Public Comment Summary Report 2

Project Title:

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

Dates:

- The Call for Public Comment ran from April 26, 2017 to June 26, 2017.
- The Public Comment Summary was made available on January 15, 2018.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the RAND Corporation to develop standardized assessment-based data elements to meet the requirements as set forth under the IMPACT Act of 2014, Section 2(a). The contract name is "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data". The contract number is HHSM-500-2013-13014I. As part of its data element development process, CMS encourages interested parties to submit comments on the data elements described in this posting, which are being considered for this project.

Project Objectives:

The project objective is to develop standardized patient assessment data elements to meet the requirements of the IMPACT Act of 2014, Section 2(a). These data elements may be used to inform a number of important things, including case-mix adjustment, medical complexity, interoperable exchange, clinical decision support, and measure development.

Information About the Comments Received:

- Web site used: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Currently-Accepting-Comments.html
- Public comments were solicited by the following methods:
    - Posting a call for public comment on the CMS public comment website
    - Notifying relevant stakeholders and stakeholder organizations via email
- Volume of responses received: CMS received 33 relevant comments and three comments that were out of scope. Thirty-two organizations submitted comments, consisting of two PAC provider organizations, two general health systems, 14 professional organizations, eight health industry companies, four hospitals, one health consultant, and one governmental agency; as well as one unaffiliated individual.

General Comments

Support

Summary: Several commenters commended CMS' intent to create clinically relevant data elements that improve care coordination among providers and improve quality of care. Other commenters supported the goals of data standardization across settings. One commenter believed developing a standardized process to evaluate post-acute care across different settings will help to improve safe care transitions for hospital patients and long-term care residents in all facilities. Another commenter supported the standardized assessment data as proposed for the areas of cognitive function and mental status, medical conditions (continence and pain), hearing and vision, medication reconciliation, care preferences, and PROMIS and believed that many of the data elements are essential for appropriate risk adjustment of cases both for the purposes of payment and for use in outcomes measures methodologies in the post-acute care settings. Another commenter supported ongoing efforts to develop standardized data collection across the four PAC provider types and believed it will play an essential role in facilitating comparison of health outcomes, promoting data exchange among the different PAC provider types, and advancing other person-centered outcomes and goals. One commenter was pleased to see the inclusion of several observation-based assessment items/item sets for use in cases where the resident/patient is unable to self-report, due to cognitive or physical deficits. Finally, one commenter applauded the process for testing data elements through alpha 1, alpha 2, and beta testing prior to the implementation of the elements across PAC settings to ensure the feasibility and reliability of the elements in PAC settings.

Response: We thank the commenters for their support and agree that standardization will improve safe care transitions, facilitate comparison of health outcomes, promote data exchange among different PAC settings, inform payment modeling, and advance other patient-centered outcomes and goals.

Burden

Summary: Several commenters were concerned that some of the proposed elements will increase the administrative burden among providers. Commenters raised concerns about burden for the following specific categories of standardized patient assessment data elements: Cognitive Function and Mental Status (DOTPA, PASS Medication Management, Behavioral Signs and Symptoms), PHQ9-OV, Continence, Pain, Medication Reconciliation, Care Preferences, and PROMIS items. One commenter asked CMS to provide estimates related to the staff time required to complete and encode the data for the draft data elements under consideration. The commenter noted that data elements currently in use are already extensive and adding new data elements, without removing both the preexisting and similar ones, would lead to increased confusion among both clinicians and patients/residents. Another commenter was concerned that some of the data elements will be unnecessarily burdensome for providers and not as useful for CMS as other elements would be. Another commenter encouraged CMS to be mindful of the impact the numerous assessment items would have on the patient-provider relationship and to assess whether they are patient-centric or intrusive. Another commenter asked CMS to consider and rate the relative benefit versus burden for each proposed item to permit a better-informed decision. Several commenters were concerned about the operational burdens associated with

standardized patient assessment data elements. One commenter noted that significant time and resources have been allocated at their institution to build, customize, and modify electronic medical records (EMRs) to meet the data collection requirements of the IMPACT Act and that each addition and/or change to the EMR requires significant education and training, involving hundreds of employees across multiple clinical departments. The additional time needed for documentation results in less time for bedside care and therapy treatment. Another commenter was concerned about the time it takes to assess and enter data that is often unrelated to the reason the person is receiving care, and/or, does not contribute to the quality or outcomes of care and recommended that any proposed assessment instrument item specification changes should identify and quantify the provider burden impact. Furthermore, this commenter noted that use of a tablet may reduce the assessment time during the item testing phases of this project, but it does not accurately reflect "real-world" assessment burden of these proposed items, both individually, and in the aggregate. The commenter stated that reporting burden is not just completing the assessment item, but also the time developing care plan approaches associated with the new items assessed, as well as related documentation and coding requirements to support the MDS item responses.

Response: At every step of the process of developing standardized patient assessment data elements to meet the intent of the IMPACT Act, we have been keenly aware of the need to minimize additional burden on providers and patients/residents. We are aware of the added burden that would be introduced by new data elements, and have been committed to engaging with stakeholders at every step of the process and will continue to do so, as we move toward meeting the intent and requirements of the IMPACT Act. Furthermore, we are mindful of the impact that additional assessment items may have on the patient-provider relationship and throughout our process continually assess whether items are patient-centric. We thank the commenter for suggesting a benefit versus burden assessment and we will consider this as we continue to develop and evaluate standardized patient assessment data elements. If data elements are proposed for adoption, we will provide estimates of staff time required to complete the assessment within the proposed rule. These estimates will consider possible differences between completion time in a testing context and 'real-world' assessment burden. Finally, we reiterate that the purpose of standardizing data elements, in accordance with the IMPACT Act, is to support care planning, clinical decision support, inform payment modeling and quality measurement, support care transitions, and to allow interoperable data exchange among PAC providers and other providers, including by using common standards and definitions.

Redundancy

Summary: Several commenters were concerned about the redundancy between assessment items introduced and those in current use. Commenters noted that multiple items used to assess and measure the same domain is redundant and inefficient resulting in more time and money spent on staff and documentation rather than providing quality, hands-on patient care. Commenters specifically pointed to redundancy for the following categories of standardized patient assessment data elements: Cognitive Function and Mental Status (DOTPA, Complex Sentence Repetition, Staff Assessment of Mental Status), PHQ9-OV, Continence, Pain, Medication Reconciliation, Care Preferences, and PROMIS items. Commenters believed the workflow burden may have a negative impact on patient outcomes over time and recommended selection of one data element to measure each domain. Another commenter noted that many of the items are nearly identical to existing hospital assessment and care practices and thus are unnecessarily repetitive and burdensome. This commenter asked CMS to consider an approach by which it implements a core set of non-duplicative standardized patient assessment items across all PAC settings, upon which it builds and supplements setting-specific assessment items as needed. Another commenter was

concerned about the potential significant increase in provider burden if the proposed data element specifications are layered on top of the MDS 3.0 assessment rather than as a replacement for existing items addressing the same or similar domain and recommended that efforts must also provide information and guidance to CMS as to what legacy assessment items are not IMPACT Act compliant, and should be phased out as new PAC cross-setting assessment items are introduced. This commenter encouraged CMS to provide a thorough mapping of these redundancies. Another commenter recommended that redundant items not be considered unless there is evidence that they provide better information than those already in use.

Response: We are mindful of the burden that redundancy creates but through our process of phased testing and stakeholder consensus building, are testing for items that are reliable, valid, and feasible to collect in a PAC setting and across PAC settings. The intent of this work is not to create redundant items, but rather create the most useful, clinically meaningful items that could be standardized and could assist in improving outcomes. We appreciate the comments pertaining to the development of a core set of non-duplicative standardized patient assessment items across all PAC settings and will take this into consideration. Further, in accounting for administrative burden, we will also consider the replacement of items already in use in our assessment instruments when appropriate to do so to avoid double documentation, provider confusion, and minimize burden.

Flow of assessment data

Summary: One commenter was concerned that there is an expectation of PACs to incorporate assessment information from other venues of care into the current assessment and noted that there are current requirements for PACs to do their own assessment and not 'copy answers' from another assessment. The commenter would like to see CMS clarify their provider assessment expectation and remediate existing rules, if this is the case.

Response: We would like to note that the intent of work underway to standardized patient assessment data elements is to develop and test items that could be standardized across PAC settings for a PAC population who receives PAC services. We reiterate that data collection in PAC settings, and the assessment instruments that support such data collection, is to support the assessment requirements of the statutorily-mandated PAC programs and the requirements that guide these programs.

Cross-setting feasibility

Summary: Commenters believed that some data elements will not accurately measure a patient's needs under specific PAC settings. These commenters were concerned about cross-setting feasibility for the following categories of standardized patient assessment data elements: Cognitive Function and Mental Status (DOTPA, Complex Sentence Repetition, PASS Medication Management, Staff Assessment of Mental Status, Behavioral Signs and Symptoms), PHQ9-OV, Continence, Pain, Care Preferences, and PROMIS items. For example, the data element measuring "Pain Interference-Therapy Activities", under the category of Pain, requires providers to ask patients if they have been offered physical, occupational or speech therapy in the past three days. The commenter believed this question would be redundant in an IRF setting since a patient's purpose at an IRF is to receive physical and occupational therapy. Another commenter noted many of the proposed data elements are not relevant in the LTCH setting because the severity of patients at LTCHs is significantly higher than in other settings and thus, interviews would not be attempted in many circumstances because the patient is either unresponsive or unable to make himself or herself understood, and would significantly add to reporting burden.

Commenters noted that many of the data elements were not applicable to the home health setting. One commenter noted that some of the data elements would unfairly penalize Home Health agencies because, for example, the expectation of improving cognition in dementia or Alzheimer's patients is not realistic, and medication reconciliation requires obtaining physician cooperation which is very difficult to obtain. Another commenter noted that home health agencies frequently receive community referrals, and that the data elements are focused on patients received from facilities. This commenter noted that the questions are biased toward inpatient facilities because home health agencies do not have control of the environment that the patient is in. Additionally, this commenter noted many HH patients are "therapy only" and skilled nursing has not been ordered, and therefore, some of the questions will not align with a therapist's training and expertise.

***Response*:** We acknowledge that the four PAC provider types have unique challenges and provide unique services and appreciate the commenters' concerns surrounding provider types and their potential variation in services and populations. Because of this, we are conducting a thorough process of phased testing and stakeholder consensus building to ensure we are considering items that align across PAC settings, yet recognize each setting's unique characteristics. We note that for the items in question we are still in the evidence-building phase and the intent is to move forward with those items identified as best-in-class. Many of the tested items capture basic clinical workflow and practices, and therefore, are consistent with day-to-day practice. We also note that there is some overlap between settings as illustrated in the PAC PRD. Through our continued deliberate process of stakeholder engagement and field testing, we aim to maximize this overlap and identify the best data elements to be used across all settings. For more information on the PAC PRD and the discussion of item overlap please see: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-Volume-1-of-3.pdf.

Validity and reliability

Summary: Commenters were concerned inadequate evidence for validity and reliability was presented. Commenters expressed concern about the psychometric properties for many of the standardized patient assessment data elements, including Cognitive Function and Mental Status (DOTPA, Complex Sentence Repetition, PASS Medication Management, Staff Assessment of Mental Status), PHQ9-OV, Continence, Medication Reconciliation, and PROMIS Anxiety. One commenter observed several instances in which the data element being considered had not been tested for reliability, but a similar measure has. The commenter believed that unless the actual data element and its associated items are tested for reliability for the methodology under consideration, the data element should not be considered reliable.

Response: We appreciate the commenters concerns about the limited testing for some of the standardized data elements that were described and agree that it is essential to thoroughly test new data elements to provide evidence that they are universally applicable and psychometrically sound in all PAC settings. Our national field testing is designed to provide the necessary evidence to confirm or refute the appropriateness of each data element for PAC standardization. In our ongoing data element development work and testing, we will carefully consider the level of evidence associated with each candidate standardized data element and only those data elements that qualify based on the level of evidence (including feasibility, validity and reliability) will continue to be considered for standardization.

Suggest additional data elements

Summary: One commenter recommended that CMS adopt data elements to assess a patient's ability to partake in activities of daily living. Another commenter recommended CMS consider additional information about patient functional limitations using the International Classification of Functioning, Disability and Health (ICF) developed by the World Health Organization. Another commenter noted that including an assessment of assistive devices is absent and that this is important to determine that improvement in independence was due, not only to personal assistance but to the use of a particularly effective assistive device to achieve that independence.

Response: We thank the commenters for this feedback and will take it under consideration in our ongoing standardized patient assessment data element development work.

Translation

Summary: One commenter suggested providing translated versions of the assessments, as a significant limitation of language-based assessments is their lack of applicability to non-native English speakers. The commenter believed that use of these elements without translated versions would be a significant concern for providers that serve multi-ethnic communities.

Response: We thank the commenters for this feedback and will take it under consideration in our ongoing standardized patient assessment data element development work.

Look-back periods

Summary: Commenters expressed concern about look-back periods for many of the standardized patient assessment data elements, including Behavioral Signs and Symptoms, PHQ9-OV, Continence, Pain, and PROMIS Anxiety. One commenter recommended that CMS strive to adopt a single look-back period among all PAC providers to reduce confusion in different PAC settings. Another commenter noted the unique challenges for look-back periods in home health agencies because, unlike an inpatient facility, the staff are not with the patient/resident 24/7. One commenter was concerned about assessment window and recommended a thorough mapping of the Medicare and Medicaid case mix groups that would be impacted by adopting a standard PAC assessment window for the proposed data elements, a thorough mapping of the PAC quality measures that would be impacted by adopting a standard PAC assessment window for the proposed data elements, and clarification of how the proposed data element assessment windows would align with or require significant changes to the existing MDS reporting schedules for short- and long-stay SNF residents. Another commenter questioned whether the assessments are done at admission or discharge and noted that questions asked at discharge can only be used for quality improvement, not for payment and or risk adjustment.

Response: We acknowledge that between settings, and even within the same item set within a setting, the look-back periods and assessment windows may vary. In our ongoing work to identify candidate data elements for standardization, we will continue to carefully consider the implications of changing look-back periods. We believe that it is important to collect the same information across settings, including over the same look-back period and assessment period, and we will work to identify the best options for reaching this ideal state of standardized assessment in the future. With this, we would like to note that we are in the process of testing several different look-back periods to determine which yield the best data for multiple purposes.

Future use of data

Summary: Commenters had concerns about how the data may be used in the future. One commenter believed the data elements are important and should be used in risk-adjustment methodologies for payment and quality measures, but was concerned about the use of these data elements to construct outcomes measures that will be used to determine payment. The commenter encouraged CMS to continue to work with stakeholders in the development of future quality measures for the post-acute care settings. Another commenter believed that the request to comment on data elements' "potential for improving quality" is inaccurate, misleading, and was concerned that it will lead to inappropriate use of the data because data collection and quality measure conceptualization reflect two inherently distinct purposes. Another commenter was concerned that adoption and implementation of the proposed PAC data element specifications without first identifying and mitigating downstream impacts on setting-specific case mix and quality measures could have unintended negative consequences on patient care and provider payments and noted two areas of specific concern: 1) the alignment of PAC assessment window durations, and 2) potential impacts on provider burden. One commenter believed that there was inadequate analysis indicating that these items adequately measure the patient attributes, and until such analysis is presented, these items should not be considered for use in describing case-mix or for use in payment modeling.

Response: We thank the commenters for their recommendations and have taken this input back to our item testing teams. We would like to reiterate that items have many uses, and knowing this, we take item usage into consideration as we assess for item reliability, usability, and feasibility. However, we cannot, at this time, note that the items being tested will be used for any purposes other than quality. The testing of the items under consideration is solely for standardization of quality outcomes, at this time. With this, we are mindful of appropriate and accurate uses of quality data and keep in mind the downstream effects of burden and unintended consequences on the patient and provider. As we have stated prior, we continue to solicit for comment and test items under consideration in order to determine the items that are most appropriate for the four PAC settings. In doing so, we are sensitive to the issue of case mix, and with guidance from our advisors and prior testing demonstrations, we will ensure that testing adequately accounts for patient attributes or case mix.

Summary: One commenter discussed the recent and ongoing stakeholder engagement and standardized data element development activities (Technical Expert Panel, regulatory public comment period, field testing) on the topic of standardized assessment in PAC to fulfill the mandate of the IMPACT Act. This commenter expressed concern that the process to identify and finalize appropriate standardized items through the TEP process is premature, considering the contemporaneous standardized data element development and testing activities that are being conducted by CMS's data element contractor. Another commenter was concerned that the timing of the public comment opportunity occurred at the same time as public comments related to FY 2018 updates to the various PAC payment systems and believed that the overlap of the existing deadline with the proposed rules did not allow providers sufficient time to adequately review, analyze, and comment and recommends that another opportunity be offered to provide feedback.

One commenter was concerned about data element overlap and the number of data elements outlined under various proposed rules and calls for comments and strongly recommended that CMS and key stakeholders involved in the project publish the full data set for review and comment even though there are elements still under development. This commenter noted that it is becoming increasingly difficult to provide feedback given the multiple calls for comments on various parts of the data set. Another commenter recommended a unified micro-site that can be used to monitor measure development, measure implementation, and education and noted that the Quality Payment Program at https://qpp.cms.gov is an outstanding resource. This commenter

believed that creating a single landing point for IMPACT and QRP programs would facilitate better information sharing and a more consistent implementation of the efforts for the IMPACT Act.

***Response**:* We greatly appreciate the ongoing and past participation of stakeholders in the standardized data element development work. We wish to clarify that the items discussed in this blueprint public comment and standardized data elements that are currently undergoing field testing have not been proposed to be adopted into any of the PAC quality reporting programs. In our past and ongoing work to identify optimal data elements for standardization, we seek input from the public, stakeholder communities, and subject matter experts.

As we move forward with further work to evaluate and test candidate data elements for standardized assessment in PAC, we will continue to connect with the stakeholder and expert communities in these ways. We welcome opportunities to partner with and learn from the practice experience of providers, provider associations, and patients and their advocates. We will also take into consideration the recommendation of the creation of an online repository for data elements. We want to emphasize that as we move through data element development and testing, we will post our timelines and key activities so that providers, patients, and advocates will be apprised of our work and next steps.

Finally, we would also like to note that the Post-Acute Care Quality Initiatives Webpage serves as a single landing point for all IMPACT Act activities, which can be accessed at this link: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures.html.

Process

Summary: One commenter suggested that the checkboxes on the mutually exclusive items be changed to radio buttons because many of the questions ask for one answer but a checkbox usually implies inclusivity, while radio buttons are standard for exclusive items.

Response: We acknowledge the commenter's concern but note that all of the checkbox items are for items where multiple responses may be checked, as per the format and make-up of the assessment instruments across PAC settings.

Comments on Specific Data Element Categories

Cognitive Function and Mental Status

Developing Outpatient Therapy Payment Alternative - Continuity Assessment Record and Evaluation (DOTPA-CARE)

Support

Summary: Many commenters expressed support for the use of DOTPA-CARE, noting it appropriately scores patient's functional performance and records the necessary level of assistance the patient requires in a more comprehensive format. It was also noted that it effectively measured whether the patient can implement strategies related to fall prevention, medication management, maintenance of chronic conditions, and other aspects pertaining to self-care/safety after home health staff leave. Moreover, appreciation was expressed for testing items before incorporating them into PAC settings. One commenter believes that all 14 proposed DOTPA CARE items may be suitable for

PAC. This commenter noted it is agnostic to resident cognition and communication impairments, so separate cognitive function item sets would not be necessary for patient response and staff observation assessments; the items are not task-specific, so cognitive function can be assessed based upon the resident's current abilities, and will not be skewed by functional impairments related to a specific task; and the item set covers multiple components of cognition so it may reduce the potential burden associated with needing separate assessments for each cognitive component (but only if other duplicative cognitive assessment items are concurrently eliminated).

Response: CMS appreciates the support received for the usefulness of the DOTPA-CARE in standardized assessment. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, feasibility, and validity/reliability, some commenters expressed concern over the potential for clinical bias and inaccuracies because the items are not getting information directly from the patient or resident. Other commenters noted the need for guidance and clarification on particular items, and one of these commenters believed there was not enough detail provided to be useful in clinical decision making.

Response: We appreciate the feedback received and note that DOTPA-CARE would be collected by a clinician who is experienced with cognitive assessments, in conjunction with staff and any others who closely interact with the patient/resident. However, we understand the concern about potential bias and will take this into consideration. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work and are committed to providing comprehensive training and guidance to ensure the fidelity of the assessment and will provide such guidance in the future.

Complex Sentence Repetition

Support

Summary: Commenters offered support for the Complex Sentence Recognition data element. One commenter expressed support for the item's feasibility across PAC settings. Another noted that Complex Sentence Recognition would be beneficial for quality improvement. Other commenters confirmed that the data element might offer moderate potential to improve the quality of care.

Response: CMS appreciates the support received for the usefulness and feasibility of the Complex Sentence Repetition item in standardized assessment element.

Concern

***Summary*:** In addition to the comments raised above regarding redundancy, feasibility, and validity/reliability, commenters expressed concern about the applicability of Complex Sentence Recognition to alternative patients like those with neurological diagnoses, children, non-verbal patients, or patients who do not speak English. Similarly, two commenters asked if provisions could be made for patients with hearing difficulties, or for those who may refuse to answer questions. Some commenters shared that they did not think the Complex Sentence Recognition data element would have any impact on quality of care. Other commenters were not sure if the data element could impact quality of care. Comments also requested clarification, particularly about the meaning of "complex sentence" and adding a "decline to answer" response options for patients/residents.

Response: We recognize the concerns about the applicability of the Complex Sentence Recognition with different types of patients such as those with neurological diagnoses, children, non-verbal patients. Assessing all populations regardless of status is critical, and we will take these concerns and recommendations into consideration in future testing efforts. Further, we do believe provisions could be made for patients with hearing difficulties or for those persons who refuse to answer. We will continue to think through and test provisions that are applicable in this instance. Finally, we appreciate the suggestion to add a refusal response option, and will consider its applicability in future testing.

PASS Medication Management

Support

Summary: Several commenters support the PASS in assessing significant functional cognition and performance-based executive function medication management issues, thus ensuring that the appropriate services are provided to remediate or compensate for impairments. One commenter noted that these multi-dimensional performance-based items combine real-world life skills and should minimize the need for multiple non-specific cognitive and performance items, pending further testing to reduce assessment time burden. One commenter suggested its best use would be as a test for those who pass the BIMS to hone into moderate or mild deficits. Some commenters noted the value of PASS is before discharge to the community and for only those who will need to manage medication. One commenter noted that the PASS could potentially improve a patient's quality of care post-discharge. One commenter noted the PASS was similar to assessments already conducted in the HH setting but highly recommends that PASS be a part of assessment on admission to a PAC setting.

Response: CMS appreciates the support received for the PASS Medication Management data element in standardized assessment element. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, cross-setting feasibility, and validity/reliability, some commenters noted that patients/ residents, particularly in the HH setting, may not own a pillbox. Additionally, commenters described concern regarding the data element's ability to determine case-mix. Clarification was requested about how PASS was modified for this assessment and if the care provider gives the patient/respondent three chances using the verbal/visual/physical assists. Another concern was voiced that the PASS test is visually difficult to follow.

***Response*:** As with all items under consideration, we plan to assess the PASS for many quality outcomes, particularly case-mix for the PAC settings. Further, as with the recommendation of the commenter, with the reliability testing of the PASS, we are also evaluating how the PASS could be modified for PAC assessment instruments. With prior alpha testing, the PASS was modified from its original form. Specifically, modifications included that when delivering the assessment, providers must provide the minimal type and amount of assistance to help with the subtask. No more than four prompts of any level of assistance should be used. We note the commenter's concern about patient/resident access to a pillbox, and will take this into consideration as we test this data element.

Staff Assessment of Mental Status

Support

Summary: One commenter noted that the Staff Assessment of Mental Status item is important to assess as it can help identify significant issues that can impact a resident's health and plan of care. Two commenters agreed that the assessment seems valid and/or reliable. It could also improve transitions of care communication for patients/residents who are unable to complete the BIMS. Another commenter noted that the item has the ability to improve care transitions through meaningful exchange of data between providers. Finally, two commenters found the item to be helpful and potentially capable of filling a void in describing case-mix associated with long and short- term memory and memory recall or ability for patients/residents who are unable to complete the BIMS.

Response: CMS appreciates the supportive comments for the Staff Assessment of Mental Status item, and agree that it is important to share across the care continuum, as this item has the possibility to facilitate improved care coordination across PAC settings.

Concern

***Summary*:** In addition to the comments raised above regarding redundancy, cross-setting feasibility, and validity/reliability, one commenter questioned the data element's impact on improving quality. One commenter did not see the value in describing case-mix due to issues with data collection from short stay patients in the IRF. Several commenters shared setting related concerns and noted that in the HH setting, staff cannot handle a patient's photographs without their permission. Further, other concerns were raised including the need for family members to be present (or available to call) when staff visit, what will happen if the patient/ resident has not visited with family in the last 7 days, and if the data element is relevant to pediatric populations. One commenter asked for clarification on items A1a and A1b, because they thought them to be vague. Additionally, a few commenters found the data element to be cumbersome.

Response: We thank the commenters for their comments on the Staff Assessment of Mental Status data element. As the Staff Assessment of Mental Status data element is an alternative for patients/ residents who cannot complete the BIMS. We are exploring the use of this item for its impact on improving quality, specifically how the item could provide information to support care transitions, care coordination, and clinical decision-making across PAC settings. Further, as we explore the use of this item, we are taking into consideration the use of this item on various PAC populations and also specifically on the item's outcome in each PAC setting, including the HH setting. We appreciate the recommendations for items A1a and A1b, streamlining this item to reduce burden, item overlap, and redundancy.

Behavioral Signs and Symptoms

Support

Summary: Several commenters expressed support for the Behavioral Signs and Symptoms assessment as this data element identifies patterns for common sources of distress currently not captured by existing items. One commenter added that it is important to ensure all clinicians are trained to recognize symptoms and how to treat them effectively to improve quality. Two commenters noted that the assessment might be useful, and expect it to provide information on case-mix.

Response: We thank the commenters for their feedback. We agree that there is value in tracking behavioral signs to inform care planning, case-mix, and patient transitions and plan to continue to assess this item for appropriates for the PAC settings and for these desired quality outcomes.

Concern:

Summary: Commenters found the Behavioral Signs and Symptoms data element important conceptually, but shared that it could be difficult to understand the cause of behavioral problems based on this item. As noted above, commenters raised concerns about burden, cross-setting feasibility, and look back periods. Further, another commenter disagrees with the idea of documenting the occurrence of disruptive behavior and linking it to resources needs. One commenter was critical of the data element's response scale.

Several commenters requested clarification about the data element, or suggested modifications to the item. One commenter noted that B1a and B1c are overlapping. The same commenter noted that the Behavioral Signs and Symptoms data element only provides a time frame, not the extent of the behavioral disturbance. Another commenter asked for clarification about what to do when there is no family member or caregiver who can provide information about the patient. A separate commenter noted that ultimately, the usefulness of this instrument is tied to the effectiveness of instructions given, which could make it difficult to code.

Response: As with various other items under consideration for use to meet the intent of the IMPACT Act, the Behavioral Signs and Symptoms data element does overlap with assessment items that are currently collected by means of the PAC assessments. However, examining the overlap and exploring what items may be used to appropriately and efficiently assess PAC populations is essential. In this data element's testing and refinement work, we are exploring how tailoring the Behavioral Signs and Symptoms data element across PAC settings will improve cross-setting relevance. Assessing behavioral symptoms across PAC settings could have an important role in promoting quality and patient-centered care. However, we acknowledge that the data element captures severe types of behavioral disturbances in comparison to a range of behavioral expressions of cognitive impairment of unmet needs exhibited by patients in PAC settings. Considering this data element captures the more severe types of behavioral signs and symptoms, it in no way limits the ability of PAC assessors to conduct further assessment of patient behaviors and potential unmet needs. With this said, we will take this recommendation into account in our testing efforts to ensure we are able to not only capture severe behavioral disturbances, but also develop and test items that assess the full extent of a behavior disturbance, if possible. Finally, we continue to evaluate the use of response scales, and monitor the reliability and feasibility of the Behavioral Signs and Symptoms data element. The recommendations for this data element are helpful and we will take these recommendations into consideration in our continued development work.

PROMIS® Anxiety Items

Support

Summary: Several commenters expressed their support that PROMIS Anxiety could improve person-centered care and care planning. One commenter expressed that PROMIS Anxiety would be helpful in describing case-mix if it's found to correlate positively with a clinical diagnosis of anxiety. An additional commenter thought there was moderate utility for describing case-mix, and another shared that the items appear to be valid and reliable, but additional testing should still support this assumption. One commenter expressed that the feasibility for implementation in PAC settings could be moderate. Other support included a comment about the relevance and meaningfulness of items of PROMIS Anxiety to patients in all PAC settings. Additionally, one commenter who expressed support shared that anxiety, along with uncontrolled pain, can result in a hospital readmission or ER visit if not addressed early during a PAC stay.

***Response**:* We thank the commenters for their support of the PROMIS Anxiety items and agree that this set of items has the potential to improve person-centered care and care planning.

Concern

Summary: In addition to the comments raised above regarding burden, redundancy, feasibility, validity/reliability, and look-back periods, some commenters believed that PROMIS Anxiety will not improve quality because it was designed for non-institutional patients, nor would it support clinical decision-making and care coordination because the items are ambiguous. Another commenter shared that if it is to be used for case-mix purposes, further analysis of an observational assessment is needed. One commenter stated that it is unclear how PROMIS Anxiety will add value in establishing treatment or describing case-mix while another commenter expressed that PROMIS Anxiety items are not the best means or useful for determining case-mix. Staff and resident concerns also emerged, including challenges of SNF residents who may not be able to self-report anxiety, general interview fatigue, the apprehension of staff to call a resident "depressed," and the reluctance of staff to complete current MDS Mood items. Another question was raised about if assessors would need to create the assessment.

***Response**:* The consideration of the PROMIS anxiety data elements is being made to bring forward the patient's voice as self-report assessments appear to expose problems that objective testing in structured settings does not capture. Taking into consideration the high incidence of anxiety-related distress experienced by patients in PAC settings, assessments such as the PROMIS anxiety data elements could offer more information that may aid in informing care planning and patient transitions. However, we appreciate the comments on the use of the PROMIS anxiety items and case-mix and will take these recommendations into consideration. We would like to note that assessors would not need to create the assessment for the PROMIS anxiety items; however, the recommendations and concerns about SNF residents and the ability to self-report anxiety are important, and we will take these concerns into consideration as we further evaluate the use of this data element set.

Patient Health Questionnaire (PHQ)

Support

***Summary*:** Three commenters supported the PHQ9-OV and believe that the information can be important for improving the quality and appropriateness of services and that it is more detailed and defined for the end-user (clinician), especially those who have not used the PHQ9 in the past, or had specific training on how the PHQ9 is to be administered. One commenter expressed that the assessment can help identify significant issues that can impact a resident's health and plan of care, and improve transitions of care. Moreover, they added that it appears valid, reliable, feasible, and could potentially fill a void in describing case mix.

***Response**:* We thank the commenters for their support of the PHQ9-OV. We agree that the PHQ9-OV may aid in filling gaps in the collection of specific quality data, and has the potential to improve the quality and appropriateness of services delivered to support care plans and transitions.

Concern

***Summary*:** As stated prior, commenters raised concern pertaining the PHQ9-OV assessment period, burden, validity/reliability, redundancy, and cross-setting relevance. In addition, one commenter stated that the PHQ2 should be used as a gateway data element to the PHQ9-OV. Other commenters

expressed confusion/concern about why CMS was proposing the complete PHQ9-OV item set while concurrently proposing the PHQ-2.

***Response**:* Due to the commonality of depressed mood in PAC settings, and considering that depression is under recognized and undertreated, we find it important to identify signs and symptoms so that treatment can be provided. With this said, we are exploring the use of an observational data element to address the need to accommodate patients/residents with severe cognitive impairments and to respond to cross-setting concerns. Prior public comment and TEP input has suggested that an observational item could be useful in terms of the collection of data with non-communicative patients/residents. Based on our prior testing in the four PAC settings, we have found that this assessment can be completed in under ten minutes, and further, due to the small fraction of patients and residents who are non-communicative, it is unlikely to pose a high burden, overall. We will continue to test the PHQ9-OV data element, as the PHQ9-OV could support clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination for patients across the spectrum of PAC facilities. Finally, we would like to note that CMS has not finalized the use for any PHQ assessment to meet the mandate of the IMPACT Act. We will continue to update stakeholders on items being considered for programmatic use and for standardization as we move through item refinement and testing.

Impairments

Continence

Support

Summary: Commenters expressed support for the continence data elements. One commenter stated the focus of the impact of incontinent events on caregivers is welcome and would be beneficial. Another appreciated the support for continence issues as they impact fall risk, discharge planning, and resource needs, and are important for case-mix. Two commenters rated the potential for improving quality and validity, feasibility and utility for describing case-mix as moderate.

Response: We thank the commenters for their support, particularly the support for continence data elements potential for improving quality, as incontinent events can impact fall risk, discharge planning, and resource needs.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, validity/reliability, cross-setting feasibility, and look back periods, commenters expressed concern with the lack of definitions of "assessment period" in the Continence data element. One commenter recommended that "hospitalization" in the Incontinence data element be changed to "incontinent events prior to the current illness or exacerbation that led to the current PAC admission," citing that it is important to look at incontinent events related to the current health event that may be responsive to intervention. Another commenter suggested removing the reference to "current setting," "prior setting," and "prior hospitalization" in Device Use and simply the response options to: "1 – device first placed (in any setting), during the current illness or exacerbation that led to the current PAC admission," or "9 – unknown." The commenter believed this change would increase feasibility in PAC settings.

Response: We thank the commenters for their recommendations to improve feasibility of the Continence standardized patient assessment data elements and will take them under consideration

as we continue to evaluate these items for PAC standardization. We are committed to providing comprehensive training and guidance to ensure the fidelity of the assessment, which includes guidance on the assessment period as well as other definitions as appropriate.

Hearing and Vision

Support

Summary: A few commenters expressed support for the corrective lenses and hearing aid data elements. Commenters believed the data elements are feasible and reliable across PAC settings and should show validity due to the simplicity. Commenters also suggested that they could contribute to quality of care. One commenter also expressed support for testing the data elements.

Response: We thank the commenters for their support of the feasibility, validity, and reliability of the data elements. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** One commenter questioned the value of the hearing and vision data elements add over the ability to hear and ability to see in adequate light data elements, or the currently collected items. A few commenters suggested that the hearing and vision data elements should be administered at the beginning of the assessment process so assessors are aware of any sensory deficits that could impact the patient's ability to participate in the assessments. One commenter stated that the data elements are appropriate for the pediatric population, but do not address the unique visual and auditory challenges that children with medical complexity often experience. One commenter suggested that the data elements may not be appropriate for broader quality measures because glasses, corrective lenses, and hearing aids are rarely covered for Medicare beneficiaries and may not be affordable. One commenter believed the coding instructions for the hearing aid data element may be misleading. A few commenters suggested alternative data elements. One suggested asking patients/residents if their vision or hearing is impairing their ability to carry out daily tasks. One suggested a follow-up question about the effectiveness of the hearing aid device. Another commenter suggested adding the ability to clean, maintain, manage, and use the assistive device be added to assess functional status and an indication of whether glasses or other visual appliances are used during the assessment. Two other commenters suggested using the version of these data elements from OASIS.

Response: We recognize the importance of the hearing and vision data elements in providing important context for administration and interpretation of other assessment categories (e.g., patient/resident need for visual/auditory aids; interpretation of information obtained from other assessment categories). While the Ability to Hear/See data elements have performed well across PAC settings in our pilot testing, knowing whether hearing aid/corrective lenses were used when determining Ability to Hear/See allows better identification of evaluation and management of hearing/vision needs. Patients/residents who do not have adequate hearing/vision, despite use of hearing/visual appliances, might benefit from a re-evaluation of the appliances used, or assessment for new causes of hearing/vision impairment. As we move through our testing efforts and considerations for item, their use and applicability, we will also take into consideration the various populations that could be assessed with these items such as the pediatric populations. Finally, we are committed to providing comprehensive training and guidance to providers, for any new data elements, including standardized data elements, in order to ensure the fidelity of the assessment. We appreciate the commenters' suggestions such as the suggestion of adding self-care, IADL, and

assistive devices to address the use of assistive devices, and will take these recommendations under consideration as we continue our data element development.

Medical Conditions

Pain

Support

Summary: A few commenters supported the assessment of pain noting the potential to improve quality of care. Commenters also believed the items are valid, reliable, and suitable for PAC settings.

Response: We thank the commenters for their support of the pain assessment data elements. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, cross-setting feasibility, and look back periods, one commenter was concerned that the data elements did not assess pain interference with patient care, which the commenter believed is the most relevant information. Another commenter believed that the Likert Scale used in each of the pain assessments is subjective which requires additional education and training for patients and clinical staff to understand the definitions. Another commenter recommended a clear definition of activities for the Interference – Other Activities data element. Other commenters believed that the Pain Effect on Sleep data element is subjective, and one noted that a variety of environmental factors may affect sleep in PAC settings that are not readily changed or modified. A few commenters were concerned with the answer options for Pain Relief; one suggested focusing the answers so they are framed in terms of "sufficient pain control" or "insufficient pain control" and another recommended modifying the measure to reflect patients'/residents' desire for relief versus refusing pain medication due to potential side effects, noting that all drugs have side effects, and patients/residents may decide that the tradeoffs for relieving symptoms are intolerable (e.g., a patient would rather be in pain if it means staying alert). Some commenters were concerned about the observational assessment of pain or distress; one commenter encouraged using standardized industry accepted and validated observational tool methods such as Pain Assessment in Advanced Dementia Scale (PAINAD) and Face, Legs, Activity, Cry, Consolability scale (FLACC), instead of developing a new assessment scale, while another commenter believe that some of the listed behaviors are clearly not specifically indicative for pain, recommending further analysis on this measure to account for non-indicative behavior. Commenters were also concerned about drug-seeking behavior and suggested the use of a gateway item to assess this.

Response: We would like to note that the Pain Relief data element was derived from the Brief Pain inventory, a widely-used measure which has shown good reliability and validity in PAC settings. This data element underwent cognitive testing and revisions were made based on PAC patient feedback, and further, demonstrated excellent reliability in pilot testing. The Observational Assessment of Pain or Distress data elements were derived from the Indicators of Possible Pain or Distress item used in the MDS 3.0 and tested in the PAC PRD, the Frequency of Pain or Distress item used in the MDS, and from the advice of technical experts. However, we will continue to evaluate the data elements' validity and reliability in ongoing field testing and evaluation. Further, we appreciate the concerns expressed by the commenters and agree that pain interference with

patient care is extremely important to assess and this is why we are evaluating the data element "Pain Interference – Therapy Activities" for standardization. As per our process for education and outreach, we will provide comprehensive training and guidance for all providers to ensure the fidelity of the pain assessment. We will take into consideration the suggestion to include a definition of activities to be considered for "Interference – Other Activities" and will consider including this in guidance.

Finally, we acknowledge that drug-seeking behaviors are a concern for patients/residents in PAC settings. However, we note that the gold-standard assessment of pain is self-report, and therefore, must be relied upon in an assessment of pain. Nonetheless, as part of overall clinical decision-making, providers should account for a range of evidence in identifying drug-seeking behavior and developing a treatment plan to address this issue.

Medication Reconciliation

Support

Summary: Several commenters expressed support for the medication reconciliation data elements, stating they have potential for improving quality and are valid and reliable, noting that completion of the process helps to prevent adverse drug events. A couple of these commenters also noted that the medication reconciliation data elements are feasible and have high utility. One commenter believed that careful medication reconciliation, performed by a pharmacotherapy specialist, results in improved clinical outcomes and reduces unnecessary hospitalizations and adverse events.

Response: We thank the commenters for their support for the validity and reliability of the medication reconciliation data elements. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, and validity/reliability, commenters were also concerned that the specified drug classes are limited and therefore provide limited information and utility, noting that adverse drug events are not easily identified by class of drugs. One commenter recommended that heart failure medications should be added, given that heart failure complications are a leading cause of hospital re-admissions. A few commenters believed that the clinical training of the assessor would affect the validity of the MR data elements and believed the validity of data collected will be higher when collected by a pharmacist, physician, or nurse practitioner, than other clinicians. One commenter noted that completing a 7-day look-back would be challenging unless acute care hospitals discharge patients with this information, while others saw little value in collecting "number of days" for use of medication in specific classes. Another commenter believed that validity might be limited and the MR completion should be treated in a more robust fashion (than a yes/no response). One commenter questioned the utility for determining case-mix. Commenters were concerned about conflating MR with drug regimen review. Some commenters recommended consolidating the information required for the MR data elements so it aligns with the Medicare Conditions of Participation. One commenter suggested adding a data element related to management of discrepancies, such as "Was the managing physician notified within 24 hours?". Another commenter suggested having a general question regarding addressing discrepancy and whether it was followed, regardless of the drug classification. One commenter recommended providing clarification on what constitutes medication indication and others wanted clarification on the definition of discrepancies.

Response: In our past and ongoing work to identify standardized data elements, we have strived to

balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. Therefore, drug classes (e.g., anticoagulants, diabetic agents, and opioids) that are related to adverse drug events (ADEs) that are common, clinically significant, preventable, and measurable are being explored for standardization. Anticoagulants, antibiotics, and diabetic agents have been implicated in an estimated 46.9% (95% CI, 44.2%-49.7%) of ED visits for adverse drug events.[1] Among older adults (aged ≥65 years), 3 drug classes (anticoagulants, diabetic agents, and opioid analgesics) have been implicated in an estimated 59.9% (95% CI, 56.8%-62.9%) of ED visits for adverse drug events. Further, antipsychotic medications have been identified as a drug class for which there is a need for increased outreach and educational efforts to reduce use among older adults. We would like to note that CMS does not direct which staff complete the assessment instruments, but do require that facilities ensure that staff with appropriate knowledge and expertise conduct and complete assessments. We strive, however, to report the most valid and reliable data for use by consumers, researchers, and patients alike. We appreciate the concern for feasibility and the look back periods. As we move through testing of these data elements, we will take into consideration the look back and feasibility of item collection. Further, in our ongoing work to identify candidate data elements for standardization, we will continue to carefully consider the implications for validity and reliability of response options. Finally, we will continue to assess the consolidation of these data items with current items in our assessment instruments and will provide clarification of item definition and concepts in the future.

Care Preferences

Support

Summary: Many commenters supported the care preferences data elements, noting their importance for clinical decision-making, care coordination/care transitions, and improving quality of care. Several commenters stated that the care preferences data element have potential to improve quality, have validity, and are feasible for use in PAC. Two of these commenters also stated the data elements have utility for determining case-mix. Another commenter specified that the data elements are patient-centric and incentivize PAC providers to have goals of care conversations.

Response: We thank the commenters for their support. We agree that the Care Preferences data elements are important for clinical decision-making, care coordination, and improving quality of care. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, and cross-setting feasibility, one commenter stated that the data elements may be challenging for specialized pediatric healthcare facilities because questions about guardianship may exist and resources may be limited to determine guardianship. Some commenters believed that the data elements would not affect the development of clinical plan of treatment and would not reflect the case-mix. Another commenter recommended adding a skip pattern based on cognition. Commenters expressed some concern about the clarity and conciseness of response options for the Preferences for Involvement in Decision Making data element, questioning what "some information" would mean to staff. One commenter recommended incorporating a standardized measure of PAC patients' preferences for advanced illness and end-of-life care. Another commenter recommended that PAC clinicians should ask patients/residents if they have discussed the issue of a designated health care agent with their proxy, and make sure they obtain the proxy's name and contact information or that the information

is in the record. The commenter also noted that the correct term for the data element should be "advance care directive or advance care planning".

Response: Eliciting, documenting, communicating, and transferring information about a patient's preferences for care and their goals for care is critical to informing the plan of care, evaluating progress, and assuring patient-centered care in PAC settings. We further acknowledge the commenters' concerns about feasibility and note that considerations in data element development include various populations such as children. As part of our ongoing evaluation, we are reviewing data from our field testing to identify appropriate skip patterns for the data elements and continuing to evaluate feasibility across settings. We thank the commenters for pointing out concerns about clarity and are committed to providing comprehensive training and guidance to providers, for any new data elements, including standardized data elements, in order to ensure the fidelity of the assessment. We thank the commenters for the important suggestions they have made and will take them under consideration in our ongoing evaluation of Care Preferences standardized patient assessment data elements.

PROMIS (Sleep Disturbance, Fatigue, Social Roles and Activities, Global Health)

Support

Summary: Several commenters noted the value of using PROMIS data elements for assessment noting their relevance across PAC settings.

Response: We thank the commenters for their support on the relevance of the PROMIS items for use in the four PAC settings. We are continuing to assess the feasibility, reliability and validity of these items throughout our standardized data element development work.

Concern

***Summary*:** In addition to the comments raised above regarding burden, redundancy, and cross-setting feasibility some commenters questioned the appropriateness of the PROMIS data elements for certain populations such as those with cognitive or language impairments who would be unable to self-report. A few commenters raised concern that the Sleep Disturbance items might be deemed intrusive and response options were hard to differentiate. Other commenters questioned the impact to quality in assessing Social Roles and Activities or Global Health

Response: We acknowledge the commenters' concern and note that we are reviewing data to determine appropriate skip patterns for assessment items that may not be appropriate for certain populations. Further, we are assessing the PROMIS items for their overall use and item response. Pertaining to the overall impact of the items: Social life is an important aspect of one's quality of life in addition to one's physical and mental health. Measuring the deterioration or improvement of social life can reflect the impact of the treatment on the patients, which can help improve quality of care. Pertaining to the Sleep Disturbance items, our intention is not to include assessment items that are intrusive or increase frustration and anxiety and as we evaluate the results of ongoing field testing for use across PAC settings, we will keep these considerations in mind. Finally, the PROMIS Global Health items have been shown to be predictive of important future events such as health care utilization,[2] which is important to inform patient-centered care.

References

1. Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013-2014. *Jama* 2016; **316**(20): 2115-25.
2. Bjorner JB, Fayers P, Idler E. Self-rated health. *Assessing quality of life* 2005: 309-23.

Public Comment Verbatim Report

The following pages detail the verbatim comments received. We did not make any changes or edits to the content.

ID	Date Posted	Text of Comments	Name or Organization of Commenter
ASHA	6/19/17	Dear Ms. Khan: On behalf of the American-Speech-Language-Hearing Association (ASHA), I appreciate the opportunity to comment on the draft technical expert panel (TEP) report entitled, "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data (Second Public Comment)." ASHA is the national professional, scientific, and credentialing association for 191,500 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. Our members work in all of the post-acute care settings affected by the Improving Post-Acute Care Transformation (IMPACT) Act. We were also pleased to serve on the TEP that provided the feedback used to develop this report. Therefore, we have a keen interest in ensuring that standardized assessment data is developed in a way that allows for improving the quality of care for Medicare beneficiaries, minimizes provider burden to the extent possible, and are inclusive and reflective of the services our members provide. Our comments focus on the following key areas: 1. Developing a framework for incorporating the TEP's recommendations in existing rulemaking; 2. Recognizing the limitations of brief screening items such as the Brief Interview of Mental Status (BIMS); 3. Assessing a patient's cognitive status in a comprehensive manner to include problem solving, memory, and attention; and 4. Ensuring a patient is adequately assessed for hearing and vision at the beginning of the patient assessment process. 1. Developing a framework for incorporating the TEP's recommendations in existing rulemaking. ASHA is pleased to have participated in two TEPs hosted by RAND, which carefully examined and selected new items in critical areas of function. The Alpha 2 phase to test these new items was scheduled to begin in April 2017. This systematic process was designed to select items that are valid, feasible, and appropriate for describing case mix. Several proposed rules for the postacute care settings—including skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals—have been released with the same deadline for comments as this draft report, June 26. In these proposed rules, many of the standardized	American Speech-Language-Hearing Association

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		assessment items under consideration in this draft report are being proposed for adoption by the Centers for Medicare & Medicaid Services (CMS). We are concerned that, with these proposals moving forward simultaneously, the process to identify and finalize appropriate standardized items through the TEP process is premature. CMS should consider delaying the finalization of standardized data items through rulemaking until the work of the TEP is complete. 2. Recognizing the limitations of brief screening items such as the Brief Interview of Mental Status (BIMS). Screening items, such as the BIMS, do not reliably detect the presence of mild cognitive impairment, differentiate it from a language impairment, or translate impairment to interpretation of functional limitation. The items in the BIMS provide insight into the patient's basic orientation to time and environment, but the limited assessment of memory as "OK" or "not OK" does not capture subtle problems in memory, problem solving, and executive function, which could interfere with a patient's safety, care planning, and eventual discharge status. Many patients who pass this very basic screening could be at risk for injury or an unnecessarily extended stay due to failure to detect a cognitive impairment and prompt referral to a speech language pathologist for further assessment. For this reason, ASHA has long advocated for the use of Development of Outpatient Therapy Payment Alternatives (DOTPA). DOTPA items, coupled with a functional screen to detect problems, need to be addressed during post-acute care. 3. Assessing a patient's cognitive status in a comprehensive manner to include problem solving, memory, and attention. ASHA was very pleased to see that our long-standing recommendation to use the DOTPA items to assess cognition were included in the draft report. We believe these items appropriately score a patient's functional performance and record the necessary level of assistance the patient requires, both of which are essential for risk adjustment and referral. Because these items are based on observation of performance, we recommend that they be scored after the PASS Medication Test is administered.	

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		4. Ensuring a patient is adequately assessed for hearing and vision at the beginning of the patient assessment. The prevalence of hearing loss among elders and the under-identification of hearing loss are well documented in the scientific literature.[1] Unidentified and unaddressed hearing impairment during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can invalidate other information obtained from the patient assessment. Therefore, we believe that the hearing and vision sections should be administered at the beginning of the patient interview/assessment process to provide the examiner with evidence regarding any sensory deficits that could affect the patient's ability to participate in the assessment. As part of this process, ASHA strongly encourages CMS to provide guidance to facilities on offering an assistive listening device to patients—if there is any indication one is necessary—before beginning the assessment. In closing, thank you for the opportunity to appoint a representative to this TEP and to provide feedback over the course of the development of standardized data elements. We continue to look forward to engaging with RAND, CMS, and other contractors as you move forward with implementation of the IMPACT Act. If you have any questions, please contact Sarah Warren, MA, ASHA's director of health care regulatory advocacy at 301-296-5696 or swarren@asha.org. Sincerely, Gail J. Richard, PhD, CCC-SLP 2017 ASHA President [1.] Hopper, T., Slaughter, S. E., Hodgetts, B., Ostevik, A., Ickert, C. (2016). Hearing Loss and Cognitive-Communication Test Performance of Long-Term Care Residents With Dementia: Effects of Amplification. Journal of Speech, Language and Hearing Research, 59, 1532-1542.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
AHPA	6/23/17	To Whom It May Concern: On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Development and Maintenance of Post-Acute Care (PAC) Cross-Setting Standardized Assessment Data. Our organization represents the perspective of five Seventh-day Adventist health systems that include 83 hospitals and more than 300 other health facilities in 17 states and the District of Columbia. AHPA operates in a variety of settings, ranging from rural Appalachia to urban teaching hospitals. We believe this broad perspective enables us to provide both reality-based and sound policy input. Our comments below are divided into two sections: general comments about standardizing assessment data across PAC settings and specific comments on the elements below. • Cognitive Function and Mental Status • Medical Conditions: Continence • Medical Conditions: Pain • Medication Reconciliation • Care Preferences • Fatigue • Ability to Participate in Certain Social Roles and Activities • Global Health General Comments The Improving Medicare Post-Acute Care Transformation (IMPACT) Act requires the reporting and development of standardized assessment-based data. The IMPACT Act also requires that quality measures and resource use be interoperable and allow for the exchange of data among PAC providers. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data seeks feedback on data elements that meet these requirements of the IMPACT Act.	Adventist Health Policy Association

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		We commend CMS' intent to create clinically relevant data elements that improve care coordination among providers and improve quality of care. While we support CMS standardizing data collection across the PAC settings, we have some general concerns regarding the proposed data elements. Administrative Burden We are concerned that some of the proposed elements will increase the administrative burden among providers. The data elements currently in use are already extensive. Adding new data elements, without removing both the preexisting and similar ones, would lead to increased confusion among both clinicians and patients/residents. We also believe that CMS should try to narrow down some of the questions in the proposed data elements so that assessments can be completed in a single patient visit. Feasibility AHPA believes that some data elements will not accurately measure a patient's needs under specific PAC settings. For example, the data element measuring "Pain Interference-Therapy Activities" requires providers to ask patients if they have been offered physical, occupational or speech therapy in the past three days. In an Inpatient Rehabilitation Facility (IRF) setting, this question would be redundant since a patient's purpose at an IRF is to receive physical and occupational therapy. Instead, we recommend that CMS adopt uniform data elements that more accurately measure quality of care across the entire health care continuum. Data Elements on Activities of Daily Living AHPA recommends that CMS adopt data elements to assess a patient's ability to partake in activities of daily living. For instance, these data elements could measure a patient's ability to care for themselves, including their ability to: dress, eat and move from seating to standing positions. This information would be useful for providers tracking the progress of patients throughout different PAC settings. Look-Back Periods	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		When adopting new data elements, AHPA recommends that CMS strive to adopt a single look-back period among all PAC providers to reduce confusion in different PAC settings. **<u>Data Elements by Category</u>** **Cognitive Function and Mental Status** CMS states that patients in PAC settings are at risk for cognitive impairment and depression. CMS describes Cognitive Impairment to include depression, traumatic brain injury and stroke as sample conditions. CMS seeks comment on this data element. Potential for Improve Quality Moderate. We are concerned that the responses of patients will vary depending on the circumstances of the assessment. In certain PAC settings, patients may be unable to answer questions because of their cognitive state. Validity Moderate. Under some circumstances, this may be a moderately valid form of assessment within certain PAC settings. However, this data element would be inappropriate for patients experiencing cognitive impairment. For example, patients with Alzheimer's disease or dementia may be unable to complete the assessment. Medically complex patients in Long Term Care (LTCs) hospitals may also have difficulty answering questions since some may be on ventilators or have tracheostomies. Therefore, we believe there needs to be an option for a patient not to answer the assessment depending on his or her level of impairment. Moreover, we also seek clarification on who would be administering the assessment. Feasibility for Use in PAC Moderate.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Utility for describing case mix Low. **DOTPA CARE Data Elements** The DOTPA Continuity Assessment Record and Evaluation (CARE) tool data elements assess cognitive function in all patients/residents to allow for a broad assessment over time of multiple cognitive components. Potential for Improving Quality High. Validity Low. These data elements use a "how often" approach in which a clinician conducts interviews and observes the patient/resident to determine how often he or she can conduct certain activities. We believe that this approach has limited validity because clinicians would have to record responses based on what the patient recalls, which could lead to inaccuracies, particularly if the patient/resident has a cognitive impairment. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. The proposed two-day look back period is too short to determine if the cognitive variance of a patient/residence is conditional versus chronic. **Complex Sentence Repetition** The data elements that comprise Complex Sentence Repetition screen for cognitive impairment. These data elements test whether a patient can perfectly repeat back to the assessor a complex sentence that was read	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		aloud. We seek clarification on what provisions are made for someone who is hard of hearing or who refuses to answer questions. Potential for Improve Quality Moderate. Validity Low. Issues such as a provider's verbal tendencies (e.g. soft spoken, verbal accent, functional annunciation, etc.) could lead to inaccurate scores. We seek clarification on the meaning of a "complex sentence" and recommend that patients should instead have to repeat back three words to the provider, such as is currently done for Alzheimer patients. We also recommend that the assessment contain an additional option that allows a patient to refuse to answer. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. These data elements do not account for patients or residents that have hearing difficulties. **Anxiety Items** These data elements assess self-reported fear, anxious misery, hyperarousal and somatic symptoms related to arousal. CMS seeks comment on this data element. Potential for Improve Quality Moderate. Validity	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Low. CMS should provide for cognitively impaired residents and/or non-communicative residents. Feasibility for Use in PAC Moderate. Utility for describing case mix Moderate. AHPA seeks clarification on whether providers will be responsible for creating these assessments. If so, we request additional information on what the font and size requirements of the assessments would be. **Medical Conditions: Continence** CMS states that impaired bladder and bowel continence is common among older persons in the United States. CMS seeks comment on this data element. Potential for Improving Quality High. Validity High. Feasibility for Use in PAC Moderate. Utility for describing case mix Moderate. **Medical Conditions: Pain** CMS states that pain is a highly prevalent medical condition that is frequently under-recognized, underdetected and undertreated. CMS seeks comment on this data element.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		AHPA believes that the data elements related to pain are generally indicative of quality. However, we have concerns related to the feasibility and utility of the "Pain Interference- Therapy Activities," which we highlight below. Pain Interference-Therapy Activities The data elements that comprise Pain Interference and Therapy Activities ask patients/residents to self-report how often pain has limited their ability to participate in rehabilitation therapy. CMS seeks comment on this data element. Potential for Improving Quality High. Validity High. Feasibility for Use in PAC High. Utility for describing case mix Moderate. Under the Medicare Conditions of Participation (CoPs), IRFs are required to provide therapy. Therefore, this data element could not be applied in the IRF setting. **Medication Reconciliation** Medication Reconciliation (MR) is a process of reviewing an individual's complete and current medication list. CMS seeks comment on the use of monitoring the medications that a patient has taken in the past seven days or since admission and start of care.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		AHPA believes that the data elements under MR have the potential for improving quality, are valid, feasible and have high utility. However, we recommend consolidating the information required for this data element so that it properly aligns with the Medicare CoPs. Medication Reconciliation – Completion Potential for Improving Quality High. Validity High. Feasibility for Use in PAC Moderate. The feasibility of this data element is questionable in the SNF setting. The assessment would likely need to address a different timeframe. We recommend considering the time of admission to be considered less than 24 hours or at the time of admission and/or discharge. Furthermore, we seek clarification on who is to complete this assessment. We recommend that the person completing the assessment be a physician or a nurse practitioner. Utility for describing case mix High. **Care Preferences** CMS states that understanding a patient's care preferences and goals for care is critical to ensuring patient-centered care through the course of a PAC episode and stay. CMS seeks comment on this data element. Potential for Improving Quality High.	

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		Validity High. Feasibility for Use in PAC High. Utility for describing case mix High. **Patient Reported Outcomes Measurement Information System** The Patient Reported Outcomes Measurement Information System (PROMIS) was developed and is held by the National Institutes of Health (NIH). PROMIS incorporates four data elements related to: Sleep Disturbance, Fatigue, Ability to Participate in Social Roles and Activities and Global Health. Below we describe our concerns regarding some of these elements. **Sleep Disturbance** This data element assesses self-reported perceptions of sleep quality, sleep depth and restoration associated with sleep. Potential for Improving Quality High. Validity Moderate. Feasibility for Use in PAC	

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		Moderate. Utility for describing case mix Low. We recommend that CMS provide guidance on what methods would be utilized to evaluate the sleep of a confused or cognitive impaired resident, as well as residents with sensory deficits. **Fatigue** CMS describes Fatigue to mean mild, subjective feelings of tiredness, or overwhelming, debilitating and sustained sense of exhaustion that can decrease a patient's ability to execute daily activities and function normally. CMS divides the experience of fatigue into frequency, duration and intensity and seeks comment on this data element. AHPA believes that measuring Fatigue has the potential for improving quality. However, we believe that these data elements are duplicative. For example, Fatigue falls under two different data elements: PROMIS and Global Health. We recommend that CMS eliminate duplications in the data elements. Potential for Improving Quality Moderate. Validity Moderate. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. **Ability to Participate in Certain Social Roles and Activities**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		CMS measures a patient's "Ability to Participate in Social Roles and Activities" by a patient's ability to take part in professional obligations and social activities with friends and family. Because patients in IRF settings may be sick and have limited ability to engage in social activities, we find this data element to be moderately feasible. Additionally, patients in Home Health Agencies (HHAs) are required by Medicare to be home-bound and may be unable to physically participate in social activities. Potential for Improving Quality Moderate. Validity Moderate. Feasibility for use in PAC Moderate. Utility for Describing Case Mix Moderate. **Global Health** CMS describes Global Health to mean the overall status of a respondent's physical health, pain, fatigue, mental health and social health. CMS states that Global Health data elements are predictive of important future events such as health care utilization and mortality. CMS seeks comment on this data element. AHPA agrees that the data elements under Global Health measure quality in PAC settings. However, some of the data elements, including both Fatigue and Social Health, are duplicative. For example, Fatigue and Social Health are also assessed under the PROMIS data element.	

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		Potential for Improving Quality High. Validity High. Feasibility for use in PAC High. Utility for Describing Case Mix High. AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like additional information, please contact Julie Zaiback, Director of AHPA, at Julie.Zaiback@ahss.org	
AHS	6/23/17	To Whom It May Concern: On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Development and Maintenance of Post-Acute Care (PAC) Cross-Setting Standardized Assessment Data. Our organization represents the perspective of five Seventh-day Adventist health systems that include 83 hospitals and more than 300 other health facilities in 17 states and the District of Columbia. AHPA operates in a variety of settings, ranging from rural Appalachia to urban teaching hospitals. We believe this broad perspective enables us to provide both reality-based and sound policy input. Our comments below are divided into two sections: general comments about standardizing assessment data across PAC settings and specific comments on the elements below. • Cognitive Function and Mental Status	Adventist Health System

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		• Medical Conditions: Continence • Medical Conditions: Pain • Medication Reconciliation • Care Preferences • Fatigue • Ability to Participate in Certain Social Roles and Activities • Global Health General Comments The Improving Medicare Post-Acute Care Transformation (IMPACT) Act requires the reporting and development of standardized assessment-based data. The IMPACT Act also requires that quality measures and resource use be interoperable and allow for the exchange of data among PAC providers. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data seeks feedback on data elements that meet these requirements of the IMPACT Act. We commend CMS' intent to create clinically relevant data elements that improve care coordination among providers and improve quality of care. While we support CMS standardizing data collection across the PAC settings, we have some general concerns regarding the proposed data elements. Administrative Burden We are concerned that some of the proposed elements will increase the administrative burden among providers. The data elements currently in use are already extensive. Adding new data elements, without removing both the preexisting and similar ones, would lead to increased confusion among both clinicians and patients/residents. We also believe that CMS should try to narrow down some of the questions in the proposed data elements so that assessments can be completed in a single patient visit. Feasibility	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		AHPA believes that some data elements will not accurately measure a patient's needs under specific PAC settings. For example, the data element measuring "Pain Interference-Therapy Activities" requires providers to ask patients if they have been offered physical, occupational or speech therapy in the past three days. In an Inpatient Rehabilitation Facility (IRF) setting, this question would be redundant since a patient's purpose at an IRF is to receive physical and occupational therapy. Instead, we recommend that CMS adopt uniform data elements that more accurately measure quality of care across the entire health care continuum. Data Elements on Activities of Daily Living AHPA recommends that CMS adopt data elements to assess a patient's ability to partake in activities of daily living. For instance, these data elements could measure a patient's ability to care for themselves, including their ability to: dress, eat and move from seating to standing positions. This information would be useful for providers tracking the progress of patients throughout different PAC settings. Look-Back Periods When adopting new data elements, AHPA recommends that CMS strive to adopt a single look-back period among all PAC providers to reduce confusion in different PAC settings. **<u>Data Elements by Category</u>** **Cognitive Function and Mental Status** CMS states that patients in PAC settings are at risk for cognitive impairment and depression. CMS describes Cognitive Impairment to include depression, traumatic brain injury and stroke as sample conditions. CMS seeks comment on this data element. Potential for Improve Quality	

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		Moderate. We are concerned that the responses of patients will vary depending on the circumstances of the assessment. In certain PAC settings, patients may be unable to answer questions because of their cognitive state. Validity Moderate. Under some circumstances, this may be a moderately valid form of assessment within certain PAC settings. However, this data element would be inappropriate for patients experiencing cognitive impairment. For example, patients with Alzheimer's disease or dementia may be unable to complete the assessment. Medically complex patients in Long Term Care (LTCs) hospitals may also have difficulty answering questions since some may be on ventilators or have tracheostomies. Therefore, we believe there needs to be an option for a patient not to answer the assessment depending on his or her level of impairment. Moreover, we also seek clarification on who would be administering the assessment. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. **DOTPA CARE Data Elements** The DOTPA Continuity Assessment Record and Evaluation (CARE) tool data elements assess cognitive function in all patients/residents to allow for a broad assessment over time of multiple cognitive components. Potential for Improving Quality High. Validity	

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		Low. These data elements use a "how often" approach in which a clinician conducts interviews and observes the patient/resident to determine how often he or she can conduct certain activities. We believe that this approach has limited validity because clinicians would have to record responses based on what the patient recalls, which could lead to inaccuracies, particularly if the patient/resident has a cognitive impairment. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. The proposed two-day look back period is too short to determine if the cognitive variance of a patient/residence is conditional versus chronic. **Complex Sentence Repetition** The data elements that comprise Complex Sentence Repetition screen for cognitive impairment. These data elements test whether a patient can perfectly repeat back to the assessor a complex sentence that was read aloud. We seek clarification on what provisions are made for someone who is hard of hearing or who refuses to answer questions. Potential for Improve Quality Moderate. Validity Low. Issues such as a provider's verbal tendencies (e.g. soft spoken, verbal accent, functional annunciation, etc.) could lead to inaccurate scores. We seek clarification on the meaning of a "complex sentence" and recommend that patients should instead have to repeat back three words to the provider, such as is currently done for Alzheimer patients. We also recommend that the assessment contain an additional option that allows a patient to refuse to answer.	

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		Feasibility for Use in PAC Moderate. Utility for describing case mix Low. These data elements do not account for patients or residents that have hearing difficulties. **Anxiety Items** These data elements assess self-reported fear, anxious misery, hyperarousal and somatic symptoms related to arousal. CMS seeks comment on this data element. Potential for Improve Quality Moderate. Validity Low. CMS should provide for cognitively impaired residents and/or non-communicative residents. Feasibility for Use in PAC Moderate. Utility for describing case mix Moderate. AHPA seeks clarification on whether providers will be responsible for creating these assessments. If so, we request additional information on what the font and size requirements of the assessments would be. **Medical Conditions: Continence** CMS states that impaired bladder and bowel continence is common among older persons in the United States. CMS seeks comment on this data element. Potential for Improving Quality	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		High. Validity High. Feasibility for Use in PAC Moderate. Utility for describing case mix Moderate. **Medical Conditions: Pain** CMS states that pain is a highly prevalent medical condition that is frequently under-recognized, underdetected and undertreated. CMS seeks comment on this data element. AHPA believes that the data elements related to pain are generally indicative of quality. However, we have concerns related to the feasibility and utility of the "Pain Interference- Therapy Activities," which we highlight below. Pain Interference-Therapy Activities The data elements that comprise Pain Interference and Therapy Activities ask patients/residents to self-report how often pain has limited their ability to participate in rehabilitation therapy. CMS seeks comment on this data element. Potential for Improving Quality High. Validity High.	

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		Feasibility for Use in PAC High. Utility for describing case mix Moderate. Under the Medicare Conditions of Participation (CoPs), IRFs are required to provide therapy. Therefore, this data element could not be applied in the IRF setting. **Medication Reconciliation** Medication Reconciliation (MR) is a process of reviewing an individual's complete and current medication list. CMS seeks comment on the use of monitoring the medications that a patient has taken in the past seven days or since admission and start of care. AHPA believes that the data elements under MR have the potential for improving quality, are valid, feasible and have high utility. However, we recommend consolidating the information required for this data element so that it properly aligns with the Medicare CoPs. Medication Reconciliation – Completion Potential for Improving Quality High. Validity High. Feasibility for Use in PAC Moderate. The feasibility of this data element is questionable in the SNF setting. The assessment would likely need to address a different timeframe. We recommend considering the time of admission to be	

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		considered less than 24 hours or at the time of admission and/or discharge. Furthermore, we seek clarification on who is to complete this assessment. We recommend that the person completing the assessment be a physician or a nurse practitioner. Utility for describing case mix High. **Care Preferences** CMS states that understanding a patient's care preferences and goals for care is critical to ensuring patient-centered care through the course of a PAC episode and stay. CMS seeks comment on this data element. Potential for Improving Quality High. Validity High. Feasibility for Use in PAC High. Utility for describing case mix High. **Patient Reported Outcomes Measurement Information System** The Patient Reported Outcomes Measurement Information System (PROMIS) was developed and is held by the National Institutes of Health (NIH). PROMIS incorporates four data elements related to: Sleep	

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		Disturbance, Fatigue, Ability to Participate in Social Roles and Activities and Global Health. Below we describe our concerns regarding some of these elements. **Sleep Disturbance** This data element assesses self-reported perceptions of sleep quality, sleep depth and restoration associated with sleep. Potential for Improving Quality High. Validity Moderate. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. We recommend that CMS provide guidance on what methods would be utilized to evaluate the sleep of a confused or cognitive impaired resident, as well as residents with sensory deficits. **Fatigue** CMS describes Fatigue to mean mild, subjective feelings of tiredness, or overwhelming, debilitating and sustained sense of exhaustion that can decrease a patient's ability to execute daily activities and function normally. CMS divides the experience of fatigue into frequency, duration and intensity and seeks comment on this data element.	

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		AHPA believes that measuring Fatigue has the potential for improving quality. However, we believe that these data elements are duplicative. For example, Fatigue falls under two different data elements: PROMIS and Global Health. We recommend that CMS eliminate duplications in the data elements. Potential for Improving Quality Moderate. Validity Moderate. Feasibility for Use in PAC Moderate. Utility for describing case mix Low. **Ability to Participate in Certain Social Roles and Activities** CMS measures a patient's "Ability to Participate in Social Roles and Activities" by a patient's ability to take part in professional obligations and social activities with friends and family. Because patients in IRF settings may be sick and have limited ability to engage in social activities, we find this data element to be moderately feasible. Additionally, patients in Home Health Agencies (HHAs) are required by Medicare to be home-bound and may be unable to physically participate in social activities. Potential for Improving Quality Moderate. Validity Moderate.	

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		Feasibility for use in PAC Moderate. Utility for Describing Case Mix Moderate. **Global Health** CMS describes Global Health to mean the overall status of a respondent's physical health, pain, fatigue, mental health and social health. CMS states that Global Health data elements are predictive of important future events such as health care utilization and mortality. CMS seeks comment on this data element. AHPA agrees that the data elements under Global Health measure quality in PAC settings. However, some of the data elements, including both Fatigue and Social Health, are duplicative. For example, Fatigue and Social Health are also assessed under the PROMIS data element. Potential for Improving Quality High. Validity High. Feasibility for use in PAC High. Utility for Describing Case Mix High.	

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		AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like additional information, please contact Julie Zaiback, Director of AHPA, at Julie.Zaiback@ahss.org	
INNO		Dear Ms. Khan: Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 36,000 non-acute care providers, including 650 long-term care pharmacies and 6,350 skilled nursing facilities (SNFs). We appreciate the ongoing efforts by the Centers for Medicare & Medicaid Services (CMS) and its contractor, the RAND Corporation, to improve post-acute care (PAC) services provided to Medicare beneficiaries. We support the goals of data standardization across PAC settings, but have concerns that some of the elements being proposed will be unnecessarily burdensome for providers and not as useful for CMS as other elements would be. Prior to submitting these comments, Innovatix held a meeting with advisory groups comprising long-term care provider members and Innovatix staff pharmacists to better understand the impact of the standardized assessment data. Innovatix has also participated in several stakeholder meetings to gain additional understanding of how the proposed data elements will affect the broader PAC community. Based on insight from our provider members and partner organizations, Innovatix developed comments outlining our concerns with the medication reconciliation data elements that are detailed on pages 87-108 of the document: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data (Data Element Specifications for Public Comment 2). We recommend that CMS reconsider several of the proposed data elements designed to ensure that medication reconciliation is properly conducted in PAC settings. <u>Medication Reconciliation and Drug Regimen Review are Distinct Services</u>	Innovatix

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		In June 2016, Innovatix submitted comments on the CMS proposed measure (CMS–1645–P) "Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care Skilled Nursing Facility Quality Reporting Program," in which we noted our concern that the proposal inappropriately incorporated drug regimen review (DRR) into the medication reconciliationmeasure that the Secretary was called upon to standardize in the IMPACT Act. Adopting a DRR- based measure for medication reconciliation moves CMS farther away from its intended goals of data standardization. Rather than standardizing measures across settings, it instead confuses the measures within SNFs and creates additional financial and operational challenges for providers. Unfortunately, although Innovatix and other stakeholders advocated against adoption of the DRR-based measure, CMS finalized it in the Final SNF Payment Rule for FY 2017 as proposed. Since RAND based its proposed data elements on the DRR-based medication reconciliation measure, this serves as the foundation for our concerns. We maintain that medication reconciliation and DRR are distinctly different services. SNFs rely on consultant pharmacists to provide DRR. The consultant pharmacist will typically visit the SNF at least once a month to perform DRR and other medication-related services. While it is possible that a consultant pharmacist may visit the SNF more than once per month based on resident or SNF needs, consultant pharmacist visits to the SNF typically adhere to the monthly DRR schedule. Medication reconciliation, on the other hand, might be required on a daily basis and could include reconciling a resident's medication list and checking a resident's prescription containers. Different members of the care team perform this service, including the physician, the nurse, or the pharmacist. While SNFs should be able to choose who provides medication reconciliation for the patients within their facility, Innovatix believes that pharmacists are ideally equipped to provide this service and should be compensated when they do. Many of our member pharmacies that provide medications to SNFs (dispensing pharmacies) routinely reconcile a resident's prescribed medications against the hospital's discharge summary as a best practice. However, CMS does not pay pharmacists for these important services, nor does the Social Security Act currently recognize pharmacists as healthcare providers eligible for Medicare reimbursement. This again underscores the need for pharmacists to receive recognition and fair compensation for the full range of services they provide. The Pharmacy and Medically Underserved Areas	

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		Enhancement Act (H.R.592/S.109), currently before Congress, would provide for coverage of pharmacist services under the Medicare program. This legislation would allow pharmacists to provide necessary healthcare services for some of our country's most vulnerable patients. We urge CMS to support this important legislation to secure provider status for pharmacists. *Recommendation: In moving forward with medication reconciliation data elements, CMS should recognize that medication reconciliation and drug regimen review are distinctly different services and confounding the two will create confusion about how to measure medication reconciliation appropriately. Data elements should focus on medication reconciliation and not drug regimen review. Further, Innovatix recommends that CMS recognize the essential role that pharmacists play in providing enhanced services, such as medication reconciliation, to beneficiaries. We urge CMS to support pharmacist provider status legislation currently pending in Congress (H.R.592/S.109) that will address this issue.* <u>Medication Reconciliation – Indication (pgs. 94-95)</u> We believe clear documentation of the indication for which a medication is prescribed is important to support patient safety. In all PAC settings, healthcare professionals should have documentation that matches with each medication the patient is taking with an indication. However, we believe this data element, which is limited to medications in specific classes of drugs, is much too narrow. This data element should be revised to include all medications the patient is taking, irrespective of the drug class. We note that for long-term care facilities (LTCFs), documentation of the indication for each medication is already a requirement under 483.45(d) of the State Operations Manual.[1] *Recommendation: The Medication Reconciliation – Indication data element should not be restricted to specific classes of medications. It should be revised to include all medications the patient is taking, irrespective of the drug class.* <u>Medication Reconciliation – Discrepancies (pgs. 96-98)</u>	

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		We believe a clear definition of "discrepancies" is needed in order for this data element to be valid. A clear definition will help CMS collect meaningful data. As proposed, it is unclear if CMS intends to capture discrepancies that are potential errors or discrepancies that are actual errors impacting the patient. Alternatively, as currently written, the assessor might respond to this element thinking that CMS is trying to gauge how effective the PAC setting is in identifying discrepancies during medication reconciliation. For example, if the old prescription containers do not mirror the new discharge summary and the prescriber makes appropriate adjustments to the drug regimen, it is unclear if this would be categorized as a discrepancy. We believe these issues must be clarified before this data element is used in any PAC setting. Without clarification, the reporting of this information will be ambiguous and not serve to improve patient care. Further, processes are already in place, especially in SNFs, to address medication issues prospectively before they would ever be captured as part of the data element requirements. For instance, pharmacies that provide medications to SNFs currently work with prescribers to resolve clinically significant medication issues before the medications are ever dispensed. This may be one of many possible explanations why a SNF may report only a few discrepancies under the structure of the proposed data elements. *Recommendation: For the Medication Reconciliation – Discrepancies data element, CMS should clarify what it considers to be a discrepancy. Furthermore, we do not believe that this data element should be limited to specific classes of drugs.* <u>Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement (pgs. 99-101)</u> Upon admission, SNF professionals examine the resident, interview the resident and caregivers, and review hospital transfer documentation to identify allergies, capture patient preferences, initiate care planning, and develop the initial medication regimen. In addition, the SNF conducts interdisciplinary care team meetings where residents and families are invited to participate and give input on the care plan. During these meetings, care issues, including those involving medications, are reviewed and discussed as part of standard	

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		procedure. Without a clear definition of what constitutes a discrepancy (consistent with our comments above), this data element would lead to SNFs responding "yes" in most instances, since these routine processes are already in place at SNFs. As such, this data would not likely be useful to CMS in assessing SNFs' performance. *Recommendation: For the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement data element, CMS should clarify what constitutes addressing a discrepancy satisfactorily to determine whether the data element will yield useful information in SNFs. Furthermore, this data element should not be limited to specific classes of drugs.* Medication Reconciliation – Discrepancies Communicated to Physician and Recommended Action Taken (pgs. 102-106) For these data elements, we agree that medication discrepancies need to be resolved with urgency, but we believe that having two separate 24-hour data elements is not reasonable. Collecting the two data elements separately (i.e., whether the prescriber was made aware of the discrepancy within 24 hours of its being detected, and then whether the PAC provider implemented the prescriber's recommendations within 24 hours of the prescriber's response) seems overly detailed and burdensome for the assessor. Also, the 48-hour discrepancy-resolution window may not properly recognize the practices in place in some PAC settings. For example, if the prescriber is unavailable, the care team at a SNF will escalate the situation to get a rapid response from an alternate prescriber who can address the issue. In other scenarios, when no threat exists to the patient's health, the prescriber or the hospitalist might need to be tracked down. This could take more than 48 hours, particularly on weekends and holidays. Also, access to information technology that supports the prompt resolution of these issues is limited in PAC settings. Therefore, we believe 72 hours is a more reasonable timeframe for the entire discrepancy-resolution process.	

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		Recommendation: For the Medication Reconciliation – Discrepancies Communicated to Physician and Recommended Action Taken data elements, CMS should change the data element to assess whether discrepancies for all medications are resolved within 72 hours. <u>Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy (pgs. 107-108)</u> We agree with the proposed data element that patients, caregivers, and care providers should have access to a reconciled medication list when providing care and during transitions in care. However, we caution against using these data elements for measurement in the near future, since communicating this type of information with these different entities and across settings presents a number of challenges for post-acute care providers. For example, because reconciled medications lists contain protected health information, communication is limited under the Health Insurance Portability and Accountability Act and may not be permissible to caregivers, family members, or the person legally responsible for a beneficiary. Additionally, many PAC providers do not have access to electronic health records or systems that facilitate communicating this information. PAC settings, unlike acute and ambulatory care settings, were not included in CMS's meaningful use program and therefore do not have funding mechanisms in place to incentivize the use of electronic health records. Therefore, many do not currently have the digital tools necessary to allow for the smooth and appropriate transfer of health information. *Recommendation: The intent of the data element for Medication Reconciliation– List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy is reasonable. However, CMS should work to provide increased access to electronic records prior to using these data elements for measurement.* Thank you in advance for considering these important issues. We hope that you will review our recommendations and revise the medication reconciliation data elements to more appropriately capture PAC provider performance. Sincerely,	

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		John P. Sganga, FACHE President & CEO, Innovatix & Essensa 1. State Operations Manual. Appendix PP - Guidance to Surveyors for Long Term Care Facilities (Rev. 168, 03-08-17) Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf	
ASCP	6/24/17	Dear Ms. Khan: The American Society of Consultant Pharmacists (ASCP) is the only international professional society devoted to optimal medication management and improved health outcomes for all older persons. ASCP's senior care consultant pharmacist members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, sub-acute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care. ASCP is pleased to have the opportunity to provide comments on the *Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment 2*. We support the goals of improving clinical outcomes and agree that a careful medication reconciliation (MR), performed by a pharmacotherapy specialist such as a pharmacist, results in improved clinical outcomes and ultimately reduces unnecessary hospitalizations and adverse events. Developing a standardized process to evaluate post-acute care across different settings can help to improve safe care transitions for hospital patients and long-term care residents in all facilities. We also support and agree with the desired outcomes of the National Quality Strategy: better care, healthy people and communities, and affordable care across all post-acute care settings. As requested, the topics of quality improvement, validity, and feasibility of use in post-acute care will be examined from the perspective of the long-term care pharmacist.	American Society of Consultant Pharmacists

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		Despite our broad appreciation of the desired beneficial clinical outcomes, there are substantial concerns with some of the data elements in the section of the draft document discussing medication reconciliation, including an ongoing concern that aspects of the Medication Regimen Review (MRR), as currently performed under F428 of the State Operations Manual, Appendix PP, are being conflated with MR, particularly as described in the data elements contained in this draft document. We have identified areas that could improve the process of MR, resulting in obtaining more accurate data. We list our concerns and suggested changes below. On October 5, 2015, ASCP submitted comments on Contract# HHSM-500-2013-130151*: IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review*. At that time, we expressed strong concern for potential confusion in conflating "drug regimen review" (DRR – note that for the purpose of these comments, both DRR and MRR define the same process) with the very different process of MR: *"As defined by CMS, these are two separate, critically important but by no means synonymous clinical services. The intent of the IMPACT Act is for both processes to occur through standardized patient assessment data that is shared across all providers. As such, the measure(s) should be changed to reflect both care processes. As the pharmacotherapy experts on the clinical care team, any meaningful discussion of medication management, including reconciliation and MRR must include the consultant and dispensing pharmacist."* Our biggest concern about the proposed process is that the measurement of quality will be fundamentally flawed because of what is being measured. The assessment tool is only measuring "yes" or "no" to show whether the process was completed. It is not measuring the quality of the process, it does not indicate who is performing the process and it does not indicate whether there were any measurable outcomes. "Medication Reconciliation" in the current draft document can be performed by any clinician and the manner in which information from that process gets into the data system (MDS in the case of long-term care) is usually via manual entry. If valid data is not getting into the system from which the data measurements are being pulled, the accuracy of the comparisons across PAC settings will not be a valid reflection of the process.	

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		While ASCP agrees that cross-setting data elements in post-acute care is essential for providing interoperability between facilities and reducing adverse medication events, we believe the cryptic level of information available will not be a true measure of quality. With that strong cautionary caveat, here are comments pertaining to Medication Reconciliation as defined on pgs. 87-108 of the draft document: **Pgs. 87-88 – Definition of Medication Reconciliation (MR)** The RAND document defines MR as, "*a process of reviewing an individual's complete and current medication list.*" The document further states that "*MR interventions have been shown to be a cost-effective way to avoid ADEs by reducing errors, especially when medications are reviewed by a pharmacist and when MR is done in conjunction with the use of electronic medication records […] The data elements in this section address the process of MR at care transition points, such as any transition between acute care hospital stays and a PAC setting, or between PAC settings. The proposed MR data elements address the five steps of MR outlined by the Joint Commission: (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare medications on the lists; (4) make clinical decisions based on the comparisons; and (5) communicate the new list to the patient/resident and appropriate caregivers.*" The definition of MR in the 2016 Joint Commission National Patient Safety Goals Hospital Accreditation Program is as follows: "*In medication reconciliation, a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolves any discrepancies. The best medication reconciliation requires a complete understanding of what the patient was prescribed and what medications the patient is actually taking.*" [1] We agree with and appreciate the acknowledgement that medication errors are reduced when MR is conducted by a pharmacist using electronic health records. We also agree that care transitions require careful MR to reduce medication errors. However, there is concern that the 5-part definition of MR listed in the	

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		RAND document includes prescriber decisions such as "developing a list of medications to be prescribed," which are not generally a part of MR itself. This introduces confusion to the process. We prefer the definition from The National Patient Safety Goals Hospital Accreditation Program as we believe it to be clearer in scope. ***ASCP RECOMMENDATIONS:*** *We recommend that in order to reduce miscommunication and confusion, the recognized and established Joint Commission National Patient Safety Goals Hospital Accreditation Program definition of MR be used throughout this document. Using different definitions for a standard process can cause errors and result in inaccurate or conflicting data collection.* **Pgs. 89-90 – Completion of MR** In this section of the proposed MR process, the assessor is asked to determine whether MR was completed during the 3-day lookback allotted time frame. Per the document, all five of the previously discussed steps should have been completed within the 3-day lookback to be considered complete. Again, steps such as "developing a list of medications to be prescribed" simply from examining a medication list, does not connote sound pharmacotherapy practice. A pharmacist can assess for accuracy (i.e., do the two medication lists match one another?) and identify medication interactions or medications without indication for use, but medication lists do not generally contain enough information to make prescribing suggestions. ***ASCP RECOMMENDATIONS:*** *The assessment tool only allows for a response of "yes" or "no," which introduces a great deal of rater validity and variability, which reduces reliability. It is suggested that MR completion, which is arguably the most important aspect of data collection, be treated in a more robust fashion, with more comprehensive assessment criteria, including questions about non-prescription medications, supplements, and PRN medications. Completion of MR should not include a list of medications to be prescribed; that is the duty of the prescriber once an accurate, complete medication list is established in the MR process. In addition, although there is no indication as to who should determine completion of MR, we would argue that this should be a pharmacist who is well-trained in identifying weaknesses in the MR process.*	

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		Pgs. 91-93 – Use of Medications in Specific Classes This section of the document assesses whether the medication list contains medications from specific classes. The document uses the HHS National Action Plan for Adverse Drug Event Prevention from the OIG, drug claims from atypical antipsychotic drug claims for elderly nursing home residents, and the CDC Core Elements of Antibiotic Stewardship for Nursing Home to determine which classes of medications are specified. Ten classes of medications are listed: anticoagulants, antiplatelets, hypoglycemic, opioids, antipsychotics, antimicrobials, antidepressants, diuretics, anxiolytics, and hypnotics. While focus on high-risk medications is a laudable goal, the classes listed are by no means a complete list of problematic agents. For example, muscle relaxants, which can be highly anticholinergic and contribute to falls or cause respiratory depression, especially when combined with other sedating medications, are not on the list. Older antidepressants such as tricyclic acids are much more sedating and anticholinergic than newer antidepressants, yet no distinction is made to address the very different pharmacological properties of these subclasses. The concern with any list of drug classes is that it is impossible to identify all possible medication concerns, as *any* medication or supplement can be problematic. One of the biggest contributors to medication misadventures is allergic reactions, and yet this list makes no reference to checking for history of allergies. In collecting data for this section, the assessor is asked to calculate how many days the patient took medications in a certain class in the past 7 days or since start of care. If a patient is taking more than one med in a class, the longest duration of time is to be used. There is no indication as to how a patient taking a medication more than once a day should be assessed. For example, if a patient takes the anxiolytic alprazolam several times a day rather than once daily, how should that be assessed? What is the impact or risk to the patient? If the assessor is not a pharmacist, it is arguably beyond the clinical scope of practice to make this sort of determination. Last, using a limited number of medication classes to assess MR is never appropriate. MR, as defined previously, is the act of comparing lists of all medications, including prescription, OTC, and supplements to determine accuracy in transitions of care. Most of the adverse medication problems can and should be	

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		identified in the MRR process by the consultant pharmacist. ***ASCP RECOMMENDATIONS:*** *Using a specified list of classes of medications in assessments can result in missed potential medication errors, and introduces enormous potential for rater/validity failures. While the pharmacist can and should identify problematic medication combinations in the MR process, in order to perform a complete analysis, the full medical record with allergy history should be used. In the case of polypharmacy, the assessment tools are not adequate to capture problematic medication combinations and should be eliminated or changed substantially. As any medication or supplement can cause medication misadventures, a complete analysis should be performed by a pharmacist, with no emphasis placed on certain classes of medications. If a list of classes must be used, the list should be refined substantially as discussed above.* **Pgs. 94-95 – Indication** In this section, the assessor notes whether there is an indication for use for all medications in the specific classes listed in the previous section. While ASCP applauds the focus on indication for use, there are distinct problems with this section of the tool. What if a patient has an unindicated medication that isn't included in the specific drug classes? Is it ignored? In addition, simply having an indication for use listed does not necessarily mean it is an *appropriate* indication. For example, quetiapine is sometimes given in low doses as sleep aid, but it is not considered an appropriate indication for use by most pharmacists. Is pain an appropriate reason for an opioid prescription? This would largely depend on the intensity and *quality* of the pain. Unfortunately, the assessment form only allows for yes/no answers in this section. In addition, the instructions indicate that "data elements can be administered by any clinician who has been trained to conduct this assessment." Would a non-pharmacist know the answers to the questions posed above? ***ASCP RECOMMENDATIONS:*** *Determining an indication for use for all medications is a laudable goal, and we support it. It should be noted that this check for indications is routinely performed during the MRR process by the consultant pharmacist. Limiting indications for use to only a list of ten medication classes will result in many medications without indication not being cited, resulting in poor data. If a non-*	

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		pharmacist performs this section of the MR tool, there is serious concern that mistakes will be made, as other clinicians may lack the training to determine appropriateness of use as discussed above. We therefore strongly recommend that the pharmacist check all medications for appropriate indications. The tool should be modified to allow for more than just yes/no answers. If interoperable health IT solutions are being used, it should be noted that there is recognized standard terminology for indication which should match the systems problem list (e.g., SNOMED CT). **Pgs. 96-98 – Discrepancies** This section of the document assesses whether any medication discrepancies have been identified. The instructions indicate that the assessment "can be administered by any clinician who has been trained to conduct this assessment." The tool examines the ten specific med classes identified earlier, and for each category, the assessor answers yes, no, or indicates that there is "missing information or lack of documentation." The nature of the missing information is apparently not documented on the form. Once again, it must be noted that unless one is a pharmacist, it would be impossible to determine many discrepancies, resulting in poor data validity. The consultant pharmacist routinely points out discrepancies to the clinical team in the MRR process. Notes are left for the prescriber and/or nursing staff, and these notes must be read and acted on. All medications are examined, not just those in the ten specified classes. The data collected in that process would almost definitely have higher validity than in this process. ***ASCP RECOMMENDATIONS:*** *In order to ensure high validity and appropriate data collection, discrepancies must be determined by a pharmacist, preferably a consultant pharmacist who routinely performs this type of analysis at an advanced level. The assessment tool should include a space for the assessor to indicate what is missing, or not documented so that the problem can be fixed. Otherwise, it is unlikely to prevent adverse events. Limiting the analysis to ten classes will by definition result in missed discrepancies. It is therefore suggested that a full analysis be performed by a consultant pharmacist on all medications as is routinely completed each month in skilled nursing facilities.* **Pgs. 99-108 – How are discrepancies addressed with patient and care team? Are discrepancies**	

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		communicated to physician? Are the recommended actions taken? Is the reconciled medication list communicated to resident/care team/pharmacy? Assuming a pharmacist performs all sections of the MR assessment up to this point, resulting in a valid MR with an analysis of *all* medications, we believe the resulting data can be communicated to the care team by a non-pharmacist in most cases. If the recommendations and assessments are made by a non-pharmacist as permitted in the draft document instructions, there is worry that inaccurate recommendations could be given, resulting in adverse medication events. ***ASCP RECOMMENDATIONS:*** *We strongly recommend that a pharmacist perform all sections of the MR tool, including identification of discrepancies. Once the analysis has been completed by the pharmacist, another member of the care team can share the recommendations to the prescriber and other clinical team members. We do not recommend that a non-pharmacist determine discrepancies or medication indications. We do not recommend limiting the process to a specified list of medication classes, but believe all medications, including prescription, OTC, and dietary supplements should be included.* ***SUMMARY:*** ASCP agrees that data collection across different post-acute care settings is needed, along with system interoperability, and we support these goals of the IMPACT Act. However, in order for these goals to be met, it is imperative to develop data collection tools and guidelines that have robust clinical evidence for use, and that result in high validity and quality data collection. The current draft document sets clinical limitations such as using a pre-defined set of medication classes that could contribute to medication misadventures rather than improving the process. There is genuine concern that the tools and assessor guidance could harm rather than ameliorate the person-centered care process and lead to inaccurate comparisons of quality across PAC settings. We respectfully suggest that CMS and RAND Corporation revisit this process to remedy the cited deficiencies with the MR assessment tools. We would be pleased to have the opportunity to work with CMS and RAND on refining the measure to make it useful and clinically appropriate for use across all sectors. Once again, we wish to thank CMS for the opportunity to share our feedback on this important document.	

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		Sincerely, Joan Baird, PharmD, BCGP, FASCP Director of Pharmacy Practice & Government Affairs 1. The Joint Commission National Patient Safety Goals Hospital Accreditation Program (Effective January 1, 2016) Available at: https://www.jointcommission.org/assets/1/6/2016_NPSG_HAP.pdf	
APTA	6/26/17	On behalf of our 93,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) submits the following comments on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data. Physical therapy is an integral service provided to Medicare beneficiaries in all post-acute care settings. Physical therapists furnish medically necessary services to patients to improve their overall health and function, and to optimize their quality of life. Across the post-acute care settings, physical therapists provide services to patients through a plan of care that engages and optimizes the patient's participation in achieving shared goals of improved functional performance, reduced risk of injurious falls, and reduced risk of acute hospitalization, thereby promoting long-term health and wellness. Physical therapists perform an examination that includes the patient's history, a systems review, and tests and measures to determine the patient's therapeutic, rehabilitative, and functional status and any environmental factors that may impact the patient's activity and/or participation. Through the evaluative process, the physical therapist develops a comprehensive plan of care to achieve the goals and outcomes of improved function. The physical therapist also instructs patients and caregivers in areas that will help to address specific impairments, activity limitations, participation restrictions, and environmental factors. This may include instruction in the use and performance of therapeutic exercises, functional activities, and assistive or	American Physical Therapy Association

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		adaptive devices, including prosthetics and orthotics. As essential members of the health care team, physical therapists play an integral role in the transition of patients to the community. Comments on the Post-Acute Care Cross-Setting Standardized Assessment Data APTA supports the goal of improving the quality of health care. Physical therapists are committed to providing high-quality, timely care and to the promotion of evidence-based and patient-centered practice. Furthermore, APTA feels it is essential that we move toward standardized data elements and a common set of quality measures across the continuum of care. Overall, APTA supports the standardized assessment data as proposed for the areas of cognitive function and mental status, medical conditions (continence and pain), hearing and vision, medication reconciliation, care preferences, and PROMIS. APTA believes that many of the data elements are essential for appropriate risk adjustment of cases both for the purposes of payment and for use in outcomes measures methodologies in the postacute care settings. However, we do have several comments and concerns, which we outline below. DOPTA CARE APTA is pleased to see the inclusion of the DOPTA CARE, as we believe that this will allow for a more comprehensive assessment of cognitive function and mental status. We believe these items appropriately score a patient's functional performance and record the necessary level of assistance the patient requires, both of which are essential for risk adjustment and referral. Hearing and vision APTA supports the inclusion of the hearing and vision elements. However, we believe that the hearing and vision sections should be administered at the beginning of the patient interview and assessment process to provide the examiner evidence regarding any sensory deficits that could affect the patient's ability to participate in the assessment. PROMIS items	

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		APTA is supportive of the PROMIS measures including sleep disturbance, fatigue, ability to participate in social roles and activities, and global health. APTA is familiar with PROMIS, and we believe that the adoption of PROMIS will continue to increase over the coming years. While we see great value in collecting these items in the PAC setting, we encourage CMS to test a shorter item set for these sections if possible, as we are concerned about the burden of the full data set. International Classification of Functioning, Disability and Health (ICF) The International Classification of Functioning, Disability and Health (ICF) is part of the "family" of international classifications developed by the World Health Organization (WHO). The ICF classification system focuses on human functioning and provides a unified, standard language and framework that captures how people with a health condition function in their daily lives rather than focusing on their diagnosis or the presence or absence of disease. APTA believes that capturing functional limitation using this system may improve understanding of outcomes and resources utilization in patients in the PAC settings. We recommend that CMS consider additional information about patient functional limitations using the ICF in the future. Functional measures for restorative versus maintenance therapy APTA does have concerns regarding the impact of functional data and measures on payment for patients who receive physical therapy services where the goal of care is to maintain function or prevent functional decline versus those patients receiving physical therapy services for the purpose of restoring or improving function. The Jimmo v. Sebelius settlement in 2013 clarified that Medicare determinations for SNF, Home Health, and Outpatient Therapy turn on the need for skilled care – not on the ability of an individual to improve. Currently, the functional measures in the PAC settings look at functional gains, these measures could create unintended consequence for providers who are treating patients with the goal of maintaining function. APTA would recommend that CMS consider removing these patients from the functional improvement measures. Future efforts should include the creation of measures for this patient population that focus on the prevention of functional decline. Provider education	

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		APTA recognizes that the overall goal of the IMPACT Act is for post-acute care providers (home health, inpatient rehab facilities, skilled nursing facilities, and long-term care hospitals) to collect and report standardized and interoperable patient assessment data, and quality and resource-use measures. APTA appreciates that CMS has strict deadlines for the implementation of cross-setting standardized assessment data under the IMPACT Act; however, as many of these data elements will be new to the respective post-acute care settings, we encourage timely, appropriate education and training for providers to ensure that there is interrater reliability. We believe that achieving a standardized and interoperable patient assessment data set and stable quality measures as quickly as possible will allow for better cross-setting comparisons as well as for the evolution of better quality measures with uniform risk standardization, thus achieving the true aim of IMPACT. Full IMPACT data set Over the last several years, CMS has been working to integrate the new data elements into the various PAC settings in compliance with the IMPACT Act. However, we have increasing concerns about data element overlap and the number of data elements outlined under various proposed rules and calls for comments. We strongly recommend that CMS and key stakeholders involved in the project, including RAND, publish the full data set for review and comment even though there are elements still under development. It is becoming increasingly difficult to provide feedback given the multiple calls for comments on various parts of the data set. We believe that CMS would receive more robust feedback if we could view the data set in its entirety—regardless of the phase of development. Additionally, we suggest that CMS consider creating a webpage where providers and stakeholders can find updates on IMPACT. Future use of data Last, while we support the standardized data elements, we do have concerns about how this data may be used in the future. As we stated, we believe the data elements are important and should be used in risk-adjustment methodologies for payment and quality measures. However, we are concerned about the use of these data elements to construct outcomes measures that will be used to determine payment. We encourage CMS to continue to work with stakeholders in the development of future quality measures for the post-acute care settings.	

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		Conclusion APTA thanks CMS and RAND for the opportunity to comment on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data, and we look forward to continuing to work with the agency throughout the implementation of the IMPACT provisions. If you have any questions regarding our comments, please contact Heather Smith, PT, MPH, director of quality, at 703/706-3140 or heathersmith@apta.org. Sincerely, Sharon L. Dunn, PT, PhD President SLD: hls	
MRH	6/26/17	To Whom It May Concern: We are writing in response to The Centers for Medicare & Medicaid Services' request for feedback on data elements being considered as part of the IMPACT Act. Below you will find general feedback on our organization's response to the IMPACT act followed by specific feedback on data elements being considered to measure cognitive function and mental status; medical conditions and co-morbidities; impairments; medication reconciliation; and care preferences. **Impact of the IMPACT Act:** To meet the data collection requirements of the IMPACT ACT, significant time and resources have been allocated in our institution to build, customize, and modify our electronic medical record (EMR). Complex technology solutions were required to assure clinicians providing patient care can effectively document this care and provide the required data needed for the IRF PAI. Ongoing modifications are implemented at each phase of the IMPACT Act.	Magee Rehabilitation Hospital

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		A full-time position was created in the Information Management Department. The role of this employee is to manage the massive amount of data being collected in the EMR on each of our patients. This employee reviews the data, confirms accuracy with support from clinical leaders in various departments and submits the IRF PAI data to CMS. The clinical leaders are allocating additional time to collaborate with the information management department to assure the data collected is accurate. This time would normally be spent providing patient care and mentoring staff. Each addition and/or change to the EMR requires significant staff education and training. This involves hundreds of employees across multiple clinical departments. Reinforcement education over time is required to assure accuracy. Ongoing education is required to adjust and adapt to the new changes with each phase of implementation of the IMPACT Act. Clinical staff are adapting to changes and new items in the EMR. The additional time needed for documentation results in less time for bedside care and therapy treatment. Additional documentation requires additional staff hours which is a financial burden to our institution. **Data Collection:** The FIM instrument is the standard outcome measure in the IRF. Clinical staff have been trained to evaluate patients using the FIM for many years and are well versed on both the terminology and definitions of 'burden of care' measured by the FIM. The CARE tool introduced by the IMPACT Act measures the exact same cognitive, ADL, and mobility items, but the scoring system is different. The FIM asks how much help the patient needs while the CARE tool asks how much help the 'helper provides'. Additionally, the numeric scores associated with each tool are slightly different. For example, if a patient requires 'Minimal Assistance' to complete a task, the numeric score on each tool would be different. It is extremely confusing for multidisciplinary staff to evaluate cognition, ADLs and mobility using two different tools, with two different scoring systems.	

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		Bowel and Bladder assessment using the FIM and CARE terminology has been difficult. Each tool describes incontinence with different language. The FIM tool describes incontinence (including spills and leaks) as "accidents." The CARE tool describes incontinence as "incontinent episodes." The definitions of "accidents" and "incontinent episodes" are not the same. The evaluation of incontinence in two slightly different ways has led to confusion and inaccuracies. Additionally, tracking incontinence episodes over 7-days is difficult especially if the information provided by the previous facility is not thorough. To manage redundancy in assessment of mobility, ADLs, cognition and bowel/bladder incontinence using the FIM and CARE tools we completely restructured our EMR, educated all of our clinical staff on the changes and consistently review documentation to assure we are in compliance. Once again, this process takes significant time, collaboration and resources. Our simple solution: Select and utilize one tool to measure each domain. The use of multiple tools to assess and measure the same domain is redundant and inefficient. More time and money is spent on workforce. The workforce spends more time documenting than providing quality, hands-on patient care. The workflow burden may have a negative impact on patient outcomes over time. **Feedback on New Data Elements:** Cognitive Function and Mental Status: • DOTPA CARE-C o Utility: This tool is redundant. We are looking at these same cognitive domains through the FIM, CARE tool and the BIMS. o Feasibility: The questions in this measure are not appropriate for patients transitioning from acute care to the IRF. Patients admitted to the IRF are acutely ill and are not able to participate in complex task assessment in the first 3 days of admission. These items may be appropriate at discharge from the IRF and can be used as the patient transitions to the next level of care.	

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		o Quality: If implemented, this will be the third tool used to assess the same cognitive domains. This is an inefficient use of time and resources. • Complex Sentence Repetition o Utility/Feasibility: This is a language-based assessment. This will not be applicable to patients admitted with neurologic diagnoses that have impacted receptive and expressive language (i.e. stroke, brain injury, dementia). Some patients may be able to comprehend but may not have the motor ability to express themselves (for example, a spinal cord injury patient on a ventilator). o Utility: Once again, this is redundant with the FIM and CARE assessment of receptive and expressive language. This would be the third tool used to measure the same cognitive domain. • PASS Medication Management o Feasibility: Patients entering an IRF may not have the cognitive or physical capacity to participate in this assessment on admission. Many of our patients do not have the hand function or cognitive ability required to follow the instructions (i.e. spinal cord injury without hand function, stroke/brain injury without language or vision). o Utility: Medication management is a complex task appropriate for patients with minimal cognitive deficits. It is not a priority in the first 3 days to determine if our patients can manage their prescriptions. Our priorities are assuring our patients are medically stable and ready to participate in intensive therapy while preventing complications. o Quality: Medication management is a goal our team works on throughout the stay to assure the patient and caregiver are prepared by discharge. This measure may be appropriate at discharge from the IRF and at admission to the next level of care. • Staff Assessment of Mental Status o Quality/Utility: If implemented, this will be the third tool used to assess the same cognitive domains. This in an inefficient use of time and resources. o Quality: Spending increased time on assessments, not interventions, will reduce individualized patient care and increase length of stay.	

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		• Behavioral Signs and Symptoms o Quality: This tool will be beneficial in our facility. This domain is not measured by any other tool. o Feasibility: Data collection over 7-days, including time in the previous facility, will be difficult. Additionally, patients are often sedated and/or restrained in the acute care environment. We may not be getting an accurate picture of behavior. As sedating medications are reduced and removed, the patient's behavior is expected to change significantly. • PROMIS® Anxiety Items o Quality: The Likert scale in this tool cannot be used for patients who are nonverbal (i.e. stroke patient with aphasia, spinal cord injury patient on a ventilator). We will need an alternative for non-verbal or observational assessment of anxiety and depression. • Patient Health Questionnaire-9 Observational Version (PHQ9-OV) o Quality: This observational screening is preferred for IRF and LTACH o Feasibility: Several items ask about mood over the last 12-14 days. • Medical Conditions: Continence o Utility: Each of the Bowel and Bladder tools is redundant with the FIM and CARE tool scoring. It is a burden on time to utilize three different tools to assess the same condition. o The Bladder/Bowel interview is asking the patient for the same information we are already collecting via FIM and CARE tool. It does not make sense to implement another way of recording this same information. o Feasibility/Utility – The bowel/bladder interview is only appropriate in the home care setting. • Medical Conditions: Pain o Utility: The Likert Scale used in each of the pain assessments is a subjective scale. Additional education will be required to assure both patients and clinical staff understand the verbal definitions of pain (mild, moderate, severe) so we are quantifying the status accurately. This will require additional resources for education and training.	

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		• Medication Reconciliation o Feasibility: The EMR will require modification to automate the collection of the Medical Reconciliation information. This will require additional time and resources from Pharmacy, Information Management and Technology. o Section F1c: It will be challenging to complete the 7-day look back unless the acute care hospitals discharge patients with this information readily available. **PROMIS®** • Sleep disturbance; Fatigue; Ability to participate in social roles and activities; Global health o Feasibility: Patient interviews are difficult to conduct with cognitively or language impaired patients. o Many of the questions are not applicable to patients who are currently hospitalized. o Significant time will be required to interview patients on all of these items. o An observational scale would be appropriate for sleep and fatigue. As you may have noted, the recurring theme is redundancy. It is critical we assess patients in the IRF for deficits in mobility, ADL, skin, cognition, and continence. However, it does not make sense to measure these areas using three or four different tools. Performing multiple, redundant assessments is a burden on health care providers and reduces time spent providing individualized patient care. Thank you for your time and consideration.	
AMRPA	6/26/17	Dear Ms. Khan: These comments are submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA) with respect to the above captioned Request for Comments. We welcome the opportunity to comment on the development of data elements pursuant to the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. AMRPA supports the principles and objectives of the Act and remains committed to working with the Centers for Medicare and Medicaid Services (CMS) and its contractor, the RAND Corporation, to achieve them.	American Medical Rehabilitation Providers Association

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		AMRPA is the national trade organization representing the interests of medical rehabilitation providers. It represents providers across the spectrum of health care settings including inpatient rehabilitation facilities (IRFs), hospital outpatient departments (HOPDs), and settings independent of the hospital, such as comprehensive outpatient rehabilitation facilities (CORFs), rehabilitation agencies, and skilled nursing facilities (SNFs) as well as a number of long-term acute care hospitals (LTACHs). AMRPA members help patients maximize their health, functional skills, independence, and participation in society so they can return to home, work, or an active retirement. **General Comments** The Request for Comment asks that the stakeholders address several topics in evaluating the data elements specified in the RAND report, "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment Round 2." One of these topics is the "potential for improving quality." As CMS is well aware, quality measures differ considerably from individual data elements. Our members are concerned that the approach to "quality," as defined in the report's narrative, is neither properly characterized nor entirely appropriate. The first phase of the IMPACT Act is focused on the development of quality and resource use measures. The Act regards standardized patient assessment information as a data collection effort to gather the information necessary to develop a unified PAC prospective payment system – not as traditional quality measurement or as a precursor to measure development. Fundamentally, data collection and quality measure conceptualization reflect two inherently distinct purposes. Hence we believe the request to comment on data elements' "potential for improving quality" is inaccurate, misleading, and we are concerned that it will lead to what we view as the inappropriate use of the data. AMRPA is concerned with the direction of developing standardized cross-setting assessment items, as it is not clear how data from many of the proposed items would improve the efficiency and quality of the care delivered. While AMRPA appreciates the desirability of using standardized data items across settings, we urge CMS and RAND to develop sensible approaches for doing so and resist subjecting our patients to inappropriate questions that distract clinicians from meaningful work and could create misleading comparisons. Many of the items are nearly identical to existing hospital assessment and care practices and thus are unnecessarily repetitive and burdensome, such as Medical Reconciliation or Care Preferences. To meet the Act's requirements, we ask the Agency to consider an approach by which it implements a core set	

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		of non-duplicative standardized patient assessment items across all PAC settings, upon which it builds and supplements *setting-specific* assessment items as needed. CMS and RAND need to prioritize and consider in concert both the administrative burden to providers of collecting data and the data's clinical effectiveness and utility. We also ask CMS and RAND to be mindful of the impact that numerous assessment or patient-reported items could have on the patient-provider relationship. We believe this aspect has been an unevaluated, yet critical, component to successful implementation of PAC assessment items. Would patients be receptive to the breadth of information being collected from them and on them? Are the items patient-centric? To some elderly and other patients, so many questions can seem intrusive and they may respond negatively to an exhaustive battery of assessment minutiae. We do believe that some of the elements can contribute to a few of the listed possible uses of the data collected, such as improving care planning, supporting clinical decision making, and care coordination. We offer the following comments and recommendations regarding the proposed data elements with respect to cognitive function and mental status, special services, treatment and interventions, medical conditions, comorbidities and impairments, as well as looking at the potential for improving quality, validity, feasibility of use in PAC and utility for describing case mix. **Cognitive Function and Mental Status** ***A. DOTPA CARE*** 1. Potential for improving quality: Our members do not think this element will necessarily improve quality as defined in the report. It may provide an indication of the burden of care for purposes of developing an individual plan of care. 2. Validity: This item appears to be valid given its prior testing in various PAC settings.	

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		3. Feasibility for use in PAC: Though the item may be administratively feasible to use across settings, we do not think it is relevant to all PAC patients. It would be better suited to a subset of IRF patients, such as brain injury, and would be burdensome to administer to all patients. 4. Utility to describe case mix: Given the concerns mentioned above, we do not think it would have much utility to describe case mix because it would only be useful to describe to a subset of patients. IRFs already assess patients based on functional performance so the DOPTA CARE would have low utility in providing new information. ***B. Complex Sentence Repetition*** 1. Potential for improving quality: We do not think this item would have an impact on the quality of care a patient receives. Our clinicians also feel that this item is redundant with the Brief Interview for Mental Status (BIMS) in how it assesses cognitive impairment. Since the BIMS is already being standardized across PAC settings, this item would not contribute utility or value beyond the information already captured by the BIMS. 2. Validity: We are skeptical that this is a valid indicator of cognitive impairment; some patients may have trouble a repeating 14-word sentence even if they do not have any cognitive issues. The report states that this item demonstrated high reliability in the Alpha 1 pilot, but does not comment on its validity. This item also has not undergone prior wider PAC testing, such as in the PAC PRD, unlike other items proposed for cognitive assessment. 3. Feasibility for use in PAC: It would be feasible for cross-setting use in that it is relatively straightforward to administer, but its utility is questionable.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		4. Utility to describe case mix: Since this item is redundant with the Brief Interview for Mental Status (BIMS), which is already being standardized across PAC settings, it would not contribute utility or value beyond what is already captured by the BIMS. ***C. PASS Medication Management*** 1. Potential for improving quality: This item evaluates a patient's ability to manage their medications and would help inform care planning and may improve medication adherence. In that sense, it could potentially improve a patient's quality of care post-discharge. 2. Validity: According to the report, this item has not been used or tested in PAC before, so we believe its validity is limited at this time. 3. Feasibility for use in PAC: If this item is implemented, we recommend that this item be administered only at discharge and only for patients who would need to manage medications. It would not be feasible to evaluate all patients on this activity at admission and discharge. 4. Utility to describe case mix: We believe it could assist in describing case mix by highlighting resource needs and therefore care planning. ***C. Staff Assessment of Mental Status*** 1. Potential for improving quality:	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		We do not think this item would improve quality because it does not provide a valid assessment of mental status acuity over time. 2. Validity: This item seems to be valid given the predominantly binary construct of the staff response options. 3. Feasibility for use in PAC: This item is intended for patients who are unable to complete the BIMS. However, the IRF PAI currently includes a BIMS-alternative for such patients. If this item is implemented across settings, we recommend that CMS remove the current BIMS-alternative from the IRF PAI. 4. Utility to describe case mix: Similar to the BIMS, the item could help assess differences in patient severity related to resource needs, and feed into developing the individual plan of care based on the resources needed. ***D. Behavioral Signs and Symptoms*** 1. General Comments The report narrative states that "behavior disturbances put additional time and resource burden on providers" and "warrant assessment and documentation to inform care planning and patient transitions." We agree conceptually with this assessment and appreciate CMS' intent to account for the higher resource intensity of some cognitively impaired patients. We also appreciate CMS addressing Rejection of Care which we have previously recommended. In reviewing this multi-question assessment item, however, we are not certain that documenting the occurrence of disruptive behavior is an effective data indicator of resource need. From a clinical and practical perspective, trying to measure all of these behaviors on a three to five-point scale assumes a level of objectivity or consistency that simply does not occur in real life. Depending on when this assessment is conducted, there is also the possibility that medications from a	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		preceding acute care hospitalization mute a patient's behavioral symptoms in which case they would only manifest when their medications are adjusted downward during their PAC stay. This nullifies any meaningful comparison of patient behavior at admission versus discharge. Finally, we are concerned that some questions in this item may conflate underlying psychiatric issues with symptoms of cognitive impairment. 2. Potential for improving quality: We do not think the item could improve quality. 3. Validity As we describe above, this item could create false positives because it would not differentiate whether a patient's behavior was due to psychiatric disorders versus cognitive impairments, or possibly due to medication side effects. 4. Feasibility for use in PAC: This item may be feasible to administer to a certain subset of IRF patients, such as those with brain injury, but it would be burdensome to administer on all IRF patients. 5. Utility to describe case mix: This item may be helpful in determining case mix, particularly if the PAC provider has a neuro-behavioral unit or otherwise serves neuro-behavioral patients. ***E. PROMIS Anxiety*** 1. Potential for improving quality: Our member clinicians agree that anxiety is a significant issue in PAC and feel that it is currently inadequately addressed by PAC assessment tools. Patients who need PAC are frequently anxious about their circumstances. Having a non-burdensome tool that could validly identify anxiety would help structure a	

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		clinical program to manage their symptoms and would indeed improve a patient's quality of care. 2. Validity: As we have noted before, the PROMIS item bank was developed for outpatient care and also has not been validated in PAC settings. Furthermore, the report did not provide evidence that the PROMIS items correlate positively with an actual clinical diagnosis of anxiety. We are concerned there would be a danger in assuming a validity that is not there. For these reasons, we do not think the PROMIS Anxiety item would be valid for PAC patients as proposed here. We recommend that CMS conduct a voluntary pilot test of the items' predictive value and validity in PAC settings. 3. Feasibility for use in PAC: In our view, several of the item questions seem redundant or duplicative. In a pilot test, CMS should also evaluate which questions can be eliminated to pare down the item set and facilitate this item's administration. 4. Utility to describe case mix: This item would be helpful to describe case mix if it is found to correlate positively with a clinical diagnosis of anxiety (*i.e.*, is a valid screen for anxiety). ***F. Patient Health Questionnaire-9 Observational Version (PHQ 9-OV)*** 1. General Comments The vast majority of IRF patients are admitted from short-stay acute care hospitals after a severe illness or catastrophic event in their lives (*e.g.* stroke, spinal cord injury, brain injury, multiple trauma). It is not uncommon for patients to have experienced a sudden and dramatic decline in function within the few days prior to the IRF admission. According to our physician members, the most operant psychological response observed in IRF patients is denial or adjustment disorder/stress response syndrome, a group of symptoms such as stress, feeling sad or hopeless, or physical symptoms that can occur after one undergoes a stressful	

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		life event. To efficaciously screen patients for depression, we support using the PHQ-2 as a gateway element, feeding into the PHQ-9-OV if needed, to economize time, reduce burden, and generate clinically meaningful information. 2. Potential for improving quality: The item could assess depression and other mood issues if utilized carefully and thereby contribute to improving quality. It would help with care planning, transitions and communications among providers and clinical decision making. 3. Validity: The report states that the PHQ-9-OV has been studied in several PAC populations, and CMS cites studies on its use as a screen for major depressive disorder in rehabilitation patients. 1,2 However, those studies examined only subsets of patients (brain injury and stroke) and we think it would be premature for CMS to conclude that the PHQ-9-OV would produce valid and meaningful information if it were administered on all IRF patients. 1 Williams LS, Brizendine EJ, Plue L, et al. Performance of the PHQ-9 as a screening tool for depression after stroke. Stroke. 2005;36(3):635-638. 2 Fann JR, Bombardier CH, Dikmen S, et al. Validity of the Patient Health Questionnaire-9 in Assessing Depression Following Traumatic Brain Injury. The Journal of head trauma rehabilitation. 2005;20(6):501-511. 5. Feasibility for use in PAC: The item is feasible to use across PAC settings if is it used with the PHQ-2 as a gateway/trigger item. 6. Utility to describe case mix: We believe the PHQ-9-OV, if used sensibly, will help ascertain case mix by helping describe severity, the burden of care and therefore resource needs.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Medical Conditions: Continence Items ***A. Bowel and Bladder – Incontinence*** 1. Potential for improving quality: These items are similar to ones already on PAC assessment instruments so we do not think they would improve the quality of care above existing practice. 2. Validity: Despite being similar in nature to current PAC items, the proposed items' grading scale differs from the seven-point frequency scale used on the IRF PAI: **Proposed Scale for Bowel and Bladder Incontinence Frequency** 0 – No incontinent events during the assessment period 1 – Incontinent events less than daily 2 – Incontinent events daily 3 - Incontinent events more than daily 8 – Not applicable 9 – Unknown **IRF PAI Scale for Bowel and Bladder Frequency of Accidents** 7 - No accidents 6 - No accidents; uses device such as a catheter 5 - One accident in the past 7 days 4 - Two accidents in the past 7 days 3 - Three accidents in the past 7 days 2 - Four accidents in the past 7 days 1 - Five or more accidents in the past 7 days with the Bowel and Bladder Patient Interview items and not combined with staff-assessed items.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		4. Utility to describe case mix: We think these items help ascertain case mix by describing the burden of care and therefore resource needs. ***B. Bowel and Bladder – Device Use*** 1. Potential for improving quality: We believe these items assess only resource use and could inform care planning decisions, but they do not contribute directly to quality improvement. 2. Validity: The report states that similar items were tested on the PAC PRD and during the Alpha 1 pilot and demonstrated moderate to excellent reliability. We agree these are generally straightforward items to assess. Our only concern is about questions regarding the reason for device insertion/use. If it was done prior to the PAC stay, then it may not be possible for the PAC provider to answer why the acute care hospital inserted the device, in which case "9. Unknown" may be a fairly common response. We did not see rationale for including this question, hence we think it is extraneous since it does not contribute to the PAC-level course of treatment. It is also unnecessarily burdensome to require PAC staff to comb through the patient's medical record to answer this item. 3. Feasibility for use in PAC: These items are feasible for PAC use with the exception of the points raised above. 4. Utility to describe case mix: These items do help describe case mix and resource need. ***C. Bowel and Bladder - Incontinence Interview*** 1. Potential for improving quality:	

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		These are novel questions to ask a patient and their caregiver and would certainly contribute to understanding the burden of care. Our members report that incontinence is a significant factor to family/caregivers to their decision as to whether or not they can support a patient's discharge to home. These items would help inform a comprehensive understanding of the patient's readiness for discharge and in that sense could improve the overall quality of their care. It is important to assess not only the frequency of events but also the perceived burden in order to understand the full picture. We appreciate CMS recognizing that incidence alone does not illustrate the burden to patients or their family/caregivers. For instance, some elderly patients may have stress incontinence but have become very capable at managing it. 2. Validity: While the patient self-assessment of burden is important, we think it is perhaps more critical to ask their caregiver these questions. However we have concerns as to how, logistically, this would occur – would the caregiver be asked these questions in front of the patient? If so, would that produce honest and valid answers? CMS should consider these administrative aspects as it continues to refine these items. 3. Feasibility for use in PAC: This item would be feasible to implement at discharge. We recommend that CMS clarify the term "caregiver," which seems to imply a home health setting. 4. Utility to describe case mix: We do not think these would be more useful than other Bowel and Bladder Incontinence items in describing case mix. These focus on patient or family/caregiver assessment of burden of care, not necessarily burden upon the provider or its resource use. **Medical Conditions: Pain** In this section's introductory paragraph, the narrative claims "evidence indicates that pain assessments can be applied broadly across PAC settings." We disagree with this statement. While it is undeniably important to observe and administer treatment for pain, healthcare's approach to assessing pain has evolved in recent	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		years. We recommend CMS take these changes into consideration as it develops standardized pain assessment items. In response to the opioid epidemic, The Joint Commission (TJC) in 2016 began revising its pain standards, stating it is a "misconception" that pain assessments should be required for all patients.3 It has been 13 years since TJC last endorsed pain as a vital sign its accreditation standards. The Commission steps away from standardizing pain assessments and instead allows providers to set their own policies regarding which patients should have pain assessed based on the population served and the services delivered. Its new pain standards focus on factors such as identifying psychosocial risk factors that may affect self-report of pain; involving patients to develop their treatment plan and setting realistic expectations and measurable goals; and focusing reassessment on *how pain impairs physical function*. None of the Commission's updates expand the scope or target of pain assessments. Inpatient rehabilitation hospitals and rehabilitation units of acute care hospitals are held to TJC standards and already evaluate pain as a part of routine physician and nursing assessments. How to address and treat pain is then folded into the patient's plan of care. The proposed standardized pain assessment items are redundant with existing practice and would unduly and significantly increase IRF regulatory burdens. As required under Medicare regulations, patients treated in IRFs must receive an intensive level of therapy services typically demonstrated by participation in a minimum of 15 hours of therapy a week. Due to the highly intensive nature of therapy services delivered in IRFs, it is not uncommon for IRF patients to experience some degree of pain or discomfort as a consequence of an effective therapy regimen. For example, an IRF patient recovering from a recent hip replacement may feel some pain after an intensive physical therapy exercise and they may also experience residual pain from the hip replacement surgery. 3See The Joint Commission Statement on Pain Management, https://www.jointcommission.org/joint_commission_statement_on_pain_management/, April 18, 2016. If CMS is concerned that certain PAC settings are "undertreating" patient's pain or otherwise stinting on necessary care, then we suggest it conduct the proper setting-specific oversight to ensure that Medicare beneficiaries are being adequately cared for and protected. However, we do not believe it advisable to require cross-setting assessments items for Pain Severity, Pain Frequency, Pain Relief, or Observational Assessment of Pain or Distress. Past experience demonstrates a mandatory and standardized approach is hardly patient-centric and is more likely to hinder any strategic efforts at improving quality or health	

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		outcomes. To our members, the interplay between a patient's pain and their physical function is critically important. While we appreciate the intent behind the proposed items Pain Effect on Sleep, and Pain Interference on Therapy Activities and Other Activities, these items were clearly developed for a non-IRF setting ("During the past 3 days, have you been offered any physical, occupational, or speech therapy?") and are too simplistic to have cross-setting utility. In our view, pain should be assessed in the context of its impact on physical functioning with assessment or patient-reported items such as: • Was your pain managed well enough that you were able to do your rehabilitation program to your satisfaction? (Yes / No) • My pain was not an impediment to the successful completion of my rehabilitation program. (Strongly Agree / Agree / Neutral / Disagree / Strongly Disagree) We encourage CMS to work with the appropriate organizations and experts to develop psychometrically appropriate measures to address pain in the medical rehabilitation context. **Impairments of Hearing and Vision** ***A. Glasses/Corrective Lenses and Hearing Aid*** 1. Potential for improving quality: As with almost all patient assessment information, these data elements could contribute to quality of care if it is made into an interoperable element and included in the medical record information shared among a patient's care providers. Beyond that, we do not think the items could improve quality. 2. Validity: This items are straightforward and would not have any validity issues. 3. Feasibility for use in PAC:	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		These data items could be used across settings once standardized. 4. Utility to describe case mix: It has utility in describing case mix in that it helps determine resource use. **Medication Reconciliation (MR)** In our view, the proposed items drastically belie the complexity of real life medication reconciliation processes taking place in hospital settings such as IRFs. Most of the proposed items are of low clinical utility and quality since they do not assess the appropriateness of a treatment or whether the correct medication was administered, focusing only on whether a specific task was accomplished for a given drug class. These items produce limited actionable data and, without a data accuracy or validation component, we are concerned that providers could simply "check the boxes" to complete a PAI without conducting the follow-up that is necessary for effective MR. Therefore, we do not think the following items have the potential to improve quality, are valid (short of a data accuracy policy), or contribute to understanding case mix. • Medication Reconciliation – Completion • Medication Reconciliation – Use of Medications in Specific Classes • Medication Reconciliation – Indication • Medication Reconciliation – Discrepancies • Medication Reconciliation – Discrepancies Communicated to Physician • Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement • Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy • Medication Reconciliation – Recommended Actions Taken Furthermore, adopting these items would needlessly burden IRFs that already have nearly identical processes into their care routine. As the Agency continues to refine MR data elements for PAC standardization, we recommend that it review The Joint Commission's Medication Reconciliation standards.	

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		CMS should not adopt assessment items that would be duplicative of or redundant with MR practices already used in hospitals. The Joint Commission's National Patient Safety Goals for Hospital Accreditation - Elements of Performance for Medication Reconciliation are: 1. "Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications. 2. Define the types of medication information to be collected in non–24-hour settings and different patient circumstances. 3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies. 4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose). 5. Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter." Finally, we respectfully remind CMS that MR is not a data collection domain required by the IMPACT Act. The Agency has already satisfied the IMPACT Act requirement to implement a MR *quality measure* for PAC settings by October 1, 2018. We believe the spirit of the IMPACT Act with regard to MR is to improve safety and reduce adverse events, *i.e.* quality improvement, not as a data collection effort entailing more documentation requirements. **Care Preferences** We have similar comments for several items and have grouped our feedback as follows. ***A. Advanced Care Directive – Healthcare Agent (Chart Review)*** ***B. Physician Orders (Chart Review)*** 1. Potential for improving quality: These items would help in clinical decision-making and care coordination. Beyond that, however, we do not	

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		believe they would directly impact quality of care. 2. Validity: These items would be valid. 3. Feasibility for use in PAC: IRFs already address these issues with patients as part of routine care processes, so these items would be duplicative though technically feasible. 4. Utility to describe case mix: We do not see how these items would contribute valuable information for describing case mix. ***C. Preference for Involvement of Family/Friends in Care Decisions (Patient Interview)*** ***D. Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview)*** 1. Potential for improving quality: We do not think these questions are aligned with one of the main objectives of inpatient rehabilitation care teams, namely, to involve the patient and their family throughout the entirety of care. Would IRF clinicians be expected to walk away from patients who do not want to know about the details of their condition and treatment? At face value, this simply seems to be at odds with an individualized plan of care required of IRFs. Therefore, we do not think these items would help improve quality. We see how they may be better suited in some settings with terminally ill patients, but they are not appropriate for IRFs. 2. Validity: These items survey for patient preferences so they are valid. 3. Feasibility for use in PAC:	

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		These items may be logistically feasible but again, are not attuned to the goals of IRF-level care. 4. Utility to describe case mix: We do not see how these items would contribute valuable information for describing case mix. **PROMIS® Profile Items** ***A. Sleep Disturbance*** ***B. Fatigue*** ***C. Ability to Participate in Social Roles and Activities*** ***D. Global Health*** General Comments on PROMIS Profile Items There is a lack of strong scientific literature or evidentiary basis that the PROMIS item bank has been satisfactorily or sufficiently validated in inpatient institutional and non-community settings, and even less so for institutional PAC settings such as IRFs, LTCHs, and SNFs. The PROMIS items were designed and intended for the outpatient setting and since they have not been tested in PAC settings, it would not be psychometrically sound to extrapolate the items' suitability for PAC at this time. We do not support using PROMIS data items for the purposes of meeting the IMPACT Act's data collection requirements, and we perceive there is a risk of negative unintended consequences for doing so. We are skeptical about the feasibility and value in implementing these types of assessment in PAC settings in a standardized fashion. To our members, it is not an effective use of clinicians' or patients' time to assess every patient against these profile questions. Unless, for instance, sleep quality is a patient's chief compliant, it is clinically meaningless to assess them with the battery of PROMIS Sleep items. Furthermore, while some of these factors -- such as sleep quality, fatigue, or depression -- play a role in patients' ability to gainfully participate in rehabilitation, there are other assessment items proposed in this comment opportunity or in current rulemaking that addresses these issues. AMRPA continues to disagree with the broad-brush assumption that the PROMIS items are appropriate data items for PAC adoption and standardization. **Conclusion** AMRPA appreciates the opportunity to provide input on the development of cross-setting PAC standardized patient assessment data elements and their proposed specifications. We seek to ensure these	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		elements achieve the data collection objectives of the IMPACT Act while being minimally burdensome for PAC providers. If you have any questions, please contact Carolyn Zollar, J.D. Executive Vice President for Government Relations and Policy Development (czollar@amrpa.org) and Mimi Zhang, AMRPA Policy and Research Associate (mzhang@amrpa.org) at 202-223-1920.	
MMORALES	6/15/17	Good afternoon, I am hoping that this is the right place to send this suggestion. If not please let me know where I send it correctly.. This is a suggestion for Medicare (SEP). We have some beneficiaries who do not enter the MONTH and YEAR they want Part B to start. Most of the times we have called them and get the info from the beneficiary themselves. If we don't get the correct date, we may go by the date that's on the Employment Verification form. I have been working on, one of many, SEP that NH wanted Part B to start on certain month (April 2017). An error in the office as well with the PC. This individual has been disadvantage by the waiting for the part B to clear. He and his wife came to the office and applied at the same time. Hers was done correctly and has Part B started on April 2017 but not his. His was not entered correctly. I called the PC and the employee there stated that he would clear it that same day. He was the one that did not clear it. The first application was not entered correctly and a letter of Refusal was sent to NH. I feel that by getting all the info corrected, the SEP enrollees would send us the correct forms so that we can take action as soon as we receive the application and hopefully the process would run smoother and cause less stress and aggravation on the Applicant. My suggestion is that the 40B could be modified. Instead of "Remarks" we can enter "What Month and Year Do You Want Medicare Part B to start".	Maggie Morales

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		If we do not get it corrected, the Beneficiary will be disadvantage and have their Supplemental insurance delayed as well. I know that we have certain Individuals who may not cooperate well but they depend on Medicare Insurance when ready to retire.	
AHCA	6/26/17	A. General Comments A.1. Overview of AHCA Comments AHCA has been a strong supporter of the objectives of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). The IMPACT Act requirements for the Centers for Medicare and Medicaid Services (CMS) to establish standardized data elements and measures across post-acute (PAC) provider settings are necessary to facilitate better patient-centered care, measure and compare the quality of that care, and inform and contribute to the development of more appropriate payment models. AHCA appreciates that CMS is soliciting comments on the development and use of standardized data elements developed to meet the IMPACT Act domains of: cognitive function and mental status; medical conditions and co-morbidities; impairments; medication reconciliation; and care preferences. In addition to general comments, CMS is specifically interested in public feedback regarding the following four dimensions: • Potential for improving quality • Validity • Feasibility for use in PAC, and • Utility for describing case mix Following the general comments in this section, the AHCA comments to each of the 39 proposed items/item sets in Sections B-H of this document are limited to these four specific dimensions related to the potential applicability of the items/item sets for PAC cross-setting standardization. Our support for any of these items/item sets, or of the four dimensions within each should not be interpreted as a current endorsement for implementation. Rather, our support or recommendations reelect our views on the feasibility for further development of the concept so that potential issues related to administrative burdens of training, additional day-to-day assessment and documentation time needed to complete additional assessment items, software and care-planning updates, et al. can be further evaluated by CMS prior to formally presenting these potential PAC cross-setting items/item sets through rulemaking. A.2 Observational Assessment Items	American Health Care Association and National Center for Assisted Living

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		We appreciate that this phase of PAC cross-setting standardized assessment item development includes several observation-based assessment items/item sets for use in cases where the resident/patient is unable to self-report, due to cognitive or physical deficits. A significant portion of PAC, and particularly SNF residents present with such deficits. We believe that the addition of the standardized PAC cross-setting observational assessment items for comparable domains as current and proposed resident self-report items, will help in the development of quality measures that adequately reflect and compare the care and outcomes for all residents, not just those able to self-report. A.3. Additional Item Development Concerns That Require Attention AHCA supports moving towards developing appropriate standardized PAC cross-setting resident assessment items in a timely and thoughtful manner. However, we believe that the assessment of these proposed data elements would not be thorough unless the proposed introduction of the standardized cross-setting data element items are considered within the context of those elements that are currently utilized in the respective PAC settings. For example, many of these proposed data elements exist in some form in the current SNF Minimum Data Set (MDS) 3.0 patient assessment. We appreciate that the data element specifications document identifies key parameters where the proposed cross-setting element name, definitions, and assessment timeframes would differ from the current MDS 3.0 data element for that domain. However, the data element specifications document does not contain information related to the potential downstream impacts of changing the data element in existing Medicare SNF PPS payment case mix or various existing SNF quality measures. We are concerned that adoption and implementation of the proposed PAC data element specifications without first identifying and mitigating downstream impacts on setting-specific case mix and quality measures could have unintended negative consequences on patient care and provider payments. Two areas of specific concern we would like to point out that would apply to some of the proposed data elements are 1) the alignment of PAC assessment window durations, and 2) potential impacts on provider burden. A.3.1 Alignment of PAC assessment window durations The data element specification document proposes to standardize the assessment window across PAC settings to a uniform timeframe. In general, this timeframe aligns with most of the Continuity Assessment Record and Evaluation (CARE) data elements evaluated as part of the Post-Acute Payment Reform Demonstration (PAC-PRD) that form the foundation for these proposed data elements. However, the SNF MDS 3.0 items that would be impacted by the proposed data elements typically require a 5-, 7-, or 14-day	

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		assessment lookback period. Items that are currently linked to Medicare and Medicaid payment case-mix and quality measures may require downstream recalibration if the proposed data elements are eventually proposed and adopted. Additionally, in the SNF setting, the MDS 3.0 patient assessment instrument is used for both short-stay and long-stay residents. It is unclear from the proposed data element specifications document whether the intent is to align all MDS 3.0 assessment items for all long- and short-stay residents with a revised standardized PAC cross-setting assessment window. We are concerned that there may be disconnects between Medicare and non-Medicare assessments. As a general principle, we ask that the following AHCA assessment window recommendations be addressed prior to recommending the adoption and implementation of any of the proposed data element. ***• Please provide a thorough mapping of the Medicare and Medicaid case mix groups that would be impacted by adopting a standard PAC assessment window for the proposed data elements.*** ***• Please provide a thorough mapping of the PAC quality measures that would be impacted by adopting a standard PAC assessment window for the proposed data elements.*** ***• Please clarify how the proposed data element assessment windows would align with or require significant changes to the existing MDS reporting schedules for short- and long-stay SNF residents.*** A.3.2. Potential impacts on provider burden While standardized resident data offers much value to patient care, communication, and evaluation of quality, et.al., one of the major drawbacks of standardized patient assessment is the time it takes to assess and enter data that is often unrelated to the reason the person is receiving care, and/or, does not contribute to the quality or outcomes of care. ***• Time spend on unnecessary or excessively burdensome administrative assessment tasks takes away from direct patient care time.*** ***• CMS must be judicious in evaluating the benefits of adding new administrative assessment data reporting requirements for the purpose of complying with the IMPACT Act, against the burdens associated with the cost and impact on direct resident care these new burdens will impose.*** Any change to the SNF MDS 3.0 assessment data elements will result in expected additional temporary and permanent provider burden associated with software updates, assessor training, assessment data collection and related data entry, and potential downstream care plan process changes. For example, provider training	

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		that would be necessary so that assessors would understand how to properly enter the item information would represent a temporary burden increase and would vary depending on the complexity of the changes introduced. Assessment data collection and related data entry changes that would be necessary as well as downstream care process changes represent more permanent burden changes (e.g. would MDS Care Area Assessment triggers increase?). In addition to any changes in the complexity of the new or revised data elements, we are concerned about the potential impacts of adding yet another assessment window timeframe to the MDS 3.0 assessment, particularly if the 3-day assessment items require a separate assessment reference and data entry date, as this could introduce staff effort and risk for reporting errors. Presently, a significant time effort is required for SNF MDS 3.0 data collection and subsequent MDS-related care planning activities. Figure 1 (below) highlights a recent 2015 time study from the American Association of Nurse Assessment Coordination (AANAC)1 that reflects recent SNF documentation burden associated with MDS 3.0 assessments. A more recent 2016 AANAC time study also includes information related to the new SNF PPS Discharge Assessment. We believe that any proposed assessment instrument item specification changes should identify and quantify the provider burden impact. We are also very concerned about the potential significant increase in provider burden if the proposed data element specifications are layered on top of the MDS 3.0 assessment rather than as a replacement for existing items addressing the same or similar domain. To date, in the interest of expediting the submission of IMPACT Act mandated standardized cross-setting data elements and quality measures, CMS has added items to the MDS 3.0 for IMPACT Act purposes that represent the same clinical domains as existing data elements, but with different definitions and reporting requirements – which has created confusion. For example, the legacy MDS 3.0 Section G -*Functional Status* items include numerous mobility and self-care items that are used in part for the SNF PPS case-mix payment system as well as several long-stay nursing facility quality measures. However, in order comply with the IMPACT Act standardized PAC cross-setting data reporting implementation deadlines, CMS requires SNFs to also report on items related to a resident's mobility and self-care at admission and discharge on the MDS 3.0 forms in Section GG – *Functional Abilities and Goals*. This data is currently used for reporting purposes only. However, in the FY 2018 SNF PPS Notice of Proposed Rulemaking (FR 82, p.21014) CMS is proposing to add 12 new mobility and self-care items in Section GG that replicate the same or similar functional activities in Section G, but with markedly different definitions (e.g. reverse dependence-independence coding scale creates confusion and errors). These new Section GG assessment items, along with several recently introduced	

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		Section GG items are also being proposed for use in four new SNF mobility and self-care functional outcomes measures to comply with IMPACT Act requirements. The maintenance and reporting of multiple dual MDS items representing the same clinical domains and functional tasks is duplicative and excessively burdensome. CMS has cited that due to the legacy payment and quality purposes of the Section G – *Functional Status* items, and the absence of information necessary to recalibrate payment case mix groups and quality measures with the new Section GG data elements, they were unable to retire the Section G item reporting requirements from the MDS as they added the new Section GG reporting requirements for the similar clinical domain. ***• Efforts such as this project to develop new PAC cross-setting assessment items, must also provide information and guidance to CMS as to what legacy assessment items that are not IMPACT Act compliant, and should be phased out as new PAC cross-setting assessment items are introduced.*** Additionally, we note that the CMS/RAND Alpha 1 testing was completed using pen and paper assessments which were extremely time consuming. In Alpha 2, tablets are being used to improve efficiencies, especially with gateway "skip" items. While a tablet may reduce the assessment time during the item testing phases of this project, it does not accurately reflect "real-world" assessment burden of these proposed items, both individually, and in the aggregate. Reporting burden is not just completing the assessment item, but also the time developing care plan approaches associated with the new items assessed, as well as related documentation and coding requirements to support the MDS item responses. We request that CMS accurately assess and report the true reporting burden associated with these proposed items. As a general principle, we ask that the following AHCA provider burden recommendations be addressed prior to recommending the adoption and implementation of any of the proposed data element. ***• Please identify and quantify the provider burden associated with transitioning from the current patient assessment reporting of each data element to the proposed new or revised data element.*** ***• Please provide a thorough mapping of those existing PAC assessment item domains and items that are essentially being duplicated by the proposed items so that CMS can work to retire the burdensome and duplicative legacy assessment items that do not comply with the IMPACT Act as cross-setting items.*** ***• Please consider and rate the relative benefit versus burden for each proposed item to permit a better-informed decision for those items in this Draft Element Specifications Document that are proposed through future rulemaking to be added to PAC assessments.***	

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		B. Cognitive Function and Mental Status Per CMS, patients/residents in PAC settings are at risk for cognitive impairment and depression. Cognitive impairment is associated with a number of disorders, conditions, and injuries (e.g., dementia, depression, traumatic brain injury [TBI], stroke) and can manifest in a variety of ways, such as difficulty communicating; impairments in learning, memory, or orientation; confusion; and behavioral symptoms. Estimated rates of clinical depression range from 9 to 28 percent in HHAs and 6 to 45 percent in SNFs, but depression generally is thought to be under-evaluated and under-detected in PAC settings. There is also a high incidence of anxiety-related distress in PAC patients/residents, and therefore, this is an important area of assessment. B.1. DOTPA CARE (p.9) Per the Data Elements Specifications Document, The DOTPA Continuity Assessment Record and Evaluation (CARE) tool data elements assess cognitive function in all patients/residents to allow for a broad assessment over time of multiple cognitive components. The subset of CARE data elements pertaining to memory, attention, and problem solving have been recommended for inclusion. These DOTPA data elements score functional performance and record level of assistance, both of which are essential for risk adjustment and discharge planning. **CMS proposes 14 DOTPA CARE items for comment:** • A5a. Does the patient/resident have any problems with memory, attention, problem solving, planning, organizing, or judgment? • A5b. Please describe the patient's/resident's problems with the following: memory, attention, problem solving, planning, organizing, and judgment. • A5c. How often is the patient/resident able to complete simple problems without assistance? • A5d. How often is the patient/resident able to complete simple problems with assistance? • A5e. How often is the patient/resident able to complete complex problems without assistance? • A5f. How often is the patient/resident able to complete complex problems with assistance? • A5g. How often is the patient/resident able to recall basic information without assistance? • A5h. How often is the patient/resident able to recall basic information with assistance? • A5i. How often is the patient/resident able to recall complex information without assistance? • A5j. How often is the patient/resident able to recall complex information with assistance? • A5k. How often is the patient/resident able to complete simple activities without assistance? • A5l. How often is the patient/resident able to completer simple activities with assistance? • A5m. How often is the patient/resident able to complete complex activities without assistance?	

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		• _A5n. How often is the patient/resident able to complete complex activities with assistance? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the cognitive function domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity –** AHCA agrees that the items appear to be valid and reliable for the proposed purpose, but should be tested in its current proposed format before considering adoption. • **Feasibility for use in PAC** – AHCA believes that all 14 proposed DOTPA CARE items may be suitable for PAC. However, they appear to be biased towards residents expected to be discharged to the community. Additionally, there appears to be some overlap/duplication of other existing and proposed assessments of mental status (e.g. BIMS). Is DOTPA CARE being considered as a potential replacement of these other items, or would it add to the data collection burden? • **Utility for describing case mix** – AHCA believes that this item set will require specific complex training due to the multidimensional nature of the questions and response options. We do not believe that the data collection description provided is sufficient to comment on as we cannot determine whether the assessors will use the same questions, or interpret the results in a similar manner, as this is not a resident interview assessment. However, we believe that if properly constructed and tested, the training burden may be offset by the significant benefits this item set could offer. First, it is agnostic to resident cognition and communication impairments, so separate cognitive function item sets would not be necessary for patient response and staff observation assessments. Second, the items are not task-specific, so cognitive function can be assessed based upon the resident's current abilities, and will not be skewed by functional impairments related to a specific task. Finally, the item set covers multiple components of cognition so it may reduce the potential burden associated with needing separate assessments for each cognitive component (but only if other duplicative cognitive assessment items are concurrently eliminated). B.2. Complex Sentence Repetition (p.16) Per the Data Elements Specifications Document, the data elements that comprise Complex Sentence Repetition screen for cognitive impairment. These data elements test whether a patient is able to perfectly repeat back to the assessor a complex sentence that was read aloud. Complex Sentence Repetition is not in use in any of the four PAC assessment instruments and was not tested in the PAC PRD. These data elements were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 2 Complex Sentence Repetition items for comment:**	

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		• F7a. Instruct patient/resident: *"I am going to read you a sentence. Repeat it after me exactly as I say it. Remember, do not begin until I have given you the whole sentence [pause]: After the bell rang, the man standing on the stairs quickly exited the building."* If the sentence is not exactly correct say, *"Let's try that again"* and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time. • F7b. Instruct patient/resident: "Now I am going to read you different sentence. Repeat after me, exactly as I say it. Remember, do not begin until I have given the whole sentence[pause]: *Though he typically watches westerns, lately he as preferred watching comedies."* If the sentence is not exactly correct say, *"Let's try that again"* and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time. **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA is not convinced that the Complex Sentence Repetition data elements will prove useful to improve quality as they only capture higher level cognitive recall ability. We do not envision how the item responses would help with a resident's health and function care planning, and improve transitions of care communications. • **Validity** – Although CMS states that these items may have demonstrated reliability in Alpha 1 testing, AHCA does not believe that the limitations of the dichotomous response options of the items have any real validity to adequately differentiate levels of cognitive impairment that would be useful for care planning purposes or be meaningful across PAC settings. • **Feasibility for use in PAC** – AHCA believes that the Complex Sentence Repetition item set is not feasible for use as a PAC cross-setting assessment item. • **Utility for describing case mix** – AHCA is concerned that due to the limitation of the dichotomous response options in this item set, a significant portion of SNF residents that present with cognitive and physical deficits with potential for improvement would be classified in the same case-mix as those without potential. This could negatively impact patient access and quality of care of case mix resources are not adequate for residents with cognitive recovery potential. B.3. PASS Medication Management (p.18) Per the Data Elements Specifications Document, the data elements that comprise the PASS Medication Management Task assess the patient's/resident's ability to manage medications by asking him or her to perform tasks including finding, reading, and understanding medication directions and putting pills correctly in a pill box. This task measures cognitive skills for activities of daily living and daily decision-making. There are two versions, one for a clinic setting and one for home, which are identical except that the home version has patients use their own medications.	

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		CMS appears to propose 4 PASS Medication Management Tasks for comment, however Subtask 3 appears to be repeated on pages 20 and 21 of the Data Elements Specifications Document. AHCA is responding to only the four unique subtasks #1, 3, 4, and 6 presented: • SUBTASK 1: A4a. Reports next time first medication is to be taken correctly (based on testing time, matches direction on label) • SUBTASK 3 A4c. Distributes pills from first pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated) • SUBTASK 4 A4d. Reports next time second medication is to be taken correctly (based on testing time, matches direction on label) • SUBTASK 6 A4f. Distributes pills from second pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated) **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the PASS Medication Management Task item set is important to assess as it can help identify significant functional cognition and performance-based executive function medication management issues that can impact a resident's health and function care planning and discharge needs, and improve transitions of care communications. • **Validity** – AHCA agrees that the unduplicated items presented appear to be valid and reliable for the proposed purpose. However, they require testing, and we ask if there would be a gateway question to completion of this item set if a cognitive or other deficit has already been noted that would indicate that this item set is inappropriate to administer. • **Feasibility for use in PAC** – AHCA believes that all 4 proposed PASS Medication Management Task are suitable for PAC, particularly for residents expected to be discharged to the community, and could have benefit in identifying care plan potential in SNF residents, even when there is a greater likelihood that they could require long-term care after PAC coverage ends. Since this is a multi-dimensional performance-based item set that combines real-world life skills of reading, communicating, interpreting, and performing medication management activities we believe it would be potentially particularly useful across PAC settings in identifying discharge environment needs. However, we are concerned that this item set could be extremely time consuming and not appropriate for all residents, and believe it may be more appropriately used in a Care Area Assessment (CAA) if triggered after other cognitive assessments, rather than as a standardized PAC assessment item. • **Utility for describing case mix** – AHCA believes that this multi-dimensional performance-based item set that combines real-world life skills of reading, communicating, interpreting, and performing medication	

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		management activities would appear to minimize the need for multiple non-specific cognitive and performance items. However, it would require much more testing to reduce the assessment time burden, and may not be appropriate for all PAC residents which may create challenges in describing case-mix. B.4. Staff Assessment of Mental Status (p.25) Per the Data Elements Specifications Document, the data elements that comprise Staff Assessment of Mental Status assess long-term memory, short-term memory, memory/recall ability, based on staff observation (NOTE: We disagree with the statement that this item set also addresses "decision-making" as this observational assessment does not replicate that component of the BIMS). These data elements are intended for use among patients/residents in all PAC settings who were unable to complete the interview-administered Brief Interview for Mental Status (BIMS) because of refusal, nonsensical answers, or inability to make him- or herself understood at least some of the time. This version is very similar to that which is in use in the MDS 3.0 items: C0700 – Short-term Memory OK, C0800 – Long-term Memory OK, and C0900 – Memory/Recall Ability. **CMS proposes 6 Staff Assessment of Mental Status items for comment:** • A1a. Short-term Memory OK • A1b. Long-term Memory OK • A1c. Memory/Recall Ability: IS THE PATIENT/RESIDENT NORMALLY ABLE TO RECALL: o A1ci. Current season A1cii Location of own room o A1ciii Staff names and faces o A1civ That he or she is in a nursing facility/hospital bed/rehabilitation facility/home **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Staff Assessment of Mental Status item set is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications for residents that are unable to complete the BIMS. • **Validity** – AHCA agrees that the items are valid and reliable for the proposed purpose • **Feasibility for use in PAC** – AHCA believes that all 6 proposed Staff Assessment of Mental Status items are suitable for PAC. They have been used effectively for care planning purposed to achieve patient outcomes for some time. However, we note that the CMS description of the proposed item set is incorrect.	

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		The CMS description includes "decision-making". However, the "decision making" item from the MDS version of this item set (C1000) was not included in these proposed items. Either that item should be included, or the description needs to delete the reference to "decision making." • **Utility for describing case mix** – AHCA agrees that this item set could potentially fill a necessary void in describing case-mix associated with assessing long-term memory, short-term memory, and memory/recall ability for those residents that are unable to complete the BIMS. However, as noted above, if CMS were to adopt the DOTPA CARE item set, then this item set would be duplicative and an unnecessary administrative burden. B.5. Behavioral Signs and Symptoms (p.28) Per the Data Elements Specifications Document, behavior disturbances put additional time and resource burden on providers; disrupt care; result in poorer patient outcomes; and place the patient at risk for injury, isolation, and inactivity. These symptoms may also disrupt the institutional or home environment and affect the safety and privacy of other patients/residents, caregivers, and staff. Behavioral disturbances warrant assessment and documentation to inform care planning and patient transitions. The data elements that comprise Behavioral Signs and Symptoms assess whether the patient has exhibited any behavioral symptoms that may indicate cognitive impairment or other issues during the assessment period. This version nearly identical to current MDS 3.0 items: E0200 – Behavioral Symptoms – Presence & Frequency, E0300 – Overall Presence of Behavioral Symptoms, E0500 – Impact on Resident, E0600 – Impact on Others, and E0800 – Rejection of Care- Presence & Frequency. **CMS proposes 11 Behavioral Signs and Symptoms items for comment:** • B1. BEHAVIORAL SYMPTOMS – PRESENCE & FREQUENCY o B1a. Physical behavioral symptoms directed toward others o B1b. Verbal behavioral symptoms directed toward others o B1c. Other behavioral symptoms not directed toward others • B1d. Were any behavioral symptoms in the prior 3 questions (B1a-c) exhibited by the patient/resident (coded 1, 2, or 3)? o B1e. Put the patient/resident at significant risk for physical illness or injury? o B1f. Significantly interfere with the patient's/resident's care? o B1g. Significantly interfere with the patient's/resident's participation in activities or social interaction? o B1h. Put others at significant risk for physical injury? o B1i. Significantly intrude on the privacy or activity of others? o B1j. Significantly disrupt the delivery of care or living environment of others?	

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		• B1k. Did the patient/resident reject evaluation of care (e.g., bloodwork, taking medications, ADL assistance) that is being offered by members of the care team or caregiver and necessary to achieve the patient's/resident's goals for health and well-being? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Behavioral Signs and Symptoms item set is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the items, which have been successfully used in SNF, are valid and reliable for the proposed purpose • **Feasibility for use in PAC** – AHCA believes that all 11 proposed Behavioral Signs and Symptoms items are suitable for PAC. They have been used effectively in SNF for care planning to achieve patient outcomes for some time. • **Utility for describing case mix** – AHCA agrees that this item set could potentially help in describing case-mix associated with Behavioral Signs and Symptoms as residents exhibiting these symptoms typically require more resources and time to achieve desired clinical and functional outcomes. B.6. PROMIS® Anxiety Items (p.33) Per the Data Elements Specifications Document, the data elements that comprise the PROMIS Anxiety Item Bank assess self-reported fear (fearfulness, panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). The PROMIS Anxiety Item Bank has a total of 29 items, from which 11 items were selected on the basis of relevance for PAC settings. These items are intended to assess levels of anxiety across a wide range of symptom severity. **CMS proposes 11 PROMIS Anxiety items for comment:** • D1a. In the past 7 days, I had difficulty sleeping • D1b. In the past 7 days, I felt worried • D1c. In the past 7 days, my worries overwhelmed me • D1d. In the past 7 days, I had trouble paying attention • D1e. In the past 7 days, I felt nervous • D1f. In the past 7 days, I felt anxious • D1g. In the past 7 days, I had difficulty calming down • D1h. In the past 7 days, I had a racing or pounding heart	

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		• D1i. In the past 7 days, I found it hard to focus on anything other than my anxiety • D1j. In the past 7 days, I felt like I needed help for my anxiety • D1k. In the past 7 days, I had sudden feelings of panic **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the anxiety domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. We are not convinced that the granularity of the burden of addressing the 11 proposed response options will translate to significant quality improvements beyond existing assessment items. • **Validity** – AHCA agrees that the items appear to be valid and reliable for the proposed purpose but testing is required to verify. • **Feasibility for use in PAC** – AHCA believes that all 11 proposed PROMIS Anxiety items may be suitable for PAC. However, we are concerned with the administrative burden and patient burden of adding 11 anxiety-related questions to the assessment when the other MDS items and other PROMIS item sets already address some of these items (e.g. resident interview PHQ-9 and observational PHQ9-OV assessment items already address sleep problems). At a minimum, these other items should serve as a gateway to the proposed PROMIS Anxiety items, rather than burdening all residents with these questions. Additionally, CMS should consider paring down the response options to a volume that does not irritate the resident. • **Utility for describing case mix** – AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting anxiety, further analysis would be needed to identify a substitute observational assessment for any future case-mix purposes. B.7 Patient Health Questionnaire-9 Observational Version (PHQ9-OV) (p.38) The data elements that comprise the Patient Health Questionnaire-9 Observational Version (PHQ9-OV) assess distressed mood in patients/residents who cannot complete a patient/resident mood interview due to an inability to communicate. Distressed mood is a common condition in PAC settings that is sometimes under-recognized and under-treated. It is particularly important to identify signs and symptoms of distressed mood among PAC patients/residents because mood disorders are often treatable. The PHQ9-OV is included in the MDS 3.0 (as item D0500) and has been validated in the nursing home population and has demonstrated feasibility in that setting. The assessment includes 10 items, each with a symptom presence and symptom frequency response. **CMS proposed 10 PHQ9-OV items for comment:**	

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		• C1a. Little interest or pleasure in doing things • C1b. Feeling or appearing down, depressed, or hopeless • C1c. Trouble falling or staying asleep, or sleeping too much • C1d. Feeling tired or having little energy • C1e. Poor appetite or overeating • C1f. Indicating that s/he feels bad about self, is a failure, or has let self or family down • C1g. Trouble concentrating on things, such as reading the newspaper or watching television • C1h. 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 • C1i. States that life isn't worth living, wishes for death, or attempts to harm self • C1j. Being short-tempered, easily annoyed **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the depression domain is important to assess, even in residents with cognitive and physical deficits that prevent completion of the PHQ-9 interview, as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the items appear to be valid and reliable for the proposed purpose and have been used successfully in SNF for some time. • **Feasibility for use in PAC** – AHCA believes that all 10 proposed PHQ9-OV depression observation assessment items may be suitable for PAC. However, we are confused that CMS is proposing the complete PHQ9-OV item set in this comments request specifications document while concurrently proposing the PHQ-2 as the PAC cross setting assessment in the FY 2018 SNF PPS NPRM (82 FR 21014). We believe consistency should be applied between the PAC resident interview and observational assessment versions of the PHQ item set. • **Utility for describing case mix** – AHCA agrees that this item set could potentially fill a necessary void in describing case-mix associated with depression for those residents that are unable to complete the PHQ-9 interview assessment. C. Medical Conditions: Continence Per CMS, impaired bladder and bowel continence is common among older persons in the United States, but age-adjusted rates differ across settings.	

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		Among persons 65 years and older, the prevalence of bladder incontinence is 24 percent in the general noninstitutionalized population, 40 percent in those receiving home health care services, 37 percent in those in skilled nursing facilities, and 70 percent in those in long-term care residents. The prevalence of bowel incontinence also varies across settings. Among persons 65 years and older, the prevalence of bladder incontinence is 17 percent in the general noninstitutionalized population, 13 percent in those receiving home health care services, 33 percent in those in skilled nursing facilities, and 60 percent in long-term care residents. C.1. Bladder - Device Use (p.45) The data elements that comprise Bladder – Device Use document use of equipment and devices to manage bladder incontinence. The PAC PRD tested similar data elements that showed good feasibility and reliability across PAC settings. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. The MDS 3.0 item H0100 – Appliances is similar to but less detailed than the proposed items. **CMS proposed 4 Bladder – Device Use items for comment:** • C1a. Does this patient/resident use an external or indwelling urinary catheter, have a urostomy, or require intermittent urinary catherization? o If yes, indicate device(s) • C1b. If patient/resident has indwelling or external CATHETER, at what point was the device first placed? • C1c. If patient/resident has an indwelling or external CATHETER, what is the reason the device was put in place? • C1d. If patient/resident has a bladder device (C1a=Yes): Does the patient/resident need assistance to manage equipment or devices related to bladder care for ANY reason (e.g. cognitive impairment/mental status, physical limitation, medical issue, etc.)? **AHCA comments on the four requested dimensions:** • **Potential for improving** quality – AHCA agrees that the Bladder - Device domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the items are valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that all 4 proposed Bladder - Device items are suitable for PAC.	

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		• **Utility for describing case** mix – AHCA agrees that this item set could be helpful in describing case-mix associated with Bladder – Device use due to additional resource use and health risks associated with this need. C.2. Bladder – Incontinence (p.49) The data elements that comprise Bladder – incontinence assess the frequency of bladder incontinence experienced by the patient during the assessment period. Similar data elements assessing the frequency of incontinent events, but which do not address whether the patient/resident experienced incontinent events immediately prior to hospitalization, are currently in use the MDS 3.0 (H0300 – Urinary Continence), the LCDS 3.0, and IRF-PAI, and they were tested in the PAC PRD. The draft data elements, depicted below were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. **CMS proposes 2 Bladder – Incontinence items for comment:** • C2a. Indicate the frequency of incontinent events. • C2b. If the patient/resident has incontinent events, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Bladder – Incontinence domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. The addition of an item related to recent incontinence history would be a beneficial addition for care planning purposes. • **Validity** – AHCA agrees that the items are valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the 2 proposed Bladder - Incontinence items are suitable for PAC. However, we suggest that CMS consider removing the reference to *"hospitalization"* in C2b, and instead refer to *"incontinent events prior to the current illness or exacerbation that led to the current PAC admission."* Current, demonstration, and future payment models may bypass hospital stays as a prerequisite for PAC care. The important factor to identify with this item is whether the incontinence is related to the current health event that may be more responsive to intervention, or a longer-standing chronic health condition. • **Utility for describing case mix** – AHCA agrees that this item set could be helpful in describing case-mix associated with Bladder – Incontinence due to additional resource use and health risks associated with this	

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		need, and for better identifying residents with continence restoration potential from those with recalcitrant chronic incontinence. C.3. Bladder - Incontinence Interview (p.52) The data elements that comprise Bladder – Incontinence Interview assess the extent to which incontinent events of the bladder are perceived as a problem or burden by the patient/resident and caregiver. The Bladder – Incontinence Interview data elements are not in use in any of the four PAC assessment instruments, and were not tested in the PAC PRD. The draft data elements were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. **CMS proposes 4 Bladder – Incontinence Interview items for comment:** • C5. Ask patient/resident: *"Have you experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"* • C5a. If patient/resident reports experiencing incontinent, Ask Patient/Resident – *"How big of a problem or burden are incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"* • C6. Ask caregiver: *"Has the patient/resident experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"* • C6a. If patient/resident experiences bladder incontinence events, ASK Caregiver – *"How big of a problem are the patient's/resident's bladder incontinent events in the context of their overall care?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Bladder - Incontinence domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. However, we believe that this item set is more burdensome and offers less prior incontinence history information than the proposed Bladder-Incontinence item set described on page 49 of the Data Element Specifications document. Additionally, the questions are not suitable for a discharge interview with a 3-day window. This information should be solicited earlier in the discharge planning process. • **Validity** – AHCA does not believe that these interview questions are suitable for a 3-day discharge assessment window. • **Feasibility for use in PAC** – AHCA believes that the 4 proposed Bladder - Device Interview items are suitable for PAC are not as feasible as the proposed Bladder – Incontinence item set described on page 49. It would also likely require gateway item logic in cases where a resident was unable to be interviewed or a caregiver is not available for interview.	

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		• **Utility for describing case mix** – AHCA is not convinced that this item set could be helpful in describing case-mix associated with Bladder – Incontinence due to potential discrepancies and conflicts or missing data in the patient/resident or the caregiver items, as well as the absence of prior incontinence history information. C.4. Bowel - Device Use (p.55) The data elements that comprise Bowel – Device Use document use of equipment and devices to manage bowel incontinence. Devices include ileostomy, colostomy, or any other fecal diversion appliance. A similar data element assessing bowel device use was tested in the PAC PRD. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. The MDS 3.0 item H0100c – Appliances: Ostomy (including urostomy, ileostomy, and colostomy) is similar to but is less detailed, and not as bowel-device-specific than the proposed items. **CMS proposed 3 Bowel – Device Use items for comment:** • C3a. Does this patient/resident use an indwelling or external device (ostomy or other fecal diversion appliance)? • C3b. If patient/resident has indwelling or external bowel device (e.g. ileostomy, colostomy), at what point was the device first placed? • C3c. If patient/resident has an indwelling or external bowel device: Does the patient/resident need assistance to manage equipment or devices related to bowel care for ANY reason (e.g. cognitive impairment/mental status, physical limitation, medical issue, etc.)? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Bowel – Incontinence domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. The addition of an item related to recent incontinence history would be a beneficial addition for care planning purposes. • **Validity** – AHCA agrees that the items are valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the 3 proposed Bowel - Incontinence items are suitable for PAC. However, we suggest that CMS consider removing the reference to "Current setting," "prior setting," and "prior hospitalization" in C3b, and instead simplify the response options to: 1 – device first placed (in any setting), during the current illness or exacerbation that led to the current PAC admission, 2-device first placed prior to the current illness or exacerbation that led to the current PAC admission, or 9 – unknown. We do not see value to the additional detail proposed. The important factor to identify with this	

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		item is whether the incontinence device is related to the current health event that may be more responsive to intervention, or a longer-standing chronic health condition. • **Utility for describing case mix** – AHCA agrees that this item set, with modification, could be helpful in describing case-mix associated with Bowel – Incontinence due to additional resource use and health risks associated with this need, and for better identifying residents with continence device training needs from those with chronic incontinence device use. C.5. Bowel – Incontinence (p.58) The data elements that comprise Bowel – Incontinence assess the frequency of bowel incontinence experienced by the patient during the assessment period, which may indicate a change in health status or need for additional assessment and/or alternative interventions. Similar data elements assessing the frequency of incontinent events, but which do not address whether the patient/resident experienced incontinent events immediately prior to hospitalization, are currently in use the MDS 3.0 (H0400 – Bowel Continence), the LCDS 3.0, OASIS C2, and IRF-PAI and were tested in the PAC PRD. The draft data elements, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. **CMS proposes 2 Bowel – Incontinence items for comment:** • C4a. Indicate the frequency of incontinent events. • C4b. If the patient/resident has incontinent events, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Bowel – Incontinence domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. The addition of an item related to recent incontinence history would be a beneficial addition for care planning purposes. • **Validity** – AHCA agrees that the items are valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the 2 proposed Bowel - Incontinence items are suitable for PAC. However, we suggest that CMS consider removing the reference to "hospitalization" in C4b, and instead refer to "incontinent events prior to the current illness or exacerbation that led to the current PAC admission." Current, demonstration, and future payment models may bypass hospital stays as a prerequisite for PAC care. The important factor to identify with this item is whether the incontinence is related to the current health event that may be more responsive to intervention, or a longer-standing chronic health condition.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		• **Utility for describing case mix** – AHCA agrees that this item set could be helpful in describing case-mix associated with Bowel – Incontinence due to additional resource use and health risks associated with this need, and for better identifying residents with continence restoration potential from those with recalcitrant chronic incontinence. C.6. Bowel - Incontinence Interview (p.61) The data elements that comprise Bowel – Incontinence Interview assess the extent to which incontinent events of the bowel are perceived as a problem or burden by the patient/resident and caregiver. The Bowel – Incontinence Interview data elements are not in use in any of the four PAC assessment instruments, and were not tested in the PAC PRD. The draft data elements were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability. **CMS proposes 4 Bowel – Incontinence Interview items for comment:** • C7. Ask patient/resident: *"Have you experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"* • C7a. If patient/resident reports experiencing incontinent events, Ask Patient/Resident – *"How big of a problem or burden are incontinent events (or "accidents" or "leaking ") to you?"* • C8. Ask caregiver: *"Has the patient/resident experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"* • C8a. If patient/resident experiences incontinent events, ASK Caregiver – *"How big of a problem are the patient's/resident's bowel incontinent events in the context of their overall care?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Bowel - Incontinence domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. However, we believe that this item set is more burdensome and offers less prior incontinence history information than the proposed Bowel-Incontinence item set described on page 58 of the Data Element Specifications document. Additionally, the questions are not suitable for a discharge interview with a 3-day window. This information should be solicited earlier in the discharge planning process. • **Validity** – AHCA does not believe that these interview questions are suitable for a 3-day discharge assessment window. • **Feasibility for use in PAC** – AHCA believes that the 4 proposed Bowel - Device Interview items are not as feasible for PAC as the proposed Bowel – Incontinence item set described on page 58. It would also	

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		likely require gateway item logic in cases where a resident was unable to be interviewed or a caregiver is not available for interview. • **Utility for describing case mix** – AHCA is not convinced that this item set could be helpful in describing case-mix associated with Bowel – Incontinence due to potential discrepancies and conflicts or missing data in the patient/resident or the caregiver items, as well as the absence of prior incontinence history information. D. Medical Conditions: Pain Per CMS, pain is a highly prevalent medical condition that is frequently under-recognized, under-detected, and undertreated. Among PAC patients/residents pain is sometimes to be expected, but assessment and effective management of pain are nevertheless essential, both to maintain a standard of care and to support recovery. D.1. Pain Frequency (p.65) The Pain Frequency data element asks patients/residents to self-report how often they have experienced pain on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. The frequency of pain is an important characteristic of the pain and pain management, and provides a basis for evaluating treatment need and response, as well as the extent to which pain may be affecting the patient's/resident's quality of life. A similar data element assessing pain frequency is currently in use in the MDS 3.0 (J0400-Pain Frequency). The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Pain Frequency item for comment:** • H2. Ask Patient/Resident: "How often during the past 3 days have you had pain or hurting?" **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain domain is extremely important to assess in PAC as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Frequency item is suitable for PAC as it has been used effectively in SNF for a while for residents that can reliably self-report. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further	

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		analysis would be needed to incorporate the proposed Observational Assessment of Pain or Distress item set for any future case-mix purposes. D.2. Pain Severity (p.67) The Pain Severity data element assesses whether the patient/resident is responding to pain medication regimens and/or non-pharmacological interventions, and consists of one numeric rating scale. A similar data element assessing pain severity is currently in use in the MDS 3.0 and was tested in the PAC PRD. The MDS item J0600 – Pain Intensity contains two options A – Numeric Rating Scale (00-10), and B – Verbal Descriptor Scale (four-point descriptor scale proposed here for PAC use). This data element as depicted below uses a four-point scale to assess pain severity, instead of a 0 to 10 rating. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Pain Severity item for comment:** • H5. Ask Patient/Resident - *"Please rate the intensity of your worst pain over the last 3 days."* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain domain is extremely important to assess in PAC as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Severity item is suitable for PAC as it has been used effectively in SNF for a while. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further analysis would be needed to incorporate the proposed Observational Assessment of pain or Distress item set for any future case-mix purposes. D.3. Pain Effect on Sleep (p.69) The Pain Effect on Sleep data element asks patients/residents to self-report how often pain has limited their ability to sleep on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. This data element may inform decisions on the need to adjust the timing of pain interventions to promote better sleep, and provides a basis for evaluating treatment schedules and response to pain treatment. A similar data element is currently in use in the MDS 3.0 (J0500A- Pain Effect on Function). The PAC PRD also tested a similar data element, which showed good feasibility and reliability across PAC settings. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.	

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		CMS proposes 1 Pain Effect on Sleep item for comment: • H3. Ask Patient/Resident - *"During the past 3 days, how often has pain limited your ability to sleep?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain domain and impact on sleep is extremely important to assess in PAC as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Effect on Sleep item is suitable for PAC as a similar item has been used effectively in SNF for a while for residents that can reliably self-report. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further analysis would be needed to incorporate the proposed Observational Assessment of pain or Distress item set for any future case-mix purposes. D.4. Pain Interference - Therapy Activities (p.71) The Pain Interference – Therapy Activities data elements ask patients/residents to self-report how often pain has limited their ability to participate in rehabilitation therapy activities on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. Assessing frequency of pain interference with therapy-related activities can help to gauge the impact of pain on quality of life during PAC and has implications for care planning. There is no comparable MDS data element, the closest being J0500B – Pain Effect on Function which asks about pain effect on "day-to-day activities." The PAC PRD tested a data element that assesses the effect of pain on participation in therapy activities, which showed good feasibility and reliability across PAC settings. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 2 Pain Interference – Therapy Activities items for comment:** • H4: Pain Interference - Therapy Activities - Ask Patient/Resident - *"During the past 3 days, have you been offered any physical, occupational, or speech therapies by your care providers?"* • H4a: Pain Interference - Therapy Activities - If yes: Ask Patient/Resident – *"During the past 3 days, how often have you limited your participation in physical, occupational, and/or speech therapy sessions due to pain?"*	

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		AHCA comments on the four requested dimensions: • **Potential for improving quality** - AHCA agrees that the pain domain and impact on participation in therapy activities is extremely important to assess in PAC as most PAC residents are receiving care to reduce functional impairments, and the items can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** - AHCA agrees that the items are valid and reliable for the proposed purpose. • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Interference – Therapy Activities items are extremely suitable for PAC for residents that can reliably self-report. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further analysis would be needed to incorporate the proposed Observational Assessment of pain or Distress item set for any future case-mix purposes. D.5. Pain Interference - Other Activities (p.74) The Pain Interference – Other Activities data element asks patients/residents to rate how often pain has limited their ability to participate in other non-therapy activities. Assessing frequency of pain interference with daily activities can help to gauge impact of pain on quality of life and ability/motivation to participate in activities that the patient/resident values and has implications for care planning. A similar data element assessing the effect of pain on participation in activities is currently in use in the MDS 3.0 (J0500B – Pain Effect on Function related to day-to-day activities). It was also tested in the PAC PRD and showed good feasibility and reliability across PAC settings. The draft data element was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Pain Interference – Other Activities item for comment:** • H4b: Pain Interference - Other Activities - Ask Patient/Resident - "*During the past 3 days, how often have you limited your participation in other activities (excluding physical, occupational, and/or speech therapy sessions) due to pain?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain domain and impact on participation in daily non-therapy activities is extremely important to assess in PAC during times when they are not being physically challenged in therapy, as the items can help identify response to therapy as well as significant issues that can impact a resident's health and function care planning, and improve transitions of care communications.	

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		• **Validity** - AHCA agrees that the items are valid and reliable for the proposed purpose • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Interference – Other Activities item is extremely suitable for PAC as a similar item has been used effectively in SNF for a while for residents that can reliably self-report. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further analysis would be needed to incorporate the proposed Observational Assessment of pain or Distress item set for any future case-mix purposes. D.6. Pain Relief (p.76) The Pain Relief data element asks patients/residents to rate how much relief they have felt from pain due to pain treatments or medications on a scale from no relief (1) to very much relief (4) within a 3-day assessment period. Asking about relief from pain is important in determining the extent to which pain management regimen could improve the patient's/resident's quality of life. The Pain Relief data element was derived from the Brief Pain inventory, a widely-used measure which has shown good reliability and validity in PAC settings. Pain Relief is not in use in any of the four PAC assessment instruments, and it was not tested in the PAC PRD. This data element underwent cognitive testing and revisions were made based on PAC patient feedback. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Pain Relief item for comment:** • H6: Pain Relief - Ask Patient/Resident – *"During the past 3 days how much relief have you felt from pain due to pain treatments and/or medications?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain relief domain is extremely important to assess in PAC, as the item can help identify response to the effectiveness of pain management approaches as well as significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** - AHCA believes that the proposed Pain Relief item is extremely suitable for PAC – however, in the context of concerns about over-medication (e.g. opiate overuse), this item should only be used in conjunction with other function-related items. It serves no purpose to place a greater emphasis on pharmacologic pain reduction that incapacitates an individual, if functional improvement is	

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		achievable through rehabilitation therapies, along with reduced-pharmacologic, or non-pharmacologic pain relief approaches. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting pain, further analysis would be needed to incorporate the proposed Observational Assessment of pain or Distress item set for any future case-mix purposes. D.7. Observational Assessment of Pain or Distress (p.78) The Observational Assessment of Pain or Distress data elements collect staff observations of patients'/residents' expressed behavioral indicators of potential pain or distress and should be administered to all patients/residents who are unable to communicate (i.e., cannot reliably make self-understood via verbal communication, written communication, communication board, eye blinks, etc.). The Observational Assessment of Pain or Distress data elements were derived from the Indicators of Possible Pain or Distress item used in the MDS 3.0 and tested in the PAC PRD, the Frequency of Pain or Distress item used in the MDS, and from the advice of technical experts. The first two items are similar to MDS J0800 – Indicators of Pain, and J0850 – Frequency Indicators of Pain or Possible Pain that are completed when a resident is unable to complete the Pain Assessment Interview MDS items J02000-J0600) **CMS proposes 3 Observational Assessment of Pain or Distress item for comment:** • E1a. OBSERVATIONAL ASSESSMENT OF PAIN OR DISTRESS. For all patients/residents who are unable to participate in the pain interview, please note whether any of the following behaviors were observed. Patients/residents should be observed twice daily (morning AND evening) during care activities: Non-verbal sounds, Vocal complaints of pain, Facial expressions, Body movements or postures, or None of these signs observed or documented. • E1b. For patients/residents who demonstrated any indicators of potential pain or distress listed in E1a (Observational Assessment of Pain or Distress), identify the frequency with which patient complains or shows evidence of potential pain or distress over the past 3 days. • E1c. For patients/residents who demonstrated any indicators of potential pain or distress listed in E1a (Observational Assessment of Pain or Distress), is there any evidence that these indicators resolved or diminished in response to pain medications or treatments over the past 3 days? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the pain domain is extremely important to assess in PAC, as thee observational items proposed can item can help identify the presence of pain and response to	

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		the effectiveness of pain management approaches as well as significant issues that can impact a resident's health and function care planning, and improve transitions of care communications in individuals that are cognitively impaired or otherwise unable to complete a pain assessment interview. • **Validity** - AHCA agrees that the items could be valid and reliable for the proposed purpose, but we have concerns related to the alpha 2 testing (see feasibility comments below). • **Feasibility for use in PAC** - AHCA believes that the proposed Observational Assessment of Pain and Distress item are extremely suitable for PAC as versions of two of these three proposed items have been effectively used in SNF for some time. However, in the context of concerns about over-medication (e.g. opiate overuse), this item should only be used as part of a future quality measure in conjunction with other function-related items. It serves no purpose to place a greater emphasis on pain reduction alone, if the pain reduction approach incapacitates an individual. Additionally, we note that the proposed requirement is for residents to be "observed" twice daily (morning and evening) – However, within the January 2017 TEP packet is the statement: *"The instructions will need to be modified to account for the design of Alpha 2 testing, as it will not be feasible for research nurses to complete 2 observational assessments per day. For Alpha 2, these data elements will require use of various data sources (i.e., medical record review [specifically, morning and evening nurse shift notes], direct care staff reports, direct patient observation"*. Will the results of Alpha 2 be feasible if not tested in the same manner as proposed? • **Utility for describing case mix** - AHCA appreciates that this observational assessment option is being proposed to address needs of the significant number of PAC and SNF beneficiaries with cognitive and other deficits that prevent completion of pain and pain relief survey assessments. Further analysis would be needed to identify if this substitute observational assessment would be an acceptable substitute for future case-mix purposes. E. Impairments of Hearing and Vision Per CMS, hearing and vision impairments are common conditions among older adults that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. E.1. Glasses/Corrective Lenses (p.83) The Glasses/Corrective Lenses data element assesses the patient/resident's dependence on any device for vision impairment. Once vision impairment has been identified, use of corrective lenses (glasses, contact lenses, magnifying glass, etc.) may help mitigate a patient's potential problems reading and understanding forms, instructions, and medication labels. Specifically, corrective devices may enable patients/residents to better understand activities relevant to their care. Many patients/residents who do not have corrective lenses	

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		could benefit from them. Others may have corrective lenses that are not sufficient, or may not be carrying them upon arrival at the PAC setting. A similar data element assessing a resident's use of corrective lenses is currently in use in the MDS 3.0 (B1200 – Corrective Lenses); however, the MDS data element records whether corrective lenses are used during the assessment, not if the resident uses corrective lenses regularly in everyday life. The draft data element performed well in the Alpha 1 pilot test. **CMS proposes 1 Glasses/Corrective Lenses item for comment:** • D1. Does the patient/resident use glasses (or other corrective lenses) regularly? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the Glasses/Corrective Lenses item is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. However, caution is necessary to ably this item as it applies to broader quality measures as glasses/corrective lenses are rarely covered for Medicare beneficiaries and they may not always be affordable or otherwise available for a resident. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose. However, a follow-up question about the effectiveness of the device could also be meaningful. • **Feasibility for use in PAC** - AHCA believes that the 1 proposed Glasses/Corrective Lenses item is suitable for PAC, and a form of this item has performed well in SNF for quite a while. • **Utility for describing case mix** – While useful for individual care planning and PAC cross-setting care transition communication activities, or to identify potential need for such devices, AHCA is uncertain as to the value of this item for case-mix purposes as it doesn't include a meaningful performance metric. E.2. Hearing Aid (p.85) The Hearing Aid data element assesses the patient/resident's dependence on any device for hearing impairment. Once a hearing impairment has been identified, use of a hearing aid may help mitigate many potential communication problems with staff and caregivers. Specifically, hearing devices may enable patients/residents to better communicate their wishes regarding their care plans and other services. Use of hearing aids—or other non-technical methods of adapting to hearing loss (speaking loudly, increasing the volume on televisions or telephone speakers)—may improve a patient's/resident's ability to engage in activities of daily living and become more sociable. Moreover, increases in ability to hear and communicate may decrease the risk of depression, falls, or injury, and improve a patient's/resident's overall quality of life. Many persons who benefit from and own hearing aids do not have them upon arrival at the nursing home, or arrive with hearing aids that are not functional. A similar data element assessing a resident's use of a hearing	

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		aid is currently in use in the MDS 3.0 (B0300 – Hearing Aid); however, the MDS data element records whether a hearing aid is used during the assessment, not if the resident uses hearing aids regularly in everyday life. The draft data element performed well in the Alpha 1 pilot. **CMS proposes 1 Hearing Aid item for comment:** • E1. Does the patient/resident use a hearing aid (or other hearing appliance) regularly? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** - AHCA agrees that the Hearing Aid item is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. However, caution is necessary to ably this item as it applies to broader quality measures as hearing aids are rarely covered for Medicare beneficiaries and they may not always be affordable or otherwise available for a resident. • **Validity** - AHCA agrees that the item is valid and reliable for the proposed purpose. However, a follow-up question about the effectiveness of the device could also be meaningful. • **Feasibility for use in PAC** - AHCA believes that the 1 proposed Hearing Aid item is suitable for PAC, and a form of this item has performed well in SNF for quite a while. • **Utility for describing case mix** – While useful for individual care planning and PAC cross-setting care transition communication activities, or to identify potential need for such devices, AHCA is uncertain as to the value of this item for case-mix purposes as it doesn't include a meaningful performance metric. F. Medication Reconciliation Per CMS, almost one-tenth of Medicare beneficiaries experienced an adverse drug event (ADE), such as delirium, bleeding, fall or injury, or constipation, during their stay in a SNF in 2011. Of these, two-thirds were classified as preventable. Approximately one-half of all hospital-related medication errors and one-fifth of ADEs occur during transitions between settings, including admission to, or discharge from a hospital to home or a PAC setting, or transfer between hospitals. Medication reconciliation (MR) is a process of reviewing an individual's complete and current medication list. Standardized MR is important because of the large numbers of ADEs in PAC settings and the potential to promote person-centered, high-quality care by, for example, facilitating better care continuity and coordination, data exchange and interoperability between settings, payment analysis, and longitudinal outcome analysis. Using results from a previous study of SNFs,19 we estimated the number of Medicare Fee-for-Service (FFS) patients in the four PAC settings with at least one ADE: 522,554 in HHAs, 206,236	

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		in SNFs, 31,659 in IRFs, and 5,502 in LTCHs. MR interventions have been shown to be a cost-effective way to avoid ADEs by reducing errors, especially when medications are reviewed by a pharmacist and when MR is done in conjunction with the use of electronic medical records. Medication discrepancies identified during MR can be resolved by changing the prescribed dose, discontinuing or restarting medications, and providing patients with better information about their prescriptions. The data elements proposed address the process of MR at care transition points, such as any transition between acute care hospital stays and a PAC setting, or between PAC settings. The proposed MR data elements address the five steps of MR outlined by the Joint Commission: (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare medications on the lists; (4) make clinical decisions based on the comparisons; and (5) communicate the new list to the patient/resident and appropriate caregivers. **AHCA General Medication Reconciliation Comments:** AHCA is are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. We note that during a CMS June 20, 2017 IMPACT ACT Open Door Forum, RAND researchers indicated that the proposed Medication Reconciliation items were very cumbersome and labor-intensive during Alpha 1 testing, and that Alpha 2 testing has shown that "more work needs to be done." Our following comments expand on these concerns. F.1. Medication Reconciliation – Completion (p.89) The Medication Reconciliation – Completion data element asks the assessor whether this process took place during the allotted time frame. If not, remaining questions may not be relevant. The assessor should base his or her answer on documentation. Subsequent MR, to improve patient safety if not previously done, is desirable; however MR currently underway should not be used to answer questions in this assessment. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The Completion draft data element will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 1 Medication Reconciliation – Completion item for comment:** • F1b. Is there documentation that medication reconciliation was done? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as	

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		a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Completion item is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item would be useful for case-mix purposes as the item is part of a multi-step clinical administrative and communication process, rather than a unique measure of clinical status or outcome. F.2. Medication Reconciliation – Use of Medications in Specific Classes (p.91) The data elements that comprise Medication Reconciliation – Use of Medications in Specific Classes assess whether and for how long a patient/resident is taking any drugs in a number of classes, most of which are most likely to cause adverse events noted by the HHS National Action Plan for Adverse Drug Event Prevention, Office of Inspector General Report on Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, and the CDC Report on The Core Elements of Antibiotic Stewardship for Nursing Homes. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The Use of Medications in Specific Classes draft data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 10 Medication Reconciliation – Use of Medications in Specific Classes items for comment:** • F1c1: Anti-coagulants • F1c2: Anti-platelets (excluding 81 mg aspirin) • F1c3: Hypoglycemics (for example, insulin) • F1c4: Opioids • F1c5: Anti-psychotics • F1c6: Anti-microbials (excluding topicals) • F1c7: Antidepressants • F1c8: Diuretics • F1c9: Antianxiety • F1c10: Hypnotics	

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		AHCA comments on the four requested dimensions: • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Use of Medications in Specific Classes process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. Identifying standardized medication classes can help with establishing care plan needs. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Use of Medications in Specific Classes item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA believes that, if burden issues are adequately addressed, this item set could be useful for case-mix purposes as the item set identifies unique clinical medication needs that may be tied to variable resource use needs (e.g. increased oversight/assessment/labs/etc. secondary to anticoagulant therapy, antimicrobials, infections, etc.) and outcomes. F.3. Medication Reconciliation – Indication (p.94) The data elements that comprise Medication Reconciliation – Indication assess whether the prescriber included an indication for each medication in the patient's/resident's list or lists of medications. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. In Alpha 1 testing, assessors reported indications in about 25 percent of patients assessed, with the rate varying by setting. Patients in SNFs had the highest rates, between 42 percent (facility nurses) and 56 percent (research nurses); while fewer than 10 percent of patients receiving home health care were assessed as having indications in their medication list(s). The draft Indication data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 10 Medication Reconciliation – Indication items for comment:** • F1d1: Anti-coagulants • F1d2: Anti-platelets (excluding 81 mg aspirin) • F1d3: Hypoglycemics (for example, insulin) • F1d4: Opioids	

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		• F1d5: Anti-psychotics • F1d6: Anti-microbials (excluding topicals) • F1d7: Antidepressants • F1d8: Diuretics • F1d9: Antianxiety • F1d10: Hypnotics **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Indication items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Indication item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome. F.4. Medication Reconciliation – Discrepancies (p.96) The data elements that comprise Medication Reconciliation – Discrepancies assess whether the review of medication lists identified any medication discrepancies. This is an important step for preventing mistakes in prescription of medicine to patients/residents. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 10 Medication Reconciliation – Discrepancies items for comment:** • F1e1: Anti-coagulants • F1e2: Anti-platelets (excluding 81 mg aspirin)	

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		• F1e3: Hypoglycemics (for example, insulin) • F1e4: Opioids • F1e5: Anti-psychotics • F1e6: Anti-microbials (excluding topicals) • F1e7: Antidepressants • F1e8: Diuretics • F1e9: Antianxiety • F1e10: Hypnotics **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Discrepancies items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Discrepancies item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome. F.5. Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement (p.99) The data elements that comprise Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement ask about the patient's/resident's involvement and the patient's/resident's family/formal caregiver's involvement in addressing high-risk discrepancies or potential adverse drug events. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements will be evaluated in a feasibility test in the spring and summer of 2017.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		CMS proposes 10 Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement items for comment: • F1f1: Anti-coagulants • F1f2: Anti-platelets (excluding 81 mg aspirin) • F1f3: Hypoglycemics (for example, insulin) • F1f4: Opioids • F1f5: Anti-psychotics • F1f6: Anti-microbials (excluding topicals) • F1f7: Antidepressants • F1f8: Diuretics • F1f9: Antianxiety • F1f10: Hypnotics **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome. F.6. Medication Reconciliation – Discrepancies Communicated to Physician (p.102) The data elements that comprise Medication Reconciliation – Discrepancies Communicated to Physician assess whether the PAC provider contacted a physician regarding the all high-risk discrepancies and	

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		potential adverse drug events within a 24-hour timeframe. It also asks about the timeline for contacting the physician. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies Communicated to Physician data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 10 Medication Reconciliation – Discrepancies Communicated to Physician items for comment:** • F1g1: Anti-coagulants • F1g2: Anti-platelets (excluding 81 mg aspirin) • F1g3: Hypoglycemics (for example, insulin) • F1g4: Opioids • F1g5: Anti-psychotics • F1g6: Anti-microbials (excluding topicals) • F1g7: Antidepressants • F1g8: Diuretics • F1g9: Antianxiety • F1g10: Hypnotics **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Discrepancies Communicated to Physician items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Discrepancies Communicated to Physician item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome. F.7. Medication Reconciliation – Recommended Actions Taken (p.105)	

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		The data elements that comprise Medication Reconciliation – Recommended Actions Taken are a follow up to Medication Reconciliation – Discrepancies Communicated to Physician. These data elements assess whether the PAC provider completed the physician prescribed/recommended actions within 24 hours of the physician's response. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Recommended Actions Taken data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 10 Medication Reconciliation – Recommended Actions Taken items for comment:** • F1h1: Anti-coagulants • F1h2: Anti-platelets (excluding 81 mg aspirin) • F1h3: Hypoglycemics (for example, insulin) • F1h4: Opioids • F1h5: Anti-psychotics • F1h6: Anti-microbials (excluding topicals) • F1h7: Antidepressants • F1h8: Diuretics • F1h9: Antianxiety • F1h10: Hypnotics **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – Recommended Actions Taken items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – Recommended Actions Taken item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set.	

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		• **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome. F.8. Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy (p.107) The Medication Reconciliation – List Communicated to Patient/Resident Caregiver data element asks about the PAC provider's communication of the reconciled medication list with the patient/resident or patient's/resident's formal caregiver, the prescribers and the care team responsible for the patient's/resident's care, and the patient's/resident's primary pharmacy. Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft List Communicated to Patient/Resident Caregiver/Care Team/Pharmacy data element, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 1 Medication Reconciliation – List Communicated to Patient/Resident Caregiver item with four (check all that apply) response options for comment:** • F1i. Was the reconciled medication list communicated to any of the following? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that completion of the Medication Reconciliation – List Communicated to Patient/Resident Caregiver items process step is important to assess as it helps prevent adverse drug events, particularly related to high-risk drug classes during care transitions. However, we are very concerned that the MDS, which was designed as a patient assessment, is now being proposed to be used to assess and document facility administrative processes on a resident-by-resident basis which we believe is an inappropriate and overly burdensome use of the MDS. • **Validity** – AHCA agrees that the item set is valid and reliable for the proposed purpose. • **Feasibility for use in PAC** – AHCA believes that the proposed Medication Reconciliation – List Communicated to Patient/Resident Caregiver item set is suitable for PAC. However, there is a significant time burden associated with addressing all medication classis identified, and to get detailed documentation in the medical record to support coding of this step of the proposed medication reconciliation process item set. • **Utility for describing case mix** – AHCA does not believe this item set would be useful for case-mix purposes as the item set is part of a multi-step clinical administrative and communication process, rather than unique measures of clinical status or outcome.	

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		G. Care Preferences Per CMS, eliciting, documenting, communicating, and transferring information about a patient's preferences for care and their goals for care is critical to informing the plan of care, evaluating progress, and assuring patient-centered care in PAC settings. In PAC settings, preferences are likely to encompass both preferences for health care as well as preferences for daily routine and lifestyle. Use of standardized patient assessment data promotes transfer of a patient's/resident's health information and care preferences to the individual, family caregivers, and providers of services that furnish data elements and services to the patient/resident as he or she transitions from acute care to another setting and from a PAC provider to another setting or back to the home. Knowing care preferences is essential for smooth care transitions that are acceptable to the patient and family. G.1. Advanced Care Directive - Healthcare Agent (Chart Review) (p.110) The Advanced Care Directive – Healthcare Agent data element assesses whether the medical record contains appropriate and necessary documentation regarding a patient's/resident's surrogate health care decision maker. A similar data element was tested in the PAC PRD and was shown to be feasible across PAC settings. The draft data element was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Advanced Care Directive – Healthcare Agent item for comment:** • G1a. Does the patient/resident have a designated Health Care Agent as authorized under state law to make healthcare decisions in the event that he/she is unable to make his or her own decisions AND there is legal documentation in the medical record? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the presence of the proposed Advanced Care Directive – Healthcare Agent information is important as it can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** – AHCA believes that the proposed item is suitable for PAC. • **Utility for describing case mix** – AHCA does not believe that this is an appropriate item for case-mix purposes as it describes an administrative, rather than an essential clinical process or outcome. G.2. Physician Orders (Chart Review) (p.112) The Physician Orders data element assesses whether the medical record contains active physician orders for specific treatment choices. The draft Physician Orders data element will be evaluated in a feasibility test in	

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		the spring and summer of 2017 and was informed by a data element in the MDS 2.0 (AQ10 – Advanced Directives). **CMS proposes 1 Physician Orders item for comment containing six (check all that apply) response options:** • G1b. Does the patient/resident have any of the following physician orders documented and active in the medical record (Do not resuscitate, Do not intubate, Do not hospitalize, Antibiotic restrictions, Comfort car preference(s), and None of the above)? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the presence of the proposed Physician Orders information is important as it can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** – AHCA believes that the proposed item is suitable for PAC, and the proposed item offers more meaningful information than the current similar MDS data element. • **Utility for describing case mix** – AHCA does not believe that this is an appropriate item for case-mix purposes as it describes an administrative, rather than an essential clinical process or outcome. G.3. Goals of Care (Chart Review) (p.114) The data elements that comprise Goals of Care (Chart Review) assess whether the medical record includes documentation of key conversations the care team may have had with the patient/resident about overall goals. The Goals of Care (Chart Review) data elements are not in use in any of the four PAC assessment instruments; however, functional discharge goals are included in existing and proposed PAC Section GG mobility and self-care items. The first data element proposed is modified from a data element tested in the PAC PRD. The draft data elements will be evaluated in a feasibility test in the spring and summer of 2017. **CMS proposes 2 Goals of Care (Chart Review) items for comment:** • G1c. Is there documentation in the medical record indicating that a conversation between the patient/resident (or representative) and the care team (or physician) took place about the patient/resident's goals for care? • G1d. Did the documented conversation about goals of care indicate any of the following types of goals (Physical, Emotional, Social, Intellectual/Mental, Other)?	

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		AHCA comments on the four requested dimensions: • **Potential for improving quality** – AHCA agrees that the presence of the proposed Goals of Care (Chart Review) information is important as it can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the items may be valid and reliable for the proposed purpose, but may require significant retooling to reduce the reporting burden. • **Feasibility for use in PAC** – AHCA believes that the proposed items may be suitable for PAC. However, we note that during a June 20, 2017 CMS IMPACT Act Open Door Forum, the RAND researchers indicated that a 30-minute chart review was "quite possible" to adequately complete this item set, which is excessively burdensome. We request further revisions and testing be completed before formally proposing. Additionally, we request that CMS evaluate whether the proposed items can replace similar questions in Section Q – Participation in Assessment and Goal Setting of the MDS. • **Utility for describing case mix** – AHCA does not believe that these are appropriate items for case-mix purposes as it describes an administrative, rather than an essential clinical process or outcome. G.4. Preference for Involvement of Family/Friends in Care Decisions (Patient Interview) (p.117) The Preference for Involvement of Family/Friends in Care Decisions data element elicits the patient's/resident's preferences regarding how much information about status and treatment should be provided to the patient's/resident's family and friends, and how decisions regarding the patient's/resident's care should be made. A related data element is currently in use in the MDS 3.0 (F0800I – Family or significant other involvement in care decisions). This data element was also tested in the PAC PRD and found to be feasible and reliable across PAC settings. The draft data element was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Preference for Involvement of Family/Friends in Care Decisions item for comment:** • A2. Ask Patient/Resident – *"It is important for us to understand how you'd like your family, friends, or significant others involved in your care. How important is it to you to have your family or close friend or significant other involved in discussions about your care?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the presence of the proposed Preference for Involvement of Family/Friends in Care Decisions information is important as it can impact a resident's health and function care planning, and improve transitions of care communications.	

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		• **Validity** – AHCA agrees that the item is valid and reliable for the proposed purpose. However, we request that CMS consider revising the terminology to be more direct. We would prefer asking the resident if they would like their family/friend involved, yes or no, versus *"how important"* their involvement is. • **Feasibility for use in PAC** – AHCA believes that the proposed item is suitable for PAC and the proposed item offers more meaningful information than the current similar MDS data element. • **Utility for describing case mix** – AHCA does not believe that this is an appropriate item for case-mix purposes as it describes an administrative, rather than an essential clinical process or outcome. G.5. Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview) (p.119) The data elements that comprise Preferences for Involvement in Decision Making (Information Preferences) elicit the patient's/resident's preferences regarding the amount of information they wish to receive regarding their condition. These data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The data elements underwent cognitive testing and revisions were made based on PAC patient feedback. The draft Preferences for Involvement in Decision Making (Information Preferences) data elements were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability. **CMS proposes 1 Preferences for Involvement in Decision Making (Information Preferences) item for comment:** • A4a. Ask Patient/Resident: *"I'd like to talk to you about how you prefer to be involved in your care. Everyone copes with their condition differently. Do you prefer to know as much as you can about the details of your condition and treatment, prefer some information, or prefer not to know or to know very little?"* **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the presence of the proposed Preferences for Involvement in Decision Making (Information Preferences) information is important as it can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the item is valid and reliable for the proposed purpose • **Feasibility for use in PAC** – AHCA believes that the proposed item is suitable for PAC. • **Utility for describing case mix** – AHCA does not believe that this is an appropriate item for case-mix purposes as it describes an administrative, rather than an essential clinical process or outcome. H. PROMIS®	

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		Per CMS, The Patient-Reported Outcomes Measurement Information System (PROMIS®) was developed and is held by the National Institutes of Health (NIH) as part of the NIH Roadmap initiative that set the standard for modern behavioral health measurement development. H.1. Sleep Disturbance (p.122) Per the Data Elements Specifications Document, the data elements that comprise the PROMIS Sleep Disturbance Item Bank assess self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. The full PROMIS Sleep Disturbance Item Bank contains 27 items. CMS states it is necessary to identify items within each item bank that may be most suitable for PAC use. **CMS proposes 12 PROMIS Sleep items for comment:** • X1a. In the past 7 days, I had difficulty falling asleep • X1b. In the past 7 days, it was easy for me to fall asleep • X1c. In the past 7 days, I worried about not being able to fall asleep • X1d. In the past 7 days, I had trouble staying asleep • X1e. In the past 7 days, I woke up and had trouble falling back to sleep • X1f. In the past 7 days, I was satisfied with my sleep. • X1g. In the past 7 days, I had trouble stopping my thoughts at bedtime • X1h. In the past 7 days, my sleep was restful • X1i. In the past 7 days, I had trouble sleeping • X1j. In the past 7 days, my sleep was restless • X1k. In the past 7 days, I got enough sleep • X1l. In the past 7 days, I had trouble getting into a comfortable position to sleep **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the sleep disturbance domain is important to assess as it can help identify significant sleep disorders that can impact a resident's health and function care planning, and improve transitions of care communications. We are not convinced that the granularity of the burden of addressing the 12 proposed response options will translate to significant quality improvements beyond the current PHQ-9 and PHQ9-OV assessment of sleep disturbance. • **Validity** – AHCA agrees that the items may be valid and reliable for the proposed purpose, if confirmed with testing. • **Feasibility for use in PAC** – At a superficial level, AHCA believes that all 12 proposed PROMIS Sleep items may be suitable for PAC. We believe that items X1a, X1d, X1h, and X1j are the strongest candidate items presented, and items X1c, X1e, X1g, and X1i are the weakest candidate items presented. However, we	

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		are concerned with the administrative burden and patient burden of adding 12 sleep-related questions to the assessment when the resident interview PHQ-9 and observational PHQ9-OV assessment items already address sleep problems. At a minimum, the PHQ items should serve as a gateway to the proposed PROMIS Sleep items, if they are capable of self-reporting, rather than burdening all residents with these questions. Additionally, CMS should consider paring down the response options to a volume that does not irritate the resident. • **Utility for describing case mix** – AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting sleep disturbances, further analysis would be needed to identify a substitute observational assessment for any future case-mix purposes. H.2. Fatigue (p.128) Per the Data Elements Specifications Document, the data elements that comprise the PROMIS Fatigue Item Bank evaluate a range of self-reported symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one's ability to execute daily activities and function normally in family or social roles. Fatigue is divided into the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities. The full PROMIS Fatigue Item Bank contains 95 items. Selected items were incorporated on the basis of relevance for PAC settings. **CMS proposes 10 PROMIS Fatigue items for comment:** • X1a. In the past 7 days, how often did you feel tired? • X1b. In the past 7 days, how often did you find yourself getting tired easily? • X1c. In the past 7 days, how often were you too tired to think clearly? • X1d. In the past 7 days, how often did your fatigue make it difficult to make decisions? • X1e. In the past 7 days, how often did you have enough energy to enjoy the things you do for fun? • X1f. In the past 7 days, I have energy • X1g. In the past 7 days, I am frustrated by being too tired to do the things I want to do • X1h. In the past 7 days, how often did you have to push yourself to get things done because of your fatigue? • X1i. In the past 7 days, how often were you too tired to take a bath or shower • X1j. In the past 7 days, I am too tired to eat **AHCA comments on the four requested dimensions:**	

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		• **Potential for improving quality** - AHCA agrees that the fatigue domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. We are not convinced that the granularity of the burden of addressing the 10 proposed response options will translate to significant quality improvements beyond the current PHQ-9 and PHQ9-OV assessment of fatigue disturbance • **Validity** - AHCA agrees that the items may be valid and reliable for the proposed purpose, if confirmed with testing. • **Feasibility for use in PAC** - At a superficial level, AHCA believes that all 10 proposed PROMIS fatigue items may be suitable for PAC. However, we are concerned with the administrative burden and patient burden of adding 10 fatigue-related questions to the assessment when the resident interview PHQ-9 and observational PHQ9-OV assessment items already address fatigue problems. At a minimum, the PHQ items should serve as a gateway to the proposed PROMIS Fatigue items, if they are capable of self-reporting, rather than burdening all residents with these questions. Additionally, CMS should consider paring down the response options to a volume that does not irritate the resident. • **Utility for describing case mix** - AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting fatigue, further analysis would be needed to identify a substitute observational assessment for any future case-mix purposes. H.3. Ability to Participate in Social Roles and Activities (p.133) Per the Data Elements Specifications Document, the data elements that comprise the PROMIS Ability to Participate in Social Roles and Activities assess self-reported perceived ability to perform one's usual social roles and activities. The activities range from professional obligations to social activities with friends and family. Selected items were incorporated on the basis of relevance for PAC settings. The full PROMIS Social Roles and Activities Item Bank contains 35 items. **CMS proposes 10 PROMIS Ability to Participate in Social Roles and Activities items for comment:** • X1a. I have trouble participating in recreational activities with others • X1b. I have trouble doing all of my regular leisure activities with others • X1c. I have to limit the things I do for fun with others • X1d. I have trouble doing all of the family activities that are really important to me • X1e. I have trouble doing all of the family activities that I want to do • X1f. I have to limit my regular family activities • X1g. I have trouble doing all of the activities with friends that are really important to me	

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		• X1h. I have trouble taking care of my regular personal responsibilities • X1i. I have to limit social activities with groups of people • X1j. I have trouble keeping in touch with others **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Ability to Participate in Social Roles and Activities domain is important to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA agrees that the items may be valid and reliable for the proposed purpose, if confirmed with testing. • **Feasibility for use in PAC** – AHCA believes that all 10 proposed PROMIS Ability to Participate in Social Roles and Activities items may be suitable for PAC. We request that if CMS proceeds with proposing this item set, then CMS should evaluate whether this item set could replace the current MDS F0500 – Interview for Activity Preferences item set. • **Utility for describing case mix** – AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting Ability to Participate in Social Roles and Activities, further analysis would be needed to identify a substitute observational assessment for any future case-mix purposes. H.4. Global Health (p.139) Per the Data Elements Specifications Document, the data elements that comprise PROMIS Global Health scale include 10 items that assess self-reported evaluations of health in general (i.e. health related quality of life) rather than specific elements of health. These items ask overall status of respondent's physical health, pain, fatigue, mental health, social health, and overall health. They are predictive of important future events such as health care utilization and mortality. The PROMIS items were found to capture a broad range of functioning across the entire continuum of physical and mental health. **CMS proposes 10 PROMIS Global Health items for comment:** • X1a. In general, would you say your health is… • X1b. In general, would you say your quality of life is… • X1c. In general, how would you rate your physical health? • X1d. In general, how would you rate your mental health, including your mood and your ability to think? • X1e. In general, how would you rate your satisfaction with your social activities and relationships? • X1f. In general, please rate how well you carry out your usual social activities and roles	

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		• X1g. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair? • X1h. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable? • X1i. How would you rate your fatigue on average? • X1j. How would you rate your pain on average? **AHCA comments on the four requested dimensions:** • **Potential for improving quality** – AHCA agrees that the Global Health domain may be useful to assess as it can help identify significant issues that can impact a resident's health and function care planning, and improve transitions of care communications. • **Validity** – AHCA is not sure if this particular item set that addresses health in general and is predictive of future events such as healthcare utilization and mortality would be useful or valid in a PAC environment where the resident is likely in the early recovery stages of a recent health event. The items seem more appropriate, if the resident is capable of self-reporting, for chronic health issues and care planning. Additionally, some of the questions related to emotional problems, fatigue, pain, etc. are already addressed under PROMIS item groups and add unnecessary burden. • **Feasibility for use in PAC** – AHCA is not convinced that the 10 proposed PROMIS Global Health items are suitable for PAC. • **Utility for describing case mix** – In addition to the concerns raised above, AHCA is concerned that since a significant portion of SNF residents present with cognitive and physical deficits that would preclude them from self-reporting Global Health, further analysis would be needed to identify a substitute observational assessment for any future case-mix purposes.	
CVSH	6/26/17	CVS Health, on behalf of its subsidiaries and affiliated entities, appreciates the opportunity to provide comments on the quality measure project titled, "Development and Maintenance of Post-Acute Care (PAC) Cross-Setting Standardized Assessment Data. " We understand that that the Centers for Medicare & Medicaid Services (CMS) has contracted with RAND Corporation to develop standardized data elements for use by the four major PAC provider types to meet requirements under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. With regard to this specific quality measure project, CMS seeks comments on standardized data elements for: 1) cognitive function and mental status; 2) medical conditions and co- morbidities ; 3) impairments ; 4) medication reconciliation ; and 5) care preferences.	CVS Health

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		CVS Health is a pharmacy innovation company helping people on their path to better health. CVS Health helps people, businesses and communities to manage health care in more affordable, effective ways. This unique integrated model increases access to quality care, delivers better health outcomes, and lowers overall health care costs. CVS Health supports these ongoing efforts to develop standardized data collection across the four PAC provider types (skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals). This standardized data collection will play an essential role in facilitating comparison of health outcomes, promoting data exchange among the different PAC provider types, and advancing other person-centered outcomes and goals. Our comments here are focused solely on the draft standardized data elements for medication reconciliation. The eight draft data elements, to be used by the four PAC providers for data collection on medication reconciliation, are as follows: 1) Completion; 2) Use of Medications in Specific Classes; 3) Indication; 4) Discrepancies ; 5) Discrepancies Addressed with Patient/Resident/Caregiver Involvement; 6) Discrepancies Communicated to Physician; 7) Recommended Actions Taken; and 8) List Communicated to Patient/Resident/Caregiver /Care Team/Pharmacy . We respectfully share the following three insights and/or recommendations for your consideration. • The Role of the Pharmacist in Medication Reconciliation: We emphasize that the medication reconciliation, which will inform the eight data elements, must be performed by a licensed pharmacist. Medication reconciliation reflects a cost-effective way to help improve safety and avoid adverse drug events, reduce medical costs, lower the risk of re- hospitalizations, optimize medication therapy, and improve overall quality of care. A pharmacist possesses the qualifications and expertise to conduct medication reconciliation to achieve these aims. We do agree that the data elements 'responder' does not have to be the same clinician that performed the medication reconciliation, yet the medication reconciliation itself must be done by a pharmacist. We envision that a report could be generated, based on the pharmacist's medication reconciliation, which would include the specific information needed for completion of the data elements by the responder.	

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		• Heart Failure Drugs and the List of Specific Classes of Medications: Information on a patient/resident's use of 10 specific classes of drugs would be included as part of the Medication Reconciliation data elements. We recommend that heart failure medications be added to the classes of drugs in this data element, given that heart failure complications are a leading cause of hospital re-admissions. While a patient/resident taking diuretics, which is currently on the list of 10 drug classes under this data element, may suggest a health failure diagnosis, we believe including the broader category of health failure drugs is warranted and appropriate. • Medication Reconciliation and the Physician Role in the Skilled PAC Setting: We point out that in skilled nursing facilities (SNFs), the target recipient for the information and findings in a medication reconciliation report is the resident's physician. The physician is the appropriate health care professional to promptly address any medication discrepancies. Yet (Flt) in the proposed data elements for Medication Reconciliation asks whether information on medication discrepancies is provided to the patient/resident/caregiver. We caution that skilled PAC providers should not be penalized if the data collection indicates that the medication reconciliation information is not provided to the patient/resident/caregiver. The relevant question, as it relates to the SNF setting, is (F1g), which asks whether any medication discrepancies have been communicated to the physician or physical designee within 24 hours of adrnission/discharge/SOC/ROC. Thank you for the opportunity to provide comments on the draft standardized data elements required under the IMPACT Act. If you have any questions or would like further information on anything mentioned above, please contact Libby Terry in our Government Affairs office at 202-772-3526 or at Libby.Terry@cvshealth.com	
NALTH	6/26/17	The National Association of Long Term Hospitals (NALTH) is pleased to submit comments on the development and maintenance of post-acute care (PAC) cross-setting standardized patient assessment data. NALTH is the only hospital trade association in the nation that is devoted exclusively to the needs of patients who require services provided by long term care hospitals (LTCHs). NALTH is committed to research, education and public policy development that further the interests of the very ill and often debilitated patient populations who receive services in LTCHs throughout the nation. LTCHs are highly specialized acute care facilities that treat complex and often critically ill patients who require hospital-level care for an extended period of time. Many LTCH patients are on a ventilator at the time of admission and spent time in an intensive care unit before being admitted to the LTCH. Beginning in	National Association of Long Term Hospitals

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		2016, the Centers for Medicare & Medicaid Services (CMS) started phasing in new patient criteria. Patients who spent 3 or more days in an intensive care unit prior to admission to the LTCH or who received at least 96 hours of mechanical ventilation during the LTCH stay are eligible for full LTCH standard payment rates. For patients not meeting criteria, LTCHs are paid significantly less (and less than their cost) for caring for these cases. Thus, LTCHs are expected to increase their share of patients coming from an intensive care unit and/or on prolonged mechanical ventilation. NALTH is supportive of the IMPACT Act of 2014, and its goal of developing standardized measures across settings to facilitate improving care and to better distinguish the types of patients treated at LTCHs as compared to other settings. Efforts to standardize measures across settings, however, must be balanced against provider reporting burden and the value from having cross-setting measures available to providers, patients, and others. We have carefully reviewed the draft data element specifications for the PAC cross-setting standardized patient assessment data and provide some comments below. **General Comments** While NALTH is supportive of CMS's efforts to standardize measures across settings, many of the proposed data elements are not relevant in the LTCH setting. As noted above, the severity of patients at LTCHs is significantly higher than in other settings. As such, we anticipate that item sets with interviews would not be attempted in many circumstances because the patient is either unresponsive or unable to make himself or herself understood. Item sets requiring complex responses engender- more opportunity for error in interpretation, potentially weakening the reliability of the data. Moreover, we see little added value in a number of the proposed measures to either improve quality or describe case mix, particularly in light of LTCH patient complexity. We ask that CMS take these comments into consideration when assessing the data elements. **Cognitive Function and Mental Status** In the FY 2018 IPPS/LTCH proposed rule, CMS is proposing to include the Brief Interview for Mental Status (BIMS), Confusion Assessment Method (CAM), Behavioral Signs and Symptoms, and Patient Health Questionnaire-2 (PHQ– 2) as standardized patient assessment data elements. If finalized, these data elements would be reported by LTCHs as part of the CARE Tool data set. While NALTH has raised concerns regarding specific aspects of these elements in our public comments to the rule, the proposed	

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		measures included in the FY 2018 IPPS/LTCH proposed rule better capture the case mix of LTCHs and would be less burdensome to collect than the collection of measures in the RAND report. We provide additional comments below. • Behavioral Signs and Symptoms: NALTH recognizes the importance of capturing behavioral signs and symptoms as behavioral issues can impair a patient's ability to improve. However, we believe that segmenting the response options by the number of days (B1a-B1c) is irrelevant to assessing patient need, but will increase provider reporting burden. The questions related to impact on others are not relevant for an LTCH setting (B1h-B1j). Patients in LTCHs are limited in their interactions with others, because of the debilitating effects of their condition. This level of detail may be appropriate for skilled nursing facilities, but it should not be required information for assessments performed in LTCHs. • PROMIS®: It is unclear to us as to why CMS needs to assess the frequency of these symptoms in the LTCH setting. As patients in the LTCH setting are severely ill, often coming from an ICU in an acute care hospital, and require an extended inpatient stay, it not uncommon for these patients to be suffering from mental stress and depression. We expect little variation to how these patients will respond to these questions. Therefore, they provide no clear value in establishing treatment or describing case mix, while adding significantly to provider burden. • DOPTA CARE, PASS Medication Management, and PHQ: There is tremendous concern that the volume of proposed data items will be burdensome to providers as they will have to augment their work flow processes, update their data infrastructures, and train staff. At the same time, it is unclear how these data elements provide value given that some of these data elements (PASS Medication Management and PHQ) are not relevant to an LTCH population. **Medical Condition: Continence** • Potential for improving quality and utility for describing case mix: NALTH views the data elements for continence as redundant with some of the data elements already collected in the LTCH CARE Data Set. The CARE Data Set includes a single question on whether a patient in incontinent and the frequency of incontinence. While we recognize that the elements in the RAND document and the one current in the CARE data are different, it is our assessment that the added	

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		burden of requiring the additional data elements for continence for LTCHs are significant relative to the value of this information for quality improvement case mix. **Medical Condition: Pain** • Potential for improving quality and utility for describing case mix: NALTH believes that pain assessment is an important indicator for purposes of potential to improve quality of care. However, we believe the proposed data elements do not assess pain and pain management in the most effective and efficient manner. We believe the most relevant information to assess pain is to determine if pain interferes with the care of the patient, which we conclude the proposed data elements do not effectively assess. **Impairments of Hearing and Vision** • Utility for describing case mix: In the FY 2018 IPPS/LTCH PPS proposed rule, CMS proposed to collect standardized patient assessment data on hearing and vision impairments. We believe the proposed data elements for hearing and vision impairments in the draft specifications do not provide additional value than what has already been proposed by CMS in the proposed rule. The draft specifications assess patients' use of hearing and vision appliances, but the proposed rule already assumes that patients' ability to hear and see in adequate light will already be assessed while wearing their appliances. NALTH believes that these data elements would be duplicating efforts and proposes not to adopt them. **Care Preferences** • Physician Orders – Physician orders may change during an LTCH stay. It is unclear whether the intent is to require that this information be collected at admission, discharge, or both. NALTH believes it should be collected on upon admission (24 and 48 hours). • Goals of Care – This information is already collected in Section GG of the CARE data set on physical function. However, question G1d is not particularly relevant for an LTCH population. • Preference for Involvement of Family – NALTH has concerns regarding this measure. Specifically, we do not see the value for purposes of improving quality in an LTCH or describing case mix. In addition, a response to this question may change depending on when the question is going to be asked. What would CMS do with this information?	

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		PROMIS NALTH does not believe that the PROMIS® questions are particularly relevant for an LTCH population. Moreover, there in redundancy in some of the question and those noted elsewhere in the RAND document. • Sleep – Identifying sleep problems and taking action to improve care can be useful. However, we believe a simple question asking about sleep problems is sufficient. The detailed questions would be burdensome with questionable value. • Fatigue – Many patients in LTCH come from an ICU. Given the patient's level of illness, questions of fatigue seem irrelevant. • Social and Global Health – It is unclear the relevance of these questions to an LTCH population. In an LTCH, it is typical that patients are very ill and quality of life is low. These questions seem most relevant after a patient leaves an acute care facility (hospital or LTCH). NALTH appreciates the opportunity to provide feedback on the cross-setting measures being considered by RAND and CMS. Many of the measures seem more relevant for a skilled nursing facility or other non-acute setting. Long-term care hospitals must meet the conditions of participation of an acute care hospital and have an average length of stay of 25 days or more. Many of the patients come from ICUs. Consequently, we believe that many of the measures are not relevant for the LTCH but would significantly add to provider reporting burden.	
UDSMR	6/26/17	UDSMR appreciates the opportunity to comment on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data (Second Public Comment). As a service provider to nearly one thousand postacute care (PAC) facilities (IRFs, SNFs, and LTCHs), and as an organization that serves over 80% of all IRF providers, we are providing the following feedback related to the consideration of data elements that meet the following IMPACT Act domains: • Cognitive function and mental status • Medical conditions and comorbidities • Impairments • Medication reconciliation • Care preferences	Uniform Data System for Medical Rehabilitation

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		For this public comment opportunity, CMS has stated that in addition to any general comments from stakeholders, they are specifically interested feedback related to the following topics addressing the draft data item specifications: • Potential for improving quality, which includes consideration of the data element's ability to improve care transitions through meaningful exchange of data between providers, to improve person-centered care and care planning, to be used for quality comparisons, and to 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, its clinical appropriateness, and its 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 We have multiple concerns to address. First, we are concerned that the timing of the public comment opportunity occurred at the same time as public comments related to FY 2018 updates to the various PAC payment systems. As we noted in a message dated June 2, 2017, the deadline for this public comment opportunity—June 26—coincided with the public comment deadlines for the IRF and SNF proposed rules and overlapped with the June 13 deadline for comments related to the LTCH proposed rule. Although we understand and appreciate that CMS and RAND have their own deadlines related to the review and consideration of these standardized patient assessment data, UDSMR and our PAC subscribers are concerned that the overlap of the existing deadline with the proposed rules noted above did not allow providers sufficient time to adequately review, analyze, and comment on this 146-page proposal, which contains more than two hundred data elements. Accordingly, we recommend that the feedback provided be considered incomplete and preliminary and that CMS and RAND offer another opportunity to PAC providers to provide feedback following full and robust consideration of the draft.	

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		Second, we would like to generally address the topic of feasibility for use in PAC. As stated above, this topic "includes consideration of the data element's potential to be standardized and made interoperable across settings, its clinical appropriateness, and its relevance to the work flow across settings." What this topic and its supporting text do not clearly address is the administrative burden that will be placed on PAC providers and their clinicians. Over the past two to three years, CMS's implementation of quality measures and standardized patient assessment data to support the IMPACT Act has placed a significant amount of administrative burden on PAC providers. For example, IRFs have seen the IRF-PAI go from three to eight to eighteen pages, and OMB-approved CMS estimates for the staff time required to complete and encode the IRF-PAI data has risen from 45 minutes to 54.5 minutes to its current estimate of 96 minutes. In the FY 2017 IRF PPS final rule, CMS implemented data collection for drug regimen review items to begin October 2018 with an OMB-approved CMS estimate of an additional 10 minutes for the staff time required to complete and encode the IRF-PAI data. Additionally, in the FY 2018 IRF PPS proposed rule, CMS has proposed implementing standardized patient assessment data for cognitive status and special treatment items that will make the IRF-PAI a twenty-four-page form, with an OMB-approved CMS estimate of an additional 14.4 minutes for the staff time required to complete and encode the IRF-PAI data. Therefore, what was once a 45-minute assessment has now become a 120-minute assessment, with IMPACT Act quality measures and standardized data elements nearly tripling the amount of time spent on administrative patient assessments. Without RAND and CMS providing estimates related to the staff time required to complete and encode the data for the draft data elements under consideration, the topic of feasibility only considers the administration of the data elements on their own, not their role as part of the overall patient assessment. While the feasibility of completing ten additional data elements may seem reasonable on its own, an observation of feasibility may be found to be unreasonable if these elements require an additional 10 to 15 minutes for a physician, a therapist, or another clinician to complete on top of the 45–120 minutes they are already required to spend on standardized patient assessment. With over two hundred new items documented in this public comment opportunity, we recommend that RAND and CMS provide estimates related to the staff time required to completeand encode the data for the draft data elements under consideration. These time estimates would allow PAC providers the ability to consider the feasibility against current requirements for standardized patient assessment data.	

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		Third, while the collection of additional data items and the interpretation of their results may have the potential to improve quality and the ability to improve care transitions, care planning, and care coordination, we question whether the these additional items under consideration provide benefit beyond information that is already being collected by PAC providers for these same purposes. RAND and CMS do not provide information for consideration as to whether any of the additional standardized patient assessment data show any additional benefit when considered alongside a patient's primary diagnosis and/or other conditions for which the patient is already receiving treatment. For example, what additional benefit will the cognitive function and mental status items under consideration provide for patients identified by physicians and other clinicians as having a cognitive deficit or another mental health condition such as depression, anxiety, or PTSD? Does the presence of a diagnosis or comorbid condition, identified by an ICD-10 code on the patient record or claim, already indicate sufficient information necessary for care transitions, care planning, and care coordination? Wouldn't the physician or clinician's expertise and screening documented in the medical record, regardless of the tool utilized, provide ample information for the purpose of improving the quality of care provided? Without evidence that these items provide better information than the items already documented and reported, we recommend that they not be considered for use as standardized patient assessment data. Fourth, most if not all of the data elements under consideration lack the necessary analysis and/or evidence of being both reliable and valid for use. In cases where reliability information is provided, consideration of the validity of the data element has not been provided. Therefore, although there is some confidence that the information is being collected in a reliable manner, we have no evidence that the data elements capture the patient attribute being assessed. We also have observed a number of instances in which the data element being considered has not been tested for reliability, but a similar measure has. Unless the actual data element and its associated items are tested for reliability for the methodology under consideration, the data element should not be considered reliable. We further note that there are a number of observational, patient-reported, or interview-style items within the data elements under consideration. We are very concerned about the reliability and validity of these items unless they account for a patient's cognitive and/or mental status prior to these items, in addition to the patient's ability to properly hear or read the question or questions, interpret and understand them, and appropriately respond to them. Until CMS and RAND provide both the necessary reliability and validity analyses, we cannot consider any of the data elements under consideration as having been deemed valid for use.	

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		Finally, for consideration related to the each data element's utility for describing case mix, while more data and information may provide additional opportunities for use in describing case mix or for use in payment modeling, in a number of instances CMS and RAND have not provided any analysis indicating that these items adequately measure the patient attributes. In a number of instances, determining varying levels of patient severity may be difficult due to the manner in which the items are presented or the scales utilized for responses. Additionally, CMS and RAND lack evidence and present no analyses indicating that these data elements are predictive of cost or measure quality. Until CMS and RAND provide the necessary analyses, we recommend that they these items not be considered for use in describing case-mix or for use in payment modeling. We would like to provide additional, detailed feedback on each of data elements, but we are unable to provide this feedback in a formal manner by the established deadline. We would welcome the opportunity to supply this information at a later time, if possible. We appreciate both the opportunity to provide public comment and the careful consideration of the comments we have provided. We welcome the opportunity to work with you to provide ongoing research regarding the selection and implementation of standardized and interoperable quality indicators. If you have any questions about these comments or require additional information, please contact us at 716-817-7800	
AOTA	6/26/17	The American Occupational Therapy Association (AOTA) is the national professional association representing the interests of more than 213,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. The science-driven, evidence based practice of occupational therapy enables people of all ages to live life to its fullest by promoting health and minimizing the functional effects of illness, injury, and disability. Many occupational therapy practitioners serve Medicare beneficiaries in post-acute care (PAC) settings, including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), home health agencies (HHAs) and long term care hospitals (LTCHs), and AOTA has been working to be a collaborative partner with Centers for Medicare and Medicaid Services staff to assist with implementation of the IMPACT Act since it significantly affects the profession of occupational therapy. The Improving Medicare Post-Acute Care Transformation (IMPACT) Act's purpose is to evaluate and realign the incentives and payment for inpatient and post-acute care (PAC) services provided under the Medicare program as well as to further quality service provision. The Act also brings attention to related issues such as resource utilization, patient safety, reducing caregiver burden and enhancing discharge planning and placement. Key to meeting these objectives is to create a measurement system that allows	American Occupational Therapy Association

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		Medicare to collect identical data across post-acute settings and to use that and other data to evaluate the effects of PAC health care services on the patient's overall health and functional status over the long term. The areas of emphasis for data and quality identified in the IMPACT Act include medical, functional, cognitive, and social supports. The IMPACT Act requires attention to these constructs for purposes of predicting post-acute care resource needs, promoting continuity of care, avoiding preventable hospital readmissions and achieving positive outcomes for Medicare beneficiaries as a result of receiving Medicare PAC services. AOTA was pleased that Congress recognized the importance of collecting data on cognitive status, mental status, continence, vision, pain, care preferences and patient reported outcomes among other areas in the IMPACT Act because each of these areas have a significant relationship to a patient's short and long term functional abilities and outcomes, as well as Medicare resource use, length of stay, caregiver burden and likelihood of hospital re-admissions. Occupational therapy has a critical role in assessing cognitive and physical functional status and ensuring that Medicare beneficiaries in acute and PAC settings receive quality care in the most appropriate setting, at the right time, using only the necessary Medicare resources. AOTA appreciates the opportunity to provide a second comment on the RAND Corporation Report on Development and Maintenance of Post-Acute Care Cross Setting Standardized Patient Assessment Data: Data Element Specifications. AOTA thanks CMS and RAND for the significant work done to develop potential data sources including the multiple technical expert panels (TEP) and the requests for stakeholder comment. In particular, AOTA applauds CMS and RAND for testing data elements through alpha 1, alpha 2, and beta testing prior to the implementation of the elements across PAC settings to ensure the feasibility and reliability of the elements in PAC settings. Our comments are organized by topic below. I. Cognitive Function and Mental Status AOTA has separated our comment regarding cognitive function from our comments regarding mental status because they are separate constructs and should be approached as such. AOTA supports the work of CMS and RAND on the continued development and testing of cognitive and mental status data elements. The currently available cognitive items are necessary, but not sufficient to fully describe case mix and improve the quality of services provided in post-acute care. It is critically important that RAND will be including a performance-based cognitive assessment, the PASS Mediation Management Task, among the items being	

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		tested. In general, AOTA supports the testing of the items proposed and also encourages testing of the Menu Task in the next phase of testing. A. Assessment of Cognition As we have commented previously (see AOTA comment letter #1 to RAND Corporation, dated September 12, 2016), AOTA has long had a strong interest and core responsibility for evaluating and treating patients with cognitive impairments because even mild impairments in cognition affect a person's ability to function and perform daily life activities. Thus, AOTA recommends that CMS broaden the assessment of cognition beyond how it has previously been evaluated. The term that we use to define this expanded view of the cognitive domain is "functional cognition," or the ability to use and integrate thinking and processing skills to accomplish complex everyday activities in dynamic clinical and community living environments. a. DOTPA CARE Caregiver and staff observations as well as the patient's medical record are important perspectives to consider when assessing cognition. We appreciate that RAND will be testing items before incorporating them into PAC settings. However, we encourage RAND to examine the validity of these items as a mechanism for characterizing case-mix. Furthermore, we believe it would be advantageous to examine the questions for parsimony. More information regarding patient functional status, quality and case-mix may be obtained by completing a performance-based assessment in context, negating the need for all 14 of the DOTPA items. b. Complex Sentence Repetition While this item demonstrated excellent reliability in the alpha 1 testing phase, the utility for quality improvement and case-mix description is unclear. This is an important consideration in the context of the larger goal of the IMPACT Act, which in this scenario is to ask is how is being able to repeat a complex sentence going to inform care planning, case-mix adjustment, and/or discharge planning for Medicare beneficiaries. a. PASS Mediation Management Task	

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		AOTA applauds RAND for testing the Performance Assessment of Self-care Skills (PASS) medication management task items. This valid, performance based measure of functional cognition provides significant information that can be used to improve quality and contribute to case-mix with increased specificity than other data elements currently in use or those that are proposed for testing. The PASS has been validated to measure functional cognition. The PASS has been tested in clinic, community and home settings for diagnostic groups including those with depression, dementia, heart failure, cardiac arrest, osteoarthritis, macular degeneration, bipolar disorder, mild cognitive impairment (MCI), Parkinsonism, stroke, and severe mental illness. PASS items are currently being used to assess people with psychiatric disabilities/mental illness who are moving out of psychiatric institutions and nursing homes to least restrictive community living via the Illinois State Williams Consent Decree/Olmstead class action lawsuit. PASS items have been more accurate than self-report for predicting home care service needs in a Canadian province population study.1 The administration of selected PASS IADL items can be used to discriminate among older adults with MCI and older adults with normal cognition with 80% accuracy.2 Thus, several PASS IADL items (in this case about 15-20 minutes of administration time) are a strong screening tool for functional cognition, and much less burdensome than several hours of neuropsychological testing and imaging. Interrater reliability, test-retest reliability, and construct validity have been established for the assessment.3 Items stand alone and can be administered independent of the entire assessment. The content validity has been established with multiple assessments of functional performance through exploratory factor analysis.4 The selection of the medication management item from the PASS is particularly appropriate given the importance of medication use to avoid re-hospitalization after discharge. 1 Brown, C. L., & Finlayson, M. L. (2013). Performance measures rather than self-report measures of functional status predic home care use in community-dwelling older adults. Canadian Journal of Occupational Therapy, 80, 284-294. 2 Rodakowski, J., Skidmore, E. R., Reynolds III, C. F., Dew, M. A., Butters, M. A., Holm, M. B., Lopez, O. L., & Rogers, J. C. (2014). Can performance of daily activities discriminate between older adults with normal cognitive function and those with Mild Cognitive Impairment? Journal of the American Geriatrics Society, 62,1347-1352. 3(Chisholm, D. (2005). Disability in older adults with depression. (Doctoral Dissertation). Retrieved 09 07, 2016, from University of Pittsburgh, Pittsburgh, PA.: http://d-scholarship.pitt.edu/9697/1/Chisholmdetd2005.pdf	

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		Foster, E. R. (2014). Foster, E. R. (2014). Instrumental Activities of Daily Living Performance Among People With Parkinson's Disease Without Dementia. American Journal of Occupational Therapy, 68(3), 353-262. Rogers, JC, Holm, MB, Beach, S, Schulz, R, Cipriani, J, Fox, A, & Starz, T. (2003). Concordance of four methods of disability assessment using performance in the home as the criterion method. Arthritis& Rheumatism (Arthritis Care & Research) 49, 640-647. Rogers, J., Holm, M., Beach S., Schulz R., & Starz, T. (2001). Task Independence, safety, and adequacy among nondisabled and osteoarthritis-disabled older women. Arthritis care & research, 45(5), 410-418. Skidmore, E.R., Rogers, J.C., Chandler, L.S., & Holm, L.B. (2006). Dynamic interactions between impairment and activity after stroke: examining the utility of decision analysis methods. Clinical rehabilitation, 20(6), 523-535. 4 Chisholm, D., Toto, P., Raina, K., Holm, M., & Rogers, J. (2014). Evaluating capacity to live independently and safely in the community: Performance Assessment of Self-care Skills. British Journal Of Occupational Therapy, 77(2), 59-63. This item has a significant potential for improving quality. The item can identify people with mild cognitive impairments and impairments in functional cognition at admission, thus ensuring that the appropriate services are provided to remediate or compensate for impairments. These items can identify people who have difficulty utilizing and integrating his or her thinking and processing skills to accomplish everyday activities in clinical and community living environments which is critical to maintain a successful discharge to the pre-morbid living arrangement. The item as described is feasible for use in PAC. AOTA would encourage RAND to test if the item may be implemented as a part of a skip pattern. The data elements will provide additional information on mild cognitive impairment, thereby distinguishing between those with impairment and those without impairment among those patients who passed the Brief Interview for Mental Status (BIMS) and the Confusion Assessment Method (CAM). Further, the PASS would not be necessary if the patient has already been identified to have a cognitive deficit after administration of the BIMS and/or CAM. The PASS demonstrates utility for describing case mix by identifying beneficiaries with cognitive impairments who would otherwise not be identified utilizing the data elements currently in use or being tested. The current case mix system does not account for people with mild to moderate cognitive	

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		impairments that would be identified by the PASS, but would not be identified by the BIMS or CAM. This group requires additional resources than similar people who do not have an impairment in functional cognition. AOTA appreciates the need to balance the data elements collected and the burden on providers to complete the assessments across PAC settings. A measure of functional cognition is critical to identify services, complete care planning and discharge planning, improve service quality, and appropriately identify the case-mix. During the next phase of testing, AOTA encourages RAND to include the Menu Task which was designed to be easy to score by any healthcare discipline with simple yes/no questions, quick to administer without equipment and sensitive to mild/moderate levels of impairment of cognition that may result in increased resource utilization and increased likelihood of hospital readmissions. AOTA believes that including a measure of functional cognition is critical. a. PROMIS Anxiety Items AOTA appreciates the efforts to include patient reported outcome measures across PAC settings. Beneficiaries who are receiving PAC have often had a life changing event and may be facing an unknown discharge disposition. Anxiety is an appropriate emotion to measure at admission and discharge from PAC services. The assessor states "these questions will help us provide you with a more individualized care plan." However, it is unclear how these data elements may influence the care plan. The measure may be made stronger by connecting interventions to address anxiety. The measure may be made stronger by connecting interventions to address anxiety. AOTA recommends that RAND research and connect the measure to best practice interventions to address anxiety in a PAC setting. We also have concern that three of the items may not be valid in a PAC setting. D1a, D1b, and D1d all may capture variability in the population that is not related to anxiety. • D1a. In the past 7 days, I had difficulty sleeping We believe that this item may measure the patient experience of PAC inpatient care as much, if not more, than anxiety. AOTA supports the measure of sleep disturbance in PAC settings; however, it may be best measured as a part of the experience of care rather than included in the PROMIS data elements to screen for anxiety. Many beneficiaries may respond "3=sometimes" or "4=often" due to medically necessary clinical	

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		care disturbances that frequently occur throughout the night in the acute care stay, or at the beginning of the PAC stay, before the assessment is administered. • D1b. In the past 7 days, I felt worried This item may also capture concerns related to the immediate need for PAC rather than being an indication of anxiety. However, it may also serve as an introduction to D1c "my worries overwhelmed me". If this item is needed to maintain the validity of the PROMIS dataset, it is appropriate to include. However, in a PAC setting, this item is also likely to capture variability that is not connected to anxiety. • D1d. In the past 7 days, I had trouble paying attention AOTA also believes that this item would capture variability outside of anxiety as the answer may be more related to a different need for PAC admission, such as cognitive impairment, rather than the desired construct. b. PHQ-9 Observational Version Occupational therapy practitioners help those with depression to restructure their daily lives, find meaning in daily occupations, and redefine their sense of identity. Occupational therapy can examine the life roles that are meaningful to clients with depression and help adapt their responsibilities to give them the opportunity to participate and gain a sense of accomplishment. AOTA supports the testing of the PHQ-9OV and believes that the information can be important for improving the quality and appropriateness of services. A. Continence AOTA appreciates and supports RAND and CMS' efforts to include both bladder and bowel continence issues, as they each impact an individual's fall risk, discharge planning, and resource needs. Thus, each issue is important for case-mix consideration. B. Pain	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		AOTA strongly supports the assessment of pain. We applaud the testing of data elements that assess the effect of pain on performance. In particular, we feel that understanding when pain impacts therapy and other daily living activities such as sleep, can improve the quality of services provided and will also tease apart the impact that pain has on function. AOTA also supports the testing of the observational assessment of pain and distress. This item should provide additional utility for describing case mix and improve the quality of services for beneficiaries who are unable to respond to specific questions related to pain. III. Impairments of Vision and Hearing Occupational therapy practitioners work to ensure that older adults are able to age in place and participate in their communities despite visual impairment. Occupational therapy practitioners are also part of coordinated rehabilitation teams that enable adults with visual impairment to acquire or continue independent living, productive employment, and the ability to drive safely. AOTA supports the testing of the items for corrective lenses and hearing aids. We recommend including these items at the beginning of the assessment to identify the needs of the beneficiary before the remaining assessment items are administered. IV. Care Preferences AOTA applauds CMS and RAND for testing care preference measures for use in PAC settings. Understanding Medicare beneficiary preferences near admission can facilitate care coordination and potentially improve the transitions of care over the course of treatment/recovery. V. PROMIS® AOTA supports testing the PROMIS data sets and is supportive of patient reported outcomes measurement in general. The constructs below represent over 40 additional data elements that would be collected across the PAC settings. Thus it will be critical to weigh patient/ provider burden against the benefit of additional information needed to support care transitions, case mix development, and the quality of PAC services when determining which elements should be included. AOTA believes all the proposed constructs are important; however, the ability to participate in social roles and activities may be the most appropriate. Brief comments for each proposed area are below. A. Sleep Disturbance	

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		We believe that while adequate sleep is critical to fully participate in activities of daily living and successfully self-manage health, this collection of PROMIS items may not be the most critical to include in PAC settings. B. Fatigue Overcoming fatigue can directly impact the health of beneficiaries. However, at admission to PAC settings, fatigue may be expected as the beneficiary is recovering from an illness or injury significant enough to require intensive, skilled services. C. Ability to Participate in Social Roles and Activities The ability to participate in social roles and activities is extremely important and can be directly impacted in PAC settings. Research supports addressing psychosocial components of chronic conditions for patients will serious illness. Different psychosocial strategies have a positive effect on side effects, such as anxiety and depression, and improve quality of life.5 5 See http://www.aota.org/~/media/Corporate/Files/Secure/Practice/CCL/Cancer/Cancer-Psychosocial-Rehabilitation-CAT.pdf; http://www.aota.org/~/media/Corporate/Files/Secure/Practice/CCL/MSD/CATRAFibroPsychoeducational.pdf; http://www.aota.org/~/media/Corporate/Files/Secure/Practice/CCL/TBI/TBI2015/CBT.pdf. Occupational therapy practitioners are well suited to developing and providing both individual and group-based therapy and treatment addressing these side effects and increasing quality of life for Medicare beneficiaries in PAC. Understanding the beneficiary response to these PROMIS items can identify services and facilitate the development of a care plan. AOTA strongly supports testing and measuring of these items because they can inform goal development and focus PAC services to improve the beneficiary's ability to fully participate in life and manage their health.	

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		D. Global Health Patient reported global health is also an important construct. A more concise list of questions may provide the same amount of information for care planning and case mix than the 10 proposed items. VI. Conclusion & Summary Recommendations AOTA appreciates the efforts of CMS to generate standardized data elements and PAC cross-cutting measures in response to the IMPACT Act. To facilitate external comments and provide a consistent message across the PAC settings, AOTA recommends a unified micro-site that can be used to monitor measure development, measure implementation, and education. CMS has demonstrated an outstanding resource and education page for the Quality Payment Program at https://qpp.cms.gov. Creating a single landing point for IMPACT and QRP programs would facilitate better information sharing and a more consistent implementation of the efforts for the IMPACT Act. CMS will need to balance the implementation of new data elements with the burden of administration by providers. When possible, data elements should be harmonized across settings and potentially duplicative data elements should be retired as soon as possible. AOTA looks forward to a continuing dialogue with CMS and the RAND Corporation on IMPACT Act policies that affect the ability of occupational therapists to provide quality post-acute care to Medicare beneficiaries.	
NAHC	6/26/17	The National Association for Home Care & Hospice (NAHC) is the largest trade association in the country representing home health care agencies. NAHC members represent the entire spectrum of home care agencies, including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and freestanding, proprietary home health agencies. NAHC members serve over several million Medicare home health care beneficiaries each year. In general, NAHC believes that many of the proposed standardized data set items under the each of the domains could provide valuable information to support quality improvement among post acute care (PAC) providers. However, NAHC has concerns with the feasibly of many of the items both in terms of the burden associated with completing the items and/or the ability to standardize the items across the post acute care settings. NAHC also has concerns regarding the potential for duplication and/or overlap with current OASIS assessment items and the implications for replacing or altering OASIS items.	National Association for Home Care & Hospice

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		The OASIS has various applications for home health agencies (i.e. payment, quality measures, Star Rating and home health value based purchasing). Almost all of the OASIS items impact one or more of these applications either directly or through risk adjustment for the quality measures. CMS must consider these applications with any modification to the OASIS assessment instrument. Further, NAHC continues to be concerned that the requirements of the IMPACT Act will result in a lengthy assessment tool that will become very burdensome for home health agencies to administer. DOTPA NAHC does not support the DOTA data set as a standardized assessment item. The item potentially would require a clinician to assess the patient on 14 individual data items. The length of the item makes it impractical for home health agencies (HHAs) to adopt. In addition, the item must be completed within 2 days, which conflicts with the 5 day time frame home health agencies are required to complete the Outcome and Assessment Information Set (OASIS) assessment data set. Complex Sentence Repetition NAHC supports the Complex Sentence Repetition item as a standardize assessment item. The item provides beneficial information for quality improvement, is feasible across all PAC settings and has utility in describing case mix. The validity of this item is unknown and would require testing. PASS Medication Management NAHC does not support the PASS Medication Management assessment item. This item is burdensome to complete and requires tasks that may be too complex for home health patients. In addition, the item requires the use of a pillbox which many home health patients do not own nor should agencies be expected to the supply the item for every patient. Staff Assessment of Mental Status	

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		NAHC does not support the Staff Assessment of Mental Status as a standardized assessment item. The item has an inpatient facility focus and requires a 7 day look back period. The 7 day look-back period conflicts with the 5 day assessment window required for home health agencies to complete the OASIS assessment. HHAs will be restricted to a 5 day look back period for this item, rendering it unfeasible to standardize across all PAC settings. Behavior Signs and Symptoms NAHC does not support the Behavior Signs and Symptoms assessment due to the burden associated with completing the item. The item consists of 11 individual assessment items. In addition, there is 7 day look back period which conflicts with the 5 day assessment window required for home health agencies to complete the OASIS assessment. HHAs will be restricted to a 5 day look back period for this item, rendering it unfeasible to standardize across all PAC settings. PROMIS® Anxiety Items NAHC does not support the PROMIS® Anxiety Items as a standardized assessment item due to the burden associated with implementing the item. The assessment item consists of 11 individual items the clinician would need to assess. NAHC does not believe the items provide more valuable information than what is already collected by HHAs through the OASIS assessment. PHQ9-OV NAHC does not support the PHQ9-OV due to the burden associated with implementing the item. The two week look back period for completion conflicts with the 5 day window home health agencies have to complete the OASIS assessment. Additionally, NAHC has concerns regarding the potential for duplication and/or overlap of the items under this domain with current OASIS assessment items (M1700 -1745) and the implications for replacing or altering OASIS items. Bladder - Device Use	

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		In general, NAHC supports this item. However, NAHC does not believe the question, C1b."….what point was the device first placed", is information that has value for home health patients. Otherwise, the item has potential for quality improvement, is feasible to implement across PAC settings, and has utility for case mix, Validity is unknown and would require testing. Bladder – Incontinence NAHC supports C2a –frequency of incontinent events in the item to assess incontinence. The item has potential for quality improvement, is feasible to implement across PAC settings, and has utility for case mix. All of the PAC settings currently have a similar item on their assessment instruments therefore the item should show validity. NAHC does not support C2b- "…prior to hospitalization…", in the item. NAHC does not believe the information adds value for quality measurement or improvement. In addition, half of home health patients are admitted from the community. Therefore, this item would be applicable to a smaller portion of patients receiving home health care than patients in the other PAC settings. Bladder- Incontinence Interview NAHC does not support this item. NAHC believes this item is too subjective when asking patients and caregivers if incontinence is a small, moderate or big problem. The two incontinence items discussed above are preferable. Additionally, NAHC has concerns regarding the potential for duplication and/or overlap of the items in this domain with current OASIS assessment items (M1610 and M1615) the implications for replacing or altering OASIS items. Domain: Medical Condition- Pain NAHC supports all the pain assessment items under this domain, except for Paine Interference – Therapy Activities. and Observational Assessment of Pain or Distress	

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		The items for pain–frequency, severity, effect on sleep, with other activities and pain relief, all have potential for improving quality, are feasible for use across PAC settings, and have utility for case mix. However, Pain Interfering with Other Activities duplicates OASIS assessment item M1242. Pain Interference – Therapy Activities This item addresses a subset of the patient population in home health care (those receiving therapy), and therefor has limited value as a quality indicator. Pain Activities– Other Activities is the preferred assessment item for addressing pain with activity. Observational Assessment of Pain or Distress This item requires an assessment period of 3 consecutive days which is not feasible in home health due to the intermittent nature of home health services. Domain: Impairments –Vision /Hearing NAHC supports the item for vision and the item for hearing. Both of the items are feasible across PAC settings, and should show validity due to the simplicity of the items. The items could contribute to improving quality and used for case mix, although NAHC does not believe there is strong a correlation with these items in improving quality or defining case mix. Domain: Medication reconciliation NAHC does not support any of the items under this domain. The medication categories addressed are limited and therefore provide limited information regarding medication reconciliation. In addition, these items are redundant with the current medication reconciliation assessment items PAC providers are collecting to comply with the IMPACT Act medication reconciliation domain required for quality measures. It is unclear why the measure developers are seeking comments on additional medication reconciliation assessment items. Domain: Care preferences	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		In general, NAHC supports the item under this domain except for Physician Orders. . NAHC believes the items for Advanced Directives, Goals of Care, and Involvement of Family/Friends, contribute to improving the quality of care and are feasible to implement across PAC settings. The validity for item is unknown and the items likely do not have much utility for case mix. Physician Orders NAHC does not support this item. It is unclear when the information would be collected. If at the SOC, the information may not be known. PROMIS® Sleep disturbance Fatigue Ability to participate in social roles and activities Global health NAHC does not support the PROMIS® assessment items due to the burden associated with implementing the item. Each category has 10-12 individual data items to be completed. NAHC does not believe these items provide more valuable information than what is already collected by HHAs through the OASIS assessment. Thank you for the opportunity to submit comments. If you need further information, please do not hesitate to contact me.	
AAPMR	6/26/17	Physical medicine and rehabilitation (PM&R) physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting edge as well as time-tested treatments to maximize function and quality of life. Many provisions in the proposed rule will impact physiatrists nationwide. We therefore, appreciate your consideration of the following comments. Medical Conditions: Pain	American Academy of Physical Medicine and Rehabilitation

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		The AAPM&R has previously provided input that the assessment of pain independent of its influence on function is irrelevant. This is particularly true in the Post-Acute Care (PAC) setting, where the goal is to improve the function of patients. Of the items proposed, AAPM&R can support the one that relates to participation in the therapies, and other activities. However, the other activities as presented is extremely broad, perhaps useful as a triage item. We encourage RAND and CMS to consider the effect of pain on more specific items, such as those in the Academy's previous input would be a better guide. However, those on that list that are only relevant to those living community should be eliminated for the PAC setting. AAPM&R believes these measures have the potential to improve quality, while the others do not. In the sense of the request, all are probably valid, but we believe only those relating to function are feasible for use in PAC. The items of pain related to function could be useful to case mix.
		
		Medication Reconciliation
		
		Medical reconciliation is an important process that currently generates great interest within the health delivery system, including The Joint Commission (TJC) that accredits hospitals. Therefore, any processes required by CMS should be compatible with those of TJC. The elements proposed in the CMS/RAND document are likely to improve quality and have validity, but would add significant data burden, thus reducing their feasibility in PAC, and would not be useful in improving case mix.
		• Potential for Improving Quality
		  • Yes – Use of medical reconciliation will likely be helpful improving quality with transitions across levels of care
		  • Assessing pain is an important issue and in the post-acute setting is more challenging. Standardizing the pain measurement scales across post-acute settings would be helpful and may improve quality in there is uniformity in assessing both needed for pain management as well as response to pain relief interventions.
		
		• Validity
		  o Yes
		  o The measurements as described appear that they would be valid in identifying pain and response to pain treatment. However, there is growing concern about the overuse of opioid pain medications and further assessment to make sure that this did not increase the widespread use of opioids further would be beneficial.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		• Feasibility for use in PAC o Burdensome – overall concern with potential for excessive time and personnel burden regarding collection, documentation and the review process o Overall concerns with the measurement as suggested is the time burning for training, performing assessments with most Scales asking for 3 repetitions of questions and documentation burden associated with utilizing the assessments. Again, concerned that this would not increase the widespread use of opioids further. • Utility for Describing Case Mix o Probably not useful in improving case mix o The pain scales on the surface appeared to be valid and measuring pain however the distinction between chronic and acute pain is not clear. The extent of acute and chronic pain and can vary especially in the different settings of PAC. AAPM&R supports the inclusion of Care Preferences because it is patient-centric and would reasonably incentivize the PAC providers to have goals of care conversations and give the patient the opportunity to articulate his/her goals and desires. These conversations should align physiatrists with the patient at an early stage of care so not to result in expending effort that the patient does not want. This could have an impact on end-of-life care. The inpatient rehabilitation faciality (IRF) is the only level of PAC where a rehabilitation physician has a role mandated by CMS. It is our contention that a physiatrist adds value to the PAC process across the continuum. Physiatry consultation is now frequently requested by more medically sophisticated patients and families in other PAC settings. For example, skilled nursing facilities (SNFs) that promote the availability of physiatry consultation may compete more effectively for short-term rehabilitation patients than those who do not provide such consultations. • Potential for Improving Quality • Yes • Validity • Yes – valid in concept	

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		• Feasibility for use in PAC
		  • Yes
		  • Not all aspects of care preferences have been thoroughly studied to be determined as feasible across the PAC settings. Would be beneficial to get details of feasibility studies prior to initiation.
		• Utility for Describing Case Mix
		  • No
		• Advanced care directive and physician's orders
		  • these items would not improve quality, are valid, feasible for use in PAC although duplicative of current processes and do not aid in case mix.
		• Preference for involvement of family/friends in decisions
		  • this is more an operational item rather than one to improve quality, is valid and feasible, and would not contribute to case mix.
		• Preferences for Involvement in decision making
		  • this is an inappropriate cross-cutting data item for PAC, as all patients in IRFs are there to improve their function, a process that requires the patient to fully understand their situation, and to participate in the selection and implementation of the strategies to improve their function.
		
		The Patient-Reported Outcomes Measurement Information System (PROMIS®)
		Development and use of certain PROMIS® elements to be used across post-acute care settings as part of implementing data standardization in accord with the IMPACT Act.
		
		AAPM&R generally agrees the PROMIS® domains of sleep disturbance, fatigue, ability to participate in social roles and activities, and global health themselves are appropriate to collect for all patients because they impact quality of life and ability to participate with therapy and treatment. However, the questions within these PROMIS® domains are currently only suitable for an outpatient individual who lives at home and interacts with their community/society, and are not appropriate for data standardization across Post-Acute Care (PAC) settings, without significant adaptation and rigorous testing of validity and reliability.	

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		Further, many individuals in post-acute care settings have relatively short lengths of stay where focus is on acute pain control and regaining function quickly. Utilization of these PROMIS® elements would provide little potential for improving quality of care as they do not lend themselves to be "actionable" by PAC providers.
		
		Several AAPM&R reviewers stated that the number of questions – 72 – left them with the impression that this section is more research protocol than something that is useable in the field. We suggest narrowing the number of questions to the most valid and impactful would be important step.
		
		Standardizing patient assessment data amongst Post-Acute Care (PAC) settings is important work that greatly impacts AAPM&R's members. To comprehensively state AAPM&R's support for data standardization, we developed Recommendations on Post-Acute Care Data Standardization and Quality Measurement that was approved by AAPM&R's Board of Directors in June 2016. This document is intended to show our support for moving towards standardizing data elements across PAC settings if reliable, feasible and risk adjusted methods are at the forefront of doing so. Attached at the end of this comment letter is AAPM&R's official stance on data standardization across PAC settings.
		
		• Potential for Improving Quality
		  • Yes, if list of questions and domains are narrowed
		
		• Validity
		  • Not certain
		
		• Feasibility for use in PAC
		  • Yes, with caveats from above
		
		• Utility of Describing Case Mix
		  • No
		
		AAPM&R in earlier comments has emphasized and recommended a unified system of outcomes data across all PAC levels of care. This will be critically important for any subsequent research into outcomes across PAC settings and levels of care.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		We appreciate the opportunity to comment on this proposed rule. The AAPM&R looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Paul Smedberg, Director of Advocacy & Government Affairs, AAPM&R. He may be reached at PSmedberg@aapmr.org or at (202)420-5907.	
SRAlab	6/26/17	1. Developing Outpatient Therapy Payment Alternatives (DOTPA) Element A5b. We suggest providing further information to guide clinicians in answering element A5b of the DOTPA Continuity Assessment Record and Evaluation, which asks PAC staff or caregivers "Please describe the patient's/resident's problems with the following: memory, attention, problem solving, planning, organizing, and judgment." The three answers (Mildly impaired, Moderately impaired, and Severely impaired) are subjective assessments, and answers will depend on the prior experience of the staff or caregiver providing the answer. For example, staff working in a skilled nursing unit that treats elective orthopedic surgeries might consider certain cognitive symptoms to reflect severe impairment, while staff in a higher-acuity inpatient setting might consider similar symptoms to reflect only mild or moderate impairment. We recommend that CMS provide guidelines and/or clear examples. Element A5m. This element asks: "How often is the patient/resident able to complete complex activities without assistance?" We assume this excludes the use of reading glasses or hearing aids, but that assumption should be made explicit in the item. 2. Complex Sentence Repetition The Complex Sentence Repetition measure is intended to screen for cognitive impairment. It includes data elements F7a and F7b, in which a patient is read the following sentences and asked to repeat them: • _Element F7a: After the bell rang, the man standing on the stairs quickly exited the building. • _Element F7b: Though he typically watches westerns, lately he has preferred watching comedies. The patient/resident gets three chances to repeat the sentence correctly, and if he or she does not exactly repeat it correctly, receives a score of "0" on each item. These sentences, particularly the second sentences mix of present tense ("he typically watches") with past-continuous tense ("he has preferred"), are complex and challenging, even to individuals without functionally	Rehabilitation Institute of Chicago d/b/a Shirley Ryan AbilityLab

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		relevant cognitive impairments. We recommend substituting these sentences with ones that employ a more simple structure. We also suggest providing translated versions, as a significant limitation of language-based assessments is their lack of applicability to non-native English speakers. Use of these elements without translated versions would be a significant concern for providers that serve multi-ethnic communities. 3. PROMIS Anxiety Items We believe the following elements related to anxiety are meaningful and relevant to patients in all PAC settings: D1b, D1c (particularly effective as it asks about anxiety in a functional context), D1e, D1f, D1g, D1h, D1i, D1j, and D1k. We recommend that the following elements be omitted, as they are redundant with assessment items in other domains: D1a (redundant with sleep disturbance item) and D1d (redundant with cognitive items assessing attention). 4. Patient Health Questionnaire-9 Observational Version (PHQ9-OV) The PHQ9-OV is intended to assess distressed mood in patients/residents who cannot complete the PHQ-9 mood interview due to an inability to communicate. We support the need to assess mood in patients who cannot communicate. However, this measure appears to be validated in nursing homes but not inpatient rehabilitation facilities. We suggest that it be validated before it is used. Of note, the US Preventive Services Task Force recommends depression screenings should only be done when there is staff-assisted depression care support in place to assure accurate diagnosis, effective treatment, and follow-up. We suggest that all PAC sites of care have this level of support when screening for depression using the PHQ9-OV. 5. Medical Conditions: Pain	

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		In the data element related to pain severity (H5), would recommend asking the patient to also rate the intensity of their pain at best over the last 3 days. It is more clinically useful to have a range for pain intensity rather than only knowing pain intensity at its worst. H6. The data element related to pain relief asks "During the past 3 days how much relief have you felt from pain due to pain treatments and/or medications?" The answers include "some relief", "quite a bit of relief," and "very much relief." It may be difficult for patients to distinguish between these different answers. We instead suggest focusing the answers so they are framed in terms of "sufficient pain control" or "insufficient pain control." 6. Observational Assessment of Pain or Distress E1. This measure collects staff observations of patients'/residents' expressed behavioral indicators of potential pain or distress, for patients who are unable to communicate. The behavioral indicators listed include non-verbal sounds, facial expressions, and different types of body movements or postures. It is important to recognize that some of the listed behaviors are clearly not pathognomonic for pain. We suggest conducting further analysis on this measure to account for non-pathognomonic behavior. 7. Impairments of Hearing and Vision Element D1 asks "Does the patient/resident use glasses (or other corrective lenses) regularly?" Element E1 asks "Does the patient/resident use a hearing aid (or other hearing appliance) regularly?" We suggest instead asking a patient/resident if their vision or hearing is impairing their ability to carry out daily tasks. Asking if the patient/resident uses glasses or hearing appliances regularly does not assess patients for new impairments that need addressing in a PAC setting. Additionally, it does not address patients who require glasses or hearing aids, but refuse to use them. 8. Medication Reconciliation We suggest adding a question related to management of discrepancies, such as "Was the managing physician notified within 24 hours?"	

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		9. Care Preferences G1d. The measure asks "Did the documented conversation about goals of care indicate any of the following types of goals:" with possible responses Physical Goals, Emotional Goals, Social Goals, Intellectual/Mental Goals, and Other. We recognize the validity of patients having these kind of goals, but do not believe the use of this measure will achieve the factors CMS has indicated are important – the potential for improving quality; validity; feasibility for use in a PAC; or utility for describing case mix. 10. PROMIS Sleep Disturbance. X1b ("In the past 7 days, it was easy for me to fall asleep") should be omitted as it is clinically redundant with measure X1a ("In the past 7 days, I had difficulty falling asleep"). X1c ("In the past 7 days, I worried about not being able to fall asleep") should be omitted as it points to anxiety symptoms, which is not the purpose of this assessment. Fatigue X1e ("In the past 7 days, how often did you have enough energy to enjoy the things you do for fun?") should be omitted because it may not be applicable to patients in all PAC settings. In higher acuity settings, patients are often not engaging in normal activities that they do for fun. They therefore are unable to accurately assess whether they have enough energy to do those activities. Ability to Participate in Social Roles and Activities The suitability of questions related to functional status and social participation depends on the timing of question administration. Many of the questions in this category are relevant after PAC discharge, once patients are back in their community environment and have resumed social activities. In addition, questions related to social participation must be asked in the context of expected functional status. For example, it is likely that a patient with new tetraplegia may have trouble doing all of his regular	

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		leisure activities with others if some of those leisure activities are not consistent with his expected functional status. The only elements in this category that may be applicable to patients in most PAC settings are X1a, X1c, and X1i. 11. Global Health While there have been discussions over many years over the use of patient-reported global health measures including the SF-36 or short version SF-12 and/or variants, we are not aware of any evidence indicating they have driven successful quality improvement activities. The following questions related to global health are meaningful and relevant to patients in all PAC settings: X1a, X1b, X1c, and X1d. X1h, X1i, and X1j are meaningful questions but may be redundant with other data elements related to mood disorders, fatigue, and pain. X1e ("I have trouble doing all of the family activities that I want to do"), X1f ("I have to limit my regular family activities"), and X1g ("I have trouble doing all of the activities with friends that are really important to me") should be omitted, as they relate to social participation and instrumental activities of daily living that are naturally constrained by receiving PAC care. In conclusion, thank you for the opportunity to provide these comments. If you have any questions or would like to discuss this matter further, please feel free to contact Sangeeta Patel, MD MPH, at 312.238.1125. We welcome the opportunity to be a resource to you and CMS as this important effort moves forward.	
AANAC	6/26/17	The American Association of Post-Acute Care Nursing is a professional association encompassing both the American Association of Directors of Nursing Services (AADNS) and the American Association of Nurse Assessment Coordination (AANAC). AADNS and AANAC represent over 15,000 long-term care nurses and professionals across the country. We respectfully submit these comments in response to the Development and Maintenance of Post- Acute Care Cross-Setting Standardized Assessment Data RAND IMPACT. AADNS and AANAC support the goal of the proposed rule to revise the Medicare payment system and the continued plans of CMS to move from a volume-based payment system to a value-based	American Association of Nurse Assessment Coordination

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		payment system. We understand that the proposed changes are necessary to promote our national healthcare system's triple aim of better care, healthy people and communities, and affordable care for all. We support CMS in the move towards standardized assessment data elements across the care continuum to facilitate cross-setting data collection, outcome comparison, and interoperable data exchange, while improving care coordination, fostering seamless transitions, improving person-centered outcomes and goals, and providing for reliable information that may support providers in making appropriate discharge placements. Our members have provided feedback to the proposed regulations, as outlined in the following pages. **<u>Item: DOTPA CARE</u>** **General Comments** DOTPA CARE – CMS's focus on the resident and his/her voice being heard is the gold standard. Therefore, we are concerned that these items are not getting the information directly from the resident and as a result seem very subjective with the potential for inaccuracy. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Data seems repetitive, and for SNF resident in therapy these items are very similar to therapy assessments. **Improve person-centered care and care planning** No, since it is not using the resident's voice. **Used for quality comparisons** Do not believe items detail cognition, as answer options would be subjective to the assessor – basic versus complex. SNFs already have some difficulty with compiling the BIMS accurately and this does not seem to improve the assessment of cognitive status. What kind of directions will be given as answer options appear very similar. For example, what is the difference between "sometimes" and "usually"? We	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		are greatly concerned with the accuracy of these items and therefore the ability to use the information for care planning. **Support clinical decision-making and care coordination** No, since it is not using the resident's voice. **Validity** **Whether it captures the patient attribute being assessed** Question validity – as very subjective based on who is asking, how it is asked, and what it shows about a resident's cognition. Do not believe we need an additional assessment to the BIMS, which is a part of the MDS. Items seem to be more applicable to other patient types, such as mentally ill and developmentally disabled. **Proven or likely inter-rater reliability** Many functions of cognition being tied together into one question leads to concern with how the data will help with person-centered care planning. Caregiver is best person in a SNF to respond to questions, but concerned with his/her ability to decipher the information to accurately drive care planning. **Feasibility** **Feasibility for use in PAC** So many assessment windows are being enforced – question how feasible it is to collect and respond to all of these items. Does not seem to be useful enough to justify the time commitment for completion. **Potential to be standardized and made interoperable across settings** **Clinical appropriateness**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Relevance to the work flow across settings We can see how this information would be valuable when the resident is transferred to another setting – but usefulness for the SNF setting is a concern. **Utility for describing case mix** **Can the data element be used with different payment models** Accuracy of these items is an overriding concern and would not want payment attached to it. **Does it measure differences in patient severity levels related to resource needs** Therapy suggests there are some other rehabilitation tools that could be used for validity, although there is a cost attached to their use. **Items: Complex Sentence Repetition** **General Comments** For the SNF we are concerned about the value of the complex sentences and the instruction that they must be repeated exactly. Would need to define "trained clinician." **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** We do not see the ability to repeat a complex sentence that has nothing to do with healthcare to have the potential to improve quality. **Improve person-centered care and care planning** No, as stated in the above comment.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Used for quality comparisons No, as stated in the above comment. **Support clinical decision-making and care coordination** No, as stated in the above comment. **Validity** **Whether it captures the patient attribute being assessed** Complex sentence – time consuming in addition to MDS. **Feasibility** **Feasibility for use in PAC** Time constraints continue to be a problem in the SNF setting. These additional items do not seem feasible when considering the time already needed to complete the MDS. **Potential to be standardized and made interoperable across settings** Not considered feasible. **Clinical appropriateness** No. **Relevance to the work flow across settings** Does not seem to be feasible.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Utility for describing case mix **Can the data element be used with different payment models** Does not seem to be reliable or valid. **Does it measure differences in patient severity levels related to resource needs** No. **<u>Item: PASS Medication Management</u>** **General Comments** Many SNFs would need to change drug packaging, resulting in a tremendous cost. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Need to consider the ramifications of health literacy. **Improve person-centered care and care planning** We are concerned that the intensity of these items could be frustrating for the resident. **Support clinical decision-making and care coordination** There is value to the items as far as successful discharge to the community, but for care services while in the SNF, we do not believe there is a great deal of usefulness. **Validity**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Whether it captures the patient attribute being assessed Appears to be a part of the medication administration process, and therefore we doubt the value. This could be considered as part of a training program before the resident is discharged to a less acute setting. **Feasibility** **Feasibility for use in PAC** Another time-consuming addition to the MDS process with little merit or value except for discharge planning. **Potential to be standardized and made interoperable across settings** If the resident is not able to meet the goal, what are the financial ramifications? **Clinical appropriateness** Instructions do address environmental safety issues, but what about visual impairments and/or loss of fine motor movements (stroke, Parkinson's disease)? **Does it measure differences in patient severity levels related to resource needs** Too many other issues beyond resident and/or facility control could impact ability to address these items. **Item: Staff Assessment of Mental Status** **General Comments** Repetitive information from staff assessment of mental status on the MDS. See no need for collecting this data.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Potential for improving quality **Ability to improve care transitions through meaningful exchange of data between providers** Cognition can fluctuate greatly based on setting and environmental factors and therefore concerned with reliability. **Improve person-centered care and care planning** No, since data does not seem valuable in the SNF setting. **Used for quality comparisons** Reveals minimal information about cognitive abilities. **Validity** **Whether it captures the patient attribute being assessed** Reliability of data in SNF is questioned and not felt to be of great value. **Feasibility** **Feasibility for use in PAC** Repetitious for the SNF since already a part of the MDS. **Can the data element be used with different payment models** SNFs use the BIMS and the Cognitive Performance Scale so does not seem needed. **Item: Behavioral Signs and Symptoms**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Repetitious of the MDS – time concerns for tracking to ensure accuracy. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Rejection of care on MDS – is difficult to code and not sure of usefulness unless it is care planned. Needs much better clarification and instructions for this item from CMS. **Improve person-centered care and care planning** Important, but staff has great troubling coding on the MDS. **Used for quality comparisons** SNFs having difficulty assessing behaviors to reach the root cause of the behaviors – these items do not seem to help get to the actual problem. **Support clinical decision-making and care coordination** Items are important for care planning, but number of items is of concern. **Validity** **Whether it captures the patient attribute being assessed** Behaviors are so prevalent in some facilities that staff becomes accustomed to them and do not note, track, or care plan. Greater training would be needed to increase understanding of behaviors and what needs to be done to help the residents. **Feasibility**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Feasibility for use in PAC Repetitious for SNFs with no additional added value seen. **Potential to be standardized and made interoperable across settings** We do not believe so – a problem for one setting may not be considered a problem in another setting. **Clinical appropriateness** No, as stated above. **Relevance to the work flow across settings** Same a above. **Utility for describing case mix** **Can the data element be used with different payment models** Residents with these types of behaviors are sometimes difficult to manage and could be important for reimbursement, but history has shown payment adjustments have been minimal. **Does it measure differences in patient severity levels related to resource needs** How would this show improvement over time to possibly impact reimbursement? **PROMIS Anxiety** **General Comments**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Staff do not want to call a resident "depressed" so will not report it; also staff concerns with qualifications to conduct the interview. Answer options are not clear. Consider the difference between "rarely" and "sometimes" over 7-day period – is that a feasible option? Another time frame for assessment – MDS has a 14-day look-back and these items are 7 days. We believe the items could have some value, but too similar to the MDS, and coding options for the resident are not clear, which generally decreases validity and reliability. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** PROMIS – like the items, but as noted above this seems to be too much like the Mood interview, which already consumes a great deal of time. **Improve person-centered care and care planning** Yes, it could, but other concerns as noted above. **Used for quality comparisons** Does not seem likely due to reluctance of some residents to complete the MDS Mood items. **Support clinical decision-making and care coordination** No, as stated above. Items are ambiguous and not culturally considerate. For example, "overwhelmed" for one person might not be the same for another person. **Validity** **Whether it captures the patient attribute being assessed** Concern remains with redundancy and answer options.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Proven or likely inter-rater reliability We do not believe that is likely. **Feasibility** **Feasibility for use in PAC** Important, but validity is a concern as noted above. **Potential to be standardized and made interoperable across settings** SNFs found that residents sometimes reluctant to report these issues to someone unfamiliar to them. Residents expressing interview fatigue – too many, too often. **Clinical appropriateness** See previous comments. **Relevance to the work flow across settings** Burdensome with minimal value in return. **Can the data element be used with different payment models** Time consuming and very similar to Mood interview on MDS. Validity and reliability of concern, since some staff very hesitant to focus on the resident's feelings. **Does it measure differences in patient severity levels related to resource needs** Yes, but many concerns as noted above. **PHQ9-OV**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Concern that staff often do not realize the symptom could be unrelated to depression or anxiety and then do not report or record it, as they believe the items only relate to mood. Assessment look-back reverts to 14-day. Sets the facility up for inaccuracies and lack of validity with so many look-back periods. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Staff would need additional training to accurately reflect the resident's mood. Too many answer options and too many questions. **Validity** **Whether it captures the patient attribute being assessed** Concerns as noted above with the resident interview – repetitious and time consuming since already completing on the MDS as needed. **Feasibility** **Feasibility for use in PAC** As noted above in resident interview items – concern that items would be required in addition to MDS. Too repetitive and time-consuming, with usefulness questioned. **Clinical appropriateness** Concerns as noted above. **<u>Medical Condition – Continence Device Use</u>**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Devices – Alpha 1 testing revealed moderate to excellent reliability and concerned about proceeding. Value for LTC is in question as many residents do not want to proceed with additional options to fix incontinence problems. **Improve person-centered care and care planning** Are there going to be guidelines when interview could stop? Again we have concerns about health literacy of our residents and whether assessor will have time to define and explain. Used for quality comparisons **Support clinical decision-making and care coordination** Items about reason and timing of indwelling catheter – useful upon admission, but after that why would there be a need to repeat? Some of this information is already difficult to collect, so will the reliability be what is desired to have validity? **Feasibility** **Feasibility for use in PAC** Time consumption is a great concern – staff already finding it difficult to get care delivered timely throughout the shifts. Instructions are to interview resident and review medical records – where will all of this information be documented so that it could be carried forward, and will it be accurate? **Clinical appropriateness** Would seem that augmentation questions related to bladder repair should be considered – history of interventions tried. Concern as to what survey ramifications will be tied to these types of questions. **Can the data element be used with different payment models**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Redundancy remains a concern as does true value of items in terms of what can be done to improve the resident's quality of life. **Does it measure differences in patient severity levels related to resource needs** Seems to be no more relevant information than already collected on the MDS. **<u>Medical Condition – Continence Bladder Incontinence Use</u>** **General Comments** We do like items asking about incontinence prior to hospitalization, but ability to get reliable information is a concern. For both bladder and bowel, facilities already have a difficult time getting the nursing assistants to document the ADLs accurately. Are facilities going to receive additional funding to ask the nursing assistants to do more than we already ask them to do? Wages and ability to provide good benefits are already a huge problem for the SNFs, as is sufficient staff. Can we pay nursing assistants enough to ask for more documentation? The nurse on the unit will generally not know the information to chart. **Ability to improve care transitions through meaningful exchange of data between providers** Repetitive – similar to the MDS. **Improve person-centered care and care planning** No additional value beyond the MDS. **Validity** **Whether it captures the patient attribute being assessed** Redundant and time consuming.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Proven or likely inter-rater reliability Information prior to hospitalization is very difficult to gather for some SNF residents. **<u>Medical Condition – Continence Incontinence Interview</u>** **General Comments** Another interview might not be appreciated by the residents, as currently they often voice frustration with the number of interviews, interruptions. Another look- back time frame – continues to add to time consumption and possible confusion and resultant reliability concerns. **Used for quality comparisons** Answer options very subjective and difficult to define. **Support clinical decision-making and care coordination** Incontinence is always a problem – question the value of defining different levels of the problem – small, moderate, big. **Validity** **Whether it captures the patient attribute being assessed** Again, question if there is a cut-off time built into these additional items. **Feasibility** **Feasibility for use in PAC** Redundant and time consuming.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Can the data element be used with different payment models Will the resident's responses or caregiver's responses be used – which would be considered more reliable? **<u>Medical Condition – Continence Devise Use</u>** **General Comments** Another interview might not be appreciated by the residents, as currently they often voice frustration with the number of interviews, interruptions. Another look- back time frame – continues to add to time consumption and possible confusion and resultant reliability concerns. Are there going to be guidelines for when interview could stop? Again we have a concern about health literacy and whether assessor will have time to define and explain. **Potential for improving quality** Please see previous comments related to a urinary incontinence device. **<u>Medical Condition – Continence Bowel – Incontinence</u>** **General Comments** We do like items asking about incontinence prior to hospitalization, but ability to get reliable info is a concern. For both bladder and bowel function we have a difficult time getting nursing assistants to accurately document ADLs – do we pay them enough to ask for more documentation? Doubt nurse will generally know the information to chart. **<u>Medical Condition – Continence Bowel – Incontinence Interview</u>** **General Comments**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Another interview might not be appreciated by the residents. Incontinence is always a problem – question the value of the value of different levels of the problem – small, moderate, big. **Validity** **Whether it captures the patient attribute being assessed** Answer options very subjective – small, moderate, big. **Clinical appropriateness** The directions are to ask the resident, to ask the caregiver, to review documentation – but who is going to document all of this? Great concern that these items are setting up facilities for survey issues. What is the purpose of gathering the information? Question related to no bowel output: what is the look-back? **Medical Condition – Pain Pain Frequency** **General Comments** Now a 3-day assessment period – too many different time frames to track for conducting the assessments. We continue to have issues with validity of MDS pain assessment now – what will change with the addition of these items? Value of these items compared to the pain assessment on the MDS is questioned. Where is the reassurance that these items would replace and not be in addition to items already on the MDS? What is the difference between severe and very severe? Maybe use "horrible" so they are different. Why not use mild, moderate, severe? **Potential for improving quality**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Ability to improve care transitions through meaningful exchange of data between providers The issue here is that the item is redundant, as it is already on the MDS. **Support clinical decision-making and care coordination** These items related to pain are missing one of the most difficult issues of pain management – drug seekers. Along this line of thinking, we would suggest a gateway question about drug-seeking behaviors. **Validity** **Whether it captures the patient attribute being assessed** Pain questions just like on the MDS – the options are vague and too similar. **Feasibility for use in PAC** Repetitious. **Medical Condition – Pain Pain Severity** **General Comments** Options are not easy to differentiate – "severe" versus "very severe, horrible"? Potential for improving quality **Ability to improve care transitions through meaningful exchange of data between providers** Same a MDS – not needed. **Improve person-centered care and care planning**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Pain management is always important and is a huge part of person-centered care. Perhaps instead of repetitious questions, it would be more beneficial to provide tools and educational programs so there is value placed on sleep-hygiene programs. **Validity** **Whether it captures the patient attribute being assessed** Due to unclear answer options we do not feel the item is valid. **Clinical appropriateness** Already on the MDS – no need to add to workload. **Medical Condition – Pain Pain Effect on Sleep** **General Comments** Very subjective. Residents are often known to say that they did not sleep, but resident appeared to be sleeping during each check. **Ability to improve care transitions through meaningful exchange of data between providers** Value of item questioned. **Improve person-centered care and care planning** The item could be helpful to determine need for sleep- hygiene program. **Used for quality comparisons**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Environmental factors have big impact on sleep in PAC settings. Not all of these factors can be changed or modified. **Validity** **Whether it captures the patient attribute being assessed** We believe that a gateway item is needed for these pain items, as there is a certain proportion of the population that does seek drugs. **Medical Condition – Pain Pain Interferene – Therapy Activities** **General Comments** Therapy activities – all put together – how can that be helpful if do not know which therapy caused pain? **Validity of item questioned** when thinking about SNF residents, who generally have had surgery or have been acutely ill and therefore the occurrence of pain would not be unusual and would not mean that the therapy was not medically necessary. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Concern that this item might have an impact on Medicare Part A coverage. If resident is experiencing pain, this item seems to indicate that the therapy is not appropriate. **Medical Condition – Pain Pain Interferene – Other Activities** **General Comments**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Other activities – is it due to pain or a lack of interest? Resident may not like what is being offered. Some would still go even if in pain, if they liked the activity. Consider a clear definition of activities, e.g., group facility activities, in-room activities, "active" activities. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Subjective and question validity. **Validity** **Whether it captures the patient attribute being assessed** No, due to limitations of the question. **Feasibility** **Feasibility for use in PAC** No, as stated above. **Rain Relief** **General Comments** In general we would want to make sure that these pain items are going to be linked to opioid addiction. **Improve person-centered care and care planning** Answer options are not well differentiated – some, quite, very much. We believe this lack of clarity will decrease validity and reliability.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Validity **Whether it captures the patient attribute being assessed** No, due to weak answer options. **Feasibility** **Feasibility for use in PAC** No, as stated in comments above. **Observational Assessment of Pain or Distress** **General Comments** Like the items about using regularly – although accuracy could be an issue. Will need clarification for the term "regularly." **Medication Reconciliation – Completion** **General Comments** Trying to determine current medications (prior to the first setting in PAC) will be difficult – it already is a problem in SNFs. Would seem that a better question would be whether the facility received a medication list from the previous provider. We believe this type of question would get to the current problems. **Ability to improve care transitions through meaningful exchange of data between providers** Seems to be linked to a facility's process, since the regulations are going to require medication reconciliation.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Validity **Whether it captures the patient attribute being assessed** Since medication reconciliation is a federal requirement, it does not seem relevant for the MDS. **Feasibility** **Feasibility for use in PAC** It is an important item across the PAC settings, but will CMS hold all settings accountable? SNFs currently have issues with getting medication records from the hospital. **Can the data element be used** Do not consider this a part of case mix. **<u>Medication Reconciliation – Use of Medications in Specific Classes</u>** **General Comments** Value of "days" information – medications would still need to be care planned. Could lead to survey deficiency if count is not accurate; seems to be process issue rather than outcome focus. **Potential to be standardized and made interoperable across settings** Already a part of the MDS, but additional classifications added. Confusion with definitional terms such as antiplatelet versus anticoagulant. Question value of additional categories, as they will not really change care planning. If the medications are similar, suggest drug categories can be combined because of similar effects. **<u>Medication Reconciliation – Indication</u>**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Item appears to be more regulatory. Knowledge of indications for medication should be known before the medication is given the first time. Wording of question leads the assessor to answer "yes," which makes it not a valid condition. **Feasibility** **Feasibility for use in PAC** No, as validity would be in doubt. **Can the data element be used with different payment models** Could lead to gaming of the system. **Medication Reconciliation – Discrepancies** **General Comments** Wording of question could lead assessors to answer "yes" and then the item would not be valid. Could lead to "gaming" the system. If assessor needed to answer "no," would get the problem fixed before submitting and change response to "yes." Seems to be more related to policy and reflective of process. These medication reconciliation items are misplaced and are related to policy and surveillance. **Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement** **General Comments** Items do not seem relevant for the MDS. More about mandating process – there is no value in mandating process by using the MDS. **Medication Reconciliation – Discrepancies Communicated to Physician**	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Another item that relates to mandating process and not appropriate for the MDS. No value in mandating process by using the MDS process. **<u>Medication Reconciliation – Recommended Actions Taken</u>** **General Comments** Perhaps a general question regarding addressing discrepancy and whether it was followed – regardless of the drug classification. Related to process and no value to SNF providers to have on the MDS. As noted above, these items encourage "gaming." **<u>Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy</u>** **General Comments** With the revision to the Requirements of Participation, this would be addressed on the baseline care plan that is due within 48 hours of admission. **Validity** **Whether it captures the patient attribute being assessed** No, as looking at process related to a survey requirement. **Feasibility** **Feasibility for use in PAC** Duplicative, since baseline care plan must be in place within 48 hours of admission.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Can the data element be used with different payment models No. **<u>Advanced Care Directives – Healthcare Agent (Chart Review)</u>** **General Comments** This item was removed from the MDS 2.0, so question reason for putting it back. Question benefit of putting back on the MDS, especially with the new Requirements of Participation, which make a greater tie to the resident's representative than to legal piece of paper. **Potential for improving quality** **Ability to improve care transitions through meaningful exchange of data between providers** Item does not appear to be necessary for the MDS. In addition, the state laws will still trump the Requirements of Participation as far as care planning and the SNF navigating multiple involved parties. **Validity** **Whether it captures the patient attribute being assessed** Could be valuable, as it guides safe transfers to identify that there is a legal document in the medical record about a healthcare agent. **Feasibility** **Feasibility for use in PAC** Next provider must validate that the information is still current, but it is not common practice to go to the MDS for this information.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Physician Orders (Chart Review) **General Comments** Value of this item on the MDS does not seem to be pertinent. Item relates to process. Would not go to the MDS for this information. **Goals of Care (Chart Review)** **General Comments** Pertinence of this on the MDS questionable; does not seem to be of value. Appears to be a process item and not related to outcomes. **Preference for Involvement of Family/Friends in Care Decisions (Patient Interview)** **General Comments** Answer options are not definitive. We question the difference between some of the options such as "somewhat important" versus "not very important." Suggest considering these answer options: "yes" and "no." **Ability to improve care transitions through meaningful exchange of data between providers** No, answer options are not clear and concise. **Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview)** **General Comments** Repetitious of Section Q – value is questionable. Question of where this item leads a facility to go for information.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Potential for improving quality **Ability to improve care transitions through meaningful exchange of data between providers** We suggest some interconnectivity or skip pattern based on cognition. **Validity** **Whether it captures the patient attribute being assessed** No, answer options are not clear and concise. If resident selects "some information," what would that be? We do not believe staff would be able to understand what information the resident did or did not want to know. **Feasibility** **Feasibility for use in PAC** Does not seem feasible for the SNF. **<u>Sleep Disturbance</u>** **General Comments** More time frames – too many questions, too many interviews. Residents consider them an intrusion. It is difficult to differentiate among the answer options. The concept of cue cards with the answer options is not totally acceptable to residents. **Whether it captures the patient attribute being assessed** No, for reasons stated above.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		<u>Fatigue</u> **General Comments** Too many questions, too many interviews – residents have interview fatigue. Items are not necessary. **Whether it captures the patient attribute being assessed** No, as stated above. **<u>Ability to Participate in Social Roles and Activities</u>** **General Comments** Too many questions. Too many interviews. Time needed for these items is beyond the facility's capabilities. Potential for improving quality **Ability to improve care transitions through meaningful exchange of data between providers** No, not needed. **<u>Global Health</u>** **General Comments** More items that are redundant and repetitious when already completing the MDS. Items are not necessary. Answer options are unclear and very subjective, with no clear meanings. Judi Kulus, RN, MSN, MAT, NHA American Association of Nurse Assessment Coordination (AANAC)	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
CERNER	6/26/17	Dear Madam, General An overall perspective of these recommendations is a concern of the significant increase in size of the patient assessments. Most of the assessment items indicated in this request are like/similar to data elements already collected in most of the Post Acute Care (PAC) settings. The RAND comments noted many of their assessment questions did not have a same or similar element in assessments other than MDS. We would like to urge RAND to reconsider those statements and review the current, and proposed FY2018 versions, for similar data elements to reconcile. We encourage CMS & RAND to carefully consider potential duplicative nature of the data elements and remove those which do not provide the level of detail another element may cover, even if they are not exact in wording. We can imagine not only the frustration of the caregiver but especially the patient with regards to the number of assessment questions and having to answer questions which seem similar in nature. This proposal adds 206 data elements which are required to be answered (some are multiple responses within one question). We also encourage CMS & RAND to review their expectations of PAC's to incorporate assessment information from other venues of care into the current assessment. There are current requirements for PACs to do their own assessment and cannot 'copy answers' from another assessment. Based on reasoning provided in the commentary of this public comment opportunity, we feel CMS expects data to be transferred from one venue of care to another through the assessment tool. We would like to see CMS clarify their provider assessment expectation and remediation of existing rules, if this is the case. Developing Outpatient Therapy Payment Alternatives (DOTPA) This information is already collected within a Brief Interview for Mental Status (BIMS) interview and Section GG for Abilities and Goals in the Skilled Nursing Facility (SNF) Minimum Data Set (MDS) assessment. We feel the addition of these 14 questions is duplicative to what is currently assessed and is unnecessary. The MDS elements could easily be added to other venue specific assessments. PASS Medication Management	Cerner Corporation

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		The Outcome and Assessment Information Set (OASIS) for Home Health Agencies (HHAs) already contains a question which evaluates the medication management. This should be utilized in other PAC venues. Further, we do not believe this is a valid question for facility patients/residents as the facility team manages the medication for the patient. We do not believe there is value to a long stay, not home-bound patient. Staff Assessment of Mental Status The current MDS assessment already incorporates a Cognitive Performance Scale (CPS) and we recommend continued use of this assessment element and potential expansion to other venues of care. We point out that this type of assessment would not be valid in an Inpatient Rehabilitation Facility (IRF) because the patient has limited time in the IRF and information from a 7-day look back period would more than likely come from an acute-facility where the responses are not standardized to a PAC assessment. We do not believe this element would be of value to a PAC PPS case-mix element due to issues with collection of data from short stay patients in the IRF, and the non-standardized observations from other venues of care. Behavioral Signs and Symptoms We feel the OASIS assessment has better questions to evaluate for homecare than what was proposed for this element. We also note, these questions are similar to the PreAdmission Screening and Resident Review (PASRR) assessment for MDS and we do consider the PASRR to be more relevant to both MDS and OASIS. Patient Reported Outcomes Measurement Information System (PROMIS) – Anxiety Items OASIS and MDS both have similar items in their current version which we feel are more relevant than PROMIS.	

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		However, if CMS feels these data elements are crucial, we ask for removal of items which are similar/duplicative in the current versions of patient assessment. Patient Health Questionaire – 9 Observational Version (PHQ9-OV) These elements are currently captured in the OASIS as well as the MDS. We feel these questions are not valid for IRF because the questions are lengthy and not as relevant. CMS has recommended inclusion of the PHQ-2 for implementation in the IRF-IAI v2.0 in FY2018; however, this RAND comment request focuses on PHQ-9. We urge CMS refrain from making substantive changes to the FY2018 IRF-PAI v2.0 regarding the Patient Health Questionnaire until CMS can standardize this element in a way that ensures its relevancy in future revisions. CMS and RAND to work together to develop a cohesive plan for current and future versions of the patient assessment requirements. To do otherwise creates undue burden on the provider to implement/train on a standard which will be changed with the next FY update. Bladder – Device Use We find this data element valid for all PAC assessments and believe it would be highly valuable as a case-mix element. Bladder – Incontinence We believe the wording for this question not work well for the HHA/OASIS process because the question is not based on the family or caregiver; nor does it work for intermittent care. The OASIS assessment already includes a bladder incontinence assessment question which would be facilitated across PAC venues. Other PAC venues (facility based) would benefit from this element and it would be valid for case-mix for those venues. Bowel – Device Use We find this valid for all PAC assessments and it would be highly valuable as a case-mix element.	

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		Pain Interference This is not a valid measurement for HHAs because the patient may not have been ordered therapy activities. Patients in a SNF facility may refuse to answer, however, there is no status to indicate this type of response Observational Pain We encourage CMS/RAND to use standardized industry accepted and validated observational tool methods such as Pain Assessment in Advanced Dementia Scale (PAINAD) and Face, Legs, Activity, Cry, Consolability scale (FLACC), instead of developing a new assessment scale. Glasses/Corrective Lenses & Hearing Aid The OASIS assessment has a much more extensive version of these questions and we would recommend review and use of it instead. Medication Reconciliation – Use of Medications in Specific Classes We feel this data collection point is of significant burden to the provider staff. We do not understand the value in collecting the "number of days" the patient has been on each medication type and how this would contribute to a case-mix valuation. We believe this requirement has little corresponding increase in beneficial outcome for the patient. We believe Medication Reconciliation is of benefit to the patient, and reporting reconciliation information to the next provider of care is important. However, the data collection of the number of days by medication type is not appropriate to the PAC assessment tool to gather this data. If CMS/RAND continues with this data collection point, we recommend other tools to develop a data collection of days by medication type from claims data in the inpatient and hospice settings (medication orders).	

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		We feel this would be an impossible task for providers who do not have Electronic Medical Record (EMR) capabilities and who are therefore at risk for manual counting errors on paper records. Medication Reconciliation – Indications for Use If retained for future use, we feel there should be greater clarification regarding what constitutes medication indication. Please consider providing greater details around: - cancels/reorders of the medication - Timepoint instruction to collect indications for use; does this include anytime they took the medication? - Define the the look-back period - Define differences between an "indication" and a "diagnosis" - Does this cover every time the medication was given? - Provide instructions on provisions for patients who have been on service for years. Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy We find this question of high value to the PAC assessment. We find it valuable in care transitions; except in the case of HHA which does not track or provide prescription orders because they do not place them. Advance Directives We feel this is a good response for care transitions, however it does not affect the development of the clinical plan of treatment and would not be reflective of a case-mix element. Physician Orders Each facility is already required to have a physician order to provide care. Most states require the Medical Orders for Scope of Treatment (MOST) or Physician Orders for Scope of Treatment (POST) already. CMS/RAND should not incorporate a new data element collection point if there is a same/similar element.	

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		The answers to these questions would not change the way the facility treats the patient, as the provider would not make clinical decisions on a transferred order unless it has been verified by the medical director for their facility. We feel this is purely informational and not sure it has relevancy or case-mix value. Goals of Care This question is based on a yes/no response if there is documentation of a conversation which took place and if the documentation had an indication of specific goals. It does not require medication list or transfer of patient goals for care during a transition. For this reason, we feel this element does not have patient value for a transition of care or for case-mix development. Preference for Involvement of Friends/Family in Care Decisions This question has limited response to "how important is it" on a Likert scale. This limited response does not provide value at transition of care or in case-mix development. Preferences for Involvement in Decision Making (Patient Interview) This question has limited response to "how important is it" on a Likert scale. This limited response does not provide value at transition of care or in case-mix development. PROMIS (all items) We feel this includes too many questions which are duplicative of prior questions and does not provide any case-mix value. We do not argue with the inclusion of the assessment but we do not see the value in the extent of questions being asked. There is usefulness in the information, but 10 questions on four focus areas (total of 40	

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		questions) for sleep disturbance, fatigue, ability to participate in social roles and activities and global health seems like excessive burden on the provider. These could be delivered/collected in a more concise manner.	
ANON	4/26/17	The resources utilization for a SNF is menial to the advocacy levels rendered or available for the beneficiaries. Letters of medical necessary, aquired, care plans excluded, pre-authorization form are available and facility staff and vehicle transportation un-utilized. I hope these changes force care providers to utilize resources available to improve quality of life for in-house and future residents.	Anonymous
LTHOMAS	4/28/17	I'm a senior citizen and have watched health care from when doctors would come to your house to treat you, to person centered care. I believe in general that the best care I've received was before government restrictions were in place and decisions were made by the patient and the doctors who the patient chose to treat them. Where the worst treatment, in my opinion, is found at the clinics such as the VA and other clinics. Competition between medical doctors and facilities is what makes for the best treatment. Also reports are required by doctors, but what about patients? They are the ones who can determine if they got good treatment or not. For instance I was, in my opinion, mistreated and suffered for it. I had 5 years to bring a lawsuit. That is what keeps doctors doing their best. Not reports. I believe all that will do is keep good doctors from accepting patients with government benefits, leaving patients no choice but to see 'bad' doctors. These doctors will flock to clinic settings. If you want the best treatment for patients, ask the patients who is better to care for them. I've seen my share of good and bad practices. I believe this testimony is not considered but is the only testimony that should be considered.	Lynn Thomas
PCEDC	4/28/17	The use of Cognitive assessment tools in the PAC setting is critical to determine how care can be provided in the most effective way. The use of the Functional Assessment Staging tool (FAST)as well as the Confusion Assessment Method (CAM)and Delirium Index(DI) allows clinicians to differentiate between those elders who have a cognitive impairment vs. those that may have delirium. Both pieces of information are critical to determine acuity of the patient. Those patients with established severe cognitive impairment, be it from dementia or delirium, require greater amounts of care. In the experience I have had over the past 5 years working on a PAC project directed at individuals being admitted to SNF from the hospital setting. I have found the tools (FAST, CAM, DI) to improve my ability as a physical therapist to establish a plan of care that is most appropriate for the type of cognitive impairment present. I have been using the FAST for the past 5 years and the CAM and delirium index for the past 6 months; both are easy to use in PAC. The FAST takes 1minute to complete and the CAM takes 1-3mintues to complete. The delirium index takes about 3 minutes to complete. With the vast amount of elders coming to PAC with some type of cognitive impairment it is critical to assess this information comprehensively. In the program I work, the use of the tools has allowed decreased rehospitalization as well as reduced length of stay due to the ability to tailor care to the elder’s needs.	Phoebe Center for Excellence in Dementia Care

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Below are outcome measures collected by use of the CARE tool that support the need for greater assessment of the cause of cognitive impairment using the listed tools to allow programs to support the elder's needs in a person centered approach. Below you will also find the validity of the tools. Thank you for your time. BioPsychoSocial Assessment Tools for the Elderly - Assessment Summary Sheet Test: Functional Assessment Staging Test (FAST) Year: 1984 Domain: Biological, Psychological, Social Assessment Tool Category: Dementia/Alzheimer's Variations/Translations: N/A Setting: Clinical, in-patient or community-based Method of Delivery: Individual is assessed by a primary care-giver or by a person with a high level of familiarity with the patient. Description: The FAST was developed for use with Alzheimer's disease (AD) patients to stage a patient's level of disability with respect to AD. The FAST is comprised of 7 major levels of functioning (from normal adult to severe AD); levels 6 and 7 are additionally divided into substages (11 total). The FAST is derived from Axis V of the Brief Cognitive Rating Scale (BCRS) (Reisberg et al., 1983), which itself is derived from the Global Deterioration Scale (GDS) (Reisberg et al., 1982). The stages and substages are thus designed to correlate with the GDS global level of cognition and functional capacity measures (Sclan & Reisberg, 1992). Scoring/Interpretation: The FAST stages AD from levels 1 to 7, with level 1 representing a normal adult and level 7 representing severe AD. Thus, the higher the stage, the higher the disability level of the patient with respect to AD. Scoring is based on the highest level of consecutive disability (Sclan & Reisberg, 1992). Time to Administer: Variable, depending on the rater's familiarity with the patient and the time required to determine disability. Availability: Available from Dr. B. Reisberg (Langone Medical Center, NYU) at no cost. Software: N/A Website: N/A Quantitative/Qualitative: Quantitative Validity (Quantitative): Concurrent validity of FAST with other psychometric and mental status assessments, including the GDS, has been established (Reisberg et al., 1984; Sclan & Reisberg, 1992).	

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		Pearson correlations between FAST and ten independent psychometric test measures ranged from 0.59 to 0.73. The Pearson correlation between FAST and the Mini-Mental State Exam (MMSE) was 0.87 (Reisberg et al., 1984). Correlation between FAST and the Ordinal Scales of Psychological Development (OSPD) was reported to be -0.60 to -0.79 for individual subtests and -0.79 overall. Ordinality of the FAST scale was determined by calculating the coefficients of reproducibility and scalability, which both demonstrated that the scale had strong validity. The coefficient of ordinality, which measures the degree to which a sample of responses approximates a unidimensional scale, was reported to be 0.9933 (>0.9 indicates a valid scale). The coefficient of scalability was reported to be 0.9827 (>0.6 indicates a truly unidimensional and cumulative scale) (Sclan & Reisberg, 1992). Reliability (Quantitative): Rater consistency (fixed effect) and rater agreement (random effect) were calculated using the intraclass correlation coefficient (ICC); excellent reliability was reported (fixed effect ICC = 0.86; random effect ICC = 0.87) (Sclan & Reisberg, 1992). References: Reisberg, B. (1988). Functional assessment staging (FAST). Psychopharmacology Bulletin, 24, 653-659. Reisberg, B., Ferris, S. H., Anand, R., de Leon, M. J., Schneck, M., Buttinger, C., & Borenstien, J. (1984). Functional staging of dementia of the Alzheimer's type. Annals of the New York Academy of Sciences, 435, 481-483. Sclan, S.G., & Reisberg, B. (1992). Functional Assessment Staging (FAST) in Alzheimer's disease: reliability, validity, and ordinality. International Psychogeriatrics, 4(Suppl. 1), 55-69. Confusion Assessment Method (CAM) Validity: Shi Q, Warren L, Saposnik G, MacDermid JC. Confusion assessment method: a systematic review and meta-analysis of diagnostic accuracy. Neuropsychiatric Disease and Treatment. 2013;9:1359-1370. doi:10.2147/NDT.S49520. Delirium Index Validity: McCusker J, Cole M, Bellavance F, Primeau F. Reliability and validity of a new measure of severity of delirium. Int Psychogeriatr. 1998;10:421–433. [PubMed]	
NLR		Transitional Living Facilities (TLFs) are licensed in the State of Florida by AHCA specifically for the purpose of providing post-acute rehabilitative care to individuals who have suffered a neurological injury such as brain and spinal cord injury.	NeuLife Rehab (NLR)

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		How would it be possible to include my organization, www.neuliferehab.com, in the IMPACT effort? We are another step on the PAC continuum and, particularly around the cognitive assessments tools, have valuable insight. Thoughts? Guidance?	
GCARDOZA	5/10/17	Hello, I am writing to state that the expectation of improving cognition in dementia or Alzheimer's patients is not realistic. All the measures that Home Care agencies are reported for, are expected to show improvement. In home care that is not going to happen with cognitively impaired patients and will result in poor scores causing decrease in VBP and STARs, and reimbursement. Also medication reconciliation requires physician cooperation and that is VERY difficult to obtain and should not be the agency responsibility. The agency is already being penalized because physicians are not completing appropriate documentation for the face to face even though the agency is not responsible for the physician. Now we are going to be penalized because physicians are not returning call or f refuse to reconcile medications because they are only covering for another physician. I feel this is extremely unfair to all HCA.	Gale Cardoza RN WCC
EG	5/22/17	Good morning, I wanted to suggest an edit to the IMPACT Act domains posted for public comment. I suggest that the checkboxes on the mutually exclusive items be changed to radio buttons. Many of the questions ask for one answer but a checkbox usually implies inclusivity. Radio buttons are standard for exclusive items.	eyeGENE
PPAL	6/26/17	Thank you for affording an opportunity for members of the general public to comment on the standardized assessment-based data elements as set forth by the IMPACT Act. In reviewing the posted document, Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data (Second Public Comment), I could not help but notice that the 34page review of comments fails to reference the multiple comments re the need to inclulde data about assistive devices.	The PPAL

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		I note that Section GG of the MDS, appears to measure changes, positive or negative, in an organization's ability to optimize self-care or mobility while a resident is in their care. These new functional quality measures allow comparisons among providers on the degree to which they succeed in enabling their care recipients to either (1) function independently without the need for caregiver assistance or (2) rely on the lowest of four levels of caregiver assistance; recognizing that some residents may arrive and remain fully dependent on caregivers. Section GG is indifferent to the use of assistive devices, measuring only the need for personal assistance to determine the level of disability. Where, in all the data being collected, will providers share the fact that the reported improvement in independence was due, not only to personal assistance but to the use of a particularly effective assistive device to achieve that independence. Please see the work of Vicki Freedman for more on the mix of personal assistance and equipment use by those living with disability: Kasper JD Freedman VA Findings From the 1st Round of the National Health and Aging Trends Study (NHATS): Introduction to a Special IssueJ Gerontol B Psychol Sci Soc Sci (2014) 69 (Suppl 1): S1-S7 doi:10.1093/geronb/gbu125 at http://psychsocgerontology.oxfordjournals.org/content/69/Suppl_1/S1.full.pdf+html and Talley KMC, Wyman JF, Bronas UG, Olson-Kellogg BJ, McCarthy TC, Zhao H. Factors Associated with Toileting Disability in Older Adults without Dementia Living in Residential Care Facilities. Nursing research. 2014;63(2):94-104. doi:10.1097/NNR.0000000000000017. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947551/. Surely, there are public policy reasons to want to know who is independent only because they are successfully accommodating their challenge with equipment; Right now, such a person would score as fully independent because they do not need personal assistance. That is only HALF the story but there will be NO WAY to know. In full disclosure, the frustrations of toileting care for our mother, now deceased, who aged with post-polio syndrome led my family to not just "grin and bear it" - Upon her death, we took her frustrations and came up	

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		with an improved design for a bedside commode which is now with Edison Nation Medical for commercialization. Change is possible, but we NEED data to measure the impact of equipment just as we need it to measure the impact of personal assistance. The data exists in the claims paid by insurers and payers for such equipment.. Yes, I know the HME/DME industry suffered a severe reputational blow due to its highly public bad actors (The Scooter Store) but clients/residents and their families should not pay the price for that. Please look into this further. It REALLY matters.	
GHS	6/11/7	As the Director of Regulatory Affairs for a healthcare group that provides home health services in multiple states, I appreciate this opportunity to comment on the proposed post-acute care (PAC) assessment data. The IMPACT Act of 2014 mandated the standardization of certain assessment data for post-acute care settings. The goal was for the data to be standardized and interoperable for exchange among providers to provide access to longitudinal information to facilitate coordinated care and improve Medicare beneficiary outcomes. With these goals in mind I have reviewed the proposed assessment data and have the following comments: 1. I can understand the potential gains from having certain common data collected from PAC providers. There would be a benefit to comparing outcomes of care and to enhancing PAC communication/transitions, but in reviewing the proposed assessment questions I fail to see how this will be accomplished and what information will be shared at transitions that is not already shared. a. Are the questions for admission and discharge? This is not clear. Questions asked at discharge can only be used for quality improvement, not for payment and or risk adjustment. b. The assessment of a patient entering a skilled nursing facility (SNF) is often very different from the same patient's home health (HH) assessment sometime later. The information gathered at the HH admission is the basis for the plan of care, along with the documents received from the SNF about the patient history, medications, and treatments. 2. The questions are needlessly complex and lengthy, which will create a tremendous burden on a home health agency's resources. I have worked with OASIS assessments since 2000 and those questions (see at end of comments) are much more concise and have been used successfully for	Graham Health System

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		payment and quality improvement. Why such detailed questions? What will be the usefulness of these lengthy questions? Will the corresponding OASIS questions be removed or will HHAs be required to complete both? Again this will be a tremendous burden on staff and agency resources and to what end? Burden of Cost & Time to Task: (conservative estimate)	

Item	Time to Complete	Per Patient Cost to Complete (Average per/hr wage $40)	Agency Cost for 70,000 Admission/year	Training 1500 st
DOPTA: 14 questions	15 minutes	$10	$730,000/year	$30000 i 30 minu
Complex Sentence Repetition: 2 questions	7 minutes	$5	$365,000/year	$15000 i 15 minu
PASS Medication Management: 5 questions	15 minutes	$10	$730,000/year	$15000 i 15 minu
Staff Assessment of Mental Status: 6 questions	10 minutes	$7	$511,000/year	$15000 i 15 minu
Behavioral Symptoms: 11 questions	10 minutes	$7	$511,000/year	$15000 i 15 minu
PROMIS Anxiety Assessment: 11 questions	10 minutes	$7	$511,000/year	$21000 20 minu training cost of cue car

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PHQ9: 20 questions	15 minutes	$10	$730,000/year	$15000 initially for 15 minutes	
Pain: 10 questions	10 minutes	$7	$511,000/year	$15000 initially for 15 minutes	
Medication Reconciliation: 8 questions	10-20 minutes	$7 to $15	$511,000/year to $1,095,000/year	$15000 initially for 15 minutes	
Care Preferences: 6 questions	5 minutes	$3.50	$255,500/year	$15000 initially for 15 minutes	
Incontinence: 19 questions	10 minutes	$7	$511,000/year	$10000 initially	
Sleep/fatigue/Activity: 33 questions	15 minutes	$10	$730,000/year	$30000 initially for 30 minutes	
Global Health: 10 questions	5 minutes	$3.50	$255,500/year	$15000 initially for 15 minutes	
Totals	137 minutes	$94	$6,351,000/year		$226,000
Additional expense: Pill boxes for patients ~ $219,000 annually					

3. Many of our patients do not come from a facility but are community referrals. The information we receive is from a physician's office and is usually limited to a medication list, history and physical, and a copy of the previous physician visit. The proposed questions are focused on patients received from facilities.

4. The current time points for HH OASIS data collection and transmission to CMS are at Start of Care, Resumption of Care, Transfer, Significant Change in Condition, and Discharge. Will these timeframes change? What is the plan for the items that are 'a 2 day period, 7 day look back, and 2 week look back'? Will these be new assessments (which would be an additional burden)? Will visits be mandated to complete these? What if these visits do not fit with the ordered visit pattern,

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		are we expected to complete a 'non-billable' visit in order to obtain the information? Or what if there has not been a visit in 7 days (based on physician orders), how would an agency complete the 'look back'? In an inpatient facility the staff are there 24/7 and there are multiple people to interview and a 24/7 medical record, but this is not the case in home health. Speaking as someone with 39 years of experience in healthcare, with the last 23 in home health, I can tell you that the questions are biased towards inpatient facilities. Home care is very different. We are in someone's home. We stay and conduct care at their discretion. It is not an environment that we can control. We cannot go into a home and spend hours observing them. We have orders for the number and frequency of the visits. You usually spend 1-2 hours with the patient at admission and then 45-60 minutes with the patient 2 to 3 times a week for 2 to 8 weeks. This is a very limited exposure to a patient's habits, living environment, and care. Many people live alone and have no one there to assist in the care or assessment of the patient between visits. 5. Many of our patients are what we call 'Therapy Only.' In other words, only physical therapy (and perhaps occupational therapy too) have been ordered. Skilled nursing has not been ordered. Therefore, some of the questions will not align with a therapist's training and expertise. Are you going to mandate 'non-billable' skilled nursing visits to complete assessments? Again, that would be a tremendous cost and burden. 6. The document mentions that OASIS does not address medication reconciliation or notifying the physician of medication issues, but there are questions on the OASIS which address these topics. Please see below questions M2001, M2005, and the multiple questions about medication management. 7. DOPTA Instructions state: a clinician with experience doing cognitive assessments will review the medical record; conduct interviews with staff; interview any others who interacted closely with the patient/resident, including family, friends, and caregivers; and observe the patient/resident in a variety of situations. The information is collected within a 2-day assessment window. a. 14 questions which would be time consuming and a burden. b. "Clinician with experience doing a cognitive assessment"…what does that mean? Will only certain clinicians be allowed to assess? What about the patients that are	

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		only physical therapy and do not have orders for skilled nursing? How can a home health agency compile this information from an admission visit (during which many other things have to be accomplished) and one additional visit the next day? There is no medical record for 24 hours of daily care to review as there is in an inpatient facility. Will the visit day 2 be mandated? What if the physician orders differ and no day 2 visit is ordered – must a non-billable visit be done? What if the patient refuses to have a visit the next day (patients often limit access to their home)? c. Why so many questions on this when the information has been gathered for years in the OASIS with a few far simpler questions? 8. PASS Medication Management Instructions state: assess the patient's/resident's ability to manage medications by asking him or her to perform tasks including finding, reading, and understanding medication directions and putting pills correctly in a pill box. This task measures cognitive skills for activities of daily living and daily decision-making. There are two versions, one for a clinic setting and one for home, which are identical except that the home version has patients use their own medications. a. Pill box? Many patients do not have a pill box. Are we mandated to buy one for each patient? We could not use the same one for multiple patients because of infection control issues. Also, there are patients whose family members visit the patient and fill a pill box for them and then remove the medication bottles from the patient's home. b. This is a time consuming process and will be a burden to HHAs. 9. Staff Assessment of Mental Status Instructions state: the assessor determines patient's/resident's long-term memory status by reviewing memorabilia (photographs, memory books, keepsakes, videos, or other recordings that are meaningful to the patient/resident) with the patient/resident or observing responses to family who visit. The assessor observes if the patient/resident remembers facility or home routines. These observations should be made by staff across all shifts and departments and by others with close contact with the patient/resident. The assessor asks direct care staff across all shifts and family or significant others about the patient's/resident's short-term memory ability. The assessor also	

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		reviews the medical record for indicators of the patient/resident's short-term memory during the **7-day look-back period**. a. If the patient does not want the staff to handle their photographs etc., we cannot. We are in *their* home. There is often no family member present (or available to call) when we visit, so there is no one to ask. Since the medical record is from the intermittent visits of HHA staff, there is no 24 hour record. b. 7 day look back period? Is this a separate assessment to be completed and transmitted to CMS after the start of care? This would cause an additional burden for time to complete and transmit to CMS. c. What are we to do if there has not been a visit within the last 7 days (per physician orders) and there is no family? 10. Behavioral Symptoms Instructions state: These data elements follow up on the 7-day look-back period used in Behavioral Symptom – Presence & Frequency. Response is based on review of the medical record, staff interviews, and interviews with others who observed the behaviors identified. Next, assessors are instructed to record whether and how often the resident rejected evaluation of care that is necessary to achieve the resident's goal for health and well-being. The Rejection of Care data element also has a **7-day look-back period**, and response is based on review of the medical record and interviews with staff and others who had close interactions with the resident. a. Again, there is often no one to ask but the patient. No other staff. No family. b. 7 day look back – a separate assessment to be transmitted to CMS? c. If this is at discharge, what is the purpose? 11. PROMIS Anxiety Assessment Instructions state: the assessor shows the interview response choices on a cue card and reads each question to the patient/resident. a. There are 11 questions in this set which is time consuming and would most likely not be able to be done at admission since there are already so many other questions to ask. b. Response cue cards? Providing these for all our clinicians would be costly. A facility can have a few sets to be used by multiple staff. We would have to make hundreds of copies since we have over 1500 staff members.	

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		12. PHQ9-OV Instructions state: The data elements that comprise the PHQ9-OV are collected through interviews of staff, family members, and other individuals who know the patient/resident well. Medical records covering the **past two weeks can** also be consulted to look for indications of how the patient/resident has been feeling or behaving. a. There are 20 questions. Very time consuming and a burden. b. There is often no one to speak with except the patient. Many people live alone and have either no family at all or no local family. c. 2 week look back period? Is this another assessment to be completed and transmitted to CMS after the admission but before discharge? If it is at discharge, then what is the purpose since it is not part of payment or risk adjustment? How would this information be used? Quality improvement? 13. Bowel and Bladder Incontinence: a. There are multiple questions here but I do not think all the information is necessary for this assessment. How does knowing why a urinary catheter was placed assist in caring for the patient? b. How will this information be used? c. The extensive questions are time consuming to complete and will be a burden to HHAs. 14. Pain Assessment: a. I certainly agree that pain should be assessed and treated, but I do not think the number of questions (10) assists in the treatments and I do believe they will be a burden to complete. b. How will these extensive questions be used? c. Is this only assessed at admission? What will these questions be used for? 15. Medication Reconciliation: a. Completion: describes the timeframe as a **3 day look back period**. When is this to be recorded? Will there be an additional assessment to be completed and transmitted to CMS? Also, the proposed rules state that OASIS does not assess this, but in fact it does. M2001 asks if a drug regimen review was completed, which by the definition in the CoPs includes medication reconciliation. b. Use of Specific classes:	

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		a. This will be very time consuming to complete and what will the information be used for? c. Discrepancies: a. Why is this broken into so many categories? How will this information improve quality of care? b. The questions are too complex and burdensome. What are the timeframes for the collection of this data? Is it just at admission? If so, I fail to see how these questions (except for the medication reconciliation assessment) will improve outcomes. Many patients do not move between PAC settings, so the data would be collected at only one time point. Also, at times it would be of minimal use to the PAC provider receiving the patient from another PAC provider since patient condition can change significantly. If for improving care transitions, how will these things be communicated across settings? Will these assessments accompany the patient? Each setting uses its assessment for developing the plan of care. Summary: Overall the proposed assessment data is too burdensome, extensive, complex, costly, and time-consuming. In addition, its focus is facility based rather than home care based. Any potential to improve quality would be lost due to the focus on 'answering the assessment questions' instead of providing quality care. The addition of these complex questions (especially if the corresponding OASIS questions are not removed) will decrease the amount of time available to provide quality care. Many questions are unanswered; for example, what are the time frames for completing, will there be additional assessments to complete and transmit to CMS, how will the burden of providing pill boxes be reimbursed, what about therapy only patients, and how will these questions be answered for home health patients who live alone. I strongly urge that the questions be simplified and reconstructed with home care limitations considered. Where is the feasibility of use for HHAs if these questions add such a burden? The definition of interoperability "is the ability of a system or a product to work with other systems or products without special effort on the part of the customer." The questions as currently proposed would require a costly and time-consuming special effort on the part of HHAs to comply.	

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		Additionally, the intended utilization of the collected data is unclear. How will it be used in a payment model if not collected at admission? Again, thank you for this opportunity to comment on this proposal. OASIS Questions Related to PAC Assessment Data **(M1018) Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days**: If this patient experienced an inpatient facility discharge or change in medical or treatment regimen within the past 14 days, indicate any conditions that existed prior to the inpatient stay or change in medical or treatment regimen. **(Mark all that apply.)** 1 - Urinary incontinence 2 - Indwelling/suprapubic catheter 3 - Intractable pain 4 - Impaired decision-making 5 - Disruptive or socially inappropriate behavior 6 - Memory loss to the extent that supervision required 7 - None of the above NA - No inpatient facility discharge and no change in medical or treatment regimen in past 14 days UK – Unknown **(M1240)** Has this patient had a formal **Pain Assessment** using a standardized, validated pain assessment tool (appropriate to the patient's ability to communicate the severity of pain)? No standardized, validated assessment conducted Yes, and it does not indicate severe pain Yes, and it indicates severe pain (M1242) Frequency of Pain Interfering with patient's activity or movement: Patient has no pain Patient has pain that does not interfere with activity or movement Less often than daily	

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		Daily, but not constantly All of the time **(M1700) Cognitive Functioning:** Patient's current (day of assessment) level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands. Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently. Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions. Requires assistance and some direction in specific situations (for example, on all tasks involving shifting of attention) or consistently requires low stimulus environment due to distractibility. Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time. Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium. (M1710) When Confused (Reported or Observed Within the Last 14 Days): Never In new or complex situations only On awakening or at night only During the day and evening, but not constantly Constantly Patient nonresponsive (M1720) When Anxious (Reported or Observed Within the Last 14 Days): None of the time Less often than daily Daily, but not constantly All of the time Patient nonresponsive **(M1730) Depression Screening:** Has the patient been screened for depression, using a standardized, validated depression screening tool? No	

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		Yes, patient was screened using the PHQ-2©* scale. PHQ-2© Instructions for this two-question tool: Ask patient: "Over the last two weeks, how often have you been bothered by any of the following problems?" **PHQ-2©*** a) Little interest or pleasure in doing things ☐0 Not at all 0 - 1 day ☐1 Several days 2 - 6 days ☐2 More than half of the days 7 – 11 days ☐3 Nearly every day 12 – 14 days ☐NA NA Unable to respond b) Feeling down, depressed, or hopeless? ☐0 ☐1 ☐2 ☐3 ☐NA	

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		(M1745) Frequency of Disruptive Behavior Symptoms (Reported or Observed): Any physical, verbal, or other disruptive/dangerous symptoms that are injurious to self or others or jeopardize personal safety. Never Less than once a month Once a month Several times each month Several times a week At least daily **(M1750)** Is this patient receiving **Psychiatric Nursing Services** at home provided by a qualified psychiatric nurse? No Yes **(M2001) Drug Regimen Review:** Did a complete drug regimen review identify potential clinically significant medication issues? No - No issues found during review [Go to M2010] Yes - Issues found during review NA - Patient is not taking any medications [Go to M2040] **(M2003) Medication Follow-up:** Did the agency contact a physician (or physician-designee) by midnight of the next calendar day and complete prescribed/recommended actions in response to the identified potential clinically significant medication issues? No Yes **(M2005) Medication Intervention:** Did the agency contact and complete physician (or physician-designee) prescribed/recommended actions by midnight of the next calendar day each time potential clinically significant medication issues were identified since the SOC/ROC? No Yes NA – There were no potential clinically significant medication issues identified since SOC/ROC or patient is not taking any medications	

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		(M2010) Patient/Caregiver High-Risk Drug Education: Has the patient/caregiver received instruction on special precautions for all high-risk medications (such as hypoglycemics, anticoagulants, etc.) and how and when to report problems that may occur? No Yes Patient not taking any high-risk drugs OR patient/caregiver fully knowledgeable about special precautions associated with all high-risk medications **(M2016) Patient/Caregiver Drug Education Intervention**: At the time of, or at any time since the most recent SOC/ROC assessment, was the patient/caregiver instructed by agency staff or other health care provider to monitor the effectiveness of drug therapy, adverse drug reactions, and significant side effects, and how and when to report problems that may occur? No Yes Patient not taking any drugs **(M2020) Management of Oral Medications:** Patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. **Excludes injectable and IV medications. (NOTE: This refers to ability, not compliance or willingness.)** Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times. Able to take medication(s) at the correct times if: (a) individual dosages are prepared in advance by another person; OR (b) another person develops a drug diary or chart. Able to take medication(s) at the correct times if given reminders by another person at the appropriate times Unable to take medication unless administered by another person. No oral medications prescribed. **M2030) Management of Injectable Medications:** Patient's current ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate times/intervals. **Excludes IV medications.** 0 Able to independently take the correct medication(s) and proper dosage(s) at the correct times. 1 Able to take injectable medication(s) at the correct times if: (a) individual syringes are prepared in advance by another person; OR (b) another person develops a drug diary or chart.	

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		2 Able to take medication(s) at the correct times if given reminders by another person based on the frequency of the injection 3 Unable to take injectable medication unless administered by another person. NA No injectable medications prescribed. **(M2040) Prior Medication Management:** Indicate the patient's usual ability with managing oral and injectable medications prior to his/her most recent illness, exacerbation or injury. a. Oral medications Independent Needed Some Help Dependent Not Applicable a. Injectable medications Independent Needed Some Help Dependent Not Applicable **(M2102) Types and Sources of Assistance:** Determine the ability and willingness of non-agency caregivers (such as family members, friends, or privately paid caregivers) to provide assistance for the following activities, if assistance is needed. Excludes all care by your agency staff. a. **ADL assistance** (for example, transfer/ ambulation, bathing, dressing, toileting, eating/feeding) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available b. **IADL assistance** (for example, meals, housekeeping, laundry, telephone, shopping, finances) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available c. **Medication administration** (for example, oral, inhaled or injectable) No assistance needed –patient is independent or does not have needs in this area	

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		Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available d. **Medical procedures/ treatments** (for example, changing wound dressing, home exercise program) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available e. **Management of Equipment** (for example, oxygen, IV/infusion equipment, enteral/ parenteral nutrition, ventilator therapy equipment or supplies) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available f. **Supervision and safety** (for example, due to cognitive impairment) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available g. **Advocacy or facilitation** of patient's participation in appropriate medical care (for example, transportation to or from appointments) No assistance needed –patient is independent or does not have needs in this area Non-agency caregiver(s) currently provide assistance Non-agency caregiver(s) need training/ supportive services to provide assistance	

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		Non-agency caregiver(s) are not likely to provide assistance OR it is unclear if they will provide assistance Assistance needed, but no non-agency caregiver(s) available **(M2110) How Often** does the patient receive **ADL or IADL assistance** from any caregiver(s) (other than home health agency staff)? At least daily Three or more times per week One to two times per week Received, but less often than weekly No assistance received Unknown (M1610) Urinary Incontinence or Urinary Catheter Presence: No incontinence or catheter (includes anuria or ostomy for urinary drainage) [Go to M1620] Patient is incontinent Patient requires a urinary catheter (specifically: external, indwelling, intermittent, or suprapubic) (M1615) When does Urinary Incontinence occur? Timed-voiding defers incontinence Occasional stress incontinence During the night only During the day only During the day and night (M1620) Bowel Incontinence Frequency: Very rarely or never has bowel incontinence Less than once weekly One to three times weekly Four to six times weekly On a daily basis More often than once daily Patient has ostomy for bowel elimination Unknown	
CAPC	6/13/17	To Whom It May Concern:	Center to Advance Palliative Care

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Thank you for the opportunity to submit feedback on the second round of data elements CMS has selected to meet the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 domains. The Center to Advance Palliative Care (CAPC) is a national organization dedicated to ensuring that all persons with serious illness have access to quality palliative care, regardless of diagnosis, treatment setting, or stage of the disease. Palliative care focuses on maximizing the quality of life for both patients and their families, by providing relief from the pain, symptoms and stress of a serious illness. It is provided at the same time as all other appropriate curative or life-prolonging disease treatments. Studies show that without palliative care, patients with serious illness and their families receive health care that is characterized by inadequately treated symptoms, fragmented care, poor communication with health care providers, and enormous strain on family members or other caregivers.By focusing on priorities that matter most to patients and their families, palliative care has been shown to improve both quality of care and quality of life during and after treatment. Furthermore, because palliative care prevents avoidable symptom crises, it helps to reduce ED and hospital utilization, resulting in overall cost savings. CAPC appreciates the steps CMS and RAND have taken to make the standardized post-acute care (PAC) measures more applicable to patients and/or residents living with serious illness. We offer the following comments for your consideration. Cognitive Function and Mental Status Behavioral Signs and Symptoms (p. 28). CAPC supports the inclusion of the behavioral signs and symptoms items in the PAC assessment which address whether the patient/resident has exhibited any behavioral symptoms that may indicate cognitive impairment or other issues. While we understand that these are primarily intended to measure disruptive behavior, systematically tracking behavioral signs and symptoms in patients/residents can help identify patterns; this is particularly important for non-verbal persons or those with cognitive impairments for whom behaviors are the manifestation of unmet need, including pain, constipation, nausea, bladder obstruction, and other common sources of distress. To increase the likelihood that this measure will improve quality, it is important to ensure that all clinicians are trained not only in how to recognize pain and other symptoms, but also how to treat them effectively. Medical Conditions and Co-Morbidities	

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		Pain: Pain Relief (p. 76). CAPC supports the intent behind the addition of the pain relief measure which asks patients/residents to rate how much relief they have felt from pain due to pain treatments or medications. That said, we suggest that CMS and RAND modify this measure so that it reflects patients'/residents' desire for relief. All drugs have side effects, and patients/residents may decide that the tradeoffs for relieving symptoms are intolerable (e.g., a patient would rather be in pain if it means staying alert). Therefore, while we appreciate the addition of measures that will encourage PAC clinicians to periodically revisit patients to determine if treatment is effective, it is important to first determine what level of relief is desired. If the patient or resident is non-verbal and the goals for care are focused on comfort, behavioral signs of relief should be substituted. Pain: Observational Assessment of Pain or Distress (p. 78). CAPC applauds the addition of this item which requires clinicians to note the presence and frequency of indicators of potential pain and distress for patients/residents who are unable to verbally report or participate in the traditional pain interview. As we have noted in our previous comments, it is critical that there are mechanisms in place to detect pain and other symptoms in people with serious illness who might not be able to communicate clearly. This item, paired with the proposed behavioral signs and symptoms items will help overcome this problem. Continued Gaps in Medical Conditions and Co-Morbidity Measures. While we appreciate the addition of more nuanced pain items in this document, we are concerned that there are still gaps in tracking other symptoms that cause significant distress in older adults and those with serious illness such as breathlessness, nausea, and constipation. As we have seen in this iteration, CMS and RAND have begun considering items beyond those included in current PAC assessments. To that end, we reiterate our previous recommendation that CMS review the Condensed Memorial Symptom Assessment Scale (CMSAS) and/or the Edmonton Symptom Assessment Scale (ESAS) for relevant data elements. Care Preferences Advanced Care Directive: Healthcare Agent (Chart Review) (p. 110). CAPC agrees that it is important to ensure that the patient/resident identify a designated Health Care Agent who is authorized to make healthcare decisions if he/she is unable to make his or her own decisions. That said, this item will only be meaningful if it is accompanied by up-to-date contact information for the agent; therefore, we recommend	

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		that PAC clinicians ask patients/residents if they have discussed the issue with their proxy, and make sure they either obtain the proxy's name and contact information (or that it is already in the record). We also want to note that while this item is currently named "Advanced Care Directive," the correct term is "Advance care directive or advance care planning." Physician Orders (Chart Review) (p. 112). We appreciate CMS's consideration of our previous comments to incorporate items tracking what medical documentation has been completed While we recognize that documented physician orders are only a small component of good quality care at the end of life, it is important to ensure this documentation is available if the patient/resident and physician have taken the time to complete the forms. We want to emphasize that this item will only be meaningful if PAC clinicians can find the documentation easily during an emergency, if it is clear, and if they are trained in how to honor the documentation. This item, paired with the newly proposed Goals of Care items (see below), will help ensure that care is more patient/resident-centered, and will serve to improve quality of life. Goals of Care (Chart Review) (p. 114). CAPC emphatically supports the addition of the two new items tracking 1) if there is documentation in the medical record indicating whether a goals of care conversation took place, and 2) if so, what types of goals were discussed (i.e., physical, emotional, social, intellectual/mental, or other) for specific PAC populations. As we noted in our previous comments, high quality goals of care conversations with seriously ill patients can be linked to better patient outcomes, improved patient and family satisfaction with care, reductions in hospital utilization and unwanted treatments at the end of life, and ultimately a greater likelihood of dying in one's preferred place of death. The construction of the proposed second item in particular will help ensure baseline familiarity with any documentation from previous goals of care conversation. It will also provide an opportunity to follow-up with the patient/resident if anything has changed and/or fill in gaps (i.e., missing types of goals) as appropriate. Again, this measure's effectiveness will be increased if all staff are trained in conducting goals of care conversations, and if there are reliable systems both within and across PAC settings to communicate those goals. Due to concerns about clinician burden, however, we suggest that CMS and RAND develop more detailed eligibility criteria for these new items, rather than apply them universally. For instance, goals of care conversations may not be necessary for patients having an elective	

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		joint replacement, followed by a four-day subacute stay. Cleared focus in the implementation of these items can help ensure that these conversations occur with patients/residents who would most benefit, while avoiding undue burden on PAC clinicians PROMIS® Global Health (p. 139). CAPC supports the proposed addition of the PROMIS® Global Health items. By asking patients/residents to rate their own physical, mental, social, and emotional health – as well as their overall quality of life – clinicians will have more information to make appropriate treatment decisions. Thank you for the opportunity to submit these comments. Please do not hesitate to contact myself or Stacie Sinclair, Senior Policy Manager at Stacie.Sinclair@mssm.edu if we can provide any further assistance.	
IHHC	6/26/17	Thank you for the opportunity to comment on the Data Element Specifications for Public Comment 2. Members of the Illinois HomeCare and Hospice Council are keenly interested in the development of cross-setting patient assessment measures that provide meaningful data to improve post-acute care. Below are IHHC's comments on some of the individual domains and their data elements. We also have the following more overarching concerns, under which many of our more specific remarks fall: • The measurement of tasks or factors irrelevant to or not present in the home health setting • Near-duplication of existing assessment items • Lack of feasibility of some assessment questions or measures in the home health setting, including the assumption that the clinician has contact with the patient throughout the day or on multiple occasions during a 24-hour period, which is extremely rare in home health Cognitive Function and Mental Status DOPTA CARE Question A5c, A5d: Using a call bell is irrelevant to patients in home setting. We suggest re-wording these questions to include asking for help via call bell, verbalization to family/caregiver in home situation, utilizing life line, etc.	Illinois HomeCare and Hospice Council

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		Question A5g, A5h: We suggest adding the names of a caregiver or family member in addition to "familiar staff." IHHC is concerned about the two-day look-back period and where in the care process this assessment is to take place. In a home health 60-day episode, would this be done at recertification time? In home care setting in which personnel are not with the patient 24/7, answering these questions would require a chart review, which are burdensome to RNs who spend most of their time in the field and typically rely on supervisors or managers to review charts when necessary. Complex Sentence Repetition We do not understand how this is tied to quality of care. If the patient cannot repeat the question after the third time, in what care step or process is improvement looked for, and what would that indicate about the post-acute care provider? Asking the patient to answer two separate questions, and if not correct repeating three times each also may be excessive and burdensome. PASS Medication Management The example does not provide a visual for SUBTASK 2, but instead duplicates SUBTASK 3. Overall, the test is visually difficult to follow. Verbal assistance, visual assistance and physical assist each has three boxes; is the care provider to give the patient/resident three chances? Not every patient has a medication box, and this task would require nurses to carry pill boxes with them from home to home, which could be cost-prohibitive and also pose an infection risk. Staff Assessment of Mental Status Question A1c: Knowing the location of one's own room in a facility is irrelevant to home health. This question could be removed, or a more universally pertinent question (such as knowing the town or state the patient lives in) could be substituted. We are concerned about the seven-day look-back period and, again, where in the care process this is to take place in the context of a home health 60-day episode.	

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		Behavioral Signs and Symptoms This is a LTC rule/assessment. To make this apply across all post-acute care settings, the language would have to be changed to reflect all patient dynamics. PROMIS Anxiety Items IHHC believes that 29 items for an anxiety assessment is very excessive for a home health RN to conduct on the start of care assessment tool. Patients are coming home sicker and quicker, and the assessment already takes several hours to conduct in the home and outside the home. Many patients will not be able to tolerate such in-depth tool. The cost burden on home health agencies could also be considerable. We estimate this assessment alone could limit an RN to only completing one admission visit per day. We suggest a smaller set of initial questions and a more in-depth assessment if initial results warrant it. Patient Health Questionaire-9 Observational Version (PHQ9-OV) With 20 questions, this tool is again too burdensome and excessive for an RN to conduct on the start of care assessment. Home health agencies currently use PQ-2, which could easily be made standard across post-acute care settings. Regarding behavioral health more generally, IHHC suggests a thorough rethinking of how behavioral health assessments are measuring or contributing to improvement, as well as the place of post-acute care in the behavioral health continuum. It is unclear to IHHC how these in-depth tools will lead to better behavioral and cognitive health among our patients. Medical Conditions: Continence IHHC believes that the focus on the impact of incontinence on caregivers is welcome and would be beneficial. Medical Condition: Pain Pain Frequency	

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		This question (along with most of the questions in this domain) is limited to individuals who can verbalize their pain levels and will not apply to those who are non-verbal or dementia patients. Also, most home health agencies are now computerized, and the nurses do not carry written forms with them, making it difficult to ask a patient to point to the response on a form. Pain Severity Again, this question is only applicable to individuals who can verbalize their interpretation of what their pain levels are, excluding non-verbal patients or dementia patients. Pain Interference-Therapy Activities IHHC is not certain that this quality measure applies to all unique post-acute care providers. For example, the patient may be getting therapy in a LTC or SNF but not at home during the episode. Observational Assessment of Pain or Distress This requires a three-day clinical look back at the record for all clinical notes related to documentation of patient's pain. It also requires multiple interviews of all staff and direct observation. Patients/residents must be observed twice daily; this is impossible in the home care setting. Medication Reconciliation Question F1b: Medication reconciliation is already required; thus, answering a question related to the process may not improve quality of the process. Home health patients enter the program with prescriptions/medications. If there are discrepancies between a medication profile and medications in the home, the physician is notified, as indicated in OASIS M2003. Answering the question is redundant and does not meet any new need/desired outcome. Completing this within three days will be difficult due to physician offices and staffing, especially over the weekends and holidays. As in many areas, there is the potential for home health agencies to be penalized for the lack of a physician response.	

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		Question F1c: While the potential to improve quality exists by identifying medication classifications, indicating the number of days is neither feasible, nor beneficial to the agency or patient/resident. Defining how to count the days would be confusing in the home care setting. For agencies without an integrated medical record, there would have no effective way to know the number of days a patient was taking meds prior to home health SOC/ROC. Simply documenting whether or not a patient is taking medications in these classes would be helpful in determining case mix as these medications could indicate higher risk, need for more stringent evaluation and/or increased education. Question F1d: While it is beneficial for the home health care team to know the indication for these medications, it is not the home health care agency staffs' responsibility to police the prescriber's completion of documenting the indication. Again, home health agencies would be held accountable for another entity's actions or nonactions. Validating the prescriber documentation of indications would not impact the case mix; only use of the medications by the patients does that. Home health care is currently required to include an indication for medications within the medical record. It would be more beneficial to require an indication within the medication profile, over which the home health care agency has control. If the goal is to have an indication completed by the prescriber, that requirement is better placed on the physician/pharmacy loop prior to filling the prescription. Question F1e: While the information may be helpful, it seems more important to actually correct the error than to track that it has been made. Without knowing how discrepancy is defined, this is difficult to gauge. As part of medication reconciliation, medications would be checked against transitions of care documents, actual medications in the home, and what the patient verbalizes as medications, so this information can be obtained. With a 48 hour window from referral to start of care, the impact of these errors would be minimalized with good medication reconciliation. Question F1f: These questions may be more pertinent to the inpatient setting where the family/formal caregiver may not be present. In the home environment, the family/caregiver are already a part of the health care team. However, this measure would be feasible in home health. Question F1g: Defining the expectation would improve quality. However, potential for high risk adverse events is not limited to these categories. This question also seems to be inherent to a current OASIS question, M2004. However, validity for the question is high, and asking it would be feasible in the home health setting.	

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		Question F1i: Rather than answering the above individual questions, this question is all encompassing and more appropriate to note actions taken with main stakeholders. Validity for the question is high, and answering it would be feasible in the home health setting. Care Preferences Home health agencies already ask patients about advanced care directives. This proposed question on advanced care directives seems to require a clinician to verify the existence of such documents and possibly read their contents. Since a patient may not have the legal document on his or her person at any given time, this could prove burdensome. PROMIS Sleep and Fatigue Understanding fatigue and difficulty sleeping is important, but physicians would likely be hesitant to prescribe treatment without first allowing the patient time to return to a baseline sleep state. IHHC is unsure of how the home health care clinician would benefit from asking and documenting the answers to these questions. From a validity standpoint, a majority of patients' home health care episodes follow an inpatient stay, so sleep will likely not be consistent with a normal state. A shortened version of this assessment may prove to be more valid, especially if asked at different timepoints. Ability to perform usual roles and activities Eligibility for home health care is, in part, dependent upon patients having difficulty with these activities-contributing to homebound status. Most home health patients would experience problems with several/most of these issues, decreasing the questions' validity. The questions would be feasible for home health care, although a waste of time with limited potential for change to the plan of care, other than those already being planned. Thank you for the opportunity to comment and participate in the process of developing measures under the IMPACT Act that contribute to care quality and a better understanding of trends in post-acute care.	

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PCCA	6/26/17	On behalf of members of the Pediatric Complex Care Association, we appreciate the opportunity to respond to the proposed standardized patient/resident data elements developed by the RAND Corporation to meet the requirements set forth under the IMPACT Act of 2014, Section 2(a). The Pediatric Complex Care Association (PCCA) is a national non-profit organization whose mission is to create opportunities for professionals to advocate, educate, network, research and promote excellence in providing a continuum of care for children with medically complex needs and their families. Our members include 38 specialized pediatric healthcare facilities that provide 24-hour post acute or long term care for children with complex medical needs and intellectual/developmental delays. The IMPACT Act of 2014 requires the Secretary of the Department of Health and Human Services to utilize the assessment instruments that the Centers for Medicare and Medicaid Services (CMS) currently require for use by home health agencies, inpatient rehabilitation facilities, long-term care hospitals and skilled nursing facilities. For skilled nursing facilities, the instrument currently in use is the Minimum Data Set (MDS 3.0). As we have noted during previous discussions with CMS and RAND Corporation staff, PCCA remains concerned that the use of data elements designed specifically for adult Medicare beneficiaries does not address the needs of an individual under the age of twenty-one, especially a child with complex medical needs that may also include an intellectual or developmental disability. Cognitive Functioning and Mental Status: The data elements identified in this area fail to appropriately assess children with medical complexity who frequently also have intellectual and developmental disabilities. The children cared for in specialized pediatric healthcare facilities are almost universally non-verbal and unable to respond to interview questions as required to score several of the proposed data elements. Additionally, the DOTPA, Complex Sentence Repetition, and PASS Medication Management measures focus on cognitive functioning skills which residents of pediatric healthcare facilities cannot be expected to have due to their chronological and/or developmental age. The measures that are based on staff observation, the Staff Assessment of Mental Status and the Patient Health Questionnaire – 9 Observational Version, contain many items that are not relevant to the pediatric population. Most importantly, a standardized assessment instrument of cognitive functioning for children should utilize a pediatric developmental and cognitive assessment tool such as the Denver Developmental Screening Test, the Bayley Scales of Infant and Toddler Development or the Cognitive Performance Scale. Use of the proposed elements will not improve quality	Pediatric Complex Care Association

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		and is not of utility for describing case mix in the population served by specialized pediatric healthcare facilities. Medical Conditions: Continence The data elements identified for bladder and bowel continence other than the bladder incontinence interview and the bowel incontinence interview are appropriate for the pediatric population. As indicted above, most of the residents of specialized pediatric healthcare facilities are nonverbal and lack the ability to respond to interview questions. What the data elements in this section do not recognize is that many of the residents in specialized pediatric healthcare facilities are incontinent due to their chronological or developmental age and cannot be expected to have bladder and bowel continence. Medical Conditions: Pain The data elements identified for pain are not appropriate to measure pain in children with medical complexity and intellectual or developmental disabilities residing in specialized pediatric healthcare facilities. Because many of the children our members serve are not able to respond verbally to questions about the presence or severity of pain, our facilities utilize the FLACC Behavioral Scale or the FACES Scale to measure pain. PCCA developed the Clinical Practice Guideline: Pain Management and we would be pleased to provide you with a copy of this document for your use in developing appropriate pain measurement data elements for children. Impairments of Hearing and Vision: The proposed data elements regarding use of glasses/corrective lenses and hearing aides are appropriate for the pediatric population. They do not, however, address the unique visual and auditory challenges that children with medical complexity often experience and which require specialized testing by optometrists/ophthalmologists and audiologists. Care Preferences: The data element regarding Advanced Care Directive – Health Care Agent would sometimes present a challenge for specialized pediatric healthcare facilities. While children cannot execute an Advanced Care	

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		Directive, they do have either a parent or a court-appointed representative through a state child welfare agency through age 18. At age 18, the residents of pediatric specialized healthcare facilities are considered legally competent to make their own decisions (although often their intellectual and developmental disabilities preclude their ability to do so) unless adjudicated incompetent by a court and appointment of a guardian. If a parent is unwilling or unable to seek guardianship, often because they lack the financial resources to do so, there is frequently no one to become the child's guardian/legal representative. Resources for public guardianship are very limited and, in many states, nonexistent. This results in health care providers relying on the consent of parents for provision of care although they have no legal authority to do so. The data elements regarding physician orders and goals of care are appropriate for the residents served in specialized pediatric healthcare facilities. The elements regarding preference for involvement of family/friends in care decisions and preferences for involvement in decision making are again inappropriate for the children our members serve due to the chronological age of the children as well as the inability of most of them to participate in an interview process. PROMIS: The PROMIS data elements are all self-reported perceptions. The children cared for in specialized pediatric healthcare facilities are almost universally non-verbal and unable to respond to interview questions as required to score these proposed data elements. To meet the intent of CMS' National Quality Strategy to improve the overall care by making healthcare more patient centered, reliable, accessible and safe, the development of a standardized pediatric assessment tool or pediatric based data elements would more accurately produce reliable quality data to drive post-acute care policies and payment structures appropriate for this population. Therefore, carving out the pediatric providers or age specific groupings data elements identified in the RAND Corporation document provides an opportunity for CMS, pediatric providers and policymakers to improve the health of the individuals 21 and under. Prior to the implementation of MDS 3.0 over thirteen years ago, CMS recognized the inadequacy of the MDS assessment instrument for the pediatric population and worked extensively with representatives from pediatric nursing facilities, now current members of PCCA, to modify the MDS to more adequately assess this population. When the project reached the beta testing phase, no funds were available to conduct the testing and the project was shelved.	

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		Only with a pediatric assessment instrument will it be possible to measure quality, outcomes, patient acuity and resource use consistently in our member organizations. We understand CMS is committed to timely implementation of the IMPACT Act. PCCA would greatly appreciate the opportunity to work together on data elements that address the strengths and deficits of the pediatric population currently served in specialized pediatric healthcare facilities. If you have any questions concerning our comments, please contact our office at 732-608-5350 or pat@PediatricComplexCare.org. Thank you for your consideration of our comments.	
HQS	6/26/17	The IMPACT Act of 2014 will facilitate better care planning and coordination across post-acute care settings. A fundamental provision of the IMPACT Act requires that CMS implement measures in five areas, one of which, crucially, pertains to "Transfer of health information and care preferences when an individual transitions" between care settings. At present, it is unclear that CMS intends to incorporate patient preferences for end-of-life and advanced illness care in its standardized assessment data that must be transferred when a patient transitions between settings. Care preferences concerning advanced illness and end-of-life care are among the most important care preferences expressed by the Post-Acute Care population, many of whom are high-need, high-cost patients moving between post-acute care settings, short stay hospitals, and ambulatory primary or specialty practices. The care preferences of these individuals regarding advanced illness and end-of-life care are frequently not communicated nor transferred effectively between these settings. Any lapse in information sharing about advanced-illness and end-of-life care preferences is particularly consequential for patients and families. In the absence of clear and readily accessible information about a patient's care preferences for advanced illness and end-of-life care, well- intended health care professionals may default to providing unwanted, ineffective and even painful care that can interfere in an individual's dignified passing in a setting of his or her choosing (literature citations available upon request). Recommendation: Incorporate into the PAC Care Cross-setting Standardized Assessment Data set a standardized measure of PAC patients' preferences for advanced illness and end-of-life care.	Health Quality Strategies, LLC

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		Much of the technical and consensus-building work needed to construct a valid and reliable measure of a patient's advanced illness and end-of-life care preferences has already been done. CMS has previously adopted NQF measure 0326 (MIPS 047) in its MACRA MIPS regulation, describing it as follows: "Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record, or documentation in the medical record that an advance care plan was discussed by the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan." In addition, the NQF 0326 (MIPS 047) measure has been embraced as a "high priority" "Core Measure" by the Core Quality Measure Collaborative. This means that NQF 0326 (MIPS 047) has not only passed muster with the National Quality Forum process and CMS' MIPS regulatory development process, but also that a diverse array of insurance plan Chief Medical Officers, leaders from CMS and the National Quality Forum (NQF), as well as national physician organizations, employers and consumers has reached consensus that these patient preference data are meaningful to patients, consumers, providers and practitioners. CMS has previously stated that measures in the Core Measure set— "will aid in promotion of measurement that is evidence-based and generates valuable information for quality improvement, consumer decision-making, value-based payment and purchasing, reduction in the variability in measure selection, and decreased provider's collection burden and cost." The Collaborative's "Core Measure" designation is relevant to the IMPACT Act Standardized Cross-setting PAC Assessment Data set because it means a multi-stakeholder process has agreed these care preference data will promote alignment and harmonization of measures and data collection across payers, providers, and practitioners in both public and private sectors. By including this patient preference information in the PAC Cross-setting data set, CMS will not only promote patient preference information flow to and among health care professionals in Post-Acute Care settings, but across many additional settings in which a patient may receive care. The advantages of taking this action include: 1) As previously noted by CMS, these data on patient care preferences will help improve care transitions through meaningful exchange of data between providers and practitioners, improve person-centered care	

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		and care planning, be useful for quality comparisons relevant to many payers, and support clinical decision-making and care coordination. 2) Data gathered for an NQF-approved measure such as NQF 0326 has passed muster for validity and reliability. 3) The feasibility of asking Post-Acute Care providers to identify patient care preferences for advanced illness and end-of-life care has been demonstrated over a quarter century, ever since CMS began implementing the Patient Self-Determination Act (PSDA) in PAC settings in 1991. Since that time, individual nursing homes, home health agencies and other providers have been required as a condition of participation in Medicare to determine whether a patient has expressed preferences for end-of-life care, and to document those preferences when they are known. By now PAC providers are capable of sharing standardized data describing these important care preferences. 4) CMS has already determined that NQF 0326 (Care Plan) is suitable for standardization across care settings that are more diverse (physician office practices) with far less experience documenting these care preferences than the Post-Acute Care providers that have long ago implemented the requirements of the PSDA. 5) CMS is already utilizing NQF 0326 (Care Plan) in its implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which is meant to foster innovative payment models for serving patients with diverse needs. Thank you for your consideration of these recommendations.	
HS	6/26/17	As the largest provider of inpatient rehabilitation facility ("IRF") services in the nation, and in partnership with Encompass Home Health, the fourth largest Medicare home health ("HH") provider, we appreciate the opportunity to submit comments on your work on behalf of the Centers for Medicare and Medicaid Services ("CMS") regarding the development and maintenance of cross-setting standardized patient assessment data ("SPAD"). As a leading provider of post-acute care ("PAC"), we have a strong interest in ensuring that SPAD assessment items and corresponding quality items will prove useful across the spectrum of PAC settings and help achieve the IMPACT Act's vision of standardized PAC quality data. We have several comments that we believe offer constructive insight to the development and design of these items and	Health South

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		measures, from technical insight to general approaches. We hope that RAND and CMS will analyze and consider these comments and how they could improve the framework for this suite of post-acute care items. I. Cognitive Functional and Mental Status a. DOPTA CARE A5a-A5b A5a should be a gateway question so clinicians can skip the remaining questions if the answer is "No." These questions are redundant to Brief Interview for Mental Status ("BIMS") and the Functional Independence Measure's ("FIM's") cognitive assessment that are currently on the IRF-PAI. Question A5b bundles six categories together and would dilute the clinical significance of any affirmative response. The scale does not define the problem area or the number of problem areas. These questions do not provide enough detail on which areas cause problems for the patient subject, only the severity of isolated problems. As such, they do not generate useful information for future clinical decision making and care planning. Furthermore, the assessment scale "marked difficulty" vs "some difficulty" is not sensitive enough and invites a high degree of subjectivity. A5d-A5n The sheer number of questions in this item creates an undue burden on the patient. To be asked "with assistance" and "without assistance" for each question is redundant and can create frustration in a patient. The focus should instead be placed on the "without assistance" query since that question stem would by default indicate whether the patient can complete the task "with assistance." b. Complex Sentence Repetition This item would not be useful in PAC and is redundant with the Brief Interview for Mental Status (BIMS). c. PASS Medication Management	

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		Useful in PAC; Concerns about Validity; Little impact on Quality or Case Mix. These five questions on medication management are cumbersome for an initial assessment. Because many IRF patients often begin their stay under high levels or stress or anxiety due to the acute injury or illness that brought them there, these questions may produce inaccurate responses under elevated levels of stress and anxiety. Timing must be appropriate for each patient based on individual needs. They might be useful later in an IRF stay. If the timing of this assessment is designed to be flexible according to a patient's individual needs, then the information obtained would be useful for care planning. d. Staff Assessment of Mental Status This item would not be useful in PAC and is redundant with the BIMS. e. Behavioral Signs and Symptoms Subitems B1a and B1c are overlapping with one another (whether the patient hits or scratches). These questions provide a time frame for the behavior, not the extent of the behavior, which may be more relevant in care planning and patient management. Additionally, these questions are not sensitive enough for clinical decision making or care planning (for example: if a patient hit someone once versus constantly, they would receive the same score). The prevalence or extent of these types of behavioral signs and symptoms need to be better articulated by these assessment items since that information is crucial to designing appropriate care plans and/or patient management strategies. f. PROMIS Anxiety Items & PHQ9-OV The IRF setting is not an appropriate place to be asking about the "last seven days" or "last two weeks" in relation to a patient's anxiety or depression status since most IRF patients have immediately come from an acute hospital and are typically recovering from a severe illness or catastrophic injury that occurred very suddenly and unexpectedly and could be "life-altering." As such, many IRF patients are in a sensitive mental state during recovery in face of all the changes that their major injury or illness will cause. Having experienced a sudden and dramatic decline in function (e.g. stroke, multiple trauma) within a few days prior to their IRF admission, answering questions that begin with the wording "within the last two weeks" are unlikely to yield any meaningful clinical insight into issues of	

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		long-term or chronic depression, and are instead likely to come across as highly insensitive to the patient's fragile condition. Additionally, screening at this acute stage, when the patient is still experiencing the effects of trauma or adjusting to major life changes, could lead to an over use of antidepressant medications, a dynamic associated with an increased risk of falls in older adults. Our clinicians found the PHQ9-OV to be extremely burdensome and time consuming without adding value to care transition or care planning. The PROMIS item set, developed for outpatient care, has not been validated in PAC settings. II. Medical Conditions We believe the following assessment items could be helpful for care transition and care planning: Bladder/Bowel Alpha 1 (C1a) – does this patient use an external or indwelling catheter, have a urostomy or require intermittent catheterization? Alpha 1 (c1b) - If patient has indwelling or external catheter, at what point was device first placed? Alpha 1 (C1c) - If patient has an indwelling or external catheter, what is the reason the device was put in place? Alpha 1 (C1d) - If patient has bladder device, does the patient need assistance to manage equipment or devices related to bladder care for ANY reason? Alpha 1 (C2b) - If patient has incontinent events, did the patient have incontinent events immediately prior to the hospitalization for current illness or exacerbation? Alpha 1 (C3a) - Does the patient use an indwelling or external device? Alpha 1 (C3b) - If patient has indwelling or external device, at what point was device first placed? Alpha 1 (C3c) - If patient has indwelling or external bowel device, does the patient need assistance to manage equipment or devices related to bladder care for ANY reason? Alpha 1 (C4b) - If patient has incontinent events, did the patient have incontinent events immediately prior to the hospitalization for current illness or exacerbation? We believe the following assessment items are too subjective:	

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		Alpha 1 (C6a) - How big of a problem are the patient's incontinent events in the context of their overall care? Alpha 1 (C7a) - How big of a problem or burden are incontinent events to you? Alpha 1 (C8a) - How big of a problem are the patient's incontinent events in the context of their overall care? Pain By definition, patients treated in IRFs (compared to those treated in other post-acute care settings) must need, be expected to benefit from, and receive intensive rehabilitative therapy treatment. Such treatment is designed to encourage patients to meet their functional and mobility goals, and can sometimes include instances of pain or discomfort. Typically, such pain or discomfort is a healthy byproduct of an effective therapy regime. For example, an IRF patient recovering from a recent hip replacement procedure may feel some pain after an intensive early mobility therapy exercise. Invasive procedures like hip replacements may naturally cause some residual pain in a patient during the IRF stay. However, this pain is not necessarily a negative quality indicator, and part of a successful rehabilitation stay often includes helping patients manage pain as part of their recovery process. At HealthSouth, our clinical practices require that nurses assess patient pain on a daily basis, including before and after each therapy session. Because pain is often an inherent part of intensive rehabilitation therapy, and frequent pain assessment is an integral part of a medical rehabilitation program and the practice of medicine in general, these items as proposed are not appropriate. A more meaningful pain measure would be designed to assess whether staff were responsive to and helped manage pain, not whether pain existed. Medication Reconciliation – Use of Medicines in Specific Classes The current drug class subdivisions listed in the SPAD items are not cross-walked to the AHFS drug categorization system, which is described by AHFS as the most comprehensive, authoritative source of evaluative, evidence-based drug information available. The most effective manner in which to report on drug events by category is to use the AHFS system, which is already a data element for each drug in the database. Using different and sometimes more general descriptions requires some subjectivity as to which AHFS categories should be used to report the data, therefore decreasing the validity of the entire set of medication reconciliation items. Mapping the categorization to the AFHS categories would be necessary prior to implementation in the assessment tools. Medication Reconciliation – Indication	

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		There is no current requirement that an actual indication for a particular medication be documented within a doctor's or pharmacist's medication order. Indications for medications can exist in many different areas within the patient's record. The ability to validate a documented indication for every drug within a category would be a highly manual process that would be burdensome for clinicians. Additionally, medication indication is not collected on any PAC assessment instrument and the results from Alpha 1 suggest that patients in other PAC settings are more likely to not receive an indication assessment, even when the items (in this case, the pilot items) are part of the assessment. Since these items were not part of the PAC PRD or other formal test, there is no current evidence that, despite the use in the Alpha 1 pilot, these items are designed so as to be used consistently and reliably across settings. G1a. Advanced Directives & Physician Orders (Chart Review) This information is relevant to clinical decision making and care coordination, but IRFs already address these issues with patients as part of the routine care of the patient. These items would be feasible, albeit redundant. G1c. Goals of Care We support the concept of this element and agree that this information is relevant across all post-acute settings. It also is information that can be important in ensuring a smooth transition of care from one setting to the next (meets requirements for potential for improving the quality of care and validity). However, due to the way it is described, it may be difficult to assess (because similar information may exist in a number of other sources within the patient's medical record and the discussions may be formal or informal and includes a wide range of goals – physical, emotional, social intellectual/mental other, some of which could conflict with one another). The chart review to collect information could be very time consuming and subject to varying degrees of interpretation, depending on the setting and the reviewer. Furthermore, most of these areas are already included in the post-acute clinical assessments and documented. We do not believe the manner in which this data element is constructed would lend itself to any increased knowledge of care preferences. We do not recommend that this data element, as it is currently designed, be added to the SPAD data collection elements without further testing.	

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		A2. Involvement of Family/friends in Care Decisions We support inclusion of this element and agree that this data information is relevant and could be easily collected across all post-acute settings. The information is important in ensuring that patient preferences are considered and known across all Post-Acute settings. It is important to know the patient's preference regarding family or caregiver involvement and is important information to know discharge planning. Time required to collect the information is minimal. Recommend this data element be included in a standardized assessment. A4a. Preferences for Involvement in Decision Making We do not recommend this data element. One of the primary goals of inpatient rehabilitation is to provide education and teaching in order to promote functional improvement and independence. Patients who do not want to know details of their condition and do not wish to be involved in decision making about their care are probably not appropriate for the IRF setting. There are also many factors that might initially influence the patient's response to these questions such as a stroke, brain injury, and cognitive deficits. The potential for improving quality is also questionable. It is not used currently in any of the PAC settings. This question needs further testing in the various PAC settings, particularly in the IRF setting. V. PROMIS® Sleep Disturbance No impact on Quality or CMI. Questionable validity. These twelve questions regarding sleep patterns that are intended to be answered in first 7 days of admission are extremely detailed and may cause frustration in new patients who are already anxious. These yes/no answers would also not provide enough information to make a difference in the plan of care. Perhaps a few less in-depth questions/answers instead of a long list of yes/no responses would provide more detail which could be used to improve quality of care, facilitate care coordination, and influence individual plans of care. Fewer but more in-depth questions would also feel less like an interrogation and more like a conversation, a dynamic which helps build trust and understanding between a patient and his/her caregiver – an element that is important to positive patient experiences of care.	

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		Ability to Participate in Social Roles and Activities No impact on Quality, CMI, or the type of PAC provided in these questions. These questions would not serve to inform the plan of care and would just be additional information gathered and not used by the clinical team. Global Health The global health questions may imply that if the patient were not generally healthy before the current episode, the expectation of improvement should be low. In other words, without disclosing what the clinical rationale is beyond "an individualized care plan," the patient may become skeptical of these very personal questions (i.e., "how would you rate your quality of life?"). From a human patient perspective, does this line of questioning send a message to the patient that their therapy would be somehow less effective or impactful than that provided for other patients who answered that they were healthier, mentally, physically, and/or socially? The opacity of the rationale behind this question makes it a difficult one to answer because it does not help the clinician build a trusting relationship with the patient. Thank you for your attention to these comments. We hope our views and insights will prove constructive in the development of these SPAD items, especially at this relatively early stage in the development process. Should you wish to discuss any content contained in this letter, please contact us at the information below.	
UPMC	6/26/17	University of Pittsburgh Medical Center (UPMC) Community Provider Services (CPS) appreciates the opportunity to comment on the Development and Maintenance of Post-Acute Care Setting Standardized Patient Assessment Data. Post-Acute Care and Community (PACC) capabilities are centrally organized and managed by UPMC Community Provider Services, a non-profit corporation held directly by the UPMC Parent. Serving Pennsylvania, CPS has seven major product-line segments including Home Health and Hospice with 52,300 home health admissions annually and the highest year-to-date hospice census approaching 550 individuals and families. CPS provides providing housing, services and care to over 2,400 seniors daily	University of Pittsburgh Medical Center

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		through Senior Communities which operates 1,047 licensed skilled nursing beds, 90 assisted living or personal care apartments, and 1148 independent living apartments or units. Other CPS product-lines include Community Life (PACE) program, Rehabilitation Therapy, Community-based Pharmacy programs, Durable Medical Equipment, Respiratory Therapy and regional Reference Laboratory testing. As part of the IMPACT measure development process, UPMC CPS has participated in two Technical Expert Panels (TEP) via Daniel Butts, MOT, OTR/L, MBA, Senior Director, Rehabilitation Operations-UPMC Rehabilitation Network; and Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data (April 2016); and Victoria Zombeck, RN, BSN, ACM, Director, Post-Acute Liaisons, Community Provider Services on Transfer of Health Information and Care Preferences When an Individual Transitions (September 2016). Moreover, under the direction of CMS, RTI, and Abt Associates Transfer of Health Information and Care Preferences (TOH) Measure Development Team, UPMC Home Health is currently participating in the field testing of the measures. We wholeheartedly acknowledge and support IMPACT ACT and its requirement for the submission of standardized data on specified assessment domains and specified quality measurement domains. It specifies that the "data be standardized and interoperable so as to allow for the exchange of such data among such post-acute care providers and other providers and the use by such providers of such data that has been exchanged, including by using common standards and definitions in order to provide access to longitudinal information for such providers to facilitate coordinated care and improved Medicare beneficiary outcomes…." As noted on the 29 March 2017 National Provider Call, will there be best practice(s) recommendation as to what discipline(s) should complete the assessment, and a determination of what education/training is preferred once new data element items are selected and implemented in PAC settings? We also acknowledge for Public Comment 2 that CMS is specifically interested in feedback addressing four dimensions and we have responded accordingly. • 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	

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		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. Pgs. 10-14 Developing Outpatient Therapy Payment Alternatives (DOPTA) Care Items Our home health psychiatric team currently conducts the MoCA (Montreal Cognitive Assessment) when seeing the patient for the first time. We believe it prevents duplication while decreasing frustration for the patient and family. In our experience, we receive a more comprehensive picture of the overall (holistic) aspects of the specific patient. The MoCA captures much of the information listed on Page 15 in the section called "Language". We believe the cognitive assessment is essential to determine if the patient is capable of implementing strategies related to fall prevention, medication management, maintenance of chronic conditions, and other items imperative for self-care/safety after the home health staff leave. We believe the DOPTA elements meet all four dimensions. Pgs. 18 – 24 PASS Medication Assessment Once again, our home health psychiatric team currently conducts a similar version to ensure the cognitively impaired individual is able to adequately self-administer medications. As noted, medications are a high safety risk category when assessing if a patient can safely be maintained in their home. We know from years of practice that medication errors can cause serious harm and even premature death in some cases. We highly recommend that PASS be a part of assessment on admission. We believe PASS meets all four dimensions. Pg. 25 – Staff Assessment of Mental Status Our psychiatric home health team determined this to be very cumbersome and believes its impact on the four dimensions is minimal. If an assessment – regardless of setting – is done on admission that resembles	

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		DOPTA/PASS, it will provide a firm baseline of functional ability which when initially tested can be repeated as treatment is begun and finally completed. Pgs. 28-32 Behavioral Signs and Symptoms We believe this section would not necessarily affect a home health patient, especially patients who live along. In a facility-based setting, staff can more easily assess if a patient has become a disruption to his/her milieu, or community. A trained RN should be able to utilize their critical thinking skills to assess and then determine if the behaviors demonstrated by the patient are treatable. If a patient is acting out, our psychiatric team typically has discovered that they are very depressed about the fact they are no longer able to live in their own home and are distraught about living in a facility. However, if the depression is treated with supportive intervention, the issue is usually resolved. Some facility-based residents never accept the fact they are no longer able to be independent, and we have found that it can take years for adjustment to occur. As a result, our psychiatric team often receives repeat referrals to facilities for these individuals. Fortunately, due to a HRSA-grant initiative, we have witnessed positive outcome when facility-based residents are able to have tele-consult with a geriatric psychiatrist. Progress is evidenced by scores via PHQ9, GAD-7, and MoCA. We believe Behavioral Signs and Symptoms meets two of the four dimensions. We remain uncertain of its validity and feasibility in Home Health. Pgs. 33 – 37 PROMIS® Anxiety Items Anxiety, especially with uncontrolled pain, will most likely result in a hospital readmission or ER visit if not addressed early on in PAC stay. In our experience, many home health psych evaluations have some form or type of anxiety as the cause for non-compliance with recommended treatments. We believe PROMIS® meets all four dimensions. Pgs. 38 – 43 Patient Health Questionnaire-9 Observational Version (PHQ9-OV) We applaud how this PHQ9 version is more detailed and defined for the end-user (clinician), especially those who have not used the PHQ9 in the past, or had specific training on how the PHQ9 is to be administered. We believe PHQ9-OV meets all four dimensions. Pgs. 45-48 Bladder Device Use The data element is straightforward and we believe it meets all four dimensions. Pgs. 49-51 Incontinence	

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		Regarding C2a the definition of the 'assessment period' needs to be specified; C2b, the term 'immediately prior' needs to be defined. Unless further specification is given, we believe the validity and feasibility are poor; otherwise, it meets the remaining two dimensions of quality and case mix. Pgs. 52-54 Incontinence Interview We believe it meets all four dimensions. The timeframe "within three days" is specific and prompts emphasis of person-centered care. Pgs. 55- 57 Device Use C3a meets the four dimensions, but we question feasibility of C3b since home health does not participate in placement of bowel devices. Pgs. 58-60 Bowel Incontinence Timeframe of term 'assessment period' needs specified as well as the term 'immediately prior.' Pg. 61-77 including Incontinence Interview and Pain Relief The questions meet all four dimensions. The timeframes are specified. We believe H6 is an excellent addition. Pgs. 78-81 Observational Assessment of Pain or Distress We believe this is not feasible for home health. Based on visit utilization patterns, how would it be implemented in home health? Pgs. 83-85 Impairments of Hearing and Vision We believe the four dimensions would rate higher with the OASIS C2 version of this question which asks "how is vision or hearing w/ corrective lenses or aides?" Pgs. 91- 93 Use of Medication in Specific Classes F1c. The question meets all four dimensions and can be especially useful in determining case mix/risk adjustment. Pgs. 94-107 Medication Reconciliation Indication / Discrepancies We believe these data elements are cumbersome and extremely time-consuming to complete.	

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		Charts F1e and F1f should be reformatted and combined for ease in documenting and referencing. As written, it is would be extremely difficult to compare, derive, communicate and notify. F1h is cumbersome and "other" medication category box is recommended. F1i (2) needs clarified and (3) may not be as feasible to home health. Home health does not currently contact the pharmacy. Thank you for the opportunity to provide feedback and we look forward to continuing our participation.	
NASL	6/29/17	The National Association for the Support of Long Term Care (NASL) is a trade association representing suppliers of ancillary services and providers to the long-term and post-acute care (LTPAC) sector. NASL members include therapy companies that employ more than 300,000 physical therapists, occupational therapists, and speech-language pathologists who furnish rehabilitation therapy to hundreds of thousands of Medicare beneficiaries in nursing facilities as well as to beneficiaries in other long-term and post-acute care settings. NASL members also include both vendors of health information technology (IT) that develop and distribute full clinical electronic medical records (EMRs), billing and point-of-care IT systems and other software solutions that serve the majority of LTPAC providers of assisted living as well as skilled nursing and ancillary care. In addition, NASL members include providers of clinical laboratory services, portable x-ray/EKG and ultrasound, complex medical equipment and other specialized supplies for the LTPAC sector. NASL is a founding member of the Long Term and Post-Acute Care Health Information Technology Collaborative (LTPAC Health IT Collaborative), which was formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders. NASL is pleased to submit these comments in response to the call for public comment on Development & Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment 2. Our comments, which can be found in the attached chart, are on Cognitive Function & Mental Status; Medical Condition: Pain; Impairments of Hearing & Vision; Medication Reconciliation; and PROMIS items. NASL stands ready to work with CMS and RAND Corporation in reviewing and refining these data element specifications for use across all PAC settings.	The National Association for the Support of Long Term Care

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		Cognitive Function & Mental Status Overall, we believe there is a need for a stratified approach and appropriate tools to determine level of impairment; impact on function and ability to participate in therapy; and impact on resource utilization. DOTPA CARE Potential to Improve Quality CARE-C was developed and trialed for a non-residential population. Without a pilot or demonstration, the ability for this to be of value toward quality improvement is highly questionable. There are important data elements included in the CARE tools' cognitive assessment sections that help to bring a focus to functional cognition that we believe should be captured in some way. Validity Validity of DOTPA CARE is questionable for the SNF population. Again, the emphasis seems to be on the CARE-C, which is odd given that 3 of the 4 PAC settings are facility-based. The final DOTPA report noted that while the CARE-C tested well, the CARE-F needed more refinement and testing and had a much smaller sample. Once piloted and refined, we could see use for home health and possibly high-level IRF patients. Feasibility for PAC Use Once piloted and refined, we could see use for home health and possibly high- level IRF patients. Utility for Describing Case-Mix We do not see this being helpful for describing case-mix. Additional Comments/Observations The DOTPA CARE data element specs are not adequate in the current form.	

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		We agree that this is an important area to study, especially with the potential impact on new proposed payment system reforms. We believe further stratification, or perhaps an algorithmic approach/skill patterns should be considered. We also recommend that CMS clearly delineate resident/facility from community populations. We understand that AOTA and other professional associations have suggestions based on Alpha 2 testing, which we encourage CMS to review. Complex Sentence Repetition Potential to Improve Quality How does this assessment help to narrow to the functional effect? It seems that there could be potentially several factors that may influence the accuracy of the sentence repetition and many causes of inaccuracies (e.g., attention, cultural, hearing, memory, etc.). Validity Not tested through PAC PRD, but found to show reliability during Alpha 1 testing Utility for Describing Case-Mix What's the purpose for the assessment? Is it memory or communication? Additional Comments/Observations What is the alternative for non-verbal patients and for patients who do not speak English or use English as a primary language? PASS Medication Management (Performance Assessment of Self-Care Skills) Potential to Improve Quality This has potential for improving quality.Based on a detailed activity analysis, thus a breakdown of steps and skills to help identify functional impact. Validity	

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		Validity would require adherence to the protocol approved by professional physicians and pharmacists. We also believe there is a need for greater clarity and understanding that this is modified version of the PASS, which is necessary to allow various disciplines to administer the assessment. Feasibility for PAC Use There is potential for PAC use, with an established protocol. We believe that it would be best as a test for those who pass BIMs to hone into moderate or mild deficits. Utility for Describing Case-Mix PASS Medication Management is not the best means for determining case-mix. Additional Comments/Observations We believe this specification needs to be tested. Staff Assessment of Mental Status Additional Comments/Observations Items A1a and A1b seem too vague; whereas A1c does provide more info on spatial and temporal orientation PROMIS® Anxiety Items Potential to Improve Quality Not for SNF Validity Not standardized for SNF Feasibility for PAC Use PROMIS® items were designed for non-institutional patients only. Utility for Describing Case-Mix We do not believe PROMIS Anxiety Items are the best means or useful for determining case-mix.	

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		Patient Health Questionnaire-9 Observational Version (PHQ9-OV) Potential to Improve Quality PHQ9-OV is ok for delirium, but not dementia. Validity PHQ9-OV was not developed and is not appropriate for the SNF patient population. Feasibility for PAC Use Not for all PAC settings Medical Conditions: Pain A true measure of quality may center on pain management and its effect on function and quality of life. NASL appreciates the addition of Section E to address the pain assessment in those patients who cannot communicate their needs. We would caution that there are already questions in Section J related to Pain; are there data elements that could be modified versus added? Are we asking the same question in different ways? We would encourage the use of existing data elements where possible. If the goal of capturing pain is to create a Quality Measure that could be used to modify clinical practices related to pain, and compare the quality of pain management within and across post-acute care (PAC) settings, we recommend that CMS use as much of the data in Section J of the MDS as possible, since this information has been collected in SNFs for quite some time. Pain Frequency Pain Severity Pain Effect on Sleep Pain Interference: Therapy Activities Pain Interference: Other Activities Pain Relief Observational Assessment of Pain or Distress	

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		Potential to Improve Quality The potential to improve quality with these pain specifications is good. We are curious regarding the clinical rationale as to the 3- day time period versus the 5-day look back already in place in the MDS. Validity These standardized data elements appear to be valid based on the research we found, specific to H5 and pain severity. We couldn't find as much data on H6 and pain relief, but these appear to be at least a good starting point. Feasibility for PAC Use Feasibility appears to be supported by either in the PAC PRD or the Alpha 1 pilot test Utility for Describing Case-Mix Pain plays a significant role in response to care and success of interventions. These data elements have the potential to demonstrate the impact of pain in order to provide insight into the resources necessary to provide appropriate care. Still question the 3-day look back for frequency, severity, etc. Additional Comments/Observations Please consider use of the already existing Section J where possible, to eliminate similar questions being asked different ways and mitigate duplication. Hearing Aid Potential to Improve Quality This item does have potential to provide improved quality care as well as accurately measuring the patient's condition. Validity To assure accuracy of patient information, this item should be included in a valid data set. Feasibility for PAC Use	

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		With respect to MDS item C1d, we should indicate if the resident normally uses a hearing aid or hearing appliance (i.e., "Is it present, operational and ultimately used at time of interview?") We believe this statement is misleading: "A code of 1 is assessed if the patient/resident fails to comprehend conversational speech…." This appears to be verifying the ability to comprehend rather than hear. Utility for Describing Case-Mix Unable to assess the utility for describing case- mix as the reasons are not outlined and should be clarified. It may assist in validity to align coding with the additional scoring process recently adopted for MDS Section GG. Additional Comments/Observations To determine functional status, shouldn't the ability to clean, maintain and manage, and use assistive device be assessed? Glasses/ Corrective Lenses Potential to Improve Quality This item does have potential to provide improved quality care as well as accurately measuring the patient's condition. Validity To assure accuracy of patient information, this item should be included in a valid data set. Feasibility for PAC Use With respect to MDS item C1c, we should indicate if glasses or other visual appliances are used (i.e., "Are they present, operational and ultimately used at time of interview?"). Utility for Describing Case-Mix The "ability to identify objects" in the instructions is misleading as we are measuring ability to see, not the ability to identify objects. As to what is cognitively impaired, aphasic etc., we question whether there should be a check box for any of these conditions that helps the interviewer/tester know what strategy to use to evaluate vision.	

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		Unable to assess because clinical reasons are not outlined and should be clarified. It may assist in validity to align coding with the additional scoring process recently adopted for MDS Section GG. Additional Comments/Observations To assess functional status, shouldn't the ability to clean, maintain and manage, and use assistive device be assessed? Medication Reconciliation NASL supports the goals of improving clinical outcomes and agree that a careful medication reconciliation can improve care and reduce unnecessary hospitalizations or adverse events. We call your attention to comments submitted by the American Society of Consultant Pharmacists (ASCP). NASL shares ASCP's concerns about some of the data elements in the section discussing medication reconciliation given the varied way the four post-acute care settings each conduct medication administration and related processes. After reviewing the data element specifications for medication reconciliation, we have several concerns – some of which augment those expressed by ASCP. The first concern we have is the inconsistency of the medication reconciliation definition. Within the RAND document medication reconciliation is defined as "a process of reviewing an individual's complete and current medication list." The term is further defined by RAND as "The definition of medication reconciliation should follow the Joint Commission's five-step process: 1) develop a list of current medications; 2) develop a list of medications to be prescribed; 3) compare medications on the lists; 4) make clinical decisions based on the comparisons; and 5) communicate the new list to the patient/resident and appropriate caregivers." However, none of the recommended data elements refer to medications – only the CLASS of a drug, which does not meet the proposed definition. Other terms requiring further definition, thereby avoiding ambiguity, include, but are not limited to, "clinician" and "discrepancies." NASL asks that a single definition be used in describing a standard measured process for medication reconciliation. Second, we strongly recommend that the process compare medication to medication and not introduce the capture of drug classes. The use of opioids, antipsychotic and psychotropic drugs already are addressed in	

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		the Requirements of Participation for Long Term Care Facilities and the Conditions of Participation for Home Care. It does not serve the patient to confuse the medication reconciliation process by adding the collection of classes of drugs, which would be difficult for clinicians other than a physician or a pharmacist to obtain. If the goal is to ensure patient safety and avoid adverse drug events, which we believe it is, then medication review should remain at a granular level. By comparing medication to medication, clinicians may identify potential side effects that could result in adverse drug events (ADEs), which is a leading cause of hospital readmissions. ADEs are not easily identified by class of drugs. Third, another concern we have is with the section on discrepancies and its instructions that "any clinician who has been trained to conduct this assessment" may do so. While that may be true, we believe the quality of the data correlates to the training and expertise of the assessor. For example, we would expect the validity of the data collected by a pharmacist or a physician who completes a medication reconciliation to be superior to data collected by another type of clinician, who may be trained to conduct this assessment. PROMIS® (Patient-Reported Outcomes Measurement Information System) Self-reporting of any of these is not reliable with a large portion of the SNF population: reliability of informant is a challenge when trying to improve quality and trying to have a valid assessment tool that is dependent on self-reporting. Ability to Participate in Social Roles and Activities Potential to Improve Quality While the elements focus on limitations and difficulties and are intended to encourage more discussion during care planning, these elements appear to lack the important perspective of patient preferences. Patient preferences and the meaningfulness of social roles and activities is an essential consideration when looking at quality of life and quality of care.	
AAPACN	6/26/17	The American Association of Post-Acute Care Nursing is a professional association encompassing both the American Association of Directors of Nursing Services (AADNS) and the American Association of Nurse Assessment Coordination (AANAC). AADNS and AANAC represent over 15,000 long-term care nurses and professionals across the country. We respectfully submit these comments in response to the Development and Maintenance of Post- Acute Care Cross-Setting Standardized Assessment Data RAND IMPACT. AADNS and AANAC support the goal of the proposed rule to revise the Medicare payment system and the continued plans of CMS to move from a volume-based payment system to a value-based	American Association of Post-Acute Care Nursing

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		payment system. We understand that the proposed changes are necessary to promote our national healthcare system's triple aim of better care, healthy people and communities, and affordable care for all. We support CMS in the move towards standardized assessment data elements across the care continuum to facilitate cross-setting data collection, outcome comparison, and interoperable data exchange, while improving care coordination, fostering seamless transitions, improving person-centered outcomes and goals, and providing for reliable information that may support providers in making appropriate discharge placements. Our members have provided feedback to the proposed regulations, as outlined in the following pages. Item: DOTPA CARE General Comments DOTPA CARE – CMS's focus on the resident and his/her voice being heard is the gold standard. Therefore, we are concerned that these items are not getting the information directly from the resident and as a result seem very subjective with the potential for inaccuracy. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Data seems repetitive, and for SNF resident in therapy these items are very similar to therapy assessments. Improve person-centered care and care planning No, since it is not using the resident's voice. Used for quality comparisons Do not believe items detail cognition, as answer options would be subjective to the assessor – basic versus complex. SNFs already have some difficulty with compiling the BIMS accurately and this does not seem to improve the assessment of cognitive status. What kind of directions will be given as answer options appear	

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		very similar. For example, what is the difference between "sometimes" and "usually"? We are greatly concerned with the accuracy of these items and therefore the ability to use the information for care planning. Support clinical decision-making and care coordination No, since it is not using the resident's voice. Validity Whether it captures the patient attribute being assessed Question validity – as very subjective based on who is asking, how it is asked, and what it shows about a resident's cognition. Do not believe we need an additional assessment to the BIMS, which is a part of the MDS. Items seem to be more applicable to other patient types, such as mentally ill and developmentally disabled. Proven or likely inter-rater reliability Many functions of cognition being tied together into one question leads to concern with how the data will help with person-centered care planning. Caregiver is best person in a SNF to respond to questions, but concerned with his/her ability to decipher the information to accurately drive care planning. Feasibility Feasibility for use in PAC So many assessment windows are being enforced – question how feasible it is to collect and respond to all of these items. Does not seem to be useful enough to justify the time commitment for completion. Potential to be standardized and made interoperable across settings Clinical appropriateness	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Relevance to the work flow across settings We can see how this information would be valuable when the resident is transferred to another setting – but usefulness for the SNF setting is a concern. Utility for describing case mix Can the data element be used with different payment models Accuracy of these items is an overriding concern and would not want payment attached to it. Does it measure differences in patient severity levels related to resource needs Therapy suggests there are some other rehabilitation tools that could be used for validity, although there is a cost attached to their use. Items: Complex Sentence Repetition General Comments For the SNF we are concerned about the value of the complex sentences and the instruction that they must be repeated exactly. Would need to define "trained clinician." Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers We do not see the ability to repeat a complex sentence that has nothing to do with healthcare to have the potential to improve quality. Improve person-centered care and care planning No, as stated in the above comment.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Used for quality comparisons No, as stated in the above comment. Support clinical decision-making and care coordination No, as stated in the above comment. Validity Whether it captures the patient attribute being assessed Complex sentence – time consuming in addition to MDS. Feasibility Feasibility for use in PAC Time constraints continue to be a problem in the SNF setting. These additional items do not seem feasible when considering the time already needed to complete the MDS. Potential to be standardized and made interoperable across settings Not considered feasible. Clinical appropriateness No. Relevance to the work flow across settings Does not seem to be feasible.	

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		Utility for describing case mix Can the data element be used with different payment models Does not seem to be reliable or valid. Does it measure differences in patient severity levels related to resource needs No. Item: PASS Medication Management General Comments Many SNFs would need to change drug packaging, resulting in a tremendous cost. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Need to consider the ramifications of health literacy. Improve person-centered care and care planning We are concerned that the intensity of these items could be frustrating for the resident. Support clinical decision-making and care coordination There is value to the items as far as successful discharge to the community, but for care services while in the SNF, we do not believe there is a great deal of usefulness. Validity	

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		Whether it captures the patient attribute being assessed Appears to be a part of the medication administration process, and therefore we doubt the value. This could be considered as part of a training program before the resident is discharged to a less acute setting. Feasibility Feasibility for use in PAC Another time-consuming addition to the MDS process with little merit or value except for discharge planning. Potential to be standardized and made interoperable across settings If the resident is not able to meet the goal, what are the financial ramifications? Clinical appropriateness Instructions do address environmental safety issues, but what about visual impairments and/or loss of fine motor movements (stroke, Parkinson's disease)? Does it measure differences in patient severity levels related to resource needs Too many other issues beyond resident and/or facility control could impact ability to address these items. Item: Staff Assessment of Mental Status General Comments Repetitive information from staff assessment of mental status on the MDS. See no need for collecting this data.	

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		Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Cognition can fluctuate greatly based on setting and environmental factors and therefore concerned with reliability. Improve person-centered care and care planning No, since data does not seem valuable in the SNF setting. Used for quality comparisons Reveals minimal information about cognitive abilities. Validity Whether it captures the patient attribute being assessed Reliability of data in SNF is questioned and not felt to be of great value. Feasibility Feasibility for use in PAC Repetitious for the SNF since already a part of the MDS. Can the data element be used with different payment models SNFs use the BIMS and the Cognitive Performance Scale so does not seem needed. Item: Behavioral Signs and Symptoms	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Repetitious of the MDS – time concerns for tracking to ensure accuracy. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Rejection of care on MDS – is difficult to code and not sure of usefulness unless it is care planned. Needs much better clarification and instructions for this item from CMS. Improve person-centered care and care planning Important, but staff has great troubling coding on the MDS. Used for quality comparisons SNFs having difficulty assessing behaviors to reach the root cause of the behaviors – these items do not seem to help get to the actual problem. Support clinical decision-making and care coordination Items are important for care planning, but number of items is of concern. Validity Whether it captures the patient attribute being assessed Behaviors are so prevalent in some facilities that staff becomes accustomed to them and do not note, track, or care plan. Greater training would be needed to increase understanding of behaviors and what needs to be done to help the residents. Feasibility	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Feasibility for use in PAC Repetitious for SNFs with no additional added value seen. Potential to be standardized and made interoperable across settings We do not believe so – a problem for one setting may not be considered a problem in another setting. Clinical appropriateness No, as stated above. Relevance to the work flow across settings Same a above. Utility for describing case mix Can the data element be used with different payment models Residents with these types of behaviors are sometimes difficult to manage and could be important for reimbursement, but history has shown payment adjustments have been minimal. Does it measure differences in patient severity levels related to resource needs How would this show improvement over time to possibly impact reimbursement? PROMIS Anxiety General Comments	

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		Staff do not want to call a resident "depressed" so will not report it; also staff concerns with qualifications to conduct the interview. Answer options are not clear. Consider the difference between "rarely" and "sometimes" over 7-day period – is that a feasible option? Another time frame for assessment – MDS has a 14-day look-back and these items are 7 days. We believe the items could have some value, but too similar to the MDS, and coding options for the resident are not clear, which generally decreases validity and reliability. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers PROMIS – like the items, but as noted above this seems to be too much like the Mood interview, which already consumes a great deal of time. Improve person-centered care and care planning Yes, it could, but other concerns as noted above. Used for quality comparisons Does not seem likely due to reluctance of some residents to complete the MDS Mood items. Support clinical decision-making and care coordination No, as stated above. Items are ambiguous and not culturally considerate. For example, "overwhelmed" for one person might not be the same for another person. Validity Whether it captures the patient attribute being assessed Concern remains with redundancy and answer options.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Proven or likely inter-rater reliability We do not believe that is likely. Feasibility Feasibility for use in PAC Important, but validity is a concern as noted above. Potential to be standardized and made interoperable across settings SNFs found that residents sometimes reluctant to report these issues to someone unfamiliar to them. Residents expressing interview fatigue – too many, too often. Clinical appropriateness See previous comments. Relevance to the work flow across settings Burdensome with minimal value in return. Can the data element be used with different payment models Time consuming and very similar to Mood interview on MDS. Validity and reliability of concern, since some staff very hesitant to focus on the resident's feelings. Does it measure differences in patient severity levels related to resource needs Yes, but many concerns as noted above. PHQ9-OV	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Concern that staff often do not realize the symptom could be unrelated to depression or anxiety and then do not report or record it, as they believe the items only relate to mood. Assessment look-back reverts to 14-day. Sets the facility up for inaccuracies and lack of validity with so many look-back periods. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Staff would need additional training to accurately reflect the resident's mood. Too many answer options and too many questions. Validity Whether it captures the patient attribute being assessed Concerns as noted above with the resident interview – repetitious and time consuming since already completing on the MDS as needed. Feasibility Feasibility for use in PAC As noted above in resident interview items – concern that items would be required in addition to MDS. Too repetitive and time-consuming, with usefulness questioned. Clinical appropriateness Concerns as noted above. Medical Condition – Continence Device Use	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Devices – Alpha 1 testing revealed moderate to excellent reliability and concerned about proceeding. Value for LTC is in question as many residents do not want to proceed with additional options to fix incontinence problems. Improve person-centered care and care planning Are there going to be guidelines when interview could stop? Again we have concerns about health literacy of our residents and whether assessor will have time to define and explain. Used for quality comparisons Support clinical decision-making and care coordination Items about reason and timing of indwelling catheter – useful upon admission, but after that why would there be a need to repeat? Some of this information is already difficult to collect, so will the reliability be what is desired to have validity? Feasibility Feasibility for use in PAC Time consumption is a great concern – staff already finding it difficult to get care delivered timely throughout the shifts. Instructions are to interview resident and review medical records – where will all of this information be documented so that it could be carried forward, and will it be accurate? Clinical appropriateness Would seem that augmentation questions related to bladder repair should be considered – history of interventions tried. Concern as to what survey ramifications will be tied to these types of questions. Can the data element be used with different payment models	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Redundancy remains a concern as does true value of items in terms of what can be done to improve the resident's quality of life. Does it measure differences in patient severity levels related to resource needs Seems to be no more relevant information than already collected on the MDS. Medical Condition – Continence Bladder Incontinence Use General Comments We do like items asking about incontinence prior to hospitalization, but ability to get reliable information is a concern. For both bladder and bowel, facilities already have a difficult time getting the nursing assistants to document the ADLs accurately. Are facilities going to receive additional funding to ask the nursing assistants to do more than we already ask them to do? Wages and ability to provide good benefits are already a huge problem for the SNFs, as is sufficient staff. Can we pay nursing assistants enough to ask for more documentation? The nurse on the unit will generally not know the information to chart. Ability to improve care transitions through meaningful exchange of data between providers Repetitive – similar to the MDS. Improve person-centered care and care planning No additional value beyond the MDS. Validity Whether it captures the patient attribute being assessed Redundant and time consuming.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Proven or likely inter-rater reliability Information prior to hospitalization is very difficult to gather for some SNF residents. Medical Condition – Continence Incontinence Interview General Comments Another interview might not be appreciated by the residents, as currently they often voice frustration with the number of interviews, interruptions. Another look- back time frame – continues to add to time consumption and possible confusion and resultant reliability concerns. Used for quality comparisons Answer options very subjective and difficult to define. Support clinical decision-making and care coordination Incontinence is always a problem – question the value of defining different levels of the problem – small, moderate, big. Validity Whether it captures the patient attribute being assessed Again, question if there is a cut-off time built into these additional items. Feasibility Feasibility for use in PAC Redundant and time consuming.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Can the data element be used with different payment models Will the resident's responses or caregiver's responses be used – which would be considered more reliable? Medical Condition – Continence Devise Use General Comments Another interview might not be appreciated by the residents, as currently they often voice frustration with the number of interviews, interruptions. Another look- back time frame – continues to add to time consumption and possible confusion and resultant reliability concerns. Are there going to be guidelines for when interview could stop? Again we have a concern about health literacy and whether assessor will have time to define and explain. Potential for improving quality Please see previous comments related to a urinary incontinence device. Medical Condition – Continence Bowel – Incontinence General Comments We do like items asking about incontinence prior to hospitalization, but ability to get reliable info is a concern. For both bladder and bowel function we have a difficult time getting nursing assistants to accurately document ADLs – do we pay them enough to ask for more documentation? Doubt nurse will generally know the information to chart. Medical Condition – Continence Bowel – Incontinence Interview General Comments	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Another interview might not be appreciated by the residents. Incontinence is always a problem – question the value of the value of different levels of the problem – small, moderate, big. Validity Whether it captures the patient attribute being assessed Answer options very subjective – small, moderate, big. Clinical appropriateness The directions are to ask the resident, to ask the caregiver, to review documentation – but who is going to document all of this? Great concern that these items are setting up facilities for survey issues. What is the purpose of gathering the information? Question related to no bowel output: what is the look-back? Medical Condition – Pain Pain Frequency General Comments Now a 3-day assessment period – too many different time frames to track for conducting the assessments. We continue to have issues with validity of MDS pain assessment now – what will change with the addition of these items? Value of these items compared to the pain assessment on the MDS is questioned. Where is the reassurance that these items would replace and not be in addition to items already on the MDS? What is the difference between severe and very severe? Maybe use "horrible" so they are different. Why not use mild, moderate, severe? Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		The issue here is that the item is redundant, as it is already on the MDS. Support clinical decision-making and care coordination These items related to pain are missing one of the most difficult issues of pain management – drug seekers. Along this line of thinking, we would suggest a gateway question about drug-seeking behaviors. Validity Whether it captures the patient attribute being assessed Pain questions just like on the MDS – the options are vague and too similar. Feasibility for use in PAC Repetitious. Medical Condition – Pain Pain Severity General Comments Options are not easy to differentiate – “severe” versus “very severe, horrible”? Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Same a MDS – not needed. Improve person-centered care and care planning	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Pain management is always important and is a huge part of person-centered care. Perhaps instead of repetitious questions, it would be more beneficial to provide tools and educational programs so there is value placed on sleep-hygiene programs. Validity Whether it captures the patient attribute being assessed Due to unclear answer options we do not feel the item is valid. Clinical appropriateness Already on the MDS – no need to add to workload. Medical Condition – Pain Pain Effect on Sleep General Comments Very subjective. Residents are often known to say that they did not sleep, but resident appeared to be sleeping during each check. Ability to improve care transitions through meaningful exchange of data between providers Value of item questioned. Improve person-centered care and care planning The item could be helpful to determine need for sleep- hygiene program. Used for quality comparisons	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Environmental factors have big impact on sleep in PAC settings. Not all of these factors can be changed or modified. Validity Whether it captures the patient attribute being assessed We believe that a gateway item is needed for these pain items, as there is a certain proportion of the population that does seek drugs. Medical Condition – Pain Pain Interferene – Therapy Activities General Comments Therapy activities – all put together – how can that be helpful if do not know which therapy caused pain? Validity of item questioned when thinking about SNF residents, who generally have had surgery or have been acutely ill and therefore the occurrence of pain would not be unusual and would not mean that the therapy was not medically necessary. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Concern that this item might have an impact on Medicare Part A coverage. If resident is experiencing pain, this item seems to indicate that the therapy is not appropriate. Medical Condition – Pain Pain Interferene – Other Activities General Comments	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Other activities – is it due to pain or a lack of interest? Resident may not like what is being offered. Some would still go even if in pain, if they liked the activity. Consider a clear definition of activities, e.g., group facility activities, in-room activities, "active" activities. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Subjective and question validity. Validity Whether it captures the patient attribute being assessed No, due to limitations of the question. Feasibility Feasibility for use in PAC No, as stated above. Rain Relief General Comments In general we would want to make sure that these pain items are going to be linked to opioid addiction. Improve person-centered care and care planning Answer options are not well differentiated – some, quite, very much. We believe this lack of clarity will decrease validity and reliability.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Validity Whether it captures the patient attribute being assessed No, due to weak answer options. Feasibility Feasibility for use in PAC No, as stated in comments above. Observational Assessment of Pain or Distress General Comments Like the items about using regularly – although accuracy could be an issue. Will need clarification for the term "regularly." Medication Reconciliation – Completion General Comments Trying to determine current medications (prior to the first setting in PAC) will be difficult – it already is a problem in SNFs. Would seem that a better question would be whether the facility received a medication list from the previous provider. We believe this type of question would get to the current problems. Ability to improve care transitions through meaningful exchange of data between providers Seems to be linked to a facility's process, since the regulations are going to require medication reconciliation.	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Validity Whether it captures the patient attribute being assessed Since medication reconciliation is a federal requirement, it does not seem relevant for the MDS. Feasibility Feasibility for use in PAC It is an important item across the PAC settings, but will CMS hold all settings accountable? SNFs currently have issues with getting medication records from the hospital. Can the data element be used Do not consider this a part of case mix. Medication Reconciliation – Use of Medications in Specific Classes General Comments Value of "days" information – medications would still need to be care planned. Could lead to survey deficiency if count is not accurate; seems to be process issue rather than outcome focus. Potential to be standardized and made interoperable across settings Already a part of the MDS, but additional classifications added. Confusion with definitional terms such as antiplatelet versus anticoagulant. Question value of additional categories, as they will not really change care planning. If the medications are similar, suggest drug categories can be combined because of similar effects. Medication Reconciliation – Indication General Comments	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Item appears to be more regulatory. Knowledge of indications for medication should be known before the medication is given the first time. Wording of question leads the assessor to answer "yes," which makes it not a valid condition. Feasibility Feasibility for use in PAC No, as validity would be in doubt. Can the data element be used with different payment models Could lead to gaming of the system. Medication Reconciliation – Discrepancies General Comments Wording of question could lead assessors to answer "yes" and then the item would not be valid. Could lead to "gaming" the system. If assessor needed to answer "no," would get the problem fixed before submitting and change response to "yes." Seems to be more related to policy and reflective of process. These medication reconciliation items are misplaced and are related to policy and surveillance. Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement General Comments Items do not seem relevant for the MDS. More about mandating process – there is no value in mandating process by using the MDS. Medication Reconciliation – Discrepancies Communicated to Physician	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Another item that relates to mandating process and not appropriate for the MDS. No value in mandating process by using the MDS process. Medication Reconciliation – Recommended Actions Taken General Comments Perhaps a general question regarding addressing discrepancy and whether it was followed – regardless of the drug classification. Related to process and no value to SNF providers to have on the MDS. As noted above, these items encourage "gaming." Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy General Comments With the revision to the Requirements of Participation, this would be addressed on the baseline care plan that is due within 48 hours of admission. Validity Whether it captures the patient attribute being assessed No, as looking at process related to a survey requirement. Feasibility Feasibility for use in PAC Duplicative, since baseline care plan must be in place within 48 hours of admission. Can the data element be used with different payment models	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		No. Advanced Care Directives – Healthcare Agent (Chart Review) General Comments This item was removed from the MDS 2.0, so question reason for putting it back. Question benefit of putting back on the MDS, especially with the new Requirements of Participation, which make a greater tie to the resident's representative than to legal piece of paper. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers Item does not appear to be necessary for the MDS. In addition, the state laws will still trump the Requirements of Participation as far as care planning and the SNF navigating multiple involved parties. Validity Whether it captures the patient attribute being assessed Could be valuable, as it guides safe transfers to identify that there is a legal document in the medical record about a healthcare agent. Feasibility Feasibility for use in PAC Next provider must validate that the information is still current, but it is not common practice to go to the MDS for this information. Physician Orders (Chart Review)	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Value of this item on the MDS does not seem to be pertinent. Item relates to process. Would not go to the MDS for this information. Goals of Care (Chart Review) General Comments Pertinence of this on the MDS questionable; does not seem to be of value. Appears to be a process item and not related to outcomes. Preference for Involvement of Family/Friends in Care Decisions (Patient Interview) General Comments Answer options are not definitive. We question the difference between some of the options such as "somewhat important" versus "not very important." Suggest considering these answer options: "yes" and "no." Ability to improve care transitions through meaningful exchange of data between providers No, answer options are not clear and concise. Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview) General Comments Repetitious of Section Q – value is questionable. Question of where this item leads a facility to go for information. Potential for improving quality	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		Ability to improve care transitions through meaningful exchange of data between providers We suggest some interconnectivity or skip pattern based on cognition. Validity Whether it captures the patient attribute being assessed No, answer options are not clear and concise. If resident selects “some information,” what would that be? We do not believe staff would be able to understand what information the resident did or did not want to know. Feasibility Feasibility for use in PAC Does not seem feasible for the SNF. Sleep Disturbance General Comments More time frames – too many questions, too many interviews. Residents consider them an intrusion. It is difficult to differentiate among the answer options. The concept of cue cards with the answer options is not totally acceptable to residents. Whether it captures the patient attribute being assessed No, for reasons stated above. Fatigue	

ID	Date Posted	Text of Comments	Name or Organization of Commenter
		General Comments Too many questions, too many interviews – residents have interview fatigue. Items are not necessary. Whether it captures the patient attribute being assessed No, as stated above. Ability to Participate in Social Roles and Activities General Comments Too many questions. Too many interviews. Time needed for these items is beyond the facility's capabilities. Potential for improving quality Ability to improve care transitions through meaningful exchange of data between providers No, not needed. Global Health General Comments More items that are redundant and repetitious when already completing the MDS. Items are not necessary. Answer options are unclear and very subjective, with no clear meanings. Judi Kulus, RN, MSN, MAT, NHA American Association of Nurse Assessment Coordination (AANAC)	
HHS	4/26/17	Hi,	Heart Health Strategies, Inc.

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		I was hoping to get clarification on the request for comment at this link: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#RAND%20IMPAC Specifically, I was wondering if you could help frame this request for public comment with respect to the proposals for IMPACT Aact standardized patient assessment data included in the IPPS Proposed Rule for long-term care hospitals, including how they relate to one another and how we should consider each request in light of the other. Any information you could provide would be greatly appreciated. Thanks, Cindy Moon Cindy H. Moon, MPP, MPH Vice President, Health Care Payment and Delivery Reform Hart Health Strategies, Inc. 202.729.9979 x 112 cmoon@hhs.com www.hhs.com	