found aspects of the Goals of Care data elements, such as how the data would be used, problematic.
- The panel questioned whether it would be helpful, or merely overwhelming, to raise care planning issues in the context of a battery of admission (or discharge) assessments.
- Some concerns over wording choices were raised; in the Goals of Care data elements, TEP members pointed out instances in which patients/residents might be asked to choose among options that have little relevance to their situation.

Special Services, Treatments & Interventions

- TEP members seemed to agree that the items under consideration, as submitted for public comment, assessed useful information for cross-setting assessment of clinical complexity, resource use, and care transition.
- The panel did not raise major concerns about additional burden during the SSTI discussion.
- Some SSTIs were suggested as additions to the list that was presented.

PROMIS Profile

- The TEP panel agreed that assessing quality of life for PAC patients/residents is an important undertaking.
- Nearly every PROMIS domain in the profile was acknowledged as important during the discussion, but overall the TEP had a number of concerns with using a PROMIS Profile score to assess quality of life. This may have been, in part, because of the novelty of using this type of assessment in this setting.
- Generally, TEP members seemed to struggle with the utility of using the proposed PROMIS Profile items, as currently constructed, in post-acute care.
- Suggestions were made for including, and excluding, certain types of items, but no clear consensus was reached on what the final Profile might constitute.
- Because no data are available to document the utility of such a score in PAC, the TEP had more questions than answers and could not get comfortable with the idea of implementing this type of assessment in a standardized fashion.

Additional Comments

Some additional comments were gathered during the wrap-up discussion, which are a follow-on from the previous TEP meeting in April 2016. The hearing and vision assessment category was discussed, with regard to obtaining the date of the last vision and hearing exams. TEP members acknowledged that this is important to obtain, but challenging in practice, and the detection of impaired hearing and vision is the more important issue that has not been addressed. One participant further suggested screening for problems with hearing and vision at the start of assessments, as a general practice. Another asked whether assessment of hearing or vision impairment should be combined with a question, such as previously on the MDS, that asks about the use of glasses or a hearing aid, and whether it would be wise to add questioning on use of the assistive device.

Appendix A: Biographical Information for TEP Members

Susan Battaglia, RN-BC, RAC-CT is the Director of Case Mix Management for Tara Cares, a consulting firm that provides supportive services to 35 facilities in seven states. Ms. Battaglia has worked in Long Term Care for over 35 years, beginning her career as a licensed practical nurse and later became a nurse manager. She is a 15 year active member of AANAC and has intimate knowledge of the MDS.

Janet Brown, MA CCC-SLP is the Director of Health Care Services in Speech Language Pathology at the American Speech-Language-Hearing Association, in Rockville, MD. She tracks trends affecting SLPs in health care settings, serves as ASHA's liaison to other organizations, and collaborates to develop products, resources, and educational programs related to professional issues and clinical topics in health care. She is also the co-coordinator of ASHA Connect.

Judy Elmore, BS is a Registered Pharmacist with a Clinical Pharmacy Degree and Vice President of Ancillary Operations at Covenant Care. She brings over 40 years of experience in health care management and operations across the continuum of care. Ms. Elmore brings a unique perspective to the TEP because of her strong interest and engagement in the practical aspects of HIT support for patient assessment. She was nominated by the National Association for the Support of Long Term Care (NASL).

Janet Herbold, PT, MPH, CHC is the Senior Administrator and Corporate Compliance Officer for Burke Rehabilitation Hospital. She has served in various clinical and administrative capacities across the continuum of care for nearly 30 years, including research on the identification of predictors for determining disposition and functional outcomes and development of an outcomes assessment tool based on the FIM for physical and occupational therapy delivered to patents in skilled nursing facilities. Additionally, she is affiliated with and was nominated by the American Medical Rehabilitation Providers Association (AMRPA).

Kathleen Lawrence, MSN, RN, CWOCN is the Wound Ostomy Continence Program Manager at Rutland Area Visiting Nurse and Hospice, a non-profit agency in rural Vermont. She has an extensive background in clinical care with a specialty focus on wound, ostomy, and continence care, including comprehensive patient assessment, medication reconciliation, and evaluation of cognition, pain status, and functional abilities. Mr. Lawrence served as past president and was nominate by the Wound Ostomy and Continence Nurses Society.

Natalie Leland, PhD, OTR/L, BCG, FAOTA is an Assistant Professor at the University of Southern California with a joint appointment in the T.H. Chan Division of Occupational Science and Occupational Therapy and the Davis School of Gerontology. She is also an Adjunct Assistant Professor of Health Services Policy & Practice at Brown University’s School of Public Health. Dr. Leland has over ten years of clinical experience working in post-acute care as an

occupational therapist. She has significant experience in conducting rehabilitation health services research with a focus on enhancing the quality of post-acute care services for older adults.

Cheryl Phillips, MD is the Senior VP for Public Policy and Health Services at Leading Age in Washington, DC. Prior to this role, she was Chief Medical Officer of On Lok Lifeways, the originator of the PACE (Program of All-Inclusive care for the Elderly) model based in San Francisco, CA. She has also served as the Medical Director for Senior Services and Chronic Disease Management, for the Sutter Health System, a network of doctors, hospitals, and other health providers in Northern California. As a fellowship-trained geriatrician, Dr. Phillips' clinical practice focused on nursing homes and the long-term care continuum.

Marc Rothman, MD is the Senior Vice President and Chief Medical Officer at Kindred Healthcare, Inc. where he oversees the company's quality and physician strategies nationwide across all four PAC settings. Prior to joining Kindred, Dr. Rothman practiced geriatric, post-acute, and palliative medicine and conducted research on patient decision-making, frailty, and post-acute care outcomes.

Chloe Slocum, MD is a Spinal Cord Injury Medicine Fellow and Physician at Spaulding Rehabilitation Hospital Boston, within Partners HealthCare Network. Dr. Slocum cares for patients with paralysis and spinal cord injuries with a special interest in urologic disorders and functional outcomes and health promotion for individuals with spinal cord injuries.

Peter W. Thomas, JD is a Principal with the Washington, DC based law firm of Powers, Pyles, Sutter & Verville. He has been a legislative and regulatory advocate for over twenty years on behalf of health care and post-acute care providers as well as consumers with injuries, illnesses, disabilities and chronic conditions. Mr. Thomas participates in multiple coalitions focused on health and disability advocacy, rehabilitation research policy and funding, and access to rehabilitation services and devices. Mr. Thomas provides a consumer perspective on the panel.

Barbara Thomsen, CDM, CFPP, RAC-CT is the MDS and Case Mix Audit Specialist at Hawkeye Care Centers in rural Iowa. Ms. Thomsen has worked across the state of Iowa with over 600 PAC facilities and agencies as the state's MDS/OASIS Automation Coordinator and Educator. Additionally, she has authored a number of articles on the MDS 3.0 and the importance of providing standardized, holistic, assessments.

John Votto, DO, FCCP is the President and CEO of The Center for Special Care, the parent organization for the Hospital for Special Care. Dr. Votto joined the Hospital for Special Care in 1985, is chair the National Association of Long Term Hospitals' admission criteria development committee, and has participated in TEPs on the development of the CARE Tool and other panels addressing quality outcome measures, classification and admission criteria.

Michael Wasserman, MD, CMD is the Director of Nursing Homes for the Quality Improvement Organization in California, Health Services Advisory Group. Dr. Wasserman has served as a clinical geriatrician and Medical Director across the continuum of care for nearly 30 years. In addition to his experience and expertise in quality improvement and implementation science, Dr. Wasserman brings the perspective of caregiver to his father-in-law to the TEP.

Kathleen Witcoskie, RN is the Vice President at Visiting Nurse Associations of America Health System. Ms. Witcoskie brings extensive knowledge in standardized patient assessment and regulations to the TEP. As an OASIS Specialist, she has completed reviews on over 500 assessments and trained over 200 clinicians. She was nominated by the Visiting Nurse Association of America.

Appendix B: TEP Meeting Agenda

Thursday, January 5th

8:00 Arrivals and Breakfast

9:00 Welcome
Charlayne Van, JD *CMS*

9:05 Overview of Agenda, Review of TEP Charter, Ground Rules, Introductions, and Instructions on Ratings
Barb Gage, PhD *George Washington University*

9:15 Guiding Principles of the IMPACT Act
Stella Mandl, RN *CMS*

9:30 Project Update and Goals for This TEP
Summary of Alpha 1 field test
Maria Edelen, PhD *RAND*

9:50 New Cognition Items for Alpha 2 Testing
- DOTPA items
- The Menu Task

Cathy Sherbourne, PhD *RAND*

10:30 Break

10:40 New Cognition Items for Alpha 2 Testing (*continued*)
- PASS Medication Management Task
- Brief Screeners for Cognitive Impairment
- The Fall-Related Impulsive Behavior Scale
- PROMIS® Cognitive Status

Cross-cutting discussion on Cognition items

12:00 Lunch

1:00 PROMIS® Anxiety
Cathy Sherbourne, PhD *RAND*

1:15 Behavioral Signs and Symptoms
Deb Saliba, MD *RAND*

1:30 Assessments for Patients/Residents Who Are Unable to Communicate: Cognition, Mood, and Pain

MDS Staff Assessment of Cognition for patients unable to complete the BIMS
Observational version of PHQ-9 going into Alpha 2
Observational pain assessment going into Alpha 2

Steven Martino, PhD *RAND*

1:45 Medication Reconciliation
Shira Fischer, MD, PhD *RAND*

3:15 Break

3:30 Wrap Up, Overview of Friday Agenda and Opportunity to Recommend Revisiting Topics, Voting Instructions
Barb Gage, PhD *George Washington University*

4:00 Break for the Day

Friday, January 6th

8:30 Arrivals and Breakfast

9:00 Plan for Day 2

9:05 Special Services, Treatments, & Interventions, including Nutritional Approaches
Laura Faherty, MD, MPH, MS *RAND*

10:00 Care Preferences
Francesca Pillemer, PhD *RAND*

10:45 Break

11:00 PROMIS Items to create an HRQOL profile score
Profile items (Physical Function, Fatigue, Sleep Disturbance, and Ability to Perform Social Roles and Activities)
Maria Edelen, PhD *RAND*

12:00 Lunch

12:45 Wrap up: Summary of Discussion and Next Steps
Maria Edelen, PhD *RAND*

1:15 Adjourn

Appendix C: TEP Rating Sheet Example

January 2017 TEP Rating Form - Day 1

Behavioral Signs and Symptoms Data Elements

37. Data Element #1: Impact on Resident

E0300. Overall Presence of Behavioral Symptoms	
Enter Code ☐	**Were any behavioral symptoms in questions E0200 coded 1, 2, or 3?** 0. **No** → Skip to E0800, Rejection of Care 1. **Yes** → Considering all of E0200, Behavioral Symptoms, answer E0500 and E0600 below
E0500. Impact on Resident	
Enter Code ☐	**Did any of the identified symptom(s):** **A. Put the resident at significant risk for physical illness or injury?** 0. **No** 1. **Yes**
Enter Code ☐	**B. Significantly interfere with the resident's care?** 0. **No** 1. **Yes**
Enter Code ☐	**C. Significantly interfere with the resident's participation in activities or social interactions?** 0. **No** 1. **Yes**
E0600. Impact on Others	
Enter Code ☐	**Did any of the identified symptom(s):** **A. Put others at significant risk for physical injury?** 0. **No** 1. **Yes**
Enter Code ☐	**B. Significantly intrude on the privacy or activity of others?** 0. **No** 1. **Yes**
Enter Code ☐	**C. Significantly disrupt care or living environment?** 0. **No** 1. **Yes**
E0800. Rejection of Care - Presence & Frequency	
Enter Code ☐	**Did the resident reject evaluation or care** (e.g., bloodwork, taking medications, ADL assistance) **that is necessary to achieve the resident's goals for health and well-being?** Do not include behaviors that have already been addressed (e.g., by discussion or care planning with the resident or family), and determined to be consistent with resident values, preferences, or goals. 0. **Behavior not exhibited** 1. **Behavior of this type occurred 1 to 3 days** 2. **Behavior of this type occurred 4 to 6 days,** but less than daily 3. **Behavior of this type occurred daily**

The questions below (focused on validity, reliability, feasibility, utility for case mix, and potential for improving quality) are specifically in reference to the Impact on Resident data element.

(see pg. 52 of the TEP notebook for further detail)

	Excellent	Very Good	Good	Fair	Poor
Validity	○	○	○	○	○
Reliability	○	○	○	○	○
Feasibility	○	○	○	○	○
Utility for Case Mix	○	○	○	○	○
Potential for Improving Quality	○	○	○	○	○

38. Data Element #1: Impact on Resident

Please add any specific comments pertaining to the data element's validity, reliability, feasibility, utility for case mix, and/or potential for improving quality in the box below.

Appendix D: Data Elements Presented to TEP

D1: Comprehensive List of Data Elements Identified for Cognition

DOTPA CARE items

ADMISSION – CARE C – SECTION III: Provider Information

III. Provider Information (cont.)

H.5a Cognitive Status

Answer **only** if you answered "Yes" to H.5 "Does the patient have any problems with memory, attention, problem solving, planning, organizing or judgment?" and if you have the skills, knowledge, or training, to provide a response; otherwise, leave this section blank.

H.5b Please describe the patient's problems with:

- **Memory**
- **Attention**
- **Problem Solving**
- **Planning**
- **Organizing**
- **Judgment**

☐ **Mildly impaired:** Demonstrates some difficulty with one or more of these cognitive abilities.

☐ **Moderately impaired:** Demonstrates marked difficulty with one or more of these cognitive abilities.

☐ **Severely impaired:** Demonstrates extreme difficulty with one or more of these cognitive abilities.

H.6a Problem Solving

Answer **only** if you answered "Yes" to H.6 "Does the patient have any problems with memory, attention, problem solving, planning, organizing or judgment?" and if you have the skills, knowledge, or training, to provide a response; otherwise, leave this section blank.

The patient solves:

Simple Problems: Following basic schedules; requesting assistance; using a call bell; identifying basic wants/needs; preparing a simple cold meal

Complex problems: Working on a computer; managing personal, medical, and financial affairs; preparing a complex hot meal; grocery shopping; route finding and map reading

	Simple Problems		Complex Problems	
	H.6b Without Assistance	**H.6c With Assistance**	**H.6d Without Assistance**	**H.6e With Assistance**
Never or Rarely	☐	☐	☐	☐
Sometimes	☐	☐	☐	☐
Usually	☐	☐	☐	☐
Always	☐	☐	☐	☐

Level of Assistance:

Without Assistance: Patient performance **without** cueing, assistive device, or other compensatory augmentative intervention

With Assistance: Patient performance **with** cueing, assistive device, or other compensatory augmentative intervention

Frequency of problem solving:

Never or Rarely: Less than 20% of the time

Sometimes: Between 20% and 49% of the time

Usually: Between 50% and 79% of the time

Always: At least 80% of the time

III. Provider Information (cont.)

H.7a Memory

Answer **only** if you answered "Yes" to H.7 "Does the patient have any problems with memory, attention, problem solving, planning, organizing or judgment?" and if you have the skills, knowledge, or training, to provide a response; otherwise, leave this section blank.

The patient recalls:

Basic Information: Personal information (e.g., family members, biographical information, physical location); basic schedules; names of familiar staff; location of therapy area

Complex Information: Complex and novel information (e.g., carry out multiple-step activities, follow a plan); anticipate future events (e.g., keeping appointments)

	Basic Information		Complex Information	
	H.7b Without Assistance	H.7c With Assistance	H.7d Without Assistance	H.7e With Assistance
Never or Rarely	☐	☐	☐	☐
Sometimes	☐	☐	☐	☐
Usually	☐	☐	☐	☐
Always	☐	☐	☐	☐

Level of Assistance:

Without Assistance: Patient performance **without** cueing, assistive device, or other compensatory augmentative intervention

With Assistance: Patient performance **with** cueing, assistive device, or other compensatory augmentative intervention

Frequency of memory:

Never or Rarely: Less than 20% of the time

Sometimes: Between 20% and 49% of the time

Usually: Between 50% and 79% of the time

Always: At least 80% of the time

H.8a Attention

Answer **only** if you answered "Yes" to H.8 "Does the patient have any problems with memory, attention, problem solving, planning, organizing or judgment?" and if you have the skills, knowledge, or training, to provide a response; otherwise, leave this section blank.

The patient maintains attention for:

Simple Activities: Following simple directions; reading environmental signs or short newspaper/magazine/ book passage; eating a meal; completing personal hygiene; dressing

Complex Activities: Watching a news program; reading a book; planning and preparing a meal; managing one's own medical, financial, and personal affairs

	Simple Activities		Complex Activities	
	H.8b Without Assistance	H.8c With Assistance	H.8d Without Assistance	H.8e With Assistance
Never or Rarely	☐	☐	☐	☐
Sometimes	☐	☐	☐	☐
Usually	☐	☐	☐	☐
Always	☐	☐	☐	☐

Level of Assistance:

Without Assistance: Patient performance **without** cueing, assistive device, or other compensatory augmentative intervention

With Assistance: Patient performance **with** cueing, assistive device, or other compensatory augmentative intervention

Frequency of maintaining attention:

Never or Rarely: Less than 20% of the time

Sometimes: Between 20% and 49% of the time

Usually: Between 50% and 79% of the time

Always: At least 80% of the time

Menu Task

INSTRUCTION SHEET

Please read these instructions carefully before starting.

Please follow the menu task completion rules listed below:

- Tell the examiner when you have finished reading these instructions
- Start the menu task when you are ready and tell the examiner as you start
- Tell the examiner when you are finished with the menu task
- You may ask questions before you start the menu task, but after you start do not speak to the examiner until you tell him/her that you are finished
- Complete the menu task as quickly and accurately as possible

Menu Selection Instructions:

- Select one meal item for each of the following meals: breakfast, lunch, and dinner
- Select one afternoon and one evening snack
- Select two beverages for breakfast, two beverages for lunch, and one beverage for dinner
- Use pen or pencil to indicate each item you select on the menu. If you select an item more than once indicate the number of times you are selecting it (for example, X2)

Please follow the menu selection rules listed below:

- Select two or more Heart Healthy food items []. Heart Healthy items can be either a snack or a meal
- Do not exceed 1800 total calories for the all the food items selected
- Do not exceed 58 total fluid ounces for all the beverages selected
- Do not count calories for beverages except for Soda (add 400 calories per soda to count/add no calories if diet soda is selected)

Menu

Breakfast

2 Eggs with Sausage, Hash Browns and Toast, *1000 calories*
Oatmeal with Raisins and Nuts, *300 calories*
Corned Beef Hash and Eggs, *1000 calories*
Waffles and Syrup, *800 calories*
Fresh Fruit Selection, *200 calories*

Fruit Juice (8 ounces) Coffee/Tea (12 ounces) Milk (12 ounces)

Lunch

Grilled Chicken Salad, *800 calories*
Hamburger and French Fries, *1200 calories*
Southwest Salad, *350 calories*
Chicken Fried Steak, *1000 calories*
Cottage Cheese and Vegetable Medley, *400 calories*

Fruit Juice (8 ounces) Coffee/Tea (12 ounces) Milk (12 ounces)
Soda (16 ounces) Diet Soda (16 ounces)

Menu

Dinner

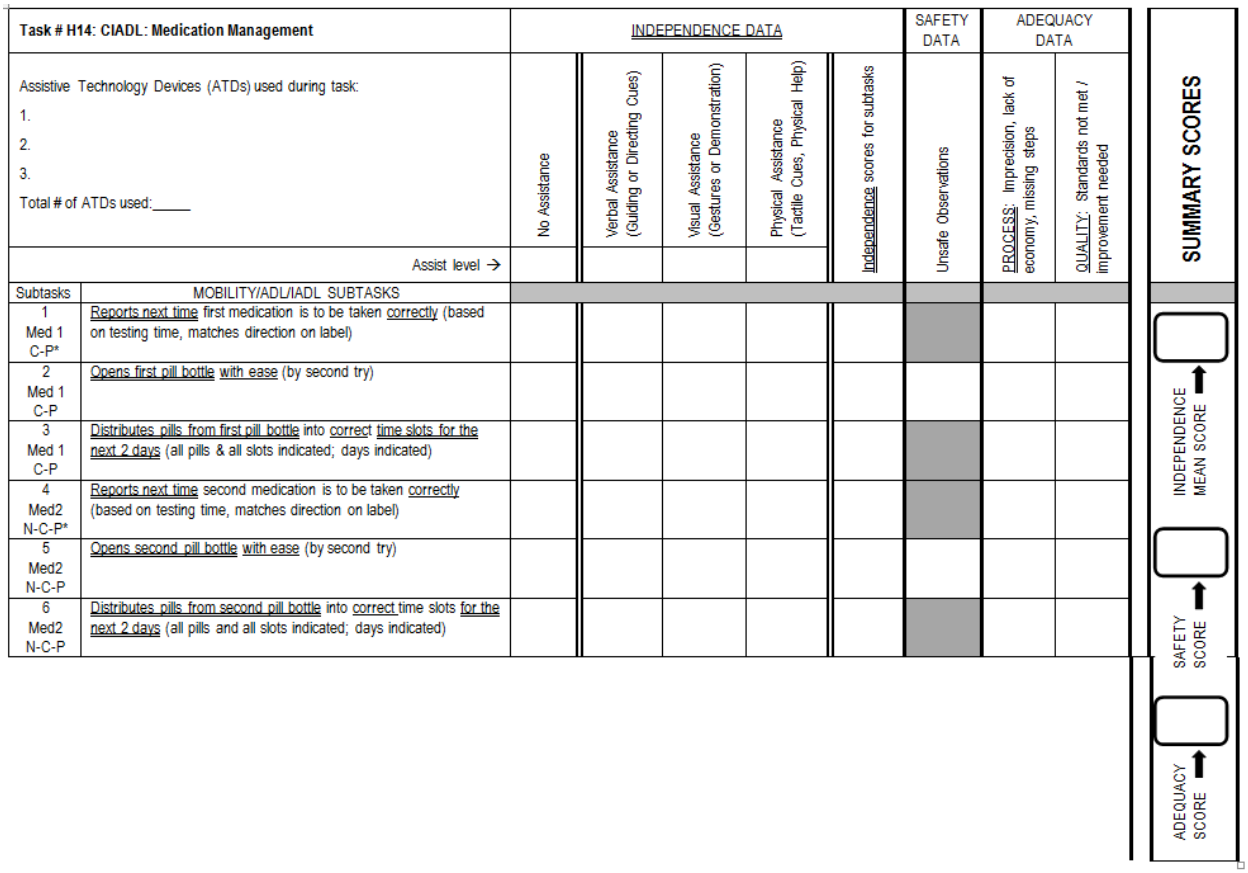
Turkey Burger and Garden Salad, *800 calories*
Lasagna, *500 calories*
Grilled Salmon and Wild Rice, *400 calories*
Southwest Salad, *350 calories*
Chicken Fried Steak, *1000 calories*

Fruit Juice (8 ounces) Coffee/Tea (12 ounces) Milk (12 ounces)
Soda (16 ounces) Diet Soda (16 ounces)

Afternoon/Evening Snack

Yogurt Cup, *280 calories*
Fresh Fruit Selection, *150 calories*
Crackers, *200 calories*
Ice Cream, *500 calories*
Jell-O, *100 calories*

PASS Medication Management Task



Task # H14: CIADL: Medication Management		INDEPENDENCE DATA					SAFETY DATA	ADEQUACY DATA		SUMMARY SCORES
Assistive Technology Devices (ATDs) used during task: 1. 2. 3. Total # of ATDs used:_____		No Assistance	Verbal Assistance (Guiding or Directing Cues)	Visual Assistance (Gestures or Demonstration)	Physical Assistance (Tactile Cues; Physical Help)	Independence scores for subtasks	Unsafe Observations	PROCESS: Imprecision, lack of economy, missing steps	QUALITY: Standards not met / Improvement needed	
Assist level →										
Subtasks	MOBILITY/ADL/IADL SUBTASKS									
1 Med 1 C-P*	Reports next time first medication is to be taken correctly (based on testing time, matches direction on label)									
2 Med 1 C-P	Opens first pill bottle with ease (by second try)									
3 Med 1 C-P	Distributes pills from first pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated)									
4 Med2 N-C-P*	Reports next time second medication is to be taken correctly (based on testing time, matches direction on label)									
5 Med2 N-C-P	Opens second pill bottle with ease (by second try)									
6 Med2 N-C-P	Distributes pills from second pill bottle into correct time slots for the next 2 days (all pills and all slots indicated; days indicated)									

Brief Screeners

Attention – Auditory Comprehension

Attention - Auditory comprehension

1. Make a fist
2. Raise your hand
3. Point to the ceiling, then to the floor
4. Tap each shoulder twice with two fingers, keeping your eyes shut
5. Say these after me: finger-jar-shoe-phone-stapler; 4-3-7; 5-2-4-8;

Executive Function – Abstract Reasoning

Executive Function – Abstract Reasoning

1. What are (up to) three reasons for someone being late?
2. Why do children go to school?
3. Why are windows made of glass?

Executive Function - Verbal Computation

Executive Function - Verbal Computation

1. Your favorite program begins at 10 pm, but you have 30 minutes to wait. What time is it?
2. If you have a prescription to take medication every six hours, how many times will you take it in one day?

Executive Function - Thought Organization

Executive Function - Thought Organization

1. Name as many animals as you can in 1 minute
2. Present cards with the words in the following order from patient's left to right: chin, boat, bag, car. Say "Please put these words in alphabetical order."

Executive Function - Convergent thinking

Executive Function - Convergent thinking

1. What are zebras, cats, and camels? Tell me in one word. They are all _____
2. What are chairs, tables, and sofas?
3. What are necklaces, earrings, and watches?

Fall-Related Impulsive Behavior Scale (FIBS)

The first FIBS question is 'Is *resident n* impulsive?' where impulsivity is operationalized as 'rushing to carry out an activity without thinking about it first'. One point is given if the answer is yes and zero if the answer is no. To identify impulsive actions during mobility tasks three further questions are asked:

How often does the resident do the following?

(1) Try to sit down before getting right up to the chair/toilet/bed?
(2) Attempt to stand before wheelchair brakes have been applied/footplates moved or walking frame places in front of them?
(3) Try to walk without help when asked not to?

The answers to these questions are graded as: never/NA (=0), occasionally (=1), often (=2), frequently (=3) or very frequently (=4). The FIBS score is calculated by summing the scores for the four questions. Residents are asked all four questions regardless of the answer to question 1.

PROMIS® Cognition

I have had trouble forming thoughts	I have had trouble finding my way to a familiar place
My thinking has been slow My thinking has been slower than usual	I have had trouble remembering new information, like phone numbers or simple instructions
My thinking has been foggy	I have had trouble speaking fluently
I have had trouble concentrating	I have had to work really hard to pay attention or I would make a mistake
I have had trouble recalling the name of an object while talking to someone	Other people have told me I seemed to have trouble remembering information
It seemed like my brain was not working as well as usual	I have had to work harder than usual to keep track of what I was doing
I have had trouble keeping track of what I was doing when interrupted	I have had to work harder than usual to express myself clearly
I have had trouble shifting back and forth between different activities that require thinking	I have had more problems conversing with others
My problems with memory, concentration or making mental mistakes have interfered with my ability to do things I enjoy	My problems with memory, concentration, or making mental mistakes have interfered with the quality of my life

PROMIS® Anxiety

I felt fearful	I was concerned about my mental health
I felt frightened	I felt upset
I felt anxious	I had a racing or pounding heart
I felt something awful would happen	I was anxious if my normal routine was disturbed
I felt worried	I had sudden feelings of panic
My worries overwhelmed me	I was easily startled
I felt nervous	I had trouble paying attention
I had trouble relaxing	I found it hard to focus on anything other than my anxiety
I felt tense	I felt uneasy
Many situations made me worry	

D2: Data Element Identified for Behavioral Signs and Symptoms

E0300. Overall Presence of Behavioral Symptoms	
Enter Code ☐	**Were any behavioral symptoms in questions E0200 coded 1, 2, or 3?** 0. **No** → Skip to E0800, Rejection of Care 1. **Yes** → Considering all of E0200, Behavioral Symptoms, answer E0500 and E0600 below
E0500. Impact on Resident	
Enter Code ☐	**Did any of the identified symptom(s):** **A. Put the resident at significant risk for physical illness or injury?** 0. **No** 1. **Yes**
Enter Code ☐	**B. Significantly interfere with the resident's care?** 0. **No** 1. **Yes**
Enter Code ☐	**C. Significantly interfere with the resident's participation in activities or social interactions?** 0. **No** 1. **Yes**
E0600. Impact on Others	
Enter Code ☐	**Did any of the identified symptom(s):** **A. Put others at significant risk for physical injury?** 0. **No** 1. **Yes**
Enter Code ☐	**B. Significantly intrude on the privacy or activity of others?** 0. **No** 1. **Yes**
Enter Code ☐	**C. Significantly disrupt care or living environment?** 0. **No** 1. **Yes**
E0800. Rejection of Care - Presence & Frequency	
Enter Code ☐	**Did the resident reject evaluation or care** (e.g., bloodwork, taking medications, ADL assistance) **that is necessary to achieve the resident's goals for health and well-being?** Do not include behaviors that have already been addressed (e.g., by discussion or care planning with the resident or family), and determined to be consistent with resident values, preferences, or goals. 0. **Behavior not exhibited** 1. **Behavior of this type occurred 1 to 3 days** 2. **Behavior of this type occurred 4 to 6 days,** but less than daily 3. **Behavior of this type occurred daily**

D3: Comprehensive List of Data Elements Identified for Observational Assessments for Patients/Residents Who Are Unable to Communicate: Cognition, Mood, and Pain

Cognition

MDS 3.0 Staff Assessment of Mental Status

C0600. Should the Staff Assessment for Mental Status (C0700 - C1000) be Conducted?

Enter Code ☐

0. **No** (resident was able to complete Brief Interview for Mental Status) → Skip to C1310, Signs and Symptoms of Delirium
1. **Yes** (resident was unable to complete Brief Interview for Mental Status) → Continue to C0700, Short-term Memory OK

Staff Assessment for Mental Status

Do not conduct if Brief Interview for Mental Status (C0200-C0500) was completed

C0700. Short-term Memory OK

Enter Code ☐

Seems or appears to recall after 5 minutes
0. **Memory OK**
1. **Memory problem**

C0800. Long-term Memory OK

Enter Code ☐

Seems or appears to recall long past
0. **Memory OK**
1. **Memory problem**

C0900. Memory/Recall Ability

↓ **Check all that the resident was normally able to recall**

- ☐ **A. Current season**
- ☐ **B. Location of own room**
- ☐ **C. Staff names and faces**
- ☐ **D. That he or she is in a nursing home/hospital swing bed**
- ☐ **Z. None of the above** were recalled

C1000. Cognitive Skills for Daily Decision Making

Enter Code ☐

Made decisions regarding tasks of daily life
0. **Independent** - decisions consistent/reasonable
1. **Modified independence** - some difficulty in new situations only
2. **Moderately impaired** - decisions poor; cues/supervision required
3. **Severely impaired** - never/rarely made decisions

Mood

Staff Assessment of Patient/Resident Mood (PHQ-9-OV)

G2. Staff Assessment of Patient/Resident Mood (PHQ-9-OV©)			
Over the last 2 weeks, did the resident have any of the following problems or behaviors? **If symptom is present, enter 1 (yes) in Column 1, Symptom Presence**			
If yes in Column 1, then indicate symptom frequency in Column 2, Symptom Frequency			
1. Symptom Presence 0. **No** (enter 0 in Column 2) 1. **Yes** (enter 0-3 in Column 2)	**2. Symptom Frequency** 0. **Never or 1 day** 1. **2-6 days** (several days) 2. **7-11 days** (half or more of the days) 3. **12-14 days** (nearly every day)	**1. Symptom Presence**	**2. Symptom Frequency**
		Enter Scores in Boxes ↓	↓
G2a1, G2a2: Little interest or pleasure in doing things		☐ a1	☐ a2
G2b1, G2b2: Feeling or appearing down, depressed, or hopeless		☐ b1	☐ b2
G2c1, G2c2: Trouble falling or staying asleep, or sleeping too much		☐ c1	☐ c2
G2d1, G2d2: Feeling tired or having little energy		☐ d1	☐ d2
G2e1, G2e2: Poor appetite or overeating		☐ e1	☐ e2
G2f1, G2f2: Indicating that s/he feels bad about self, is a failure, or has let self or family down		☐ f1	☐ f2
G2g1, G2g2: Trouble concentrating on things, such as reading the newspaper or watching television		☐ g1	☐ g2
G2h1, G2h2: Moving or speaking so slowly that other people have noticed. Or the opposite – being so fidgety or restless that s/he has been moving around a lot more than usual		☐ h1	☐ h2
G2i1, G2i2: States that life isn't worth living, wishes for death, or attempts to harm self		☐ i1	☐ i2
G2j1, G2j2: Being short-tempered, easily annoyed		☐ j1	☐ j2
PHQ-9-OV TOTAL: Add values in boxes a2, b2, c2, d2, e2, f2, g2, h2, i2 and j2 →			☐

Pain

Observational Assessment of Pain or Distress

***[Data Element #]*. Observational Assessment of Pain or Distress.** For all patients who are unable to participate in the pain interview, please note whether any of the following behaviors were observed. Patients should be observed twice daily during morning AND evening care (i.e., during transfer procedures, repositioning, bathing, toileting, wound care/dressing changes, range of motion, ambulating, or other exercises, etc.), when behavioral signs of potential pain or distress are most likely to be expressed; over the course of 3 consecutive days.	
Check all that apply	
☐	**a. Non-verbal sounds (e.g., crying, whining, gasping, moaning, or groaning)**
☐	**b. Vocal complaints of pain (e.g., "that hurts, ouch, stop")**
☐	**c. Facial expressions (e.g., grimaces, winces, wrinkled forehead, furrowed brow, clenched teeth or jaw, rapid eye blinking; tightly closed eyes)**
☐	**d. Body movements or postures (e.g., bracing, guarding, rubbing or massaging a body part/area, clutching or holding a body part during movement, rigid, tense body posture; fidgeting; increased pacing, rocking; restricted movement; gait or mobility changes)**
☐	**e. None of these signs observed or documented.**

Frequency of Observed Indicators of Pain or Distress

***[Data Element #]*. For patients who demonstrated <u>any</u> indicators of potential pain or distress listed above, identify the frequency with which patient complains or shows evidence of potential pain or distress over the past 3 days.**

1. Indicators of potential pain or distress observed less than daily

2. Indicators of potential pain or distress observed daily (once per day on each day of the assessment window)

3. Indicators of potential pain or distress observed more than daily (more than once per day on each day of the assessment window)

Effect of Pain Medications or Treatments on Observed Indicators of Pain or Distress

[Data Element #]. **For patients who demonstrated any indicators of potential pain or distress listed above, is there any evidence that these indicators resolved or diminished in response to pain medications or treatments over the past 3 days?**

0. No

1. Yes

8. Not applicable – patient/resident has not received pain medications or treatments within the past 3 days

D4: Comprehensive List of Data Elements Identified for Medication Reconciliation

Step 1: Obtain a current list of medications from various sources

SECTION B MEDICATION RECONCILIATION	
B1. How many of the patient/resident's information sources were used to obtain medication lists?	
Enter Code ☐	0. No medication lists available **[END SECTION]** 1. 1 2. More than 1 8. N/A; Patient/Resident is not taking any medications **[END SECTION]**
B2. Is there documentation that medication reconciliation was completed within 3 days of admission/discharge/ROC/SOC?	
Enter Code ☐	0. No 1. Yes

Step 2: Compare lists from multiple sources ensuring that medications are appropriate, side effects are documented, and medication errors are resolved

B3. Is the patient/resident taking any of the following types of medications? Check all that apply.	
Check all that apply	
☐	None of the below **[SKIP TO B10]**
☐	Anti-coagulants
☐	Anti-platelets
☐	Anti-diabetics [for example, insulin]
☐	Opioids
☐	Anti-psychotics
☐	Anti-microbials
☐	Other medications listed in the Beers Criteria for patients 65 years of age or older
B4. Did the patient's medication list or lists include an indication for each high-risk medication identified in question B3?	
Enter Code ☐	0. No 1. Yes
B5. Did the patient have any medication discrepancies involving any of the high-risk medications identified in question B3?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation

Step 3: Adjudicate and derive a list of medications

B6. Were the patient's high-risk discrepancies addressed immediately after admission/discharge/SOC/ROC?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation
B7. Were the patient's high-risk discrepancies addressed by involving the patient/resident or patient's/resident's family/formal caregiver?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation
B8. Was the patient's physician (or physician-designee) contacted about all of the patient's high-risk discrepancies?	
Enter Code ☐	0. No **[SKIP TO B10]** 1. Yes 8. Missing information sources or lack of documentation
B9. Were the physician (or physician-designee) prescribed/recommended actions in response to all of the patient's high-risk discrepancies carried out?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation

Steps 4 & 5

B10. Was the reconciled medication list communicated to the patient/resident or patient's/resident's family/formal caregiver?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation list
B11. Was the reconciled medication list communicated to all of the patient's/resident's primary care providers responsible for the patient's/resident's care following admission/discharge/SOC/ROC?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation
B12. Was the reconciled medication list communicated to the patient's/resident's pharmacy that will be filling most of the medications following admission/discharge/SOC/ROC?	
Enter Code ☐	0. No 1. Yes 8. Missing information sources or lack of documentation

D5: Comprehensive List of Data Elements Identified for Special Services, Treatments, and Interventions

Nutritional Status

Section K	Swallowing/Nutritional Status	
K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days of admission.		
		1. Performed during the first 3 days of admission **Check all that apply** ↓
A. Parenteral/IV feeding		☐
B. Feeding tube - nasogastric or abdominal (e.g., PEG)		☐
C. Mechanically altered diet - require change in texture of food or liquids (e.g., pureed food, thickened liquids)		☐
D. Therapeutic diet (e.g., low salt, diabetic, low cholesterol)		☐
Z. None of the above		☐

Cancer Treatments and Respiratory Treatments

Section O	Special Treatments, Procedures, and Programs	
O0110. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		a. Performed during the first 3 days of admission **Check all that apply** ↓
Cancer Treatments		
	A1. Chemotherapy (if checked, please specify below)	☐
	A2. IV	☐
	A3. Oral	☐
	A10. Other	☐
	B1. Radiation	☐
Respiratory Treatments		
	C1. Oxygen therapy (if checked, please specify below)	☐
	C2. Continuous	☐
	C3. Intermittent	☐
	D1. Suctioning (if checked, please specify below)	☐
	D2. Scheduled	☐
	D3. As needed	☐
	E1. Tracheostomy care	☐
	F1. Invasive Mechanical Ventilator	☐
	G1. Non-invasive Mechanical Ventilator (BiPAP/CPAP) (if checked, please specify below)	☐
	G2. BiPAP	☐
	G3. CPAP	☐

Other Treatments

Other Treatments		
	H1. IV Medications (if checked, please specify below)	☐
	H2. Vasoactive medications (i.e., continuous infusions of vasopressors or inotropes)	☐
	H3. Antibiotics	☐
	H4. Anticoagulation	☐
	H10. Other	☐
	I1. Transfusions	☐
	J1. Dialysis (if checked, please specify below)	☐
	J2. Hemodialysis	☐
	J3. Peritoneal dialysis	☐
	O1. IV Access (if checked, please specify below)	☐
	O2. Peripheral IV	☐
	O3. Midline	☐
	O4. Central line (e.g., PICC, tunneled, port)	☐
	O10. Other	☐
None of the Above		
Z1. None of the above		☐

D6: Comprehensive List of Data Elements Identified for Care Preferences

Advance Directives

Advance Directives

A. Does the patient/resident have a legally authorized advance health care directive in the medical record providing instructions for future health care and treatment in the event that the patient/resident is unable to speak for themselves?
   0. No
   1. Yes

B. Does the patient/resident have any of the following physician orders documented and active in the medical record?
   1. Do not resuscitate (DNR)
   2. Do not intubate (DNI)
   3. Do not hospitalize (DNH)
   4. None of the above

C. Does the patient/resident have a legally authorized Health Care Agent/Proxy *to make health care decisions in the event that the patient/resident is unable to make his or her own decisions* AND there is supporting legal documentation in the medical record?
   0. No
   1. Yes (Specify): _____

Expansion into Subareas of Goals of Care ("Drilling Down")

Subareas of goals of care	**Item(s) assessing the subarea**
Taking Care of Your Body	1. How important is it to you to be able to take care of your own body? By taking care of your own body, I mean things like being able to bathe by yourself, use the toilet by yourself or getting dressed on your own.
Living Independently	1. How important is it to you to be able to do your everyday activities on your own or with little help? By everyday activities, I mean things like preparing a simple meal, light housework or doing laundry.
Physical Activity	1. How important is it to you to maintain or improve your physical abilities? By physical ability, I mean things like your ability to walk up the stairs, walk short distances, or get onto or off a chair without trouble. 2. How important is it to you to be physically active? By physically active, I mean things like getting fit, exercising, or physical recreation.
Social Engagement	1. How important is to you to have meaningful relationships with others? I mean things like spending time with family and friends, being intimate with a partner/loved one, or going to family gatherings.
Intellectual Capacity	1. How important is it to you to maintain your basic thinking ability? By thinking ability, I mean things like being able to remember day-to-day things, and feel free from confusion. 2. How important is it to you to be intellectually active? By intellectually active, I mean being able to process information quickly, learning new things and maintaining older skills.
Comfort	1. How important is it to you to maintain or improve your physical comfort? By physical comfort, I mean not having unpleasant symptoms or sensations, such as pain, nausea, itching or burning.
Emotional Health & Growth	1. How important is it to you to feel emotionally healthy? I mean things like feeling free of sadness, worry and anxiety, or having a positive outlook on life. 2. How important is it for you to pursue meaningful activities? By meaningful activities, I mean those that would contribute to your sense of fulfillment and your personal identity.

** Response Scale for each item: Very important; Somewhat important; Not very important; Not important at all; Important, but can't do or no choice; No response or non-responsive*

Health Outcomes and Tradeoffs Scale ("Pushing to Priorities")

Subscale 1: Tradeoffs between Quality and Quantity of Life

Subscale 2: Tradeoffs between Future and Present Health

Subscale 1: Tradeoffs between Quality and Quantity of Life
1. The most important thing to me is living as long as I can, no matter what my quality of life it. 2. I would rather live a shorter life than lose my ability to take care of myself (daily activities). 3. It is more important to me to maintain my thinking ability than to live as long as possible. 4. If I had to choose between living as long as possible or being free from pain, I would choose living as long as possible.
Subscale 2: Tradeoffs between Future and Present Health
1. I am willing to have side effects right now if it means I could have a better quality of life in the future. 2. I would prefer to take fewer medications, even if it meant that I would not live as long. 3. I am willing to put up with more doctors' visits and dietary restrictions now if that means that in the future I will be less likely to develop a new disease. 4. I would prefer to have fewer medical tests and doctors' visits, even if it meant that I would not live as long. 5. It is more important for me to feel well right now that to feel well in the future. 6. I would prefer to take fewer medications, even if it meant that my chances of dying would be higher.

** Response categories: Strongly Agree (5); Agree (4); Neither Agree nor Disagree (3); Disagree (2); Strongly Disagree (1).*
*** Scoring: Agreement (i.e.; higher numbers) suggests that quantity of life/future health more important than quality of life/current health. Italicized items are reverse-scored.*

D7: Comprehensive List of Candidate PROMIS Profile® Items

Physical Function

Recommended PROMIS Physical Function Items
Are you able to do use your hands, such as for turning faucets, using kitchen gadgets, or sewing?
Are you able to lift a full cup or glass to your mouth?
Are you able to button your shirt?
Are you able to put on a pullover sweater?
Does your health now limit you in taking care of your personal needs (dress, comb hair, toilet, eat, bathe)?
Are you able to get in and out of bed?
Are you able to put on a shirt or blouse?
Does your health now limit you in taking a shower?
Does your health now limit you in bathing or dressing yourself?
How much difficulty do you have doing your daily physical activities, because of your health?
To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
Are you able to stand unsupported for 10 minutes?
Does your health now limit you in going for a short walk (less than 15 minutes)?
Does your health now limit you in doing moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
Are you able to go up and down stairs at a normal pace?
Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?

Fatigue

Recommended PROMIS Fatigue Items
How often were you energetic?
How energetic were you on average?
How often did you feel tired?
How tired did you feel on average?
How often did you find yourself getting tired easily?
How often were you bothered by your fatigue?
How often were you less effective at home due to your fatigue?
How often did you feel tired even when you hadn't done anything?
How often did you have enough energy to enjoy the things you do for fun?
To what degree did you have to push yourself to get things done because of your fatigue?
How often were you less effective at work due to your fatigue (include work at home)?
I need to sleep during the day
How often did you have trouble finishing things because of your fatigue?
How often did your fatigue interfere with your social activities?
To what degree did your fatigue interfere with your ability to engage in recreational activities?
To what degree did your fatigue interfere with your physical functioning?
How often did you experience extreme exhaustion?
To what degree did your fatigue make you feel slowed down in your thinking?
I have to limit my social activity because I am tired
How hard was it for you to carry on a conversation because of your fatigue?

Sleep Disturbance

Recommended PROMIS Sleep Disturbance Items
My sleep was restful.
My sleep quality was…
I got enough sleep.
I was satisfied with my sleep.
I felt lousy when I woke up.
It was easy for me to fall asleep.
I had trouble staying asleep.
I woke up and had trouble falling back to sleep.

Ability to Participate in Social Roles and Activities

Recommended PROMIS Satisfaction with Participation in Social Roles Items
I have trouble participating in recreational activities with others
I have trouble doing all of the family activities that I feel I should do
I have trouble doing all of my regular leisure activities with others
I have trouble doing all of the activities with friends that are really important to me
I have trouble doing all of my usual work (include work at home)
I have trouble doing all of the work that is really important to me (include work at home)
I have trouble taking care of my regular personal responsibilities
I have trouble doing all of the activities with friends that I want to do

Appendix E: PROMIS Depression Items Webinar Summary

Follow-Up TEP discussion: The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data-PROMIS
July 24, 2017

On July 24, 2017, RAND, on behalf of CMS, convened a one-hour follow-up Technical Expert Panel (TEP) webinar meeting. The purpose of the follow-up webinar meeting was to provide an update on project activities, especially as they pertain to PROMIS item set decisions and to finalize the subset of PROMIS Depression items selected for inclusion in Beta testing. In addition to briefly discussing recent changes to three of the previously-discussed item sets (Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities), the webinar discussion focused primarily on the PROMIS Depression items, as they had not been discussed during the in-person TEP convened on January 4-5, 2017.

Following a brief update on project testing activities to date, including preliminary results from Alpha 2 field testing and plans for the national Beta test, RAND shared shortened item lists for Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities and provided the rationale for the reduced item count relative to what was presented in January. TEP members were asked whether they approved the further reduction of the item lists for Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities and agreed with the rationale for the cuts. See below for the list of items that the TEP agreed upon.

Final Item Sets for Fatigue, Sleep Disturbance and Social Domains

Fatigue: 7 item subset selected for beta testing

In the past 7 days:

1. How often did you feel tired?
2. How often did you find yourself getting tired easily?
3. How often were you too tired to think clearly?
4. How often did your fatigue make it difficult to make decisions?
5. How often did you have enough energy to enjoy the things you do for fun?
6. How often did you have to push yourself to get things done because of your fatigue?
7. How often were you too tired to take a bath or shower?

** Items deleted from top 10:*

1. I am frustrated by being too tired to do the things I want to do
2. I am too tired to eat
3. I have energy

Sleep Disturbance: 8 items from the original bank

In the past 7 days:

1. I had trouble sleeping
2. I had trouble staying asleep
3. I woke up and had trouble falling back to sleep
4. I worried about not being able to fall asleep
5. I had difficulty falling asleep
6. I had trouble stopping my thoughts at bedtime
7. I had trouble getting into a comfortable position to sleep
8. My sleep was restless

** Items deleted from top 12:*

1. My sleep was restful
2. It was easy for me to fall asleep;
3. I was satisfied with my sleep.
4. I got enough sleep.

Ability to Participate in Social Roles and Activities: 8 item subset selected for beta testing

1. I have trouble participating in recreational activities with others
2. I have trouble doing all of my regular leisure activities with others
3. I have trouble doing all of the family activities that are really important to me
4. I have to limit the things I do for fun with others
5. I have trouble doing all of the activities with friends that are really important to me
6. I have trouble taking care of my regular personal responsibilities
7. I have to limit social activities with groups of people
8. I have trouble keeping in touch with others

Items deleted from top 10:

1. *I have trouble doing all of the family activities that I want to do.*
2. *I have to limit my regular family activities*

Next, RAND presented the PROMIS Depression item selection process and items proposed for inclusion in Beta and asked TEP participants to agree upon a subset of items from the initial list of 28 Depression items. RAND explained that the initial list of 28 Depression items was reduced to 11 items based on input from stakeholders, including the TEP members themselves, and the Northwestern University PROMIS development team. From this input, five of these 11 items received the highest ratings in terms of suitability for administration across post-acute care (PAC) settings and the remaining six were also highly rated (see below for the list of items). Prior to the webinar meeting, TEP members were asked to reduce the six items down to three that seemed best for administering across PAC settings. Out of the three TEP

members who responded to the request, items 6 (“I felt worthless”), 7 (“I felt helpless”), and 8 (“I felt lonely”) were most preferred.

During the webinar meeting, one TEP member, who responded to the original request, reiterated that she had voted to include items 6 and 7. The presenter then asked if anyone preferred items 9 (“I felt that I wanted to give up on everything”), 10 (“I felt discouraged about the future”), and 11 (“I felt my life was empty”) for inclusion in Beta testing. Another TEP member who had previously responded to the request stated that she agreed with including items 6-8. She also voiced that items 9 and 10 were duplicative of items 1-5 and felt neutral towards item 11. Three other TEP members agreed with these thoughts.

The TEP appreciated being engaged in this work, and members were generally supportive of the decisions that were made including the selection of the final eight PROMIS Depression items. The list of items is below.

Proposed PROMIS Depression Items

Highest Ratings based on Stakeholder and Northwestern University PROMIS Team Input:

1. I felt that I had nothing to look forward to
2. I felt sad
3. I felt depressed
4. I felt I had no reason for living
5. I felt hopeless

Additional Items – Also Highly Rated:

6. I felt worthless*
7. I felt helpless*
8. I felt lonely*
9. I felt that I wanted to give up on everything
10. I felt discouraged about the future
11. I felt my life was empty

*Items 6-8 preferred based on TEP response.