

Public Comment Summary Report

Project Title:

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

Dates:

- The Call for Public Comment ran from August 12, 2016 to September 12, 2016.

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 requires the collection of input from stakeholders and the public.

Project Objectives:

The project objectives include developing standardized assessment-based data elements to meet the requirements as set forth under the IMPACT Act of 2014, Section 2(a). These 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. The development of standardized data elements included conducting environmental scans of the evidence, data element conceptualization, drafting data element specifications, convening technical expert panels, and feasibility piloting.

Information About the Comments Received:

- Web site used: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>
- Public comments were solicited by the following methods:
 - Posting a call for public comment on the CMS public comment website
 - Advertising the Call for Public Comment in CMS’ MLN email Newsletter
- Volume of responses received: CMS received 66 comments. Forty-nine organizations submitted comments, consisting of 16 post-acute care provider organizations, 14 general health systems, 10 professional organizations, 6 health industry companies, 2 hospitals, and 1 governmental agency, as well as 10 unaffiliated individuals.

General Comments:

Scope of Contract/Call for Public Comment

Summary: We received many comments on topics related to quality measures and PAC facilities that were outside the scope of this call for public comments. Some comments received discussed patient and social factors that affect access to care and care coordination for Medicare patients. Other comments related to quality measures and changes to PAC assessment instruments.

Response: The RAND Corporation is working with CMS to identify, implement, and maintain data elements that are appropriate for standardized patient assessment in PAC facilities. We appreciate the feedback pertaining to the work related to quality measure development, and have forwarded the comments to the contractors that are working with CMS to develop these quality measures.

Standardization as Trigger for Additional Patient Care

Summary: A few commenters anticipated that additional standardized assessment data elements will increase the perceived level of patients' care needs, and therefore cause greater resource use by PAC providers.

Response: CMS acknowledges that assessment information associated with patient health status may invoke provider services surrounding patient care needs.

Comments On Data Element Domains Not Addressed In Public Comment Posting

Summary: We received comments that pointed to gaps in the data elements, and/or encouraged consideration of additional areas for standardized assessment. Some commenters expressed concern that using standardized data elements would fail to capture important differences in the patient population of one care setting or in some types of patients. An additional concern was that the domains and data elements listed in this call omitted content that would be important to collect in a PAC setting. Suggestions included that we assess additional topics related to cognition (e.g., to include components of cognition other than short term memory), mood (e.g., to include anxiety), and pain (e.g., to include interference due to pain), and additional work to address the domains of medication reconciliation and care preferences.

Response: We appreciate the input identifying potential gaps in the data element list posted for comment and suggestions for other data elements to be considered. We intend to utilize public comment to inform future efforts in the area of data standardization. We anticipate utilizing input received from this comment period to inform not only the content for which we sought comment but to also inform next steps, including additional activities associated with future data standardization. With regard to the comment expressing concern that these elements would fail to appropriately assess for population or setting variation, we note that the Post-Acute Care Payment Reform Demonstration (PAC PRD)¹ found significant overlap in the types of populations served across PAC settings. We are working to identify and implement data elements that are appropriate for standardized patient assessment in PAC facilities and are meaningful across PAC populations and case mix. We intend to take into consideration comments pertaining to gaps in our data element list and suggestions of data elements for

testing.

Differences Between PAC Settings

Summary: We received comments about the unique strengths and challenges of the different PAC settings and providers.

Response: We interpret the comments pertaining to unique strengths and specializations to mean that while the four PAC provider types may have some overlap they have unique challenges and provide unique services. We appreciate the commenters' concerns surrounding provider types and their potential variation in services and populations and acknowledge specializations by provider design, while also acknowledging the existence of overlap, as illustrated in the PAC PRD.

General Concerns Pertaining to Burden

Summary: We received many comments expressing concern about the completion of additional patient assessment data elements and the burden that would place on PAC staff and providers.

Response: We appreciate the importance of minimizing burden and intend to do so when able as we work to fulfill the intent and requirements of the IMPACT Act.

Effects of Standardized Data Elements on Existing Payment and Quality Calculations

Summary: Many commenters expressed concerns about how new or modified data elements will affect payment models and quality measures.

Response: We appreciate the multiple dependencies related to data element use, e.g., payment and quality measure calculations, for some data elements in the existing assessment instruments. We will take into consideration how existing elements are used in our process of identifying potential data elements for use in meeting the IMPACT Act's requirement for modification of the patient assessment instruments to incorporate standardized assessment data.

Timing of Assessments

Summary: Many commenters had questions and concerns about if or how timing of assessments and look back periods would be standardized across assessment instruments.

Response: We understand the concerns about timing and look back periods related to standardized assessment data elements, and are considering how these factors affect reliability and validity of data, as well as the impacts on interoperability. The data elements that were listed in the solicitation of public comment focus on clinical characteristics (e.g., hearing impairment) and/or are based on patient/resident performance during an interview or task (e.g., BIMS). Such elements would not be likely to vary across different look back periods. Additionally, some widely-used data elements use their own look back period (e.g., PHQ), and altering the look back could affect the comparability of the data element with the assessment instruments currently in widespread use. Nonetheless, as we work through the developmental process of data element standardization, we will undoubtedly take into consideration the issue of look back periods. We understand that look back periods could alter the outcomes of standardization, and will be proactive in our approaches to rectify such issues in data element standardization.

Comments on the Public Comment Period

Comment: We received a few comments expressing dissatisfaction with the length of the public comment period, which was originally 14 days.

Response: We thank all commenters for expressing their concerns pertaining to the length of the public comment period. In response to comments received, we extended the length of the public comment period from 14 days to 32 days. Therefore, the public comment period was open from August 12, 2016 to September 12, 2016.

Comments on Specific Data Element Categories

a. Cognitive Function and Mental Status

CMS received several comments on data elements within the category of cognitive function and mental status. In general, commenters affirmed that appropriate assessment of cognition is important. Comments pertaining to specific data elements are described below.

1. Brief Interview for Mental Status (BIMS)

Summary: Many commenters expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients. These comments noted that the data collected through the BIMS will provide a clearer picture of patient complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers.

Response: We appreciate the support received for the usefulness of the BIMS in standardized assessment.

Summary: A few comments questioned the utility of the BIMS for assessment across settings. More specifically, a commenter raised concerns that the lack of information about the validity of BIMS in wide range of settings and populations makes selecting this assessment premature. Another comment questioned if this assessment is appropriate to use in the home health setting. Finally, the General Practitioner Assessment of Cognition (GP-COG) and the Allen Cognitive Level Screen-5 (ACLS-5) were suggested as alternatives to the BIMS.

Response: We appreciate the comments on the use of the BIMS. We have documented several instances of BIMS testing. The BIMS was tested in the PAC PRD, where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.¹ The lowest agreement was on the “repetition of three words” memory question, with a kappa of 0.71, which still falls within the range of substantial agreement. In addition, it was found to be predictive of cost. The BIMS demonstrates excellent reliability and high correlation with the well-validated Modified Mini-Mental State (3MS) test in nursing home populations.^{2,3} It is also currently used in the MDS 3.0 and in the IRF-PAI. CMS plans to continue monitoring the element performance for cross-setting use. We appreciate the suggestion to consider the GP-COG and the ACLS-5. CMS is considering those assessments for use in standardization.

Usefulness of the BIMS over Time

Summary: One commenter noted that this information may be less useful over time as patient's cognitive status changes more frequently at the end of life. Another comment expressed concern that the BIMS score would not be useful for measuring outcomes because the score may not necessarily improve with treatment – and moreover, may not be something that therapists are working to change.

Response: CMS appreciates the comments received related to usefulness of the BIMS over time and the usefulness related to outcome measurement. We note that the BIMS is currently used in the MDS 3.0 and in the IRF-PAI, and was also tested in the PAC PRD, where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.¹ In addition, it was found to be predictive of cost.

Burden Imposed by the BIMS

Summary: While one commenter did not feel that the BIMS would add significant burden or change for most providers, others believed it would. Specifically, it was noted that the BIMS overlaps with OASIS data element M1710 and that signs and symptoms of delirium and problems with recall are already assessed through the CAM and the element “Ability to Understand Others,” respectively, and that use of the BIMS for cross setting assessment would result in added burden.

Response: We appreciate the concerns expressed by commenters that changes may result in added burden for providers. We wish to emphasize the strengths of the BIMS, including that it is a performance-based element with excellent reliability. We are committed to balancing burden with the importance of meeting the goals set forward by the National Quality Strategy of improving the delivery of health care services, patient health outcomes, and overall population health. Our effort to balance burden may include replacing legacy data collection items when appropriate to do so.

Gaps and Limitations of the BIMS

Summary: A few commenters expressed concern regarding gaps in what the BIMS assesses. Commenters noted that the BIMS does not measure all constructs of cognition. In particular, constructs such as the cognitive capacity to perform everyday activities, problem solving, and attention also need to be assessed. One commenter recommended the CARE-C Tool as an example that includes all of the cognition elements that should be included. Without all of these elements, one commenter was concerned the BIMS would not be able to provide the care team with enough information to develop a comprehensive care plan.

Another shortcoming of the BIMS identified by commenters was that it does not adequately differentiate between patients with mild cognitive impairment and no cognitive impairment. For example, there might be patients whose cognitive abilities are above the ceiling identified in the BIMS, but still have limitations that need to be addressed. This limitation may also have implications for successfully separating patients in an appropriate case mix.

Response: We appreciate concerns related to the limitations of the BIMS. We note that the BIMS is a brief yet reliable assessment of cognitive function and is already implemented in PAC settings. However, we recognize that the BIMS does not provide a complete assessment of

cognition and we are continuing to evaluate and test additional data elements for standardized assessment of cognitive function, which include elements to assess executive functioning and attention.

Applicability of BIMS for Patients Who Cannot Complete Interview Assessments

Summary: Some commenters expressed concern that the BIMS would not be completed for many patients who are unable to communicate well enough to complete the interview. One commenter suggested that this would limit the information for care transitions, coordination, and clinical decision-making provided by the BIMS for those patients. Additionally, commenters did not think it was clear how to code individual elements when a patient is unable to respond. Another commenter also thought there should be an option for patients to refuse to complete the interview.

Response: We recognize that there are limitations of the BIMS for patient populations who are unable to communicate for various reasons. For this reason, we are currently evaluating the feasibility of several observational cognitive assessment data elements for use in patients across PAC settings who are unable to complete an interview-based assessment. In addition, we will take the comments pertaining to coding and completion of the interview into consideration, including with any applicable guidance documents that set forth instructions for use.

How BIMS Data Element Captures Reasons for Non-Completion

Summary: Many commenters supported the addition of element B1b. However, some commenters suggested changes to the response scale such as changing “unable to make self understood” to “patient unable to make self understood,” and adding “behavioral impairment” as a response option.

Response: CMS appreciates the commenters’ suggestions and will take them into consideration.

2. Confusion Assessment Method (CAM)

Usefulness of the CAM

Summary: Many commenters believed the CAM would provide important information for care planning and care coordination, therefore contributing to quality improvement. They noted it is particularly helpful in distinguishing delirium and reversible confusion from other cognitive impairments. One commenter also suggested that the CAM would be useful if it drove reimbursement for additional care that might be required based on the assessment outcomes. Other commenters, however, questioned how useful the information collected by the CAM will be. One commenter did not believe it would contribute to quality improvement while another noted it would not be useful for outcome measurement because it is not sensitive to change and therapists do not necessarily try to change the outcomes it measures. Instead, one commenter suggested the CAM may be more useful as a screener for more detailed assessment. Another commenter questioned whether the CAM really measures delirium and not other cognitive impairments that might impact the responses to the CAM elements. Similarly, multiple commenters noted that the CAM does not assess all aspects of cognition that are important to assess, such as executive function and cognitive capacity to perform activities of daily living.

Response: CMS appreciates the support received for the use of the CAM in standardized assessment. We note that the Short CAM is effective in identifying delirium in validated research studies.⁴⁻⁶ The four elements selected for the Short CAM were found to best distinguish delirium from other types of cognitive impairment and are not necessarily related to therapy. When tested in the PAC PRD, the CAM had substantial inter-rater reliability agreement for the “Inattention and Disorganized Thinking” questions (kappa range of 0.70 to 0.73); and the “Altered Level of Consciousness” question showed moderate agreement (kappa of 0.58).¹ CMS will consider the concerns of the commenters as we continue to evaluate the CAM and additional data elements for standardized assessment of cognitive function.

CAM for Specific Settings

Summary: Many commenters believed the feasibility and utility of the CAM would vary from one setting to another and there were several setting-specific comments. Commenters also expressed concern that the CAM is not appropriate for certain settings and populations, such as patients undergoing short-term rehabilitation. Two comments related to IRFs suggested that delirium is uncommon among IRF patients and routine screening for it is unnecessary. The commenters did acknowledge that cognitive impairment is common among IRF patients and should be assessed, however they did not believe the CAM is an acceptable measure of cognitive impairment. Additionally, one commenter noted that the typical length of stay of an IRF patient is not long enough to distinguish confusion and delirium. Multiple comments related to home health care, suggesting that it would not be feasible to collect this information over a continuous 3-day period. This is due to the fact that providers are not in the patient’s home every day. As home health providers may have limited time to observe the patient, they may have to rely more heavily on caregiver responses. Some commenters noted that relying on caregiver responses may be problematic since caregiver responses may be less reliable and it may be difficult to find a time to speak with them. One commenter recommended that as an alternative, the elements could be answered based on the last three encounters the provider had with the patient.

Response: Regardless of the length of stay of patients or the type of provider providing patient care services, distinguishing delirium from other types of impairment is imperative across all PAC settings for ensuring the safety of the patient. Delirium can be a serious and life threatening syndrome warranting often time-sensitive medical and nursing intervention. Delirium has an acute onset and is secondary to an underlying cause or issue. We note that the short CAM has key features that distinguish delirium from other types of cognitive impairment and showed substantial reliability when tested in the PAC PRD across settings.⁴⁻⁶

Overlap with Current Assessments

Summary: A few comments mentioned that the CAM overlaps with OASIS element M1740. One commenter wanted to know if the proposed version of the CAM would replace the current delirium section on the MDS 3.0 and others cautioned that adding the CAM would create duplicative assessments and add unnecessary burden. One commenter noted that element M1740 is used in quality measures so it should not be replaced. Another commenter suggested that the CAM might not even be necessary since this information can be captured from and ICD-10 code for delirium or cognitive impairment.

Response: We appreciate the suggestions surrounding relevance and presence of the CAM or synonymous data collection in the OASIS, and further note that the CAM is specific to assessing delirium in a standardized manner. Given that ICD coding is used for billing purposes we do not

believe that capturing via ICD coding would enable real-time assessment and intervention. With regard to duplicity and burden, we note that the CAM is collected in the MDS 3.0 and in the Long Term Care Hospital (LTCH) CARE data set (LCDS).

Validity and Reliability of CAM

Summary: A few commenters questioned the validity and reliability of the proposed version of the CAM. They posited that due to the proposed changes, results from prior psychometric testing may not be applicable therefore more information is needed to support it. Another commenter added that the CAM assessment may be inaccurate since determining the presence of confusion or delirium requires assessments over time and comparison to a baseline measure. One comment also suggested that additional reliability testing is needed because the kappa value for the CAM is low. Lastly, one commenter noted that the CAM has not been tested in certain patient populations, such as those with psychiatric conditions and traumatic brain injuries, who experience many changes in mental status that are not related to delirium that the CAM might not be able to differentiate.

Response: We appreciated the commenters' concerns. We note that when tested in the PAC PRD, the CAM had substantial inter-rater reliability agreement for the "Inattention and Disorganized Thinking" questions (kappa range of 0.70 to 0.73); and the "Altered Level of Consciousness" question showed moderate agreement (kappa of 0.58).¹

CAM Response Options

Summary: While one commenter supported the proposed CAM response options, noting that they were more descriptive than the previous ones, other commenters suggested revisions to the response scale. Some commenters were concerned that a yes/no response for section E would not provide sufficient information about the patient's condition. One comment recommended stratifying the answers to include "E1. Alert (normal)," "E2. Vigilant," "E3. Lethargic," "E4. Stupor," and "E5. Coma." Other comments were related to the response option "Vigilant" in section E. One commenter thought "hyperalert" was a poor way to describe vigilant and recommended using the MDS 3.0 description of "startled easily to any sound or touch." Another commenter did not believe "vigilant" was an appropriate representation of an altered level of consciousness and thought the response should be rephrased.

Response: While we note that the CAM was developed and tested using the response options that exist within it, we will take into consideration the feedback received on response options.

3. Expression of Ideas and Wants

Usefulness, Validity, and Reliability of the Data Element, Expression of Ideas and Wants

Summary: Commenters generally supported using the data element, Expression of Ideas and Wants. Commenters suggested that this data element would provide useful information that can be used to improve quality, facilitate care coordination, influence care planning, and describe case mix.

Response: CMS appreciates the support received for use of the data element, Expression of Ideas and Wants.

Summary: A few commenters questioned the utility of the information provided by the Expression of Ideas and Wants. One commenter noted that it will not be useful for outcomes measurement because the scales are limited and lack evidence that they are sensitive to change. Additionally, the Expression of Ideas and Wants data element is not necessarily an outcome therapists try to change. Some commenters were concerned about how this data element will be used in care planning. They questioned whether it may prevent patients who need rehabilitation from being referred to it and what will happen to patients who lack the motor or cognitive skills to express themselves.

Response: We note that the standardized assessment data elements included in the public comment period for use in satisfaction of the IMPACT Act may not serve all of the data sharing needs between settings nor patient care needs. The data elements included in the public comment are in no way intended to limit additional assessment that is useful for care planning.

Summary: A few commenters raised questions regarding the validity of the Expression of Ideas and Wants data element. One commenter noted that the data element may actually measure assertiveness, which may be interpreted as a negative characteristic although increased assertiveness can be a sign of clinical improvement for brain injury patients. Comments suggested that CMS consider the ability to ascertain validity. Since the data element was tested in conjunction with the data element Understanding Verbal Content, one commenter also noted there is not enough evidence regarding how the Expression of Ideas and Wants data element will perform on its own. The data element's inter-rater reliability was also questioned, since multiple provider types will be collecting this information.

Response: We wish to note that we are exploring the use of the data elements, Expression of Ideas and Wants and Understanding Verbal Content, to be used together to assess communication and will continue to consider validity in ongoing assessment. We further note the substantial agreement for inter-rater reliability (kappa range of 0.74 to 0.80) found in the PAC PRD for the composite Communication variable, when tested across settings.¹

Overlap with Current Assessments

Summary: A few commenters pointed out that the data element, Expression of Ideas and Wants duplicates an item contained in the Functional Independence Measure (FIM) in the IRF-PAI and OASIS element M1230. A few of these commenters thought the data element that appeared in the public comment document would be useful if it replaced but was not added as an additional data element to avoid duplication. One commenter noted that the proposed data element is clearer than that which is currently used within the MDS 3.0. However, a few other commenters thought the data elements in current use were better options. The rationale for maintaining current data elements were that the Expression of Ideas and Wants data element is not as sensitive, nor is the scoring as specific, as the FIM, and does not capture patient complexity as well as the OASIS element.

Response: We appreciate the commenters' support of the posted data elements, as well as feedback related to burden and duplicity related to the Expression of Ideas and Wants data element. As noted previously, we appreciate the importance of minimizing burden and intend to do so as we work to reach the intent and requirements of the IMPACT Act, to include replacing legacy data collection items when appropriate to do so. We acknowledge that persons may be able to effectively express themselves nonverbally to communicate with healthcare providers, and this is captured in the Expression of Ideas and Wants data element, unlike some others that

focus only on verbal communication. We appreciate the importance of item sensitivity and intend to continue to evaluate how data elements capture patient complexity as part of our ongoing evaluation.

Expression of Ideas and Wants Response Options and Title

Summary: Two commenters suggested revisions to the answer scale, particularly the “unknown” and “unable to assess” responses. Commenters recommended that the elements should require additional information about why the answer was “unknown” or “unable to assess.” Furthermore, one commenter noted that there were no instructions for assessing special populations such as patients on ventilators, language other than English (LOTE) speakers, or non-verbal patients. One comment suggested that CMS rename Expression of Ideas and Wants to “Ability to Express Ideas and Words.” One commenter shared agreement with the removal of the phrase “or speech is not clear.”

Response: We appreciate the feedback received on response options to this data element and will consider these comments to inform any applicable guidance documents that set forth instructions for use of the data elements.

4. *Ability to Understand Others: Understanding Verbal Content*

Usefulness of Ability to Understand Others: Understanding Verbal Content

Summary: Several commenters agreed that the “Ability to Understand Others” data element could be feasibly implemented across all settings and would provide useful information that will contribute to quality improvement. In particular, commenters suggested that the “Ability to Understand Others” data element may indicate an individual’s ability to understand instructions and consequently their ability to benefit from therapies or potential safety issues. Commenters also believed the information from this element will contribute to care planning and care coordination.

Response: We appreciate the support for use of the data element, Ability to Understand Others: Understanding Verbal Content, in standardized assessment.

Summary: A few commenters noted limitations of the Ability to Understand Others: Understanding Verbal Content data element. One shortcoming noted by commenters was that the usefulness of this information is limited since a patient’s ability to perform what the assessment is evaluating will change over time, particularly during the first couple of days of a PAC stay. One commenter noted that this data element might be better suited as a screener for more in-depth assessment. Another commenter questioned the data element’s ability to contribute to outcome measurement, due to insufficient evidence that it is sensitive to change and noted therapists are not necessarily trying to improve what it is measuring. In addition, another comment specific to IRFs noted that this information is not useful in this setting because patient stays are often too short for patients to show improvement on this element. Another commenter expressed concern that a patient’s ability to understand others can vary significantly from one moment to another and recommended additional variables be taken into account in order to aptly describe the patient’s ability. Lastly, one commenter expressed concern that it would not be feasible to collect the data as instructed. They believed it was unreasonable to expect assessors to consult with all clinical caregivers and family members, as well as review the medical records.

Response: We appreciate the concerns conveyed by several commenters related to the applicability and breadth of assessment associated with the assessment pertaining to the Ability to Understand Others: Understanding Verbal Content and will evaluate the utility of this data element. We wish to clarify that this assessment pertains to a single point in time, and is not intended to serve as the sole nor comprehensive assessment. While the PAC PRD demonstrated feasibility and reliability for use of this data element across settings, the data elements included in the public comment are in no way intended to limit additional assessment that is useful for care planning. We reiterate that the purpose of standardizing data elements, in accordance with the IMPACT Act, is to support care planning, clinical decision support, inform case-mix and quality measurement, support care transitions, and to enable interoperable data exchange and data sharing between post-acute care settings. We further note that we intend to minimize burden while working towards the larger goals set forward by the National Quality Strategy.

Validity of Ability to Understand Others: Understanding Verbal Content

Summary: Commenters questioned the data element’s validity. Similar to Expression of Ideas and Wants, a comment suggested that CMS consider the ability to ascertain validity, as this is a part of the IRF-PAI 1.4. Commenters noted that the Ability to Understand Others data element had previously been tested with the Expression of Ideas and Wants data element; therefore there is a lack of information about how this data element will perform on its own. However, one commenter noted that it would be valuable to combine these two data elements.

Response: We appreciate the feedback received and note that we are exploring using the data from Expression of Ideas and Wants and Understanding Verbal Content, in relation to existing data collection to assess communication. While we intend to further evaluate validity, we also wish to note the substantial agreement for inter-rater reliability (kappa range of 0.74 to 0.80) found in the PAC PRD for the composite Communication variable, when tested across settings.¹

Ability to Understand Others: Understanding Verbal Content Response Options

Summary: Two commenters suggested revisions to the response options. One commenter thought the response options: “unable to assess” and “unknown” needed further clarification as to what they mean and when these codes would be chosen. Similarly, another commenter suggested that clinicians should explain why the information could not be obtained if one of these answers is chosen.

Response: To clarify, the “unable to assess” and “unknown” response options are given when the assessment cannot be completed or the determination is unknown. We appreciate the suggestions we received on response options to this data element and will take these into consideration.

5. Behavioral Signs and Symptoms

Usefulness and Reliability of Behavioral Signs and Symptoms

Summary: Several commenters believed the Behavioral Signs and Symptoms data element would provide useful information to indicate cognitive impairment and contribute to care planning. They noted that this information is important at both admission and discharge, and provides important insight into what treatment is appropriate for the patient and what resources will be needed.

Response: We appreciate the support received for using the data element, Behavioral Signs and Symptoms, in standardized assessment and agree with the commenters that this information would be beneficial in providing person-centered care.

Summary: A few commenters did not believe collecting Behavioral Signs and Symptoms would be useful. One commenter did not think this element could be used for outcome measurement because the scale is not sensitive to change and therapists do not necessarily try to change this outcome. Instead, the commenter recommended using the data element as a screening element for additional assessment. Another commenter expressed concern that the data element does not identify subtle signs or symptoms which may indicate cognitive impairment, consequentially limiting its utility for contributing to care planning, and improving quality and outcomes. Two commenters expressed concern that the data element could incorrectly indicate dementia in persons recovering from brain injury because aggression is often part of their healing process. The commenters requested that further testing be done to assess this potential issue. Another commenter suggested that CMS consider adding the Cohen-Mansfield Agitation Inventory (short version) to capture dementia.

We appreciate the concerns noted by commenters and will evaluate the utility of this data element, including the exploration of additional data elements to capture subtle signs and symptoms related to agitation and anxiety. We acknowledge that the data captured is intended to be used for screening to indicate if there is a need for further evaluation and follow-up and that it would be beyond the scope of the data element to demonstrate causality. Moreover, we acknowledge that there could be a range of treatable etiologies reflected by behavioral signs and symptoms, including brain injury. We also note that the longer 29-item Cohen Mansfield Agitation Inventory was used as the criterion measure against which we tested the Behavioral Signs and Symptoms data elements. They were very highly correlated (physical toward others: kappa = 0.856; verbal towards others: kappa = .725; other: kappa = .532).⁷

Summary: Two commenters questioned the reliability of the Behavioral Signs and Symptoms data element, suggesting that there was not sufficient data on inter-rater reliability.

Response: We consider reliability very important. In researching the use of this data element, we found that it exhibited high reliability in the National Evaluation Study (kappa = 0.972, verbal behavioral symptoms; perfect agreement for physical behavioral symptoms).⁷

Setting-Specific Topics

Summary: Multiple comments expressed concerns regarding the feasibility of implementing the Behavioral Signs and Symptoms data element in the home health setting. In particular, they noted that home health care providers do not see patients every day, therefore assessing a patient over a 3-day period would not be possible. Consequently, one commenter explained that providers may rely heavily on caregiver responses which may be less reliable and it may be difficult to find a time to speak with family members or other caregivers. As an alternative, one commenter recommended that the assessment be based on the last three encounters with the patient.

Response: We appreciate the unique challenges in the home health setting and will take these into consideration. Specifically, if the data element is adopted, we would evaluate such issues and any need for further information or clarification to be included in the assessment instructions within the respective manuals.

Overlap with Current Assessments

Summary: A few commenters raised the issue that the Behavioral Signs and Symptoms data element overlaps with OASIS element M1740 – Cognitive, Behavior, and Psychiatric Symptoms, therefore adding the proposed data element would require an unnecessary duplication of effort. One of the commenters recommended the OASIS element as a superior data element because it has a more extensive response scale and it is used to calculate and risk adjust quality measures. Another commenter shared that they expect “no impact” on the use of these data elements because they are very similar to existing measures.

Response: We appreciate this comment and note that we are continuing to evaluate improvements to the data element, Behavioral Signs and Symptoms, including to the response scale. We will take these comments under consideration in ongoing evaluation of how the assessment can be improved, including to capture severity. As noted previously, we appreciate the importance of minimizing burden and intend to do so as we work to reach the intent and requirements of the IMPACT Act, to include replacing legacy data collection items when appropriate to do so.

Behavioral Signs and Symptoms Response Options

Summary: Multiple comments focused on the response options for this data element. One commenter agreed that the proposed response options are more descriptive and are improvements on the prior ones. However, several commenters recommended revisions to the response scale. Two commenters suggested adding a response option, or an additional data element, that would capture patient refusal of care since that information can be useful in determining how patients react to treatments. Another comment expressed concern that the data element does not distinguish whether patients are continually confused or only agitated at certain times, and recommended adding a frequency metric to address this shortcoming.

Response: We appreciate the input and suggestions provided regarding response options and additional attributes, i.e., the inclusion a frequency component to the data gathered for Behavioral Signs and Symptoms, and will take these into consideration. We also note that while the standardized data could serve as a screening tool, it may not accomplish all necessary additional evaluations that the provider would apply so as to provide patient-centered services.

6. Patient Health Questionnaire (PHQ)

Suitability of the PHQ for PAC Cross Setting Standardization

Summary: Many commenters provided feedback on using the PHQ for the assessment of mood. Overall, commenters felt that collecting this data element across PAC settings was appropriate, given the role that depression plays in well-being.

Response: We appreciate the support received for including depression screening in cross-setting assessment, as well as the specific support received for the PHQ. Given their scientific validity, current use, coupled with the importance for screening depression, we believe the PHQ would serve to support patient care in a variety of ways. The PHQ-2 is a validated depression screening tool for older populations^{8,9} and these data elements are predictive of resource utilization and may affect outcomes. Patients with depression have been reported to receive two to four times as much nonpsychiatric care as patients without depression.¹⁰ The PHQ-2 is currently in use in the home

health setting, while the PHQ-9 is currently in use in skilled nursing facilities.

PHQ-2, PHQ-9, and PHQ-2/9 Gateway Approach

Summary: Several commenters felt that using the PHQ-2 as a gateway to the longer PHQ-9 would reduce burden on patients and test administrators and expressed strong support for this approach. These commenters noted that a gateway approach would balance reporting burden with the ability to collect more in-depth information about signs and symptoms of depression in patients. One commenter pointed out that patients can feel overwhelmed upon admission to a PAC facility and that a tiered approach would benefit patients by allowing for a less invasive mental health screen.

Response: We appreciate those comments that echo their agreement that using the PHQ-2, as a gateway to the PHQ-9, is a viable option. As commenters pointed out, the intent of the gateway approach, as outlined in the public comment posting, is to decrease burden for providers and patients.

Summary: A few commenters expressed caution against making any changes to the protocol for assessing mood with the PHQ-9, including the approach to use the PHQ-2 as a gateway to the PHQ-9. Some commenters believed that a change in current practice from the PHQ-9 to the PHQ-2 (either as stand-alone or as a gateway) would lead to under diagnosis (citing a recent meta-analysis) and create a burden associated with training and assessment scheduling. One commenter who supported the gateway approach also suggested using a low threshold level for the PHQ-2, to ensure that patients who require further evaluation would not be missed. Commenters discussed the importance of targeting “sub-syndromal levels (i.e., mild levels) of depressive symptoms” to prevent patients developing more severe depression. One commenter suggested picking either the PHQ-2 or PHQ-9, but not using the gateway approach, as it would unnecessarily screen patients twice. Finally, one commenter urged CMS to eliminate the PHQ-2 and PHQ-9 from the cross-setting assessment list and allow current clinical practice to continue (which would include screening for depression, if found to be medically necessary, but not the reporting of these data via the assessment instruments).

Response: We appreciate the comments regarding the perceived burden associated with the use of the PHQ-2 as a gateway item. With that, we appreciate the concern some commenters also expressed about the sensitivity of the PHQ-2 and the potential for under diagnosis. In our literature review,^{9,11-16} while we found that the sensitivity of the PHQ-2 could be slightly inferior to the PHQ-9 and use of the gateway approach could bring with it the potential to under screen some patients who could benefit from screening for additional symptoms, we also found the use of the PHQ-2 has suggested that its usefulness and efficacy supports its inclusion as a screening tool within any assessment.^{11,17} In our continued evaluation of this data element for this purpose, we will evaluate the reliability for the use of the PHQ-2 as a gateway item.

We also appreciate the concerns expressed around changes to the current assessment, and we are continuing to evaluate the impact any changes will have on patients and providers. In response to the commenter who expressed concern that the gateway approach would cause patients to be screened twice, we clarify that with the gateway approach, patients will still be screened once. Patients for whom the PHQ-2 indicates the presence of signs of depression are screened more thoroughly than those for whom the PHQ-2 does not indicate the presence of signs of depression.

Summary: One commenter raised concern that proposed modifications to the commonly used PHQ-9 will lead to lower PHQ-9 scores.

Response: We appreciate the comment and will consider use of the commonly used PHQ-9. We note that the version put forward in public comment is not modified from the version currently in use in the MDS. Although slightly different versions of the PHQ-9 have been used in other settings, the version in use in the MDS has been shown to be highly correlated with a physician diagnosis of depression in residents of SNFs.^{7,18}

Summary: One commenter noted support for the PHQ-2/9 as a depression screening tool, but was also concerned that this would not capture a substantial portion of patients with anxiety.

Response: While the PHQ is not a screening tool for anxiety, we appreciate the recommendation to consider the assessment of anxiety and will further explore this in ongoing development of assessment items.

Case Mix, Quality and Outcome Measures

Summary: Several commenters questioned how such changes would impact payment case mix, quality, and outcome measures. One commenter noted that many of the screening tools discussed in the current round of public comment, including the PHQ, have limited scales and have not been validated as being sensitive to change. Commenters asked for more information on how these elements will be evaluated for the ability to contribute to case-mix risk adjustment.

Response: We appreciate the commenters' concern for how assessment changes could affect payment case mix, quality, and outcome measures. We wish to note that we are considering how existing data elements are currently used by PAC providers and their various reporting requirements as we evaluate the use of particular data elements in satisfaction of the IMPACT Act.

PHQ for Specific Settings and Populations

Summary: CMS also received comments that addressed applicability of the PHQ to specific settings and patient populations. Some commenters felt the PHQ-2 was sufficient for the home health setting and that the PHQ-9 would not provide additional quality improvement. Other commenters felt that the PHQ would not be a valid screening tool for patients with short stays in an acute setting, such as an inpatient rehabilitation facility. Another commenter felt the PHQ was not appropriate for patients treated in the LTCH setting because of the severity of illness. This commenter stated that LTCH patients are likely to show depressive symptoms during the two week period prior to administering the questionnaire since that period would likely include a stay in an intensive care unit. A number of commenters were concerned about the use of the PHQ-2/9 in patients with cognitive deficits, stroke, traumatic brain injury, or those who are unable to communicate for various reasons.

Response: Regardless of the length of stay of patients, and of the timeframe over which they may have been experiencing signs and symptoms of depression, it is the responsibility of the PAC setting to deliver high quality care for all the symptoms or conditions a patient may have. Neither the idea that the onset of depression may predate the PAC stay, nor the expectation that the episode of care will be short, exempts a PAC provider from screening and treating patients for the full range of physical and mental health problems. For patients in long-term care hospitals, we note that the DSM-V does not distinguish among variants of depression based on the precipitating factor. Depressed mood, regardless of its cause, requires attention and care because unaddressed depressed mood can slow down recovery. It may be that depressed mood brought on

by the circumstances that lead someone to end up in an LTCH can be addressed within a therapeutic session rather than medication, but that determination is one that needs to be made by a clinician.

CMS recognizes that there are limitations of the PHQ for patients who are unable to communicate for various reasons. For this reason, we are currently evaluating the feasibility of an observational version of the PHQ-9 for use in patients across PAC settings who are unable to complete an interview-based assessment.

Follow-up Care for Patients with Signs and Symptoms of Depression

Summary: One commenter noted the recommendation by the U.S. Preventative Services Task Force that, “screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up” and asked CMS to consider whether all PAC sites have such systems in place.

Response: We appreciate the commenter’s suggestion to include the U.S. Preventative Services Task Force recommendations and will take this into consideration.

7. *Other Domains/Assessments of Mental Status*

Summary: A few commenters suggested that additional domains of mental status should be considered for data element standardization efforts such as functional cognition, comprehension, social interaction, and problem solving. Another commenter urged CMS to consider the value of assessing positive emotional responses alongside the negative and recommended the Thriving Questionnaire, which can make assessment of the signs and symptoms of depressed mood more enjoyable for patients by gathering a more comprehensive overview of patients’ emotional resources, some of which focus on strengths.

Response: CMS appreciates the recommendation to additionally consider additional domains of mental status, as well as positive emotional responses. CMS recognizes the value in patient satisfaction during data collection and is interested in developing data elements that are more enjoyable to patients. We note that many factors contribute to the selection of data elements for assessment, including ability to improve quality, outcomes, and patient and provider burden.

b. Medical Conditions:

1. Pain Presence

Support and Benefits of Standardized Pain Assessment in PAC

Summary: Several commenters shared that it is important to capture pain presence for PAC residents/patients and across the care continuum. One commenter described how assessing the presence of pain symptoms would help capture underlying conditions and direct treatment approaches for patients. Another comment detailed that the pain presence data element could assist in determining case mix by highlighting resource needs. Commenters suggested that a standardized set of data elements could help PAC providers assess patient pain uniformly across the continuum of care and improve care for patients.

Response: We appreciate the comments supporting the standardization of data related to pain. We agree that it is important to capture pain presence for PAC residents and patients in order to assess pain uniformly across care settings, to support care coordination and for improvements in care overall. We agree on the importance of standardizing data elements for purposes such as ensuring high quality care that serves to meet individualized needs while within the care of one PAC provider as well as during care transitions, and that medical complexity associated with pain can be important in illustrating case-mix.

Questions about Look Back Period for Standardized Pain Assessment Elements

Summary: Several commenters noted that the Pain Presence data element put forward for this public comment was similar to existing data elements, but that the look back period was specified at 3 days rather than the 5 days currently used in the MDS 3.0 pain presence data element. There were questions and concern about how such a change in look back would affect responses and, subsequently, payment case mix models for the SNF PPS, for example.

Response: As discussed previously, on an item-by-item basis, we intend to evaluate the implications related to assessment periods and the public's input and recommendations on this topic. Specifically, we intend to evaluate how the associated look backs would affect responses, case mix, and other factors such as quality measurement and health information technology vocabularies.

Acceptability of Pain and Impact of Pain on Patient

Summary: A few commenters noted that the Pain Presence data element may not capture if pain is tolerable. Assessing pain tolerance might better address core patient concerns. Comments suggested CMS should consider if this data element would capture what is most important. For example, pain is subjective and the mix could vary with each resident's pain threshold. CMS should study question 9 of the Brief Pain Inventory (BPI). A comment suggested that CMS consider combining the pain presence and pain severity data elements. Another comment called for additional description of the "unable to answer or no response" option.

Response: We intend to explore concepts associated with the capturing of a patient's experience with pain, including adequacy of pain management, interference with sleep, activities, and therapies. We believe pain can be subjective, and recognize that pain presence may vary for individuals.

PAC Provider (type)-Specific Comments for Pain and Timing

Summary: One commenter expressed concern that due to the nature of IRF therapy, which is highly intense and accordingly, it is not uncommon for some IRF patients to experience some degree of pain, the pain presence data element may not be a valuable element across PAC settings and will not improve the quality of care. Specifically commenting on home health services, a commenter noted that it is not feasible to assess pain presence over multiple days if there is no clinical reason to see the patient each day. They also suggested that more clarification is needed surrounding the timing associated with data element administration. For example, interviewing a patient after physical therapy could result in a different response when compared to interviewing a patient in the absence of such therapy.

Additionally, a commenter suggested that the data element's current presentation would neither demonstrate nor reflect quality improvement efforts or outcomes across care settings, while

another commenter questioned the ability of the data element to capture the presence of pain in patients with cognitive dysfunction. In addition, the commenter suggested that a review for the need for a pain assessment after each treatment administration should be conducted in order to evaluate the effect of the intervention and determine the need for treatment modification.

Response: We appreciate the concerns expressed related to the assessment of pain and factors that may exist and influence the presence of pain and its assessment. We believe that understanding and addressing the presence of pain, regardless of PAC provider type, has critical implications for informing care planning and pain management strategies. For example, inadequate management of pain may limit participation in therapy services and therefore, the management would be important for appropriate care planning and ensuring quality of care. Pain that is poorly managed in an any population can contribute to diminished quality of life, depressed mood, sleep disturbance, and more, which can reduce patient motivation to participate in therapies.

We appreciate the commenter's concern surrounding pain assessment with patients with cognitive impairments. We wish to note that to date, evidence suggests that pain presence can be reliably reported among patients with cognitive impairments. To that end, we intend to test additional observational pain presence elements. In response to the comment on a need for pain assessment after treatment administration, we are testing repeated pain assessment over the course of care to support care planning, patient-centered care, and appropriate treatment modifications.

With regard to the time frames associated with home health services, we would like clarify that separate assessments are not required each day, but rather collected by means of a look back period in which the presence of pain is evaluated by with regard to a period of time. With this, and to the commenter's point, we are exploring the implications of timing surrounding data element administration as we move through the development of these elements and agree that additional guidance on how assessments should be conducted would support standardization.

Combining Pain Presence/ Severity Data Elements and Need for Data Elements

Summary: One commenter suggested that the pain presence and pain severity data elements should be combined into one overall element. The commenter suggested the possibility of the element wording being revised in that the patient has an opportunity to respond to the level of pain they have felt in the last 3 days, using a scale of 0 to 10. Unresponsive patients would have an entry of 88 in the assessment.

Response: CMS thanks the commenters for their input on the pain data elements. As we continue development and testing of all pain data elements, we will take these recommendations into consideration. We would like to note that we presented both pain data elements and solicited those elements for comment as pain is likely to vary over time. CMS is soliciting comment on these data elements knowing that combining the elements may potentially limit the information that could be gathered from the collection of these elements. However, we will take into consideration the combining of these elements. As noted many times in this document, CMS intends to decrease burden of collection of data elements and test for skip patterns with all data elements to be able to alleviate any provider burden from the addition of data elements. In addition, we are continuing to test the pain presence data element to determine suitability in PAC populations.

2. Pain Severity

Support for and Benefits of Standardized Pain Assessment in PAC

Summary: Commenters suggested that the pain severity data element is important information to share across the care continuum to facilitate care coordination. One commenter shared that it is important to monitor patient response to pain medication and/or non-pharmacological interventions by assessing pain severity. Several other commenters reinforced the importance for the pain severity data element.

Response: CMS appreciates the supportive comments for the data element standardization process and agree that it is important to capture pain severity in PAC facilities and across the care continuum. We believe that it is important to monitor the effects from pain medication regimens and/or non-pharmacological interventions.

Request for Additional Evaluation, Burden

Summary: One commenter outlined the changes proposed to the data element when compared to the existing MDS 3.0 element J0600 (Pain Intensity), noting that an evaluation should be conducted to assess downstream impacts on payment case mix and quality measures. Finally, the commenter suggested that CMS should consider the burden associated with any assessment item changes. Another commenter expressed that they were uncertain that the data element pertaining to the presence of pain, or its severity, is appropriate for PAC use as currently written.

Response: We agree that it is important to evaluate any potential changes that could occur as a result of the modifications of the assessment instruments, such as case mix and burden. With that, for any such changes we would intend to monitor for any downstream affects. We also note that while pain presence and severity are being evaluated at this time however we intend to further explore assessment data elements which capture a full range of a patient's experience with pain will be considered in ongoing evaluation.

Questions about Look Back Period for Standardized Pain Assessment Elements and Case Mix

Summary: Several commenters expressed concern about reducing the look back period changing from 5 days to 3 days. One commenter was pleased that the look back period was changing to 3 days, as it would improve the quality for patients by providing more accurate information than a 5-day period. Additionally, commenters shared that they expected the element would have utility for understanding PAC patient case mix.

Response: We appreciate the commenters' feedback on look back periods. We intend to test the elements for variability across look back periods in assessments as we continue to evaluate the impacts of these data elements on many outcomes such as care planning, quality, and case mix.

Acceptability of Pain and Impact of Pain on Patient and Timing

Summary: Commenters expressed concern that responses in the data related to pain would be subjective. One commenter attributed this to the fact that no predetermined definitions may be offered to patients. Further, pain severity is not meaningful if there is no scale provided to patients when they are asked to rate their pain. Another commenter questioned if this element will truly explain how pain impacts the patient. A separate commenter specifically referenced the importance of documenting the ability to engage in activity and movement in home health

settings. Relatedly, another commenter documented concern about capturing pain accurately in home health settings due to intermittent care rather than 24/7 custodial care. Lastly, a commenter asked that the data be collected at a standard point in time to avoid variation in reporting. Additional commenters echoed concern in assessment variation due to data collection. For example, a male patient may be hesitant to tell a female clinician his true pain level, or a patient's response immediately following a physical or occupational therapy session may be much different when compared to the response of a patient at rest.

Response: We appreciate that pain is subjective and that various influences can affect one's willingness or perceived level of pain, and while pain is often assessed through other means, many patients are capable of self-reporting their pain. For the purposes of this data collection, patients would be provided with a scale to rate their pain, ranging from 0 to 10 (no pain to worst pain). We agree and appreciate the suggestions surrounding other attributes associated with pain and while some may be outside of our feasibility to account for, such as willingness to state one's pain to a clinician, we do intend to explore concepts that are related to a patient's experience with pain, including adequacy of pain management, interference with sleep, activities, and therapies. With regard to home health services, as discussed previously, separate assessments are not required each day, but rather the data element assessment would capture a time period covering three days.

Other Specific Concerns for Pain Severity

Summary: A commenter was concerned that patients who have cognitive impairments or hearing/language issues will not be able to respond appropriately. The commenter suggests using the Wong-Baker Faces Pain Rating Scale or other visual scales with such patients. Additionally, the commenter suggested that for other more communicative patients, CMS should consider using the verbal descriptor scale.

Response: We thank the commenters for their comments and recommendations for other scales for pain. We will take the scale recommendations into consideration in PAC populations.

Need for a Non-Verbal Pain Data Element

Summary: A few commenters asked CMS to consider including a non-verbal pain data element. A commenter shared that the current element may not be sufficient for patients in PAC settings who are unable to self-report. The MDS 3.0 approach could be an option for gathering non-verbal pain data (see J0800 – Indicators of Pain or Possible Pain). Other possible assessment tools shared include the Pain Assessment in Advanced Dementia Scale (PAINAD), Checklist of Nonverbal Pain Indicators (CNPI), Certified Nursing Assistant Pain Assessment Tool (CPAT), and the Mahoney Pain Scale.

Response: CMS thanks the commenters for their comments and recommendations. We intend to assess data elements that use an observational approach. In addition, we intend to explore the concept of capturing a patient's experience with pain, including using observational methods. CMS will also consider how the specifically mentioned tools, including the current MDS 3.0 J0800, could be used in other PAC settings.

Additional Data Element Suggestions

Summary: One commenter iterated that pain elements should focus on function, or the ability of the patient to engage in activities like sleep, movement, activity, and exercise. Additionally, CMS should explore the need to include an indicator of how pain is being managed with pharmacologic vs. non-pharmacologic interventions. The MDS 3.0's J0500 (Pain Effect on Function) element is suggested for consideration. Another commenter suggested the Patient-Reported Outcomes Measurement Systems (PROMIS).

Response: We thank the commenters for their recommendations and agree that it is important to approach pain from a functional perspective. We also appreciate the comments pertaining to the use of PROMIS, and how pain is being managed with pharmacologic vs. non-pharmacologic interventions. CMS will consider the MDS 3.0's J0500. We can confirm that we will be developing and assessing elements that explore a patient's perceptions of the adequacy of pain management/control in response to pain treatments. In addition to this development, we will consider the stated recommendations in future development efforts.

Summary: A commenter observed that patients could encounter difficulty when questioned about pain. For example, the commenter shared that patients might say that they do not have "pain," but later describe aching, discomfort, etc. Greater clarity is also requested on how proposed pain data elements will be used with existing OASIS pain elements. Lastly, another commenter noted that the current elements are not appropriate to measure pain in children with medical complexity and intellectual or developmental disabilities in specialized pediatric healthcare facilities. The FLACC Behavioral Scale or the FACES Scale could be more applicable to measure pain in children.

Response: We appreciate the commenter's comments and recommendations and wish to note that considerations in element development include various populations such as children or those medically complex populations. In addition, we appreciate the commenter's recommendation of the FLACC scale. We will take this recommendation to our development team to assess and consider for use in our element standardization efforts.

c. Impairments of Hearing and Vision

1. Ability to Hear

Support for the Ability to Hear Data Element

Summary: Several commenters supported using this data element. Rationale for the data element's implementation is based on its value for self-care ability, potential for improving quality, and the fact that similar information is already being collected by post-acute care settings. Additionally, one commenter stated that the proposed data element has the ability to improve quality of care if information on hearing is included in patient/resident medical records, which would improve care coordination and facilitate the development of patient-centered treatment plans.

Response: CMS appreciates the supportive comments for this data element. We agree that the Ability to Hear element is important to share across the care continuum, as this data element has the possibility to facilitate improved care coordination across PAC settings.

Clarification of Response Options

Summary: Two commenters requested clarification on how to code the “Unable to Assess” and/or “Unknown” response options. In particular, one commenter stated that while the proposed Ability to Hear response options are improved over the current B0200 – Hearing response options, he/she would like further information on how to code the “Unable to Assess” and “Unknown” response options. The other commenter was unsure about why the Unknown response option would be marked, and thus recommended that “its purpose should be clarified, or the response should be removed.”

Response: We will take the commenter’s concerns surrounding the hearing response options for “unable to assess” and “unknown” response options into consideration.

Use Among Specific Populations

Summary: One commenter expressed concern about how to gather information pertaining to this data element from children with medical complexity. The commenter noted that many children in this subgroup are not able to respond in a verbal manner about what they can hear. Therefore, testing by health professionals, such as optometrists, ophthalmologists, or audiologists, is necessary to assess hearing among this group.

Response: We will take the commenter’s concerns surrounding the hearing assessment and factors such as those described that may make such an assessment impossible to conduct into consideration.

Complexity of the Ability to Hear Data Element Instructions

Summary: One commenter mentioned that the methods for collecting information as outlined in the data element specification were unrealistic and would not be able to be performed consistently across all PAC settings, which would result in poor inter-rater reliability and feasibility of the measure.

Response: We appreciate the commenter’s concern and appreciate this response. CMS agrees that as standardized elements are developed, standardized guidance is also necessary to ensure uniform outcomes. We will consider accompanying guidance for all PAC settings to ensure appropriate inter-rater reliability and feasibility of the measure. We also note that the Ability to Hear data element was tested in the PAC PRD and showed substantial agreement for inter-rater reliability across settings (kappa of 0.78).

2. Ability to See in Adequate Light

Support for the Ability to See in Adequate Light Data Element

Summary: Many commenters believed the Ability to See in Adequate Light data element would provide important information that would facilitate care coordination and care planning, and consequently, improve the quality of care. Regarding care planning, one commenter specifically noted that this element would provide useful indications of patients’ abilities to care for themselves. Other comments suggested it would be helpful for describing case mix since it is an indicator of resource use. Additional comments noted that this element could feasibly be implemented across PAC settings and its kappa scores from the PAC PRD support its validity.

Response: We appreciate the supportive comments for this data element and agree that the Ability to See in Adequate Light element is important to share across the care continuum, as this element may facilitate improved care coordination across the PAC settings.

Limitations of Ability to See in Adequate Light and Potential for Use in Quality Measurement and Case Mix Adjustment

Summary: Some commenters questioned the use of Ability to See in Adequate Light for quality measurement. One commenter noted that the proposal does not indicate which measures this element would impact, and was concerned that without an indicated use for quality measurement, Ability to See in Adequate Light would just be collecting information that serves no purpose. Another comment shared concerns that Ability to See in Adequate Light does not assess functional vision, or the ability to use vision during daily activities. The commenter posited that this information is essential for care planning and improving care transitions and care coordination. They also added that it would be useful for describing case mix, since patients with limited functional vision will require excess care and resource use and will have different outcomes from peers with less visual impairment. Other commenters identified additional gaps in what Ability to See in Adequate Light assesses, such as visual-spatial ability and visual-perceptual recovery. An additional commenter suggested that Ability to See in Adequate Light does not clearly distinguish vision and reading, and although the similar OASIS element does not do so perfectly either, it was recommended as a superior option.

Response: As previously discussed, we appreciate the use cases in which data is used, such as quality reporting. We are also mindful of the burden associated with data collection and would intend to only require such data collection if purposeful. While we have considered a variety of data elements to assess vision, the Ability to See in Adequate Light data element received the highest overall rating from our technical expert panel. However, we will continue to assess any gaps that may result from using this data element in ongoing evaluation.

Validity and Reliability of Ability to See in Adequate Light

Summary: Multiple commenters expressed concerns about the validity and inter-rater reliability of the Ability to See in Adequate Light data element. One commenter noted that visual abilities fluctuate throughout the day and are influenced by a number of factors such as medications and the patient's environment. The same commenter added that, regarding the newspaper task, patients might have difficulty reading for reasons other than poor vision, such as dyslexia and primary language, and variation in newspaper fonts and layouts may affect a patient's response. The commenter recommended that a standardized text be included in the assessment to combat these issues. Another concern shared by multiple commenters was that there was no standard definition for "adequate lighting" which may vary across settings, especially between institutional and home settings where lighting resources vary, and assessors may interpret "adequate lighting" differently. They also noted that this complexity would add significant burden for providers.

Response: The Ability to See in Adequate Light data element was found to have substantial agreement for inter-rater reliability across settings (kappa of 0.74) when tested in the PAC PRD assessment. We will consider accompanying guidance for all PAC settings to ensure appropriate inter-rater reliability and feasibility of the measure.

We appreciate the commenter's response about the possibility that patients may have difficulty reading a newspaper for reasons other than poor vision. We are considering accompanying guidance that will provide alternate ways of assessing patients. This guidance could also offer a definition of adequate lighting. We intend to explore ways to minimize burden where able.

Assessment Period

Summary: Some commenters addressed the assessment period for the Ability to See in Adequate Light data element. One commenter noted that there was no assessment period listed in the proposal. Others were concerned that changing the assessment window from 7 to 3 days for SNFs might affect payment models and quality measures and that the time frame was too short to collect the necessary information. Two commenters recommended that the assessment window be standardized across settings.

Response: As previously discussed, we are considering how factors associated with data collection periods affect reliability and validity of data, as well as the impacts on data interoperability.

Overlap with Current Assessments

Summary: Multiple commenters noted that the proposed data element, Ability to See in Adequate Light, overlaps with current elements in the MDS and OASIS. One commenter recommended using the current MDS element until further testing of the proposed elements identifies how it will impact payment and quality measures. Another commenter shared that they did not have a preference whether the proposed element or current OASIS element was used, as long as more information on the impact on risk adjustment and quality measures is provided.

Response: As previously discussed, we intend to evaluate the implications of any updates to data collection on use cases such as case mix and quality measures.

Ability to See in Adequate Light Response Scale

Summary: Additional commenters referred to the response scale. One commenter supported the changes to the response scale, noting that it had more meaningful descriptors. Two commenters requested additional instructions about how to code the response options “8 – Unable to assess” and “9 – Unknown.” Another commenter thought that there was too wide of a gap between response options “2 – Mildly to moderately impaired” and “1 – Severely impaired.” The commenter cautioned that this might lead to subjective interpretations of the responses and an incorrect number of patients being assessed as mildly to moderately impaired.

Response: We appreciate the feedback related to the response scale for this data element and will consider these recommendations. We will also consider accompanying guidance for all PAC settings to ensure appropriate interpretations of the response options and note that the Ability to See in Adequate Light data element was tested in the PAC PRD and showed substantial agreement for inter-rater reliability across settings (kappa of 0.74).

d. Special Services, Treatments, and Interventions

1. Overall Category Comments

Overall Category Comments: Potential Effects on Case Mix

Summary: With regard to the data elements that were presented for comment within the category of Special Services, Treatments, and Interventions, one commenter suggested that CMS identify the impact of the Special Services, Treatments, and Interventions data elements on payment case mix and quality measures before any changes to data elements are implemented. A few suggested the usefulness of these data elements for describing case mix. One commenter

expressed that while these data elements are generally useful for case mix grouping, they would not be appropriate to use as quality measures.

Response: As discussed, we appreciate the multiple use cases that exist with regard to the current data elements and the dependencies related to patient complexity and case mix for purposes such as care planning, payment, and quality reporting, as well as other purposes. With that, we intend to take such factors into consideration as we evaluate the use of the legacy data collection items in relation to new data elements.

Overall Category Comments: Duplication or Replacement of Existing Data Elements

Summary: Several commenters observed that some data elements in the public comment posting already appeared in some settings' assessment instrument, and voiced support for including the same data elements across PAC assessments in the interest of standardizing assessment across PAC settings. A few commenters raised concerns that data elements were, in some cases, not the same as existing data elements (e.g., IV Chemotherapy in public comment versus Chemotherapy in the MDS) and would disrupt current models for payment and quality measures. In other cases, data elements in the public comment were logically related, and one commenter wondered if new data elements would replace existing data elements, or if existing data elements would serve as a gateway to data elements in the public comment (e.g., Central Line Management in public comment and IV Medications in the MDS).

Response: We appreciate the support for the elements in cross-setting use as well as the commenters' concerns. As described earlier, the purpose of standardizing data elements is to improve the delivery of health care services, patient health outcomes, and overall population health. We appreciate the importance of minimizing burden and intend to do so as we work to reach the intent and requirements of the IMPACT Act, to include replacing legacy data collection items when appropriate to do so.

Overall Category Comments: Look Back Periods for Data Elements in the Special Services, Treatments, and Interventions Category

Summary: We received several comments and questions about the look back period associated with the data elements in this domain and what impact this would have on existing payment models. One commenter cautioned against shortening the look back period of these data elements, as they appear in the MDS, from 14 to 3 days until effects on payment case mix and quality measures are determined and addressed.

Response: As we move through data element development and standardization, we are considering how developmental factors such as look back periods affect the overall reliability and validity of data, as well as the impacts on data interoperability. One particular aspect of this developmental work that we are currently working on is the different timing of the admission assessments and the coding of the data elements across PAC settings. However, through consultation with clinical advisors and with assessment experts at CMS, we have also been made aware that, in practice, the number of patients who would change their status (e.g., stop or start use of Special Services, Treatments, or Interventions) on many of these data elements over the course of 3 versus 7 versus 14 days is likely to be quite small. We are continuing to conduct analysis and to engage in data element development to better understand these issues, as well as any effects on payment and the feasibility of changing look back periods for Special Services, Treatments, and Interventions.

Overall Category Comments: Recommendation to Reduce Burden in Assessment of Special Services, Treatments, and Interventions

Summary: One commenter supported the possibility of removing the “while a resident or not” checklist column from the Section O checklist in the MDS for all data elements in this domain.

Response: While we appreciate the suggestion for removing existing non-standardized data elements, the removal of such data elements is out of scope of the current call for public comments. However, we will take this under consideration in the event that we engage in future work on this topic.

2. Hemodialysis

Support for the Hemodialysis Data Element

Summary: Several commenters expressed support for the Hemodialysis data element, noting its relevance in retrieving data that could be leveraged for information-sharing across the care continuum to facilitate care coordination and care transitions. In addition, these commenters suggested the collection of the Hemodialysis data element could be used to improve quality, and the feasibility for use in PAC settings. Additionally, one commenter shared that they believed the Hemodialysis data element might be useful in improving patient transitions of care.

Response: We appreciate the support for the Hemodialysis data element and agree with the commenters’ appraisal of the importance, feasibility, and usefulness of a data element on hemodialysis.

Recommendation to Collect Information on Peritoneal Dialysis

Summary: Several commenters disagreed with exclusion of peritoneal dialysis from the public comment data element on dialysis. Commenters provided rationale for the inclusion of a peritoneal dialysis element, noting that patients receiving peritoneal dialysis will have different needs at post-acute discharge compared to those who do not need any dialysis and because they may require different and sometimes additional resources compared to those receiving hemodialysis. One commenter raised concerns that not collecting information on peritoneal dialysis would negatively impact quality of care, case mix weights, Medicaid payment systems, and quality measures, as both types of dialysis are currently assessed and used in payment and quality measure calculations in the MDS.

Response: We appreciate the commenters’ concerns and will take this into consideration as we develop a standardized data element on the topic of dialysis for cross-setting use.

Recommendation to Collect Information on Established versus New Dialysis Treatment

Summary: Another commenter recommended assessing whether an individual is a new or established dialysis patient (e.g., by assessing use of either a fistula or a vascath) because of how this affects their likely site of receiving dialysis (i.e., in the PAC setting versus in a dialysis center).

Response: We appreciate the commenter’s concern for patients who are new to dialysis may require a higher level of nursing care and monitoring. We appreciate the interest in capturing site of dialysis care; however, we do not have evidence on how site of dialysis treatment is likely to affect resource intensity. That said, we appreciate the comment and will take this recommendation under consideration.

3. *IV Chemotherapy*

Support for the IV Chemotherapy Data Element

Summary: Several commenters provided support for the IV Chemotherapy data element. In particular, two commenters stated that assessing the presence of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions. Another commenter noted the validity of the data element.

Response: We appreciate the support for this data element.

Criticism of the IV Chemotherapy Data Element and Recommendations

Summary: A few commenters disagreed with the focus on chemotherapy delivered by IV only. One commenter recommended including oral chemotherapy in reporting, while another suggested amending the IV Chemotherapy data element to include all forms of chemotherapy, but providing exclusions based on lower cancer acuity.

Response: We appreciate the comments on how best to assess chemotherapy services in PAC patients and will take these recommendations into consideration.

Wording Change for Home Health

Summary: One commenter pointed out that the use of the term “resident” in the IV Chemotherapy data element would make it inappropriate for use in the home health setting.

Response: We appreciate the concerns related to terminology and intend to apply the appropriate corresponding term “patient” if this data element is leveraged for use in the OASIS instrument.

4. *Radiation*

Support for the Radiation Data Element

Summary: Several commenters provided support for the Radiation data element, noting its relevance to facilitating care coordination and supporting care transitions, the feasibility of its use, and its potential to improve quality.

Response: We appreciate the support for the Radiation data element.

5. *Central Line Management*

Support for the Central Line Management Data Element

Summary: Several commenters provided support for the Central Line Management data element, noting feasibility and importance for facilitating care coordination and care transitions.

Response: We appreciate the support for the Central Line Management data element.

Specifications of the Central Line Management Data Element

Summary: A few commenters criticized and offered recommendations on the Central Line Management data element. One commenter wondered whether the Central Line Management data element in the public comment would replace the existing IV Management in the MDS 3.0. Two other commenters recommended including peripherally inserted central catheters (“PICC lines”)

in this data element. One of these commenters also asked CMS to clarify whether midline IVs are included, and if not, to create a separate data element or response category to capture this type of IV. Another commenter expressed concerns that the Central Line Management data element is focused too narrowly (i.e., it is just limited to central lines) and recommended that the focus should be broadened.

Response: We appreciate the comments pertaining to the limitations of a data elements focused only on Central Lines, and will take these recommendations into consideration.

6. *Total Parenteral Nutrition (TPN)*

Support for the Total Parenteral Nutrition Data Element

Summary: Several commenters wrote in support of the TPN data element, noting its relevance to facilitating care coordination and supporting care transitions.

Response: We appreciate the support for the TPN data element.

Criticism of the Total Parenteral Nutrition Data Element and Recommendations

Summary: One commenter sought clarity on whether the TPN data element would replace or be added to the existing MDS 3.0 IV Management item, and whether it might be used as a gateway element, after which type of nutrition would be recorded. This commenter felt that a failure to resolve this issue would create a burden associated with training and assessment scheduling.

Response: We appreciate the suggestions and recommendations related to the TPN data element, and will take these recommendations into consideration. We will also take into consideration the use of this data element as a gateway element in the commonly used assessment instruments.

Importance of Patient Attribution When Assessing Total Parenteral Nutrition

Summary: One commenter was concerned that this data element could reflect TPN that began in an acute care setting prior to transfer to the PAC setting, and would improperly be attributed to the PAC provider. The commenter urged CMS to provide appropriate guidance to ensure that the correct provider is held accountable for the care they provide.

Response: We interpret this comment to be concern that the collection of the data element, TPN, could be used as part of a quality measure that evaluates outcomes of patients receiving TPN, including that provided in the prior setting. In this scenario, a patient with TPN that was begun in an acute care setting and perhaps managed poorly could be discharged to a PAC provider who would then be evaluated based on the outcomes of this patient's TPN (e.g., rates of infection). We wish to note that the scope of this call for public comments was to receive input about a selection of data elements under consideration for cross-setting standardization, and does not indicate future plan with regard to developing quality measure based on these data elements.

Criticism of the Timing of Total Parenteral Nutrition Data Element

Summary: There were a few concerns related to timing of assessment of TPN, with one commenter questioning the usefulness of a 3-day look back, and another recommending that TPN be assessed on day 1, rather than day 3, since patients should not be admitted to post-acute care if TPN is needed between days 1 and 3. In their opinion, waiting until day 3 to gather this information may increase the likelihood of noncompliant coding by the PAC facility.

Response: We appreciate these concerns and suggestions about the timing of assessment of TPN and will take these recommendations into consideration.

7. *Enteral Nutrition*

Support for the Enteral Nutrition Data Element

Summary: Several commenters provided support for the Enteral Nutrition data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions.

Response: We appreciate the support for the Enteral Nutrition data element.

Criticism of the Enteral Nutrition Data Element and Recommendations

Summary: One commenter felt that the Enteral Nutrition data element should include measures of swallowing ability and presence of assistive devices (e.g., a feeding tube).

Response: We appreciate the perspective related to swallowing and will take into consideration these additional factors.

8. *Vasoactive Medications*

Support for the Vasoactive Medications Data Element

Summary: Two commenters wrote in support of the Vasoactive Medications data element, one of whom noted the importance of this data element in supporting care transitions.

Response: We appreciate the support for the Vasoactive Medications data element.

Criticism of Scope of the Vasoactive Medications Data Element

Summary: A few comments criticized the need for and scope of the Vasoactive Medication data element. One commenter felt that the clinical significance of vasoactive medications administration was not high enough in post-acute care settings to merit mandated assessment, and noted that related and likely more useful information could be captured in an element like O0100 – IV Medications, an element in current use in the MDS 3.0. This commenter was also concerned about the potential downstream impacts to quality measures of the Vasoactive Medications data element in public comment. Another commenter stated that the Vasoactive Medications data element would not have the potential to improve quality and is not feasible for use in all PAC settings because the proposed element is too narrowly focused (i.e., it would just focus on vasoactive IV medications).

Response: We appreciate the commenters' feedback and will take them into consideration. We also note that the Vasoactive Medications data element within the public comment is intended to cover any medications that are used for their vasoactive properties. Although intentionally limited in scope, the assessment of vasoactive medication is important because patients on these medications can experience extreme changes in blood pressure or heart rate, and use of these medications requires close monitoring and observation.

Requests for Clarification of Specifications for Vasoactive Medications Data Element

Summary: A few commenters asked for clarity pertaining to the Vasoactive Medications data element collection and reporting. One commenter was uncertain about whether information

collected on the Vasoactive Medications data element would result in restrictions to the settings in which the medications would be administered and whether further monitoring of patients receiving these medications would be required. This individual and another commenter also requested lists of vasoactive medications that would be reported on and would qualify under the category of medications. Finally, one commenter sought information on how “continuous medication for pulmonary edema” was defined.

Response: We appreciate the comments and would like to clarify that the Vasoactive Medication data element would include a definition of the vasoactive properties associated with such medications. With regard to the commenter’s concern about placing restrictions on settings or requiring further monitoring of patients receiving vasoactive medications, we note that facility practices must follow local, state and Federal policies and regulatory requirements.

9. Oxygen (Intermittent or Continuous)

Support for the Oxygen (Intermittent or Continuous) Data Element

Summary: Several commenters supported the Oxygen (Intermittent or Continuous) data element, noting its feasibility in PAC settings, and its relevance in facilitating care coordination and supporting care transitions.

Response: We appreciate the support for the Oxygen (Intermittent or Continuous) data element.

Recommendations on Oxygen (Intermittent or Continuous) Data Element

Summary: One commenter noted a limitation of the data element, Oxygen (Intermittent or Continuous), in that it only gathers information on high concentration oxygen delivery. This commenter recommended that all methods of oxygen delivery be assessed. Other feedback came from two commenters who recommended that a two-part question be utilized, which would “assess whether a patient received oxygen and, if yes, whether the patient received high flow oxygen.” Another commenter mentioned that it might be worthwhile to also collect information on the level of oxygen and manner of delivery. Finally, one commenter suggested that “A better question to ask is, does oxygen requirement/use/supplementation limit the patient’s functional ability?”

Response: We appreciate the concerns expressed about the type of oxygen delivery and whether oxygen delivery limits functional status and will take these recommendations under consideration. We note that while the Oxygen (Intermittent or Continuous) data element, as tested in the PAC PRD was limited to high concentration oxygen delivery, its scope as included in public comment is not limited in this way.

10. BiPAP/CPAP

Support for the BiPAP/CPAP Data Element

Summary: Several commenters wrote in support of the BiPAP/CPAP data element, noting feasibility of this element in PAC settings, and the relevance of this data element to facilitating care coordination and supporting care transitions.

Response: We appreciate the support for the BiPAP/CPAP data element.

Recommendations for the BiPAP/CPAP Data Element

Summary: Three commenters expressed that the BiPAP/CPAP data element should be split into two separate data elements. Commenters reasoned that the burden of care and types of diseases/patients for which BiPAP is used varies from those for which CPAP is used. One commenter recommended gathering data on the reason a device is used to provide information on the patient/resident's health condition.

Response: We appreciate this feedback and will take these recommendations under consideration.

11. Invasive Mechanical Ventilator: Weaning Status

Support for the Invasive Mechanical Ventilator: Weaning Status Data Element

Summary: Several commenters expressed support for the data element, Invasive Mechanical Ventilator: Weaning Status, discussing the importance of collecting this information to support care coordination and care transitions. These commenters also mentioned that the proposed data element would be beneficial for patient transitions, care delivery, PAC care coordination, and case mix purposes. Another commenter expressed support for the Invasive Mechanical Ventilator: Weaning Status data element stating that it was essential to support rising staffing needs, particularly in SNF settings.

Response: We appreciate the support for the data element, Invasive Mechanical Ventilator: Weaning Status, and recognition that it can be used to support proper work flow.

Appropriateness of Invasive Mechanical Ventilator: Weaning Status Data Element for Cross-Setting Use

Summary: Two commenters stated that the data element, Invasive Mechanical Ventilator: Weaning Status, is not feasible for use in all PAC settings, such as the home health setting, where patients are not normally weaned off of ventilators.

Response: We appreciate the concern for feasibility of the data element, Invasive Mechanical Ventilator: Weaning Status, expressed by the commenters and will take this under consideration.

Recommendation for Timing of Assessing Invasive Mechanical Ventilator: Weaning Status

Summary: One commenter recommended that the Invasive Mechanical Ventilator: Weaning Status data element be only collected at admission, as is done in the LTCH CARE Data Set v3.0, instead of during both admission and discharge in order to reduce burden for LTCH data collectors.

Response: We appreciate the concern that including this data element would create burden and will take this recommendation under consideration.

Specification of Invasive Mechanical Ventilator: Weaning Status Data Element

Summary: Two commenters requested clarity regarding the Invasive Mechanical Ventilator: Weaning Status data element, including how the data will be collected and how weaning is defined. Another commenter asserted that the data element, Invasive Mechanical Ventilator: Weaning Status, does not adequately assess quality of care since it does not distinguish patients who are not appropriate candidates for being weaned from ventilators. This commenter suggested that information should be gathered to “understand whether the patient is a candidate to wean

from the ventilator, if the patient is successfully weaned from the ventilator, and the outcome of the weaning in terms of the patient’s functional abilities.”

Response: We appreciate the commenter’s concerns and suggestions and will take these recommendations under consideration. We note that the definitions of elements and all element instructions are provided in the guidance manuals for each standardized PAC assessment.

12. Suctioning

Support for the Suctioning Data Element

Summary: Several commenters expressed support of the Suctioning data element, noting its feasibility in PAC settings, and its relevance in facilitating care coordination and supporting care transitions.

Response: We appreciate the support for the Suctioning data element.

Recommendations for Frequency and Type of Suctioning to be Captured in the Data Element

Summary: One commenter asserted that the Suctioning data element does not adequately assess quality of care since it solely measures the presence or absence of suctioning. This commenter suggested examining frequency of suctioning since this would help to provide an understanding of staff time and the impact on a patient’s capacity to speak and swallow. Another commenter also recommended that including a report of suctioning frequency since need for suctioning is a risk factor and may influence the likelihood of whether different types of PAC setting would accept a patient. Finally, one commenter urged CMS to include gastric suction in a standardized data element suctioning.

Response: We appreciate these concerns and suggestions about collecting type and frequency of suctioning and will take these recommendations into consideration as we continue data element development.

13. Tracheostomy Care

Support for the Tracheostomy Care Data Element

Summary: Several commenters expressed support of the Tracheostomy Care data element, noting the feasibility of this element in PAC settings, and the relevance of this data element in facilitating care coordination and supporting care transitions.

Response: We appreciate the support for the Tracheostomy Care data element.

Specification of the Tracheostomy Care Data Element and Recommendations

Summary: We received a few comments criticizing the specification of the Tracheostomy Care data element and recommending alternative strategies. One commenter felt that a measurement of “tracheostomy care” was not valuable since all patients with tracheostomy receive care. Another commenter was critical of the assessment of tracheostomy care since it solely examines maintenance and cleaning. This commenter felt additional elements should be considered for inclusion including: the time of the tracheostomy device, whether the size of the device decreased over time, appropriateness for weaning from the device, and if a patient was weaned from the device, whether or not a speaking valve is present.

Response: We appreciate the feedback pertaining to the limitations of a data element focused only on patients with tracheostomies, and will take these recommendations into consideration as we continue element development. We note that for the development of data elements for standardized assessment, for the purposes previously described, such information may not include the level of detail captured in the surrounding medical record.

Preliminary Recommendations:

CMS and RAND appreciate the comments received for the cross-setting standardized assessment data elements for post-acute care. The comments and feedback received provided useful input for the development and implementation of the cross-setting standardized assessment data elements. All comments are reproduced verbatim in the tables on the following pages. We will take these comments into consideration as we continue data element development to meet the mandate of the IMPACT Act of 2014.

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Public Comment Verbatim Report

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

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter
RCPC1	8/15/16	<p>ALL THE VARIOUS “MEASUREMENTS” OF THIS AND THAT ARE BURDENSOME, TIME CONSUMING IN THE EXTEME, AND WILL HAVE ONE MAJOR IMPACT: GUARANTEED CONTINUED EMPLOYMENT FOR GOVERNMENT WORKERS.</p> <p>2. THERE WILL BE NO REAL IMPROVEMENTS IN PRACTICE, AND THERE WILL BE A DEGRADATION OF PATIENT SATISFACTION AND OF PHYSICIAN CONCERN, DUE TO TIME SPENT FOLLOWING THE MANDATES, AND INSUFFICIENT TIME SPENT WITH THE PATIENTS</p> <p>3. WHO GOVERNS LEAST GOVERNS BEST IS STILL VALID, AND YOU HAVE FORGOTTEN THIS</p>	C. H. Hood, M.D
RCPC2	8/16/16	As a Home Health nurse, I find that most agencies do not provide Psychiatric nursing and most cognitive issues do not improve. It will be extremely difficult to show improvement. Most cognitively impaired patients in Home Care have the diagnosis of Dementia or Alzheimer’s and this will not improve. If you try to have quality data to show improvement, with the present Oasis questions, it will be impossible.	Gale Cardoza RN WCC; Community VNA
RCPC3	8/16/16	I am a QAPI nurse at a LTC facility. I agree with many of the Quality Measures that CMS is standardizing. Hospital Readmission is concerning. Preventable readmission is understandable and the care provided by a SNF should support this goal. My concern is that the financial impact of serving high risk individuals may compromise the options for both the SNF and the patient. Should the facility accept a patient with multiple comorbidities, CRF, CHF, COPD, and any other health condition that increases risk for readmission? The pending financial penalty will require this to be a consideration and may be to the detriment of many patients.	Gloria Magarelli RN QAPI; Hartley Hall Nursing and Rehabilitation Center
RCPC4	8/16/16	<p>The American Health Care Association and the National Center for Assisted Living (AHCA/NCAL) represents over 13,000 members who provide care to approximately 1.7 million residents and patients each year. The Association represents the vast majority of skilled nursing facilities (SNFs) and a rapidly growing number of assisted living residences (ALRs). On behalf of our membership, we are requesting an extension of the public comment period for the <i>Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data – Data Element Specifications</i> that is currently posted to close on August 26, 2016, to a date <u>no earlier than September 15, 2016</u>.</p> <p>We are strong supporters of the IMPACT Act and the alignment of meaningful standardized data</p>	Daniel Ciolek; American Health Care Association

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter
		<p>across care settings to facilitate improvements in care coordination and patient care outcomes. However, we do not believe that 14 days is an adequate timeframe to pull together our association and member resources to both review and comment in a thoughtful way on the extensive list of proposed data elements that represent diverse clinical domains. We believe a 30-60 day comment period would be more appropriate. We would be happy to discuss further.</p> <p>Thank you for your consideration of this request.</p>	
RCPC5	8/16/16	<p>I believe the data will be useful but you have to choose one level of scoring. If you continue to use the FIM score in rehab and no other location it is 100% contradictory to the other scoring levels even the new IRF-PAI. It's asking the same functional questions but requires two different scoring guide lines. FIMS need to be excluded out of all information. Also on the return to community that is not nor has ever been the goal of Rehab. Rehab's job is to get patients at their highest functional capacity to decrease the burden of care. You cannot compare a rural setting hospital that has no in-home services or transportation services and penalize them for not having a higher population return home. Our facility's average age is 4 years older than the national average, our patients have no access to out-patient therapy or any other home assistance so our discharge to nursing homes is nationally higher. It is not because we did not meet their rehab goals that they need not go home it's because they do not have follow-up services to aide them.</p>	Ramona Staton
RCPC6	8/16/16	<p>Need to require reporting on transportation access to follow up appointments. This is low hanging fruit that is often ignored. For example, a patient can call a primary care provider and usually get in to see them the same day if it is urgent, but how do they get there? If they can't, they can call 911 and go to hospital in an ambulance. I live in Clearwater, Florida and volunteered for Baycare a couple of years driving patients to appointments on Baycare campuses. With seniors, this can be a major problem when they don't drive anymore.. .</p>	Bart Grigg
RCPC7	8/16/16	<p>I feel that under cognition the PAC standardized assessment should also address if the resident has behaviors. For communities such as our, who care specifically for individuals with varying types of Dementia, this can severely impact the care received, therapy cooperation, the staff hours required to care for a resident, and the outcome results of a resident's stay. If the resident has a diagnosis of Dementia, that an assessment such as the Cohen-Mansfield Agitation Inventory (Short Version) should be taken into consideration.</p>	Beth McCurdy, RN, BSN; Silverado Clinical Services
RCPC8	8/17/16	<p>Thank you for the opportunity to submit comments.</p>	Scott D. McDonald,

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter
		<p>Regarding the cognitive assessment measure discussed (CAM aside), I am not at all familiar with the Brief Interview for Mental Status (BIMS). It seems that its validity has only been explored in two studies (overlapping samples?) of nursing home residents and compared only to MDS 2.0 Cognitive Performance Scale (CPS) and the Modified Mini-Mental State Examination (3MS). Considering (1) the wide range of cognitive screening measures available, (2) the lack of validation for the BIMS vs. comprehensive neuropsychological testing vs. diagnoses of dementia/neurocognitive disorders, and (3) the lack of information about validity in a wide range of settings and populations, the recommended use of the BIMS seems premature.</p> <p>The PHQ-2/9 is recommended for tapping depression. I noticed that the version they describe is slightly different from the commonly used Kroenke et al. (2001) version, in that the CMS version (1) inquires about symptom presence prior to asking about frequency, (2) provides specific ranges for frequency in days, and (3) the clinical significance criterion probe (“how difficulty have these problems made it for you...”) is absent. My guess is that the modified administration method will reduce the PHQ-9 score.</p>	PhD; Hunter Holmes McGuire VA Medical Center
RCPC9	8/18/16	<p>This is another law without teeth. So now the patient knows (as if they understand) that they will pay more for post-discharge services, meds, etc. There is NOTHING they can do. The comment is to discuss with your MD. The MD does NOT make this decision: a group of case managers from the insurance companies and the hospital decide on inpatient/outpatient status. Try being a physician bucking this system!!!!</p> <p>I am both a physician and a medicare recipient, I understand the issue, and I guarantee that I would not be able to change my status at any hospital. We need to change the rule to “three days of combined inpatient-outpatient”. I do not understand how CMS manages to miss the true point in their “decisions”.</p>	Dianne Barnard, M.D., F.A.C.C
RCPC10	8/18/16	<p>I would like to comment on the Project Title: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data with respect to your Utility for describing case mix.</p> <p>I have worked both in the home health setting, acute care setting and outpatient care setting as well as consulted with rural hospice and individual patients for specialty related health issues. I have been hired by FirstLight Home Care as a nurse consultant. I do not provide patient care in this position.</p> <p>Pain and depression are issues that I have frequently encountered with my patients, in the past, who are often times elderly with similar age spouses. Their working caregivers struggle to manage the daily living obligations of supporting themselves and their immediate families and coordinating care necessitated by the recent discharge from an acute care facility. The elderly patient recognizes the burden that they have placed</p>	Cecilia Krusling MS, APRN, ACNS-BC, CWOCN

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter
		<p>on these family members and will draw it inward enhancing the depression that is a normal phenomenon of recent change in health status. Your assessment forms look to collect this data as well as data rating the patient's pain condition. You are working to standardize these forms for better care across the continuum. My question to you is are you addressing some of the issues that are emotionally aggravating these two conditions. I have seen many of our patients worried about being a burden to their families. Stressing about their elderly spouse trying to navigate the family vehicle through the heavy traffic to keep scheduled Provider visits and other appointments for needed health care such as physical and occupational therapy. The anxiety of having a child struggle financially because they need assistance with transport, perhaps a second car at the Rehab department and reinforcement of the exercises when at home. These clients want to stay in their homes. Home care is available to them if they meet the skilled need. Many times the patient benefits from being discharged from the Home Care Agency in order to utilize equipment that is not available to them in their home.</p> <p>I recently took care of a 84 year old gentleman who lived independently with his like aged wife in their home. He had a stroke 19 years prior after a cardiac procedure. He was maintaining in his home with a bit of assist from his wife and grandchildren, when they were not in school or at work. She was driving him several times a week for maintenance therapy at the local Physical Therapy department. After a simple double hernia repair, he was placed in a skilled nursing facility (SNF) for rehab as he had lost quite a bit of mobility due to the pain of the surgery. He developed a hematoma, that unfortunately was not adequately addressed when sent to the emergency room and promptly sent back to the SNF. He was forced to be transported to another acute care facility, resulting in unscheduled critical surgery and admission to the Intensive Care unit as a result of a dangerously low Hemoglobin of 4.2. Thankfully he survived, was sent to a different SNF for wound care and rehab until his wife decided that she was able to get him in and out of bed and to the bathroom. She contacted me to guide her with wound care decisions, which is how I became aware of their situation. He was set up with a Wound Clinic for the management of his large wound, and it was necessary for him to make weekly visits approximating a 60 minute drive each way. Home Health was set up to provide the Negative Pressure Wound Therapy which healed the wound faster than traditional therapy, but the wife began demonstrating health issues related to the stress of the situation. The patient's depression due to his stroke increased although we were able to manage his wound pain.</p> <p>Where in your questionnaire do you address situations and causes of depression and pain, such as this, which is an all too common condition? Including a payment source for a caregiver to drive the patient and spouse to the wound clinic, be available to take notes and drive them back home for this care would have eliminated a great source of the depression that increased due the to post acute care scenario. The patient saved for their retirement in a wise manner but did not anticipate the stroke resulting from his cardiac</p>	

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter
		surgery. He does not want to be a burden or return to the hospital unnecessarily. He does need to keep his appointments with the wound clinic that was set up at the hospital following his unfortunate complication for the necessary hernia repair. His family tries to help as often as possible. Providing a payor source for such a non medical process will save CMS immensely in the future.	
RCPC11	8/22/16	<p>We are an IRF, preparing for implementation of the IRF-PAI 1.4.</p> <p>Regarding “<u>Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data</u>”, here are comments:</p> <ol style="list-style-type: none"> 1. Expression of Ideas and Wants – <ol style="list-style-type: none"> a. Agree with removing the words “with speech that is clear and easy to understand”. b. VALIDITY may be difficult to ascertain, as it will be confusing to IRF front-line staff, as this is a part of the IRF-PAI 1.4 using FIM language. c. This indicator MAY be a utility for describing case mix. Our population is a higher-acuity case mix, and this may assist with describing it. 2. Ability to Understand Others: Understanding Verbal Content <ol style="list-style-type: none"> a. VALIDITY may be difficult to ascertain, as it will be confusing to IRF front-line staff, as this is a part of the IRF-PAI 1.4 using FIM language. b. This indicator MAY be a utility for describing case mix. Our population is a higher-acuity case mix, and this may assist with describing it. 3. Total Parenteral Nutrition (TPN) <ol style="list-style-type: none"> a. As this is not included #24 of the IRF-PAI, it is helpful to identify and demonstrate as a clinical measure that caregivers must treat for. b. Validity will be relatively high as it is either present, or not. However, it is measured on #27 of the IRF-PAI “Swallowing Status” – <u>this is duplicative reporting.</u> c. It is feasible for the PAC. d. Utility for describing case mix - it will not affect Case Mix Index as a QRP indicator. 4. Enteral Nutrition <ol style="list-style-type: none"> a. Potential for improving quality – yes, it has potential. b. Validity will be relatively high as it is either present, or not. However, it is measured on #27 of the IRF-PAI “Swallowing Status” – <u>this is duplicative reporting.</u> c. Feasibility for use in PAC – it is feasible. d. Utility for describing case mix - it will not affect Case Mix Index as a QRP indicator. 	Tim Williams, M.B.A., O.T., Program Manager, UTSW Inpatient Rehabilitation

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RCPC12	8/22/16	<p>I am writing in response to the CMS open door forum public comment regarding the use of cognitive standardized assessments (IMPACT). The Cognitive Disabilities Model (CDM) was introduced in the 1960's by an OT, Claudia Allen, as a guide for occupational therapy practice with adults in mental health settings who had temporary or permanent impairments in global cognitive processing capacities that affected their ability to participate in meaningful daily activities and occupations and was later extended to an older adult population with dementia. When using this model in practice, therapists plan interventions that compensate for the impact of cognitive disabilities on occupational performance and optimize the use of remaining cognitive abilities.</p> <p>There are a number of standardized assessments (Allen Battery) using the Cognitive Disabilities Model as a foundation. The one recommended for use to improve quality of life and describe case mix with the most validity and reliability is the Allen Cognitive Level Screen -5 (ACLS-5). This standardized assessment includes learning 3 visual-motor tasks (leather lacing stitches) with increasingly complex activity demands. Completion of the 3 tasks requires that the person attend to, understand, and use sensory and motor cues from the objects, administrator's verbal and demonstrated instructions and cues, and feedback from motor actions while making the stitches. It measures global cognitive processing capacities, learning potential, and performance abilities. The scores obtained are interpreted using the Allen Cognitive Scale of levels and modes of performance. There are 6 cognitive levels ranging from 1 to 6 and within the 6 levels there are 26 modes of performance. An occupational therapist along with other health care professionals who have been trained in the use of the Cognitive Disabilities Model may administer the ACLS-5.</p> <p>There is a strong body of research supporting the reliability and validity of the ACLS-5. This assessment allows clinicians to identify a person's remaining abilities, monitor change over time, help plan treatment interventions, train caregivers, and make appropriate discharge recommendations. If you have any questions, please feel free to contact me.</p>	Emily King, OTR/RAC-CT/CADDCT; Proactive Medical Review
RCPC13	8/22/16	<p>I have comments specific to the standardized assessment-based data elements developed under the IMPACT Act to meet the domains of: cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. (CMS is seeking public comment on the whether elements have the potential for improving quality, the utility of the elements for describing case mix, the feasibility of the elements for use in post-acute care settings, and the validity of the elements.) I have organized my comments following the order of the table of contents for the document: "Development and Maintenance of Post Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment"</p> <p>Cognitive function and Status page 9-10: Consider evaluating and using the General Practitioner Assessment of Cognition (GP-COG) assessment tool vs. the BIMS tool. The GP-COG contains both cognitive assessment and <u>informant interview</u>.</p>	Joanne McNamara RPh MBA, Director Clinical Pharmacy; hMetrix

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		<p>http://www.gpcog.com.au/</p> <p>Medical Conditions Pain page 31-35: The post-acute care standardized assessments are only looking at two components; presence of pain and severity of pain. These two components alone do not have the potential to improve quality. The PQRST method of assessing pain is a valuable tool to accurately describe, assess and document a patient’s pain. The method also aids in the selection of appropriate pain medication and evaluating the response to treatment. http://www.thenursepath.com/pics1/PQRST.pdf</p> <p>Special Services, Treatments, and Interventions page 41: Hemodialysis page 42 While I agree that the indication of hemodialysis has some utility in describing case mix, CMS is missing critical data sets specific to renal function. Specifically the following data sets should be included and shared with all professional disciplines for purposes of improving the quality of Medicare Post-Acute Care.</p> <ul style="list-style-type: none"> <input type="checkbox"/> National Kidney Foundation K/DOQI staging system for chronic kidney disease. (Note stage 5 correlates with hemodialysis) <input type="checkbox"/> Data needed for equations to determine dosing of really cleared medications (Cockcroft-Gault equation and Modification of Diet in Renal Disease MDRD study equation) <ul style="list-style-type: none"> o Age o Weight o Sex o Serum creatinine o Race o Serum urea nitrogen o Serum albumin <p>Chronic kidney disease (CKD) and renal dysfunction can alter medications’ renal elimination and lead to sub therapeutic or supratherapeutic drug concentrations, which may decrease efficacy or increase toxicity. Drug dosing errors are common in patients with renal impairment and can cause adverse effects and poor outcomes. In particular, geriatric patients are at a higher risk of developing advanced disease and related adverse events caused by age-related decline in renal function and the use of multiple medications to treat comorbid conditions. Chronic kidney disease can affect glomerular blood flow and filtration, tubular secretion and reabsorption, and renal bioactivation and metabolism. Drug absorption, bioavailability, protein binding, distribution volume, and non-renal clearance (metabolism) also can be altered in these patients. Dosages of drugs cleared really should be adjusted. The Cockcroft-Gault equation or the Modification of Diet in Renal Disease (MDRD) equations helps guide the appropriate dosage of really-excreted</p>	

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		<p>medications.1 Renal damage can alter clearance of active drug metabolites, potentially causing accumulation.2 Altered renal function can also affect dosing intervals of really-eliminated medications. References 1. Munar MY, et al. Drug dosing adjustments in patients with chronic kidney disease. American Academy of Fam Physicians. aafp.org/afp/2007/0515/p1487.pdf. 2. Doogue MP, et al. Drug dosing in renal disease. Clin Biochem. 2011;32:69-73.</p> <p>Vasoactive Medications page 54-55</p> <p>The post-acute care assessment should include a listing of ALL medications not just vasoactive medications and IV chemotherapy. All medications have the potential to cause undesired adverse consequences if used inappropriately for an individual patient.</p> <p>The medication list should include the following:</p> <ul style="list-style-type: none"> Medication Name Medication Indication Medication Strength Medication Dose Medication Route Medication Frequency Medication Start Date and length of therapy Prescriber contact information Pharmacist contact information <p>I understand there is a quality measure for “medication reconciliation” and encourage CMS to integrate MEDICATION THERAPY ASSESSMENT by a licensed Pharmacist into the post-acute care assessment process. The data elements I listed as needed for evaluation of renal dosing are required (along with other lab data and the complete assessment instrument) to perform a clinically sound medication therapy assessment that would improve quality of care and decrease hospital readmissions.</p> <p>Additional information is available at: http://www.pharmacist.com/sites/default/files/PatientCareProcess.pdf</p> <p>Also see separate document – “Medication therapy assessments by a Pharmacist”</p>	
RCPC14	8/22/16	Dear CMS/IMPACT staff: I have reviewed the proposal for the discharge planning COP that has been	Janet Comrey,

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		<p>proposed as outlined in the IMPACT ACT. Comments were offered last winter but I have not seen a final rule regarding the discharge planning aspects.</p> <p>Have I missed the communication on a final ruling related to the discharge planning COP?</p>	RN, BSN, MHTSA; <i>Geisinger Health System</i>
RCPC15	8/23/16	<p>This public comment thing is really hogging up needed Internet infrastructure. Needs are: resecure public integrity as the intended use and actual use are too blurred to process on given capacity anyway and the reality is uncertain to anyone. Need to rescore hospitals intranet for</p> <ol style="list-style-type: none"> 1. Intra hospital communication by phone. 2. Intra hospital lab, pharmacy, imaging, with link to inpatient EMR/ EHR (same thing here) and direct phone 3. Data analytics dedicated line for Quality and Informatics. 4. HL7 Internet lines dedicated for research articles 5. Separate line to receive other data elements. Secured. Isolated . For Informatics dept. 6. Secure data input on locked ports to be used when needed and otherwise for secure relaying storage. People may want to keep records stored at their local hospital. 7. Executive secure line. <p>8. WiFi basic purgable cycle port for visitors and patients and to keep storage isolated and purge the wifi back to itself. Keep wifi out of imaging areas.</p> <p>Partner with County Government to lay communities with:</p> <ol style="list-style-type: none"> 1. Internet high speed (wifi run off as an accelerant) 2. Intranet business level wifi for in home printer sharing 3. dedicated line for gaming or business analytics capacity. 4 wifi towers to isolate smart phones away from hard lines. 5. Need hard line phone line <p>County needs to model home standards but with government level direct link laid.</p> <p>The answer is laying Infrastructure and architecture is a secure linking box for hookup to each home or household if more than 1 in a home.</p>	Michelle Lispi

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		<p>keep the gaming line. It is needed.</p> <p>Encourage Internet Infrastructure work. This will improve health outcomes.</p> <p>The president knows what everyone has done to bridge this gap to clarify the needs. You must keep yours and keep the community with whatvthey need. Dont forget Labs and imaging places need secure HL7 one-way (and secure email dedicated for doctors input and pt. Record hand off point. Need capacity for pt. record hand off- high security dedicated isolated.</p> <p>Provider access to National database, complete access.</p>	
RCPC16	8/18/16	<p>Is there a chance that the public comment period can be extended for the Project Title :Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data? Two weeks is not enough time to provide a thorough review and feedback on these data elements. In addition, this is a busy time of year for providers due to competing priorities. I appreciate your consideration in this matter.</p>	Mary Carr, NAHC
RCPC17	8/23/16	<p>I highly recommend that the time limit for filing complaints against a Medicare approved doctor be extended beyond the one year limit. Now, even with new information obtained at a later date, that doctor cannot be reported after one year.</p> <p>Our experience. In 2012 my husband had surgery at San Martin Hospital in Las Vegas. Dr. Elizabeth Hamilton was called to be the medical specialist to care for him. He was hospitalized for 5 days while he was “watched.” It was determined by Dr. Hamilton that he had a bowel obstruction and he was to have the first level of treatment before further treatment. It was clear after a few days that he had more than a bowel obstruction, all his symptoms were identical to the ischemic bowel issue and surgery several years prior. It was only after I spoke with the person in charge of emergency that further action was taken. I went to the cafeteria for coffee and returned to find that my husband was in the process of being taken to surgery. The doctor took great pains, and a lot of time, obtaining a consent. To do this she had to contact an agency which provided translation. I mention this because she took more interest in this than in anything we can know about that follows.</p> <p>After the surgery she said she couldn’t do the job she wanted to do because his heart stopped during surgery causing her to hurry. I took him to her office twice for follow-up. Both a complete waste of time. He was in bad shape and could barely make it to the office even in a wheelchair. The first time she did get up and look at the surgery...which was a mess. The second time she did not even get up to look at the wound. Simply sat on her chair across the room.</p> <p>HERE’S THE PROBLEM</p>	Betty Yang

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		<p>The surgery was in 2012. It has never closed. The wrong size staples were used, put in the wrong way. We are not sure what happened with the suture material but he was left with a string hanging out of his abdomen which apparently caused continued infections until now, 2016, when we have obtained wound care doctors that really care and have worked to get the infection gone, removed one string. Several staples have worked their way out and one long piece of suture thread has also worked its way out. The first doctor I took my husband to after this surgery loudly exclaimed, "Oh my God." He said with a surgery botched like this we would never get a doctor to take the case.</p> <p>Back to Dr. Hamilton. After the surgery she said two important things. (1) Because this was an emergency, she could not do the job she wanted. It was not an emergency at that point. He had been in the hospital already 5 days. (2) She said his heart had stopped during surgery.</p> <p>When the wound care doctors took on the case about 4 months ago they began asking questions about the surgery. I went to Dr. Hamilton's office to obtain her records. THERE WAS NO MENTION OF HIS HEART STOPPING DURING THE SURGERY. THIS WOULD HAVE BEEN A MAJOR THING TO MENTION. HERE, MAYBE WE HAD AN ISSUE TO AT LEAST FILE A COMPLAINT AGAINST HER AS IT WAS TOO LATE TO TAKE LEGAL ACTION. SO THIS NEW, IMPORTANT INFORMATION OBTAINED 4 YEARS AFTER THE SURGERY DID NOT ALLOW FOR EVEN A COMPLAINT TO BE FILED AGAINST THIS DOCTOR.</p> <p>MY HUSBAND HAS BEEN THROUGH 4 YEARS OF HELL BECAUSE OF HER. INFECTION AFTER INFECTION. CHANGING BANDAGES TWICE A DAY. UNABLE TO WALK, SEVERELY LIMITED MOBILITY.</p> <p>MEDICARE RULES NEED TO BE CHANGED TO ALLOW COMPLAINTS TO BE FILED FOR A LONGER PERIOD OR AT MINIMUM WHEN NEW INFORMATION IS LEARNED. SOMEONE ELSE LIKELY HAS EXPERIENCED THE SAME ISSUE WITH THIS DOCTOR.</p> <p>PLEASE CONSIDER THIS CHANGE. IF THIS IS THE WRONG OFFICE, PLEASE FORWARD TO THE RIGHT ONE. THANK YOU.</p> <p>DR. BETTY YANG</p>	
RCPC18	8/24/16	Staff and Residents/Resident Family should be educated on Jimmo vs Sebelius when it comes to their Medicare coverage. Not only patient care is important, it's a HUGE strain knowing the expense of the stay	Unknown ("sue12244")

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		<p>in a Nursing Home. Educate family of resident, resident if they comprehend or their POA so everyone is on the same page and understanding the facts... honest facts.</p>	
RCPC19	8/25/16	I think the revisions will be very helpful in promoting continuity across PAC providers.	Shelly Nanney, RN, RAC-CT; Texas Dept. of Aging & Disability Services (DADS)
RCPC20	8/25/16	<p>Section GG for SNFs is not feasible. The definitions and coding are incongruent with the existing section G. I am struggling now to produce a data collection tool for the direct care staff that incorporates these conflicting definitions and coding criteria. It is inefficient to code on the same action two different ways. I suggest the entire section G of the OBRA and SNF MDS be modified to incorporate the goals of the IMPACT Act so that we are just giving the direct care staff one set of definitions and one set of coding criteria across all of the Medicare part A entities.</p> <p>The SNF Discharge MDS will burden staff. The OMRA system is currently ungainly. I have a SNF resident right now who has already had two COTs. Adding a discharge OMRA is going to force SNFs to compromise their other programs further to make time to produce yet another MDS. I question the entire PPS system. It would be more efficient to let the SNFs just bill for the services provided. I have to give the billing office a RUG for a time period, and a week later have to give them a different RUG that goes back and covers part of that same period. And in the case of two COTs, one week later I have to do it again. It is inefficient because the biller has to redo the bill twice, so they are setting up the bill three times! And in the case that the COT reduces the payment rate, the SNF is spending money doing a COT and changing the billing, to receive less money.</p> <p>The IMPACT act can be done in a different way. The two actions of GG and the SNF Discharge MDS, will burden the SNFs to the point that I believe some SNFs will just drop Medicare part A. It will not pay enough for the cost of staff hours for collecting all of this data and creating reports, staff hours in IT to create the data collection programs, and the expense of software purchases. The facilities that continue with Medicare part A will have to reduce staff-patient contact because staff will be required to increase the amount of time they spend on the computer entering data for these reports. The results of the current realization of the IMPACT Act will be fewer choices for the customer seeking SNF care, and once they are in the SNF they will get less contact with staff and raises the likelihood of poor outcomes.</p>	Ann Pasek, RN-BC, RAC-CT; MDS Coordinator West Park Long Term Care Center

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RCPC21	8/25/16	<p>Ability to understand others..... Potential for improving quality- yes it will to the provision of care thereby improving quality • Validity- it is a current measuring tool for MDS 3.0 so no changes there. • Feasibility for use in PAC- it's feasible for use in long term care. • Utility for describing case mix- unsure of the impact in this area.</p> <p>The CAM can be used in PAC, the shortened version would be best. Would it replace the current delirium section of the MDS 3.0?</p> <p>Behavioral Signs and Symptoms- no impact as a similar process exists.</p> <p>PHQ 2- we currently use a PHQ9 therefore the 2 would be shorter and less of a burden on the staff, I am unsure how the endsplit for the appropriate RUGS would be calculated.</p> <p>Pain Presence- No significant change to current process.</p> <p>Ability to Hear- No significant change to current process.</p> <p>Ability to See in Adequate Light- No significant change to current process.</p> <p>Hemodialysis, Chemotherapy, Radiation, TPN, Central line, Enteral Feeding - currently captured with a longer look back frame. Will there be an option for while not a patient. NY is a casemix state and utilizes RUGS III.... Interested to know this.</p> <p>Vasoactive medication- Would this be via any route?</p> <p>O2, Bipap, Cpap, Ventilator- currently captured, would we be able to capture while not a patient, i.e., and ED visit or inpatient hospital stay?</p> <p>Suctioning and trach care- no change.</p> <p>Would these data elements be introduced as an additional section like section GG??</p> <p>Kind regards,</p>	<p>Akia Blandon, MS, RN, RAC-CT; Vice President, Clinic Integration and Quality Corporate Compliance</p>

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		Akia	
RCPC22	8/25/16	<p>Thank you for the opportunity to provide public opinion on the efforts to harmonize the post-acute quality measures. The Patient Health Questionnaire (PHQ), a validated depression screener within Cognitive Function and Mental Status section of the data element specifications, provides an excellent tool for providers to address depression, an important mental health issue in the post-acute care population.</p> <p>Of the three PHQ options presented, PHQ-2 only, PHQ-9 only, or the hybrid option of using PHQ-2 as a gateway or pre-screener for the remainder of the PHQ-9 elements, the hybrid option appears to strike the best balance of minimizing staff/patient burden. It also provides enough information about signs and symptoms of depression to approximate the severity of the depressive symptoms in order to deliver appropriate interventions.</p> <p>After almost six years of experience using the PHQ-9 in a skilled nursing facility setting, there are two additional considerations that we would like to offer which can increase the effectiveness of this valuable tool. The first recommendation relates to the use of identifying and targeting sub-syndromal levels (i.e., mild levels) of depressive symptoms in order to prevent more severe and potential treatment resistant levels of depression. We also recommend the administration of a few additional elements which would tap into the level and availability of patients' positive emotional resources as well as balance out an emphasis on depressive symptomology during patient interviews.</p> <p>An estimated five million people have subsyndromal depression, symptoms that fall short of meeting the full diagnostic criteria for a disorder^{1,2}. Subsyndromal depression is especially common among older persons and is associated with a greater than four time risk of developing major depression³. Approximately 50% of those with new-onset Major Depressive Disorder had subsyndromal depression in the prior year³.</p> <p>A recent successful 8-month quality improvement depression collaborative involving 40 skilled nursing facilities across the Commonwealth of Pennsylvania included a focus on subsyndromal depression (PHQ-9 scores of 5-9, mild range)⁴. Results found a greater than 50% relative reduction in the percentage of residents with moderate-to-severe depressive symptoms when interventions are applied early⁴.</p> <p>Lastly, since late 2010, skilled nursing facility residents have been asked questions about depressive symptoms minimally on a quarterly basis, but sometimes more frequently (e.g., due to hospitalization or change of condition). Not much is known in the literature about the impact of administering a depression screener with such frequency. However, anecdotally, at one large nursing facility, comments offered by</p>	<p>Cheryl Phillips on behalf of:</p> <p>Scott D. Crespy, Ph.D.;</p> <p>LeadingAge Quality Management Task Force Member; Vice President of Quality & Innovation;</p> <p>Madlyn and Leonard Abramson Center for Jewish Life</p>

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		<p>residents suggest focusing solely on depressive symptomology biases an interview toward pulling for negative emotions. It may be time for the post-acute setting to offer a more balanced set of questions that can also reveal patients' positive emotional resources which are often critical for successful recoveries and overall well-being.</p> <p>One such source of elements is the Thriving Questionnaire⁵. This questionnaire, which assesses thriving in the nursing home setting, offers many applicable elements which can potentially be adapted to the post-acute population across settings. For example, the following questions (using a six-point Likert-type response format, ranging from 1 = 'No, I disagree completely' to 6 = 'Yes, I agree completely') can tap into patient resources:</p> <ul style="list-style-type: none"> • I try to make the best out of my current life situation. • I have meaningful relationships with [my fellow residents] <i>others in my life</i>* • I participate in meaningful activities. <p>*Bracketed wording part of the original element, italicized portion offered as a more generic option to the post-acute population setting.</p> <p>In sum, using PHQ-2 as a gateway or pre-screener for the remainder of the PHQ-9 elements offers an effective and efficient option for identifying depressive symptoms across post-acute settings. Leveraging what is known about the impact of identifying and attending to mild, often early, symptoms of depression can have a powerful preventative impact. Lastly, including elements that tap into positive emotional resources can make the administration of the PHQ more enjoyable to patients as well as allow for a complete picture of patients' emotional resources central to a successful recovery.</p> <p>Sincerely, Scott D. Crespy, Ph.D. LeadingAge Quality Management Task Force Member</p> <p>Vice President of Quality & Innovation Madlyn and Leonard Abramson Center for Jewish Life 1425 Horsham Road North Wales, PA 19454 Phone: (215) 371-1810</p>	

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		<ol style="list-style-type: none"> 1. Narrow, W.E. One-year prevalence of depressive disorders among adults 18 and over in the U.S.: NIMH ECA prospective data. Population estimates based on U.S. Census estimated residential population age 18 and over on July 1, 1998, Unpublished table. 2. Alexopoulos G. Mood Disorders. In: Sadock BJ, Sadock VA, editors. Kaplan & Sadock's Comprehensive Textbook of Psychiatry. 2. II. Philadelphia: Lippincott Williams & Wilkins; 2000. pp. 3060–3068. 3. Horwath, E., Johnson, J., Klerman, G., & Weissman, M. Depressive symptoms as relative and attributable risk factors for first onset major depression. Arch Gen Psychiatry 1992;49:817–823. 4. Crespy, S., Van Haitsma, K., Kleban, M., Hann, C., (In Press). Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative. Journal for Healthcare Quality. Doi-10.1097/JHQ.000000000000009. 5. Bergland, A., Hofoss, D., Kirkevold, M., Sandman, PO., Vassbo, T., & Edvardsson, D. (2013). Thriving in long-term care facilities: instrument development, correspondence between proxy and residents' self-ratings and internal consistency in the Norwegian version. Journal of Advanced Nursing doi: 10.1111/jan.12332, [Epub ahead of print]. 	
RCPC23	8/26/16	<p>Barbara, There is conflicting information on the Call for Public Comments announcement https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#36</p> <p>The Call for Public Comment period opens on August 12, 2016 and closes on September 12, 2016. Comments are due by 08/26/2016 by 11:59pm ET. Which date is correct?</p> <p>Also can you please clarify if elements such as manual wheelchairs, power wheelchairs, wheelchair seating, wheelchair accessories, durable medical equipment, complex rehabilitation technology and assistive technology considered special services, treatments, and interventions.</p> <p>Thank you.</p>	<p>Laura J. Cohen PhD, PT, ATP/SMS; Principal, Rehabilitation & Technology Consultants, LLC; Executive Director, Clinician Task Force</p>

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RCPC24	8/26/16	<p>Emily, Thank you for your quick response and clarification.</p> <p>I just left you a voice mail. If Durable Medical Equipment, Complex Rehabilitation Technology and Assistive Technology do not fall under this posting for PAC Cross-Setting Standardized Assessment Data can you please help me understand why they are not included here?</p> <p>Are there other places/initiatives/ I should be monitoring? Would you kindly direct me to any resources or people I could reach out to for more information about how DME/CRT/AT fits into these initiatives and conversations?</p> <p>I believe these domains (DME,CRT,AT) are inclusive of special services, treatments and interventions critical to transitions of care. Barriers to access for these elements frequently result in an individuals inability to transition to less restrictive environments and impedes safety, functioning, health and well-being. Without these elements included in consideration of the defined data element's the ability to improve care transitions through meaningful exchange of data between providers is impeded impacting improvements in person-centered care and care planning; quality comparisons; and clinical decision-making and care coordination supports. How do you suggest we join the conversation?</p> <p>Thank you in advance for any guidance you can provide.</p>	<p>Laura J. Cohen PhD, PT, ATP/SMS; Principal, Rehabilitation & Technology Consultants, LLC; Executive Director, Clinician Task Force</p>
RCPC25	8/26/16	<p>I am submitting a comment on behalf of Morgan Memorial Hospital in Madison Georgia. We are a Critical Access Hospital (CAH). While I do not wish to exclude CAH hospitals from this regulation, I would ask that you consider to the feasibility of it. I am the Case Management Manager, the Utilization Coordinator, the EHR Clinical Specialist, and work in the Operating Room (OR) when needed. I have one discharge planner on a half time basis, who also works in the OR when needed and she is picking up Infection Control. We do not have a liaison in the Emergency Department (ED), nor will we be able to anytime soon. While I know I need to do what I can to decrease readmissions, how do we do it to the extent that is going to be required? We will be hurt financially either way, either by hiring other case workers, or by not doing so and risk penalties. Our department is only operational, again due to financial constraints, Monday through Friday 8-5. This change will mean adding days and hours to our department which will mean at 2-3 more employees.</p>	<p>Juanita Wren, RN CHTS – CP, PW, TR Case Management Manager Utilization Review Coordinator EHR Clinical</p>

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		<p>We find ourselves in the situation also that we will have to follow the IMPACT processes on acute care, emergency department, and our subacute patients.</p> <p>Thank you for considering the “Impact” this change will have on the small hospitals.</p>	Specialist Morgan Memorial Hospital
RCPC26	8/26/16	<p>We thank you for the opportunity to submit comments, which are as follows:</p> <ul style="list-style-type: none"> · Although the concept of normalizing assessments across the PAC environment is valid, it is a challenge to see how the PAC providers will benefit in the near future without clear specific goals and incentives for the potential outcomes. The MDS assessment does the best job of noting cognitive function, specialty services, and accurately capturing conditions and status, however, this is also too much information to be collected in all PAC areas, such as Home Health. If there will be a single common assessment, there should be strong consideration for minimizing the amount of data and complexity of collection to facilitate providing care in concert with collecting and reporting data. The overall goal should include minimizing the amount of time to conduct the assessments along with standardizing them. · The PAC community is heavily burdened with a multitude of major changes and sees limited or no financial incentives to offset the costs of changes mandated. These include but are not limited to IMPACT Act, PAMA Act, Alternative Payment Models, Bundled Payment Pilots (CJR, BPCI, Pending Cardiac Bundle), Value Based Purchasing, New Quality Measure Reporting, and Staffing Reporting (PBJ). There is simply an overwhelming amount of changes at one time to successfully implement. · CMS and DHS have continually left PAC providers out of the financial incentive loop to implement the organizational, systematic and programmatic changes mandated by the Affordable Care Act. CMS focus on hospitals, physicians and healthcare insurance plans to realign and improve outcomes of PAC care assumes these providers understand quality PAC, and ignores the expertise of the providers of PAC services. While there is general agreement that long-term care and services are primarily funded by “gaming” the use of Medicare to support the losses of serving Medicaid beneficiaries, an overall strategic plan to address the Medicaid financial failures is missing in CMS planning. · CMA and DHS have continually left PAC providers out of the financial incentive program to implement sophisticated EHR systems that support success in these new environments. The VBP model removes re-imburement off the top, and allows a pathway to recover some of these finances. There must be additional financial incentives for quality providers which embrace the 	Timothy Carlson R.N. Resource Clinical Advisor Los Angeles Jewish Home 7150 Tampa Ave., Reseda, CA 91335

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		<p>PAC changes to succeed. What is proposed for providers is not “incentive payments” but rather a proposed-“recovery of withheld” payments.</p> <p>CMS should enact a moratorium on additional data collection over the next 5 years to allow the PAC community to address and excel at changes that have or are near occurring. These programs cannot be successful if unfunded programmatic and delivery changes are continually piled up one upon the other.</p>	
RCPC27	8/26/16	<p>I have the following general comments:</p> <ol style="list-style-type: none"> 1. Please integrate the new elements into the existing required assessments in the SNF to the maximum extent possible to avoid the variance on observation periods for same or very similar SNF MDS elements. 2. Facilitate the data by providing skip patterns for the special treatments when none are present; coordinate when PQRS2 then PQRS 9 is used... if the SNF MDS requires PQRS 9 then don't make 2 step process required unless particular pt. circumstances warrant <p>Thank you for the opportunity to comment at this point in the development process.</p>	<p>Julia (Judy) Powell Senior Vice President, Patient Services</p>
RCPC28	8/30/16	<p>Dear RAND representative:</p> <p>The Spectrum Health System (SHS) appreciates the opportunity to provide comments on the report prepared by RAND Corporation for Centers for Medicare and Medicaid Services (CMS) looking at the data elements to meet the IMPACT Act domains. SHS is an integrated health system and is the largest non-profit health care system in Western Michigan, with 12 hospitals, 170 ambulatory service sites and more than 1,938 licensed beds system wide. Additionally, the system includes a 1,200-provider medical group and Priority Health, which covers more than 700,000 lives throughout the state of Michigan. Within this system are 5 Skilled Nursing Facilities (SNF) 2 Home Health agencies, Hospice, as well as an acute rehab facility and a long term acute care hospital.</p> <p>General Comments: SHS supports the CMS’ efforts to standardize specified data elements across post-acute entities to improve data exchange and provide a comparison for measurement of quality and outcomes. To decrease provider burden SHS urges CMS to review the individual assessments used by the different entities for elements that are not value added or validity tested and remove them as they add new or change other elements. In addition, caution needs to be taken when changing any of the definitions for assessment time frames to determine if this change will add burden to providers. SHS recommends clarification on some of the element sets to give definition to “unable to assess” or “unknown” as this may seem redundant. For example, the date for the OASIS assessment used for home health care is collected on the</p>	<p>Chad Tuttle, President, Spectrum Health Continuing Care (SHCC)</p>

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		<p>day of admission and does not have documented observation of other staff members to review when scoring the assessment. Elements that require multiple days will need to be obtained via interview with the client and caregivers. This may cause different information than other inpatient entities that have observation data documented.</p> <p>SHS recommends that a similar format be required for these assessments. Currently, the Minimal Data Set (MDS) assessment used in the SNFs uses a scoring system that is inverted from the scoring system in these measures. SHS recommends having one scoring system throughout each assessment type. Furthermore, SHS recommends the OASIS format be changed to the same formatting used by other entities to enable easier comparison.</p> <p>Comments on Various Data Elements by Category:</p> <p>BIMS: SHS supports the use of this validity tested measure across entities as a value for measuring quality and calculating into case mix.</p> <p>Expressions of Ideas and Words: SHS recommends changing the title to better reflect the purpose of the section to ‘Ability to Express Ideas and Words’.</p> <p>Behavior Signs/ symptoms: The element may not be equally valid across entities especially for home health agencies as minimal observation data would be available when the OASIS assessment is completed. However, it would be beneficial in describing case mix. In addition, SHS recommends adding ‘Refusal of care’ to the data collection element if used. The patient’s acceptance of and following the plan of care are key elements to the measurement of improved quality.</p> <p>PHQ-2/ PHQ-9: SHS supports the inclusion of this measure in the recognition of the tremendous role depression plays in overall wellbeing. In balancing data collection with provider burden SHS supports using the PHQ-2 as a gateway data element for the PHQ-9.</p> <p>Impairments of Hearing and Vision: While both these elements may impact case mix they would not directly impact improving quality. SHS recommends removing these as cross-entity measures.</p> <p>Special Services, Treatments, and Interventions:</p> <p>Vasoactive Medications: While SHS acknowledges that these medications may cause “extreme changes in blood pressure or heart rate”, comparison across entities is not equivalent. Inpatient entities may initiate a new medication or utilize an intravenous form of the medication which has higher risk for negative impact than a patient who has been on the same oral medication for many years. Moreover, many medications, for example antipsychotic medications, have equally impactful side effects. Therefore, SHS recommends not utilizing this measure as it is not equivalent across entities and not directly impacting case mix or quality.</p> <p>Ventilator Weaning and Non-weaning : home health agencies are not involved with vent weaning as they do</p>	

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		<p>not provide 24/7 service in client homes. Use of ventilators would impact case mix calculation along with weaning from a ventilator. SHS supports the use of Ventilator non-weaning measure across the entities but recommend ventilator weaning be removed as service typically not seen across entities.</p> <p>SUMMARY Thank you for consideration of our comments. We believe that our recommended changes would result in a positive outcome for measuring services for Medicare beneficiaries across the various entities. Should you have any questions regarding these comments or if you would like any additional information, please contact Donna Elston, Compliance Analyst Senior for Spectrum Health Continuing Care at Donna.Elston@spectrumhealth.org. Sincerely, Chad Tuttle President, SHCC</p>	
RCPC29	8/31/16	<p>I think if you are going to change the post-acute care documents across the board, you should just do it all at once. It took my company nearly 3 months to get everything in place for the new IRF-PAI 1.4 and now the thought of more elements being added or some being removed aggravates me and many others. Since you are not Medicare and do not have the same bureaucratic method of operation I hope that you will see the importance of changing everything one time and not making hundreds of little changes over the course of a few years (“death by a thousand cuts”)... it would also be beneficial if the change was started (such as you can start submitting the data on October 1st 2017) but not required until a year later to give everyone time to adjust, learn, and teach on the new elements (this would also force companies such as UDS to incorporate the new information now rather than waiting until the day the change takes effect). It is hard to believe that 4-6 years ago the IRF-PAI was 1 page and now it is 18 pages. I am the third person to take this position since these changes started (the position of being responsible for the IRF-PAIs and their transmission in addition to other things). I am beginning to understand why my predecessors left the position. Thank you, Jason Bennett, BSN, AS, RN, PPS Coordinator Reeves Rehab 210-358-4269 “The best cure for the body is a quiet mind.” ~<i>Napoleon Bonaparte</i></p>	Jason Bennett, BSN, AS, RN, PPS Coordinator; Reeves Rehab
RCPC30	9/1/16	<p>My husband was in the emergency room and the doctor said he should be admitted for observation. He agreed. My husband was taken upstairs to a room. The following day he received a document stating that he was a outpatient and Medicare payments would be different then in patient. I questioned the social worker</p>	Kathleen Applegate

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		<p>who said emergency room Dr said you husband and was being admitted for observation. My reply how would I know that observation means out patient she said it was in Medicare booklet which it was. My question this was our first time being admitted for observation and under stressful situation you might not remember. My comment to her was maybe the document should be handed out when you are asked to sign for billing this way there would be no surprises.</p> <p>Sincerely Kathleen Applegate</p>	
RCPC31	9/4/16	<p>1. CMS's RAI Version 3.0 Manual CH 3: MDS Elements [D] October 2016 Page D-2 D0100: Should Resident Mood Interview Be Conducted? (cont.) Coding Instructions</p> <ul style="list-style-type: none"> • Code 0, no: if the interview should not be conducted. This option should be selected for residents who are rarely/never understood, or who need an interpreter (A1100 = 1) but one was not available. Skip to element D0500, Staff Assessment of Resident Mood (PHQ-9-OV©). • Code 1, yes: if the resident interview should be conducted. This option should be selected for residents who are able to be understood, and for whom an interpreter is not needed or is present. Continue to element D0200, Resident Mood Interview (PHQ-9©). <p>For some of the short term memory loss residents, they can make some needs know and understood sometimes, but not rarely/never understood. The score from interview doesn't true reflect their mood for these residents all the times. You heard the staff talking about resident exhibited depressive mood and was observed with multiple episodes of calling for help and crying, but the assessor could only code what resident said that he/or she was fine for the past 14 days, and not what others said or observed on this resident. There is no other choice in this section D to review the documentation along with interview if assessor want to capture information in the medical record. It only allows you to review the chart or interview staff when resident is rarely/never understood.</p> <p>2. CMS's RAI Version 3.0 Manual CH 3: MDS Elements [C] October 2016 Page C-1 SECTION C: COGNITIVE PATTERNS Coding Instructions <i>Record whether the cognitive interview should be attempted with the resident.</i></p> <ul style="list-style-type: none"> • Code 0, no: if the interview should not be attempted because the resident is rarely/never understood, cannot respond verbally or in writing, or an interpreter is needed but not available. Skip to C0700, Staff 	Yuh-Ling Tseng RN, RAC-CT

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		<p>Assessment of Mental Status.</p> <ul style="list-style-type: none"> • Code 1, yes: if the interview should be attempted because the resident is at least sometimes understood verbally or in writing, and if an interpreter is needed, one is available. Proceed to C0200, Repetition of Three Words. <p>Comment- If the ARD were passed and the interview can't be done due to the RAI rule for this particular assessment. If the assessor coded 0, no, the answer is not applied, because the patient is understood, and if it's coded yes, the answer will need to be dashed, because it passed the interview window.</p> <p>3. G0110: Activities of Daily Living (ADL) Assistance (cont.) Instructions for the Rule of 3: When an ADL activity has occurred three or more times, apply the steps of the Rule of 3 below (keeping the ADL coding level definitions and the above exceptions in mind) to determine the code to enter in Column 1, ADL Self-Performance. These steps must be used in sequence. Use the first instruction encountered that meets the coding scenario (e.g., if #1 applies, stop and code that level).</p> <p>5. Scenario: During the look-back period, Mr. S was able to toilet independently without assistance 18 times. The other two times toileting occurred during the 7-day look-back period, he required the assistance of staff to pull the zipper up on his pants. This assistance is classified as non-weight-bearing assistance. The assessor determined that the appropriate code for G0100I, Toilet use was Code 1, Supervision.</p> <p>Rationale: Toilet use occurred 20 times during the look-back period. Non-weight-bearing assistance was provided two times and 18 times the resident used the toilet independently. When the assessor began looking at the ADL Self-Performance coding level definitions, she determined that Independent (i.e., Code 0) cannot be the code entered on the MDS for this ADL activity because in order to be coded as Independent (0), the resident must complete the ADL without any help or oversight from staff every time. Since Mr. S did require assistance to complete the ADL two times, Code 0 does not apply. Code 7, Activity occurred only once or twice, did not apply to this scenario because even though assistance was provided twice during the look-back period, the activity itself actually occurred 20 times. The assessor also determined that the assistance provided to the resident does not meet the definition for Limited Assistance (2) because even though the assistance was non-weight-bearing, it was only provided twice in the look-back period, and that the ADL Self-Performance coding level definitions for Codes 1, 3 and 4 did not apply directly to this scenario either. The assessor continued to apply the coding instructions, looking at the Rule of 3. The first Rule of 3 does not apply because even though the ADL activity occurred three or more times, the non-weight-bearing</p>	

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		<p>assistance occurred only twice. The second Rule of 3 does not apply because even though the ADL occurred three or more times it did not occur three times at multiple levels and the third Rule of 3 does not apply because even though the ADL occurred three or more times, it did not occur at multiple levels or three times at any one level. Since the third Rule of 3 did not apply, the assessor knew not to apply any of the sub-elements. However, there is one final instruction to the provider, that when none of the ADL Self-Performance coding level definitions and the Rule of 3 do not apply, the appropriate code to enter in Column 1, ADL Self-Performance, is Supervision (1); therefore, in G0110I, Toilet use the code Supervision (1) was entered.</p> <p>Concern- Due to the Rule of three- These steps must be used in sequence. The Scenario above only gives example of two limited assistance. How about one non-weight bearing, one weight bearing, and one total dependent in this scenario? Do we follow #1 (can't code independent but supervision) or #3C? There are many debates, saying we should code supervision due to the multiple independent, secondary to the verbiage must be used in sequence. Could you give another Scenario when there is a combination of full staff performance/weight-bearing assistance, and/or non-weight-bearing assistance, with multiple independent or multiple supervision, what do we code in this instance? Supervision or Limited assistance? How about two limited, two extensive, and two total dependent assistance with three supervision/or three independent in the look back 7 days, this is also coded as supervision now. The supervision coding doesn't reflect care of the resident need, it give the care taker a missed information what is resident required support. To code total dependence in the section G, the ADL assistance has to be total dependence 7 days/21 shift, what about gap in the between? Does it also affect the total dependence coding?</p> <p>4. CMS's RAI Version 3.0 Manual CH 3: MDS Elements [J] October 2016 Page J-5 J0200: Should Pain Assessment Interview Be Conducted? (cont.) Coding Instructions <i>Attempt to complete the interview if the resident is at least sometimes understood and an interpreter is present or not required.</i></p> <ul style="list-style-type: none"> • Code 0, no: if the resident is rarely/never understood or an interpreter is required but not available. Skip to Indicators of Pain or Possible Pain element (J0800). • Code 1, yes: if the resident is at least sometimes understood and an interpreter is present or not required. Continue to Pain Presence element (J0300). 	

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		<p>Same concern as question #1 and #2. For our short term memory loss elderly in the SNF.</p> <p>5. • N0410A, Antipsychotic: Record the number of days an antipsychotic medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).</p> <p>Is Compazine continually listed as Antipsychotic or GI med in SOM updated rule?</p> <p>6. O0300: Pneumococcal Vaccine (cont.) Coding Instructions O0300A, Is the Resident’s Pneumococcal Vaccination Up to Date? • Code 0, no: if the resident’s pneumococcal vaccination status is not up to date or cannot be determined. Proceed to element O0300B, If Pneumococcal vaccine not received, state reason. • Code 1, yes: if the resident’s pneumococcal vaccination status is up to date. Skip to O0400, Therapies.</p> <p>Coding Instructions O0300B, If Pneumococcal Vaccine Not Received, State Reason <i>If the resident has not received a pneumococcal vaccine, code the reason from the following list:</i> • Code 1, Not eligible: if the resident is not eligible due to medical contraindications, including a life-threatening allergic reaction to the pneumococcal vaccine or any vaccine component(s) or a physician order not to immunize. • Code 2, Offered and declined: resident or responsible party/legal guardian has been informed of what is being offered and chooses not to accept the pneumococcal vaccine. • Code 3, Not offered: resident or responsible party/legal guardian not offered the pneumococcal vaccine.</p> <p>There is no code for none of the above in the O0300B PNA Vaccine if none of above codes are applied.</p> <p>7. CMS’s RAI Version 3.0 Manual CH 3: MDS Elements [A] October 2016 Page A-25 A1800: Entered From (cont.) • Code 07, hospice: if the resident was admitted from a program for terminally ill persons where an array of services is necessary for the palliation and management of terminal illness and related conditions. The hospice must be licensed by the State as a hospice provider and/or certified under the Medicare program as a hospice provider. Includes community-based or inpatient hospice programs.</p> <p>Coding Tips and Special Populations</p>	

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		<p>• If an individual was enrolled in a home-based hospice program enter 07, Hospice, instead of 01, Community.</p> <p>Question- If an individual went to acute for acute illness then later enrolled in Hospice program during acute stay. Do we coded entered from 03, Acute Hospital or code 07, hospice in the MDS entry assessment in the SNF?</p> <p>8. CMS's RAI Version 3.0 Manual CH 6: Medicare SNF PPS- October 2016 Page 6-56</p> <p>ARD Outside the Medicare Part A SNF Benefit A SNF may not use a date outside the SNF Part A Medicare Benefit (i.e., 100 days) as the ARD for a scheduled PPS assessment. For example, the resident returns to the SNF on December 11 following a hospital stay, requires and receives SNF skilled services (and meets all other required coverage criteria), and has 3 days left in his/her SNF benefit period. The SNF must set the ARD for the PPS assessment on December 11, 12, or 13 to bill for the RUG category associated with the assessment. A SNF may use a date. The RAI or Medicare Claims Processing Manual doesn't give instruction about billing in this instance -if the ARD of assessment set on the Dec. 14 which is another payer (i.e., Hospice) during the stay, the MDS was accepted and resident is no longer covered under Med A, will it be provider liable for these three Med A stays?</p> <p>Thank you so much for giving the opportunity to us for our opinions!!!</p>	
RCPC32	9/5/16	<p>To Whom It May Concern,</p> <p>This letter is in response to the call for comments on the standardized assessment-based data elements including cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities and impairments. In light of the demands of the IMPACT Act and the need to implement these changes as soon as possible, we recognize the unique challenges that the RAND Corporation is facing. However, as they are currently being proposed, we feel these assessments and data elements have several concerning problems, not only to our level of care (inpatient rehabilitation facility), but to all levels of post-acute care involved.</p> <p>First, if the goal of these changes is to look at and compare each level of post-acute care, the data gathered</p>	<p>Craig Alberts PT; Joy-Fuller Rehabilitation Center Winter Haven Hospital</p>

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		<p>should be the same across each level of care. However, most of the proposed elements are not included in each level of care's instrument, and if they are, they are conducted over different time frames (assessment periods). Speaking from the standpoint of an IRF, we serve individuals that are now dealing with acute and chronic issues that include confusion, depression, pain, etc. – however, we are not being asked to collect this data as the other levels of care are (via the CAM, PHQ, and pain assessments). This seems to be inconsistent with the goal of standardized post-acute assessments.</p> <p>Second, these proposed assessment-based data elements are only gathered during the initial assessment period. If these elements are considered "quality" elements, and therefore important components of the patient's plan of care, then assessing these elements again at discharge is indicated. The comparison between the initial assessment and discharge assessment is one method to determine the benefit the patient received from the program. We agree that the cognitive and communicative status of the patient impacts all aspects of the program including discharge to the community and overall life participation. It is equal in importance to the physical challenges the patient faces. We strongly believe that the lack of discharge data limits your ability to accurately develop a post- acute care episode of care program that accurately represents the needs of the Medicare beneficiary.</p> <p>Third, the special services/treatments/interventions elements are also inconsistent across the instruments. Speaking from the standpoint of an IRF, we are frequently treating individuals that are requiring hemodialysis, vasoactive medications, oxygen, BiPAP/CPAP, suctioning, and tracheostomy care. As indicated in your recent documentation outlining these elements - "Special services, treatments, and interventions can have a profound effect on an individual's health status, self-image, and quality of life. Reevaluation of special services, treatments and interventions received and performed is important to ensure the continued appropriateness of care and support care transitions. The assessment of special services, treatments, and interventions may also help to identify resource use intensity by capturing the medical complexity of patients/residents". Again, if the goal is to identify and compare care across post-acute settings, we feel these elements should be assessed on each instrument.</p> <p>In conclusion, while we understand the rationale for the proposed changes and empathize with the challenges of implementing a standardized assessment, we do not believe that this current format will provide accurate data for comparing each level of post-acute care.</p> <p>Respectively submitted, The Joy-Fuller Rehabilitation Center Winter Haven Hospital</p>	

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RCPC33	9/8/16	<p>We, here at St. Mary-Corwin Regional Medical Center IRF Unit, have many concerns with the PAC standardized assessment data. We do see a potential benefit in improving meaningful exchange of information between providers. We also see a benefit in quality comparisons between all PAC settings.</p> <p>At this time, we see many more risks.</p> <p>Potential for improving quality- <u>Concern:</u> We believe that we deliver person centered care and care planning. These quality measures take away from the care that will be delivered by the increased in cost and resources utilized to gather this required information that could not be valid across various PAC settings. We do see a potential benefit in quality comparison; if the information, is able to be gathered in a way that is valid across various settings.</p> <p>Validity-Capturing the patient attribute being assessed.</p> <p>Section GG0130 and GG0170 <u>Concern:</u> Across all PAC settings we are only required to document on one assessment for quality reporting. If each setting picks a different quality element, then there will not be anything to compare across all PAC setting. <u>Solution:</u> Option 1. Select one for us to use in all PAC settings. Or Option 2 have us use all elements in all PAC settings. If it isn't appropriate then we have the ability to answer with 88 or 09.</p> <p>Section GG0170 Mobility section 1. A. and C. <u>Concern:</u> In some post-acute care settings, IRF, SNF and LTCH have hospital beds. In home health care, the beneficiary might or might not have a hospital bed. In a SNF setting, bed rails are not allowed as they are considered restraints. IRF may have both a hospital bed with rails and standard home beds. Per the coding for this section, assistive devices are not captured. A person who utilizes a bed rail and an elevated head of bed will be able to roll, transfer from lying to sit much easier than with the bed elevated without a bed rail and/or with the bed flat. This is not taken into consideration in this skill set. Hospital beds are also generally made with a pressure relief system that recesses the middle of the bed, which increases the difficulty for a person to get out of the bed. Whereas, a standard bed generally has the same consistency of mattress, is more firm and is significantly different to get out of bed. Depending on the person's conditions and diagnosis, one type of bed could be significantly easier to get out of than another. There is not a standard bed type. There is not a standardization of measurement. If we are not measuring the same task in the same way, it is not comparable. This is not a valid comparison.</p>	<p>Darla M. Carlock, LPTA, CCI, PPSC, IRF-PAI Coordinator; St. Mary-Corwin Medical Center</p>

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		<p><u>Solution</u>: A valid comparison would take into consideration assistive devices such as bed rails and specify type of bed.</p> <p>Section GG00170 Mobility Section 1. D. and E. Sit to stand and Chair/Bed-to-Chair transfer</p> <p><u>Concern</u>: A person attempting to stand from various surfaces could have increased ease or difficulty depending on that surface. A recliner generally has a higher floor to seat height than a wheelchair. Therefore, a person standing from a recliner requires less effort and potentially scoring higher than the person standing from a wheelchair. A person who is home standing from a dining room chair without armrests will require more strength than a person standing up from a chair or wheelchair with armrests. Lack of standardization decreases the validity of the reporting. This is not a valid comparison.</p> <p><u>Solution</u>: A valid comparison would include use of assistive devices and specify surface such as recliner to stand versus bed to chair transfers.</p> <p>Section GG00170 Mobility 1. L. Walking 10 Feet on Uneven Surfaces</p> <p><u>Concern</u>: Per PAC training, we have been instructed that changing surfaces from carpet to tile count. A person in an IRF setting, or possibly a home setting, is going to be challenged outdoors for returning to community. Often a person in an IRF setting is going to go outside and be instructed to walk on gravel, grass, asphalt, and cement sidewalks. This is much more challenging for that person than walking on tile, or low profile carpet. In a home setting with thicker plush or shag carpeting, this could even be more of a challenge. Potentially a person who is in an LTCH or SNF setting walking 10 feet on carpet to tile would be coded higher than the same person walking 10 feet on a more challenging setting of home or IRF. Lack of standardization decreases the validity of the reporting.</p> <p><u>Solution</u>: A valid comparison would specify type of surface but keep in mind that it isn't reasonable for all patients' to perform outdoor activities as some regions would have limited seasonal ability to perform outdoor activities and PAC settings would have limited area to build a simulation area and additional cost involvement to do so.</p> <p>Feasibility for use in PAC</p> <p><u>Concern</u>: All PAC settings have our own required skill measures. We are already required to document on and submit to CMS on our various different reports. For IRF, all of the elements in the Section B and Section GG are being collected in a slightly different manner. These requirements are redundant, and challenging because of the different scales being utilized. This has already significantly impacted all PAC</p>	

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		<p>burden for training of the persons responsible for inputting the data into the PAI, MDS, OASIS and LTCH CARE Data Set. There is an increased cost for staff education and training to insure that the proper documentation is present to be gathered from the chart to be filled into these forms. Significant time is being taken away from patient care for this training. There is an additional time and cost to build into our current EHR systems. This time and cost will continue burden to all PAC facilities to input this data into our CMS required documentation systems for timely submission without an increase in reimbursement. Subjective terms, such as frequently and always decrease inter and intra user reliability. At this point, there is not a mastery examination for the required elements.</p> <p><u>Solution:</u> The FIM is utilized regularly there is a mastery examination. All IRF units must be credentialed. There is intra and inter user reliability as shown by mastery and successful passing test scores. We are already gathering that information. There would not be an extra burden of education, training, time consuming double documentation or cost to the IRF facilities. The FIM instrument also takes into consideration of the use of assistive devices and specifies bed to chair transfer surfaces. This would eliminate the additional ten pages that will be added to the IRF-PAI beginning on Oct. 1, 2016.</p> <p>Thank you for your time and consideration in this matter. St. Mary-Corwin Medical Center IRF</p>	
RCPC34	9/12/16	<p>I am writing on behalf of the Pennsylvania Homecare Association to comment on RAND Corporation's development of post-acute care cross-setting standardized assessment data on behalf of CMS. Home health providers are excited to soon have access to cross-setting data under the IMPACT Act that will allow agencies to better compare their performance with their post-acute care (PAC) partners and plan for innovations in care delivery. However, home health agencies (HHAs) often operate on very slim financial margins with limited reimbursement from Medicare that is shrinking with each year, so it is important that new data collection activities do not place an undue administrative burden on providers or become a barrier to patient care.</p> <p>In addition, it is important for RAND and CMS to keep in mind the unique nature of home health care as compared to other facility-based PAC providers. Home-based care involves a one-to-one relationship between the patient and each member of the HHA's interdisciplinary team who visits the patient in their home a few times a week. Unlike our facility partners, we do not have constant access to the patient to monitor for data elements such as a change in behavior. By its very nature and by regulation, home health care is meant to be intermittent and short term. PHA hopes RAND will keep this aspect of homecare in mind</p>	Vicki Hoak, CEO; Pennsylvania Homecare Association

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		<p>as it seeks to establish a measure set that can be broadly applied to all PAC providers.</p> <p><u>Cognitive Impairment</u> Some measures in the cognitive impairment domain do not fit into the home health model for the reasons discussed above. For instance, the Confusion Assessment Method and Behavioral Signs and Symptoms measures call for a 3-day assessment period during which the patient is observed in a variety of situations and staff across all “shifts and disciplines” are interviewed to determine if the patient exhibited any behavioral symptoms in the past 3 days. PHA providers predict they will not be able to collect the information called for by these measures because they are not in the patient’s home to interact with them in person every day as facility providers do.</p> <p>Home health care plans call for nursing or therapy visits only a few times per week. Therefore, there will be many instances where a patient is not observed by HHA staff over a continuous 3-day period. PHA suggests instead measuring based on the last 3 <i>encounters</i> with the patient in order to accommodate the nature of home-based care.</p> <p>We would also like to point out that patient cognition can change when the PAC setting changes. Some patients experience a decline in cognitive function, whether temporary or long-term, when they enter a facility setting such as a nursing home. The data collected under this domain should be able to account for that shift in settings and measure the impact on a patient when they are transferred between PAC settings.</p> <p><u>Medical Conditions: Pain</u> PHA supports the incorporation of data elements that are already being collected on the OASIS regarding pain assessment and supports the expansion of the OASIS elements to standardize pain assessment information across settings.</p> <p>Unfortunately, this measure domain also contemplates the same 3-day assessment period as the Cognitive Impairment measures discussed above. We reiterate our concern that HHAs will not be able to accurately capture this information given that home health orders are for intermittent care rather than the 24/7 custodial care that is provided by a PAC facility.</p> <p><u>Remaining Domains</u> PHA supports the measures outlined in the remaining two domains: Impairments of Hearing and Vision and Special Services, Treatments and Interventions. We appreciate the efforts by RAND and CMS to incorporate existing data collection elements on the OASIS that will fit into these domains rather than requiring</p>	

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		<p>extensive additional reporting by providers.</p> <p>We thank CMS and RAND for the opportunity to provide feedback on these measures and others being developed under the IMPACT Act. PHA member agencies would be glad to participate in any further discussion or testing on these measures as this project moves forward.</p> <p>Sincerely, Vicki Hoak, CEO</p>	
RCPC35	9/12/16	<p>To Whom It May Concern:</p> <p>Thank you for the opportunity to submit feedback on the data elements CMS has selected to meet the IMPACT Act domains.</p> <p>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, setting of treatment, or state of the disease. The Association of Professional Chaplains (APC) advocates for quality chaplaincy care of all persons in health care facilities, correctional institutions, long-term care units, rehabilitation centers, hospice, the military, and other specialized settings. Palliative care is an interdisciplinary, team-based model of care that emphasizes care coordination, pain and symptom management, shared decision making, and patient-centered goal-setting. It is appropriate for any patient with serious illness or functional impairment, regardless of diagnosis or prognosis.</p> <p>Earlier this year, CAPC submitted comments in response to CMS’s request for input on the IMPACT Act Uniform Assessment. In these comments we noted that post-acute care (PAC) providers are the ones often taking care of the population that can benefit most from palliative care, and that the goals of the IMPACT Act are very much aligned with the goals of palliative care. In addition to the medical status, functional status, cognitive status and social support categories proposed, we recommended that the standardized assessment include elements to:</p> <ol style="list-style-type: none"> 1. Fully assess pain and symptom burden; 2. Screen for depression; 3. Collect and document patient goals of care; 4. Assess caregiver burden; 5. Collect additional information for potential risk-stratification; and 6. Collect and document wishes concerning life-sustaining treatment. <p>We are very pleased to see some of these recommendations incorporated into the draft Data Element</p>	Stacie Sinclair, MPP, LSWA; Center to Advance Palliative Care (CAPC)

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		<p>Specifications. In particular, we applaud the inclusion of the PHQ-9 to detect signs and symptoms of depression, as well as the two elements looking at presence and severity of pain. That being said, there are still critical gaps in the standardized assessment which, if left unaddressed, could lead to needless suffering in the PAC population.</p> <p>Recommendation #1 – Include a Non-Verbal Pain Scale for Patients/Residents Unable to Self-Report While we appreciate the inclusion of the two pain elements in the uniform assessment, we are concerned that this will not be sufficient for a significant portion of patients or residents in the PAC-LTC settings who may be unable to self-report. These include older adults with advanced dementia, critically ill/unconscious patients, and patients at the end of life. Studies have shown that between 30-50 percent of people with dementia experience persistent pain, much of which is due to inadequate assessment and treatment.¹ Consequences of untreated pain can include poor appetite and weight loss, disturbed sleep, withdrawal, sadness, anxiety, depression, physical and verbal aggression, and even increased morbidity and mortality. Therefore, the standardized assessment must include both instructions for patients who are unable to self-report, as well as data elements to assess pain for this subpopulation. Possible assessment tools include:</p> <ul style="list-style-type: none"> • Pain Assessment in Advanced Dementia Scale (PAINAD) • Checklist of Nonverbal Pain Indicators (CNPI) • Certified Nursing Assistant Pain Assessment Tool (CPAT) • Mahoney Pain Scale <p>Alternatively, we suggest that CMS to consider incorporating an additional data element from the MDS 3.0 to assess for additional indicators of pain (including non-verbal sounds):</p> <div data-bbox="327 1076 995 1230" style="border: 1px solid black; padding: 5px;"> <p>J0800. Indicators of Pain or Possible Pain in the last 5 days</p> <p>↓ Check all that apply</p> <p><input type="checkbox"/> A. Non-verbal sounds (e.g., crying, whining, gasping, moaning, or groaning)</p> <p><input type="checkbox"/> B. Vocal complaints of pain (e.g., that hurts, ouch, stop)</p> <p><input type="checkbox"/> C. Facial expressions (e.g., grimaces, wincing, wrinkled forehead, furrowed brow, clenched teeth or jaw)</p> <p><input type="checkbox"/> D. Protective body movements or postures (e.g., bracing, guarding, rubbing or massaging a body part/area, clutching or holding a body part during movement)</p> <p><input type="checkbox"/> Z. None of these signs observed or documented → If checked, skip to J1100, Shortness of Breath (dyspnea)</p> </div> <p>Recommendation #2 – Include Data Elements to Assess Non-Pain Symptoms In addition to pain, there are a number of other symptoms that can cause significant distress in older adults and those with serious illness, including breathlessness, nausea, constipation, drowsiness, and fatigue. We reiterate the need to assess patients/residents for the presence and severity of these symptoms in order to arrange treatment, and recommend that CMS review the following instruments for relevant data elements:</p>	

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		<ul style="list-style-type: none"> • Condensed Memorial Symptom Assessment Scale (CMSAS) • Edmonton Symptom Assessment Scale (ESAS) <p>Recommendation #3 – Collect and Document Patient Goals of Care</p> <p>We also reiterate from our previous letter that it is critical to discuss patients’/residents’ goals in order to ensure that the care delivered is appropriate and aligned with their wishes. The standardization of the PAC assessment form across settings presents an unparalleled opportunity to ensure that patients’ preferences are known and honored, regardless of their location. Studies have shown that high quality goals of care conversations 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.^{2,3} But in order to be most effective, these conversations should occur early in the illness trajectory – and certainly before any serious decisions must be made. To that end, we urge CMS to reconsider the resources proposed in our previous letter:</p> <ul style="list-style-type: none"> • Five Wishes, a tool to support patients and families to define their wishes for medical treatment, comfort levels, decision-making, and legacy. Five Wishes is a product of Aging with Dignity and can be accessed at www.agingwithdignity.org. • The Center for Bioethics has published a guide for patients and families to have conversations and reflect on their values and preferences. The full guide can be accessed at http://practicalbioethics.org/files/caring-conversations/Caring-Conversations.pdf. • The Serious Illness Care Project from Ariadne Labs at Harvard has developed both a screening tool and a documentation template that can be accessed at https://www.ariadnelabs.org/areas-of-work/serious-illness-care/resources/ <p>If these options are infeasible, we urge CMS to consider incorporating at least one of the following elements from the SNF instrument:</p> <p><i>Advance Directive</i> (MDS 2.0, full assessment, Section A., Element 10). While the evidence is mixed as to whether that inclusion of this element in the MDS has increased completion of advance directives or improved related care planning, this may have been due to the fact that the information has not been consistently collected across care settings.</p>	

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		<p>10. ADVANCED DIRECTIVES (For those items with supporting documentation in the medical record, check all that apply)</p> <table border="1" data-bbox="464 386 995 506"> <tr> <td>Living will</td> <td>a.</td> <td>Feeding restrictions</td> <td>f.</td> </tr> <tr> <td>Do not resuscitate</td> <td>b.</td> <td>Medication restrictions</td> <td>g.</td> </tr> <tr> <td>Do not hospitalize</td> <td>c.</td> <td>Other treatment restrictions</td> <td>h.</td> </tr> <tr> <td>Organ donation</td> <td>d.</td> <td></td> <td>i.</td> </tr> <tr> <td>Autopsy request</td> <td>e.</td> <td>NONE OF ABOVE</td> <td></td> </tr> </table> <p><i>Resident's Overall Expectation</i> (MDS 3.0, full assessment, Section Q., Element 0300). We agree with the experts' opinion in the MDS 3.0 Final Report that a data element assessing residents' goals of care for their stay is an improvement over indicating the presence of an advance directive (which in practice becomes a checkbox measure rather than a catalyst for a meaningful discussion). We recognize that the element "Expects to be discharged to the community" might not be appropriate for those receiving services from HHAs; however, we would be happy to partner with CMS to adjust this element or select a new measure that reflects the overall concept (soliciting patients' goals and preferences) so that it can be used across settings.</p> <p>Q0300. Resident's Overall Expectation Complete only if A0310E = 1</p> <p>Enter Code <input type="checkbox"/> A. Select one for resident's overall goal established during assessment process</p> <ol style="list-style-type: none"> 1. Expects to be discharged to the community 2. Expects to remain in this facility 3. Expects to be discharged to another facility/institution 9. Unknown or uncertain <p>Enter Code <input type="checkbox"/> B. Indicate information source for Q0300A</p> <ol style="list-style-type: none"> 1. Resident 2. If not resident, then family or significant other 3. If not resident, family, or significant other, then guardian or legally authorized representative 9. Unknown or uncertain <p>Conclusion CAPC and APC continue to appreciate CMS's thoughtful work in the creation of a uniform set of assessment measures. With a few small additions to the assessment, clinicians can gain a more comprehensive understanding of the things that matter the most to their patients and residents. This in turn will lead to better, more person-centered care across post-acute settings.</p> <p>Thank you again for the opportunity to submit our recommendations. Please do not hesitate to contact us or Stacie Sinclair, Policy Manager at Stacie.Sinclair@mssm.edu if we can provide any additional detail or assistance.</p>	Living will	a.	Feeding restrictions	f.	Do not resuscitate	b.	Medication restrictions	g.	Do not hospitalize	c.	Other treatment restrictions	h.	Organ donation	d.		i.	Autopsy request	e.	NONE OF ABOVE		
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RCPC36	9/12/16	The Healthcare Association of New York State (HANYs), on behalf of our 500 member non-profit and public hospitals, nursing homes, home health agencies, and other healthcare providers, welcomes the	Debora LeBarron																				

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		<p>opportunity to comment on the Data Element Specifications for Post-Acute Care Cross-Setting Standardized Patient Assessment Data.</p> <p>HANYS appreciates the opportunity to provide feedback on the proposed Standardized Patient Assessment Data elements to be collected from post-acute care (PAC) providers using the assessment instruments that the Centers for Medicare and Medicaid Services (CMS) currently requires for use by home health agencies, inpatient rehabilitation facilities, long-term acute care hospitals, and skilled nursing facilities.</p> <p>HANYS agrees data elements in these various domains help clinicians to identify and address the person-centered needs of patients in PAC settings; however, we have concerns about the feasibility of use for some of these data in PAC settings and the potential added burdens the data present to patients and providers.</p> <p><u>Feasibility of Data</u> PAC providers currently conduct their own screens for these patient data in their preadmission process to determine a referral patient’s appropriateness for admission. Based on those screen results and clinical necessity, they again, in a more comprehensive way, conduct assessments during post-admission and care planning processes. The Confusion Assessment Method (CAM) instrument and the Patient Health Questionnaire (PHQ) are examples of this.</p> <p><i>Confusion Assessment Method</i> Patients are routinely screened for confusion and mental status prior to a PAC admission, and especially for rehabilitation. A vital component of rehabilitation is the patient’s ability to actively participate in his or her treatment plan. PAC providers recognize the importance of conducting a behavioral health assessment as part of the pre-admission screening process to determine recommendations for PAC admission and develop an individualized plan of care. Required testing after admission would be duplicative and presents an additional burden to the patient and provider.</p> <p>HANYS urges CMS to eliminate CAM from the proposed list and allow current clinical practice to continue, which would include CAM screening when and if it is found to be medically necessary in the PAC setting.</p> <p><i>Patient Health Questionnaire</i> As RAND Corporation noted in its report, there are two commonly used versions of the PHQ: the PHQ-9 and the PHQ-2. Both are clinically meaningful and reliable tools, but they are very different in length and comprehensiveness.</p>	Senior Director, Continuing Care; Health Association of New York State

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		<p>As with CAM, PAC providers include mental outlook in their clinical pre-admission screening process, as it is an important factor in predicting patients' level of participation in their plan of care. HANYS believes that a required comprehensive assessment after admission, in the absence of clinical indicators identified in a screen, would be duplicative and present an additional burden to the patient and provider.</p> <p>HANYS urges CMS to eliminate PHQ-2 and PHQ-9 from the proposed list and allow current clinical practice to continue, which would include PHQ-2 screen when and if it is found to be medically necessary in the PAC setting.</p> <p><i>Special Services, Treatments, and Interventions</i></p> <p>Because inpatient rehabilitation services are elective and non-urgent, patients are routinely screened for intensity and type of service needed, and the facility's capacity to provide such services is also evaluated. Patient medical needs are re-assessed on admission, and are documented in providers' histories and physicals, and in nursing assessments.</p> <p>In addition, RAND noted the Post-Acute Care Payment Reform Demonstration (PAC PRD), and the uniform patient assessment instrument, called the Continuity Assessment Record and Evaluation (CARE) tool. The use of the CARE tool across settings in the PAC-PRD provided much data on the medical status of patients. However, the RAND report makes no reference to those data and the insight provided on the utility of special services, treatments, and interventions for describing case mix.</p> <p>HANYS asks that CMS provide additional information as to the need for the special services, treatments, and interventions checklist.</p> <p><u>Provider Burden</u></p> <p>In addition to conducting patient screens, assessments, and care plan development, PAC providers are currently required to report a significant amount of patient data to the Centers for Medicare and Medicaid Services (CMS) on Medicare's setting-specific assessment instruments.</p> <p>RAND's report compares standardized data to that of the same or similar data already collected and reported by specific PAC settings as part of their completion of required Medicare assessment instruments. However, the RAND report does not discuss how this standardized data would be collected and reported by providers going forward, in light of many existing similar or same data already reported to CMS. HANYS is very concerned that collecting and reporting standardized data can present an additional burden to patients and</p>	

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		<p>providers.</p> <p>HANYS urges that the final cross-setting standardized data elements used to meet the Improving Medicare Post-Acute Care Transformation (IMPACT) Act domains not add new requirements to providers for conducting patient assessments and reporting data in PAC settings.</p> <p>Again, thank you for the opportunity to comment on these data specifications. If you have any questions regarding our comments, please contact me at dlebarro@hanys.org, or at (518) 431-7702.</p> <p>Debora LeBarron Senior Director, Continuing Care</p>	
RCPC37		<p>On behalf of the Association of Rehabilitation Nurses (ARN) – representing more than 5,400 rehabilitation nurses and more than 13,000 Certified Registered Rehabilitation Nurses (CRRNs) that work to enhance the quality of life for those affected by physical disability and/or chronic illness – we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and RAND Corporation’s (RAND) Development and Maintenance of Post-Acute Care (PAC) Cross-Setting Standardized Assessment Data. Rehabilitation nurses take a holistic approach to meeting patients’ nursing and medical, vocational, educational, environmental, and spiritual needs. Rehabilitation nurses begin to work with individuals and their families soon after the onset of a disabling injury or chronic illness. We continue to provide support and care, including patient and family education, which empowers these individuals when they return home, or to work, or school. Rehabilitation nurses often teach patients and their caregivers how to access systems and resources.</p> <p>Rehabilitation nursing is a philosophy of care, not a work setting or a phase of treatment. We base our practice on rehabilitative and restorative principles by: (1) managing complex medical issues; (2) collaborating with other specialists; (3) providing ongoing patient/caregiver education; (4) setting goals for maximum independence; and (5) establishing plans of care to maintain optimal wellness. Rehabilitation nurses practice in all settings, including freestanding inpatient rehabilitation facilities (IRFs), hospitals, long-term subacute care facilities/skilled nursing facilities (SNFs), long-term acute care facilities (LTCHs), comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), and private practices.</p> <p>ARN supports efforts to ensure people with physical disability and chronic illness have access to comprehensive quality care in whichever care setting is most appropriate for them. Specifically, as a part of its mission, ARN stands ready to work with policymakers at the local, state, and federal levels to advance</p>	<p>Jordan Wildermuth, MSW; Manager, Health Policy & Advocacy; ARN (Assoc. of Rehabilitation Nurses)</p>

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		<p>policies and programs that promote maximum independence for people living with physical disability and/or chronic illness, particularly among the Medicare population.</p> <p>Overview of Rehabilitation Nursing and the Care Transition Process Rehabilitation nurses are key contributors to the care of individuals with chronic conditions and disability and they are uniquely prepared to lead team-based care coordination, including transitional care. Rehabilitation is provided by professionals who collaborate with each other and the patient and family to develop patient-centered goals and objectives. This team approach values all members of the team, with the patient and family in the center of the team. It is critical that individuals with chronic and disabling conditions are served in a PAC setting that includes the provision of services that will optimize health outcomes and quality of life.</p> <p>Rehabilitation nurses appreciate the available PAC levels and have a thorough understanding and knowledge of the resources available at each PAC level. Additionally, rehabilitation nurses are highly knowledgeable health care professionals that can educate patients on HHA, SNF, IRF, and LTCH data on quality and resource use measures, appropriately weigh a patient’s treatment needs and preferences, and guide a patient through a successful care transition.</p> <p>The care transition process often is confusing and stressful for patients and families. Ensuring patients receive rehabilitation education will result in more appropriate care transitions and has the potential to reduce 30-day readmission rates and the unnecessary utilization of limited health care resources.</p> <p>Additionally, prior to a patient’s transition to a PAC setting, the primary care physician should be required to consult with the rehabilitation interprofessional team, specifically the rehabilitation nurse, to ensure successful care coordination. ARN’s white paper, <i>The Essential Role of the Rehabilitation Nurse in Facilitating Care Transitions</i>, emphasizes this lack of coordination in current practice. The white paper alludes that care is fragmented, disorganized, and guided by factors unrelated to the quality of care or patient outcomes, and decision-makers often lack the information needed to adequately render the best decision during care transition planning. Appropriate care transitions promote the greatest value and the most effective and efficient care for individuals with chronic conditions.</p> <p>Data Elements by Category Given the scope and limitations of current measurement instruments, including the Functional Independence Measure (FIM) and the Continuity Assessment Record and Evaluation (CARE) tools, often it is difficult to measure the impact of the care furnished to patients. Tools such as the FIM and CARE are narrow in scope</p>	

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		<p>and fail to accurately capture the tangible progress of many of our patients. It is imperative that future assessment tools capture – in a meaningful way – patients’ outcomes and the cost effectiveness of medical interventions.</p> <p>Cognitive Function and Mental Status Brief Interview for Mental Status (BIMS) ARN supports the utilization of the BIMS in evaluating a patient’s cognitive status and believes it is valid and reliable in its assessment. Given the relatively low burden of administering the assessment and its ability to generally predict a cognitive impairment, we believe clinicians should be encouraged to administer the assessment on a regular basis as a means to evaluate whether there are changes in the patient’s cognition. However, ARN has concerns regarding the BIMS’ limitations. The BIMS has been shown to be unable to differentiate between patients with a mild cognitive impairment and those with no cognitive impairment;² further, it cannot provide a completely clear picture of a patient’s cognitive status. We urge CMS and RAND to clarify what, if any, additional tools will be used to detect potential cognitive impairment or dementia, such as collecting information from the patient’s family or caregivers to confirm or provide supplemental data.</p> <p>Behavioral Signs and Symptoms Behavioral signs and symptoms could indicate a patient has a cognitive dysfunction or is uncomfortable and needs assistance. The development of an individualized, person-centered care plan depends on accurate assessment and preventative methods. As members of interdisciplinary teams, nurses collaborate with physicians, social workers, psychologists, therapists, and case managers. Because of these relationship and interactions, nurses are well-equipped to identify and respond to patients with potential behavioral issues. ARN recognizes the need to monitor and assess behavioral signs and symptoms in an effort to better inform a patient’s treatment plan. We have concerns, however, that the scope of the Behavioral Signs and Symptoms assessment is limited and may be ineffective for increasing quality of care and improving patient outcomes. The assessment does not capture subtle signs or symptoms, such as agitation or anxiety, which could indicate a cognitive impairment. If a patient exhibits such symptoms, it is unlikely to be referenced in the assessment, which could lead to the development of a care plan that does not fully reflect the patient’s condition. Specific questions that help the clinician/assessor identify subtle behavioral signs or symptoms should be included in this assessment to assist in the development of a patient’s care plan.</p> <p>Patient Health Questionnaire (PHQ) ARN is supportive of the PHQ and believes the PHQ-2 and PHQ-9 are useful, valid clinical tools. Both questionnaires assist clinicians in determining the severity of symptoms upon admission and throughout the delivery of care in the PAC setting. ARN recommends that the PHQ should initially be presented to patients in the most basic form (PHQ-2), and then administered in its more thorough form if these initial screening</p>	

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		<p>questions are positive. Upon admission into a PAC facility, patients are overwhelmed, creating a situation in which some individuals may not feel comfortable with a more invasive mental health screening. Utilizing a shorter form will reduce the burden experienced by clinicians in collecting assessment data.</p> <p>While we appreciate CMS's efforts to limit the administrative burden on patients and providers by proposing to utilize the PHQ-2 as an initial screen for depression, potentially eliminating the need for conducting the PHQ-9 in some circumstances, we have concerns the PHQ-2 is unable to identify the more subtle signs and symptoms of depression. Should CMS move forward with adopting the PHQ-2 as a gateway tool for the PHQ-9 across PAC settings, we recommend CMS utilize a low threshold level for the PHQ-2, to ensure clinicians do not miss those patients who require further evaluation.</p> <p>Medical Conditions: Pain</p> <p>Rehabilitation nurses play a critical role in assessing and managing acute and chronic pain. The goal of pain management for rehabilitation patients is to maximize the level of functioning and the quality of living and to treat pain with appropriate, patient-centered interventions and compassion. As pain is addressed in settings throughout the continuum of care, rehabilitation nurses may play a role in pain management in any health care setting.³</p> <p>In this role, the rehabilitation nurse serves as a coordinator of care and a patient advocate to facilitate a self-management plan; provides pain management information and educates patients and families to promote wellness in order to improve functional abilities; and has a clinical understanding of physiological, pathophysiological, and psychosocial factors and uses pharmacological and non-pharmacologic methods to prevent, identify, and alleviate pain. Moreover, specialized advanced practice nursing roles in pain management can influence and educate best practices for rehabilitation nurses.</p> <p>Pain Presence</p> <p>The accurate assessment of the presence of pain is the first step in developing a successful pain management plan of care. Inadequately managed pain can lead to adverse physical and psychological patient outcomes for patients and their families.⁵ Unfortunately, it often is difficult to adequately assess the presence of pain in patients, particularly in those with cognitive dysfunctions.</p> <p>We recommend that CMS revise the pain presence data element. Upon admission, should the patient be unable to self-report the presence of pain due to dementia or another cognitive condition, the clinician should be prompted to question family members/caregivers, as well as to observe patient behavior. Discussions with those who know the patient, in addition to further investigation or observation, is likely to lead to improved patient outcomes and increased patient satisfaction.</p> <p>Additionally, it is imperative that a pain assessment is conducted after the administration of each treatment,</p>	

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		<p>to evaluate the effect of the intervention and determine whether a modification to the treatment plan is necessary.</p> <p>Pain Severity The treatment of PAC patients is difficult due to the presence of multiple comorbidities and chronic conditions, in addition to the number of medications they may have. While we support the use of the numeric rating scale to measure a patient’s level of pain, given its simplicity of use and sensitivity to minor changes in pain, we have concerns that the use of the numeric rating scale with patients who have cognitive impairments or hearing/language issues will lead to inaccurate results. We encourage CMS to modify the pain severity tool to allow for the use of the Wong-Baker Faces Pain Rating Scale and other visual scales with such patients. Additionally, more communicative, articulate patients, or patients for whom it is difficult to quantify pain using the numeric scale, will be better served by expressing to the clinician their level of pain. For such patients, we encourage the use of the verbal descriptor scale. ARN recommends CMS modify the Pain Severity assessment to account for the different capabilities and characteristics of PAC patients.</p> <p>Conclusion ARN very much appreciates the opportunity to provide comments to CMS and RAND on the Development and Maintenance of PAC Cross-Setting Standardized Assessment Data. We are available to work with you, your colleagues, the rehabilitation community, and other stakeholders to develop and implement payment policy changes that ensure access to quality care for Medicare beneficiaries with physical disabilities and/or chronic disease. If you have any questions, please contact me or have your staff contact our Health Policy Associate, Kara Gainer (kara.gainer@dbr.com or 202-230-5649). We thank you for your consideration of our concerns, recommendations, and requests.</p> <p>Respectfully submitted, Cheryl Lehman, PhD RN CNS-BS RN-BC CRRN</p>	
RCPC38	9/12/16	<p>Dear RAND Corporation:</p> <p>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 for of the Centers for Medicare and Medicaid Services (“CMS”) regarding the development of cross setting standardized patient assessment data. We have several comments that will serve as constructive additions to the development of these measures. We hope that RAND Corporation and CMS will analyze and consider these comments and how they could improve the standardized patient assessment data framework for post-acute care.</p>	Mary Ellen Debardeleben Associate Director, Quality, HealthSouth

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		<p>Constraints of Comment Timing</p> <p>We appreciate CMS extending the comment period from August 26 to September 12, but are still concerned about the general timing of the comment period. IRFs and SNFs will begin reporting the CARE functional elements for patients discharged on or after October 1, 2016. With the average patient stay lasting several weeks in both settings, these providers must begin assessing patients on the new functional elements in mid-September in order to ensure that patients discharged on October 1 have the new admission assessments. Most providers have been finalizing staff education on how to perform and code these lengthy assessments (estimated by CMS to be an additional 40 minutes per patient in IRFs) during August and September. Any post-acute provider that offers IRF or SNF services has had an extremely busy summer training a vast majority of their staff on how to assess dozens of new elements accurately and consistently. The ability for these providers to meaningfully comment at this time on over twenty proposed standardized patient assessment data elements is materially limited. Given the potential effects that these additional elements could have on a Quality Reporting Program (“QRP”), the timing of their release and the accompanying abbreviated comment period are problematic. We urge CMS and its contractors to make these elements available for comment several more times before finalization, and with longer comment periods.</p> <p>Furthermore, while the data element specifications state that the elements are currently used in the IRF PAI v. 1.4, this is inaccurate and misleading. This version of the IRF PAI is not effective until October 1, 2016 – so elements for which comments are due prior to the October 1 date are not being collected. IRF providers therefore have not collected these standardized elements and do not have experience with them, making it difficult to determine their clinical value.</p> <p>Standardized Data Elements should be Carefully Selected</p> <p>We support the intent of creating meaningful, clinically relevant data elements and improving care coordination across providers; however, we have concerns about the amount of data elements that are being added and the value that they provide patients/residents, families, providers, and policy makers. Standardized data elements should be carefully selected to maximize the benefit they provide to improving quality of care and minimizing reporting burden. As additional standardized data elements continue to increase for each provider, more time is taken away from clinically meaningful activities, <i>yet providers’ priorities must always be to provide care to the patient and not just assess them for research purposes.</i> Collecting data elements that do not increase a provider’s ability to improve quality of care is not an effective use of clinical time for patients or the clinicians who treat them.</p>	

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		<p>One way CMS can reduce reporting burden is by utilizing data elements already collected and submitted to CMS. The IMPACT Act itself explicitly states that data collected under the newly proposed measures should not duplicate data currently collected by IRFs.¹ CMS also states in the FY2016 Final Rule that one of its goals in developing measures under the IMPACT Act is the “avoidance of duplication of existing assessment elements.”² Some of the data elements proposed, particularly in the “special services, treatments, and interventions” could be obtained through existing Medicare claims data and ICD-10 documentation. Such redundant reporting seems at odds with the intent of the IMPACT Act and indicative of a disjointed data collection framework.</p> <p>HealthSouth does not support the addition of additional process measures to the IRF QRP. It simply adds unnecessary administrative burden and expense to clinicians and caregivers and distracts their attention from patient care and legitimate quality improvement activities. In contrast, outcome measures – particularly when they are timely distributed and include patient-level information that is relevant to the provider’s performance on the particular outcome measure at issue – are more meaningful to patients and healthcare providers.</p> <p>An additional reason to be parsimonious over the mounting number of standardized data elements is that moving toward standardization is a move away from the individualized patient-centered care approach envisioned under the IMPACT Act, an unfortunate consequence. For example, assessing every patient for delirium, when most patients do not exhibit symptoms of delirium, takes time away from care that could be provided specific to the patient needs of most non-delirium patients. CMS should therefore strive to select standardized measures that provide the maximum benefit to the maximum number of patients. Additional measures may also prove to be a patient dissatisfier as patients begin to be asked the exact same questions at each level of post-acute care that neither improve nor inform their care. Each assessment may only add an extra few minutes, but these elements add up. How often must a patient hear, “I’d like to ask you a few more questions,” when the questions may not match his/her situation, yet are duplicative and cover multiple pages of assessments?</p> <p>Cross-Setting Standardization In order to achieve standardized data elements across the post-acute care settings, it is imperative that data elements be collected under identical circumstances, regardless of the data elements selected. This includes the timeframe for the data assessment and collection as well as the wording of the data element.</p> <p>Utility for Describing Case-mix</p>	

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		<p>CMS is specifically asking for feedback on whether the elements as proposed could be used in describing case-mix (and therefore, whether they could be used in different payment models to measure patient severity as related to relative resource use). Without a more formal study designed to analyze the correlation between the proposed assessment elements and case-mix (and thus, resource use), our views on this topic would rest only on a potentially unsupported sense of the relationship. The current request for feedback on these elements seems to indicate that no such study or other formal evidence currently exists to link these elements to case-mix, and therefore to post-acute payment. If there were, we expect CMS and its contractors to provide such source material in the proposal (as provided in proposed rules). Given the extremely short comment window afforded for this initial review of these assessment elements, at this point we are unable to undertake any formal review of how they may or may not relate to case-mix and post-acute provider payment. Unless and until there is a proven link between these and other assessment elements and post-acute payment metrics, such as case-mix, we refrain from offering subjective notions and believe CMS should proceed with caution in incorporating such elements into a payment structure.</p> <p>Conclusion</p> <p>Thank you for your attention to these comments, please be in touch at the contact information below if you have any questions or would like to follow-up further. We look forward to several additional opportunities to review and provide feedback on these elements as they are developed further. We anticipate CMS providing entities with a more traditional 60-day comment period on these and other IMPACT Act-required elements in the future. The design of these elements are critical to future post-acute policy decisions, as indicated by CMS' request for feedback on case-mix description capacity, and therefore stakeholders deserve an opportunity to deeply consider their impacts. Unlike this and the other IMPACT Act measure development comment periods conducted in late 2015, all of which were extended either at or near the end of the initial comment receipt timeline, a more reasonable 60-day comment period should be the original timeline for generating comments.</p>	
RCPC39	9/12/16	<p>Dear Ms. Hennessey,</p> <p>Partners Continuing Care (PCC) is pleased to comment on the draft data element specifications for standardized assessment-based data elements developed in response to the Improving Medicare Post-Acute Care Transformation Act of 2014. PCC is comprised of the Spaulding Rehabilitation Network and Partners Healthcare at Home, and includes the following institutions:</p> <p>Institutions and Provider Numbers: Spaulding Rehabilitation Hospital (SRH), 22-3034 Spaulding Rehabilitation Hospital - Cape Cod (SCC), 22-3032</p>	<p>Karen S. Nelson Vice President, Quality, Compliance & Regulatory Affairs Partners Continuing Care</p>

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		<p>Spaulding Hospital Cambridge, Inc. (SHC), 22-2000 Spaulding Nursing and Therapy Center – North End (SNE), 22-5506 Spaulding Nursing and Therapy Center – West Roxbury (SWR), 22-5014A Partners Healthcare at Home (PHH), 22-7207B</p> <p>All of the institutions listed are not-for-profit organizations that provide post-acute care and rehabilitation services to a wide spectrum of patients. SRH, SCC, SHC, SNE and SWR are accredited by the Joint Commission (TJC). SRH and SCC are accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF), and all facilities are licensed by the Massachusetts Department of Public Health.</p> <p>Overview Responsive to RAND’s request for comments on these specific topics, we have provided two appendices with feedback on:</p> <ol style="list-style-type: none"> 1. Potential for improving quality, which includes consideration of the data element’s ability to improve care transitions through meaningful exchange of data between providers; improve person-centered care and care planning; be used for quality comparisons; and support clinical decision-making and care coordination; 2. 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); 3. 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; 4. 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. <p>These comments are provided in Appendix A relevant to PCC’s inpatient facilities and in Appendix B relevant to home care. Our more general comments follow. <u>Feasibility and clinical workload:</u> While each of these proposed additional assessments may offer some value in their potential to improve quality and care transitions, collectively, they create the specter of a licensed clinician spending an additional 60, 120, or 180 minutes on data collection for each patient, instead of providing care and services. We appreciate that RAND is currently conducting a pilot of these additional assessment probes in the LTCH setting, and understand that the additional time burden on clinical staff is found to be extensive. With the additional assessments and data elements for LTCH as of April 1, 2016, we have already experienced an added 30 to 60 minutes of a therapist’s and/or nurses’ time to each patient they care for. We suspect that the manifold increase in assessment probes will create an untenable situation</p>	

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		<p>wherein a clinical provider spends more time documenting than delivering care.</p> <p><u>Utility for describing case mix:</u> Assessment periods at admission and discharge may be insufficient to capture the clinical conditions, severity of illness and resource utilization, particularly so in the chronically acutely ill population in LTCHs. Rather, an additional assessment should be considered when there is a significant change in condition, e.g., patient resumes care on a ventilator. Further, many of these assessments will be impacted or altered if the patient has altered mental status or intermittently altered mental status. If assessment data are collected only during the day, it could miss the condition of patients whose mental status alters after dark. We expect that data experts and statisticians will comment more explicitly on the validity and utility of the assessment tools.</p> <p><u>Inter-rater reliability:</u> The proposed assessments and data collection by “any clinician who has been trained to conduct this assessment” is concerning in terms of inter-rater reliability. For other important assessments such as the FIM, there is an expectation for initial and ongoing competency evaluations of staff. We are not suggesting additional resource burdens on provider organizations which collect these data, but only pointing out that the data may have limitations if training is undefined and variable.</p> <p><u>Utilization:</u> The data generated by the many assessments in this proposal will be wasted unless there is a means for this information to be integrated into an Electronic Health Record (EHR) and to become accessible to other providers besides the dedicated data collector. The way that the OASIS, MDS, IRF-PAI and LCDS tools and software are organized at the present, the data are not always reusable to clinicians in the same facility/setting, and are not interoperable where PAC providers are not utilizing the same EHR or when their EHR is not interoperable with other healthcare systems.</p> <p>We share the optimism expressed by RAND that “At the national level, standardized assessment data elements will make it possible to measure and compare quality, outcomes, patient acuity, and resource use consistently across PAC settings and longitudinally, guiding policies and PAC payment reform based on patient/resident populations.” This optimism is tempered by the limited developments we have seen since the PAC providers’ QRP programs were initiated in Oct. 2012. We are disappointed that little has been done by CMS to date with the data collected in the PAC settings since Oct. 2012, but for application of non-payment for failure to provide complete data.</p> <p>Thank you for the opportunity to comment on these proposed measures.</p> <p>Enc. Appendices A and B</p>	
RCPC40	9/12/16	<p>To Whom It May Concern:</p> <p>I am writing on behalf of the Alliance for Home Health Quality and Innovation (the “Alliance”) in response to the data elements specifications document on “Development and Maintenance of Post-Acute Care Cross-</p>	Teresa Lee, JD, MPH Executive Director

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		<p>Setting Standardized Patient Assessment.” Thank you for the opportunity to provide comments on the specifications document.</p> <p>About the Alliance for Home Health Quality and Innovation</p> <p>The Alliance is a non-profit 501(c)(3) organization with the mission to lead and support research and education on the value of home health care to patients and the U.S. health care system. Working with researchers, key experts and thought leaders, and providers across the spectrum of care, we strive to foster solutions that will improve health care in America. The Alliance is a membership-based organization comprised of not-for-profit and proprietary home health care providers and other organizations dedicated to improving patient care and the nation’s healthcare system. For more information about our organization, please visit: http://ahhqi.org/.</p> <p>The Alliance offers the following recommendations and considerations to CMS and RAND.</p> <p>First, the Alliance is concerned that many of the specified assessment elements overlap with existing OASIS measures, with the result being overall lengthening of the time and burden associated with assessment. Consistent with the IMPACT Act, CMS and RAND seek to development cross-setting standardized assessment by making changes to the existing assessment instruments, including OASIS. However, in some cases, the changes envisioned would not replace existing OASIS elements, even though the new and existing elements overlap. This is the case with the proposed behavioral signs and symptoms element, which appears to overlap with the existing 5-point scale. In cases where a proposed new element would overlap with an existing element, CMS should strive to streamline the instrument instead of simply adding on. CMS should ideally either keep the existing element or consider replacing the existing element with the new element. In making such decisions, CMS should take into consideration the Data Specifications for PAC Cross-Setting Assessment relationship between these elements and the various other programs administered by CMS that depend upon the OASIS. For example, a given OASIS data element may influence a measure in the home health value-based purchasing model, star ratings, and more. The Alliance urges CMS to prioritize a least burdensome approach to assessment, while taking into consideration the impact of assessment changes on payment for home health care and the publicly available information for consumers.</p> <p>Second, for several assessment elements, the utility of the new elements for describing case mix is not clear or proven. For example, the addition of the PHQ-9 is an example of an addition to OASIS that may not be necessary. Although the PHQ-9 has a slightly higher positive predictive value, the PHQ-2 has also been tested and both are considered tested, valid and reliable. The Alliance recommends simply picking either the</p>	<p>Alliance for Home Health Quality and Innovation</p>

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		<p>PHQ-2 or the PHQ-9 as the standard for post-acute care, rather than using a gateway approach. The gateway approach (using PHQ-2 to screen, and then skipping PHQ-9 unless the PHQ-2 is positive) would essentially screen patients twice and the utility of this is questionable and unnecessary. The Visiting Nurse Associations of America and the National Association for Home Care and Hospice also are providing comments to CMS and RAND on these data specifications and the Alliance urges consideration of the various clinically based comments that are raised in the letters from these organizations.</p> <p>Third, the data assessment elements do not specify when such questions would be asked. For example, it is unclear whether the elements would be asked to patients at both start of care and the end of care, or only one or the other. Understanding when questions would be asked is critical. In some cases, there may be questions that would only be useful and relevant at the end of care to plan for discharge to community (without home health support). The Alliance urges CMS and RAND to shed light on when it plans to require various assessment elements to be asked in the instruments for each post-acute care setting.</p> <p>* * *</p> <p>The Alliance greatly appreciates the opportunity to comment. Should you have any questions about the Alliance's comments, please contact me at (571) 527-1530 or tlee@ahhqj.org.</p>	
RCPC41	9/12/16	<p>Dear Ms. Hennessey:</p> <p>On behalf of our 39 hospitals in Arizona, California and Nevada, Dignity Health appreciates the opportunity to comment on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment. The fifth-largest hospital system in the nation, Dignity Health is proud of our commitment to our mission to provide quality, affordable care to all, especially the poor and disenfranchised. Post-acute care (PAC) providers deliver patient interventions to the most frail, and often within a care team setting, creating treatment plans in concert with a number of specialists to address complex health care needs. Dignity Health has a robust Home Health program that provided 306,119 home care visits to approximately 24,655 patients annually in California and Nevada in fiscal year 2016, and operates 11 Inpatient Rehab Facilities (IRFs) and 5 Skilled Nursing Facilities (SNFs) across the system. Dignity Health is proud of our partnership with the government. Approximately 70% of the patients Dignity Health serves are enrolled in a government program, primarily either Medicare or Medicaid, but only 50% of our revenue is from the government. This dynamic makes Dignity Health particularly sensitive to increased reporting requirements and changes in reimbursement policies. Dignity Health believes humanity is the very core of health care and encourages the development of measures that</p>	Linda Stutz, RN, BSN, MBA Vice President, Care Coordinaton

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		<p>truly measure quality and create opportunities to improve care across the spectrum, not just to simply “check the box.” As CMS works to implement standardized data sets, and moves toward bringing PAC into value based care, Dignity Health urges CMS to consider the additional resources required to implement assessment tools and submit data. While we agree with the standardization of data elements, PAC providers have are underfunded. CMS should consider including risk adjustments for providers that serve the most vulnerable communities and continue working with providers to establish a vision for PAC and the important role they play in the spectrum of care.</p> <p>Under that frame, Dignity Health is proud to submit the comments below:</p> <p>COGNITIVE FUNCTION AND MENTAL STATUS</p> <p>Cognitive impairment is associated with a number of disorders, conditions, and injuries and can manifest in a variety of ways, such as difficulty communicating, impairments in learning, memory or orientation, confusion, and behavioral symptoms. Conducting cognitive assessments is critically important in order to screen for cognitive impairment, assess the severity of disorder, develop a care plan, and monitor progression. CMS solicits comments on a number of data elements it is considering to include in a standardized clinical assessment of cognitive function and mental status:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Brief Interview for Mental Status (BIMS) <input type="checkbox"/> Expression of Ideas and Wants <input type="checkbox"/> Ability to Understand Others: Understanding Verbal Content <input type="checkbox"/> Confusion and Assessment Method (CAM) <input type="checkbox"/> Behavioral Signs and Symptoms <input type="checkbox"/> Patient Health Questionnaire (PHQ) <p>Dignity Health agrees a patient’s cognitive function has a profound impact on the type of care available to them and agrees the data elements above are appropriate. Prior to implementation, however, Dignity Health urges CMS to consider the impact these elements may have on the placement of patients in the most appropriate setting, whether these elements will inflate facilities’ case mix, and provide clear guidelines about the types of specialists expected to be involved in developing a care plan. Patient Health Questionnaire (PHQ) CMS is soliciting comment on the use of the Patient Health Questionnaire (PHQ). Specifically, CMS is soliciting comment on the advantages and limitations of various versions of the PHQ, for purposes of assessment data standardization. The PHQ-9 and the PHQ-2 are both clinically meaningful and reliable assessments, but they are very different in length and comprehensiveness. The PHQ-9 collects more</p>	

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		<p>information that the PHQ-2, but poses additional burden to patients/ residents and assessors. On the other hand, the brevity of the PHQ-2 may be seen as a limitation, especially when trying to obtain information on people who screen positive for signs and symptoms of depression. An alternative to choosing between the two data elements is to fashion a data element that utilizes the PHQ-2 as a gateway element for the longer PHQ-9. A “gateway” element is an element that, when scored a certain way, governs how scoring is completed for one or more additional elements. This is called a “skip pattern.” When a skip pattern is encountered, the assessor “skips” over the next time(s) and goes onto the next element active on the patient/resident assessment. Patients/residents who reported few or no depressive symptoms in the PHQ-2 would not be asked the additional elements on the PHQ-9.</p> <p>Dignity Health agrees using the PHQ-2 as a gateway is more appropriate than using the PHQ-9. The PHQ-2 is better received by patients and families and avoids having to ask questions that have already been answered. Using the PHQ-2 also provides more clear answers.</p> <p>MEDICAL CONDITIONS: PAIN</p> <p>Pain is often under-recognized, under detected and undertreated. In the context of post-acute care (PAC) patients/residents, although pain is sometimes to be expected, assessment and effective management of pain are nevertheless essential. Medical recovery without pain management has been shown to lead to functional decline and complications; uncontrolled pain often heads to lower participation in rehabilitation and, ultimately, increased health care utilization and cost. A standardized set of pain assessment data elements could help PAC providers assess patient/ resident pain uniformly across the continuum of care. CMS is proposing to include two data elements to standardize clinical assessment of Pain:</p> <p>Pain Presence and Pain Severity.</p> <p>Dignity Health agrees assessing pain is an important data element that has an impact on the quality of care patients receive in PAC. There is some concern, however, that while the data elements may be standardized, the time of assessment should also be standardized to provide a clear picture of a patient/resident’s experience. For example, a patient’s response immediately prior to or after a physical therapy (PT) or occupational therapy (OT) session may be much different from an assessment that occurred in the absence of these types of therapies. Dignity Health recommends either excluding assessments post, during or immediately following therapy sessions, or adding a “while at rest” severity level to provide more clarity. In much the same way, Dignity Health is concerned the timing of the assessment could be skewed based on when a patient received pain medication and recommends CMS give clear direction on when PAC providers should make this assessment to ensure standardized responses.</p>	

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		<p>SPECIAL SERVICES, TREATMENTS AND INTERVENTIONS</p> <p>Special services, treatments and interventions can have a profound effect on an individual’s health status, self-image and quality of life. Reevaluation of special services, treatments and interventions received and performed is important to ensure the continued appropriateness of care and support care transition. The assessment of special services, treatments, and interventions may also help to identify resource use intensity by capturing the medical complexity of patients/ residents.</p> <p>Hemodialysis</p> <p>Hemodialysis is primarily used to provide replacement for lost kidney function. It may be needed for a short period, or permanently if the kidneys have stopped function. Dignity Health supports the inclusion of the hemodialysis data element, but recommends assessing whether the patient is an established dialysis patient or a new dialysis patient to hold the right provider accountable for the quality of that care. This can be done by recording whether a fistula or a vascath is being used. The vascath indicates the patient is an established dialysis patient and should be managed at a dialysis center, not at a PAC facility.</p> <p>Total Parenteral Nutrition (TPN)</p> <p>With Total Parenteral Nutrition (TPN), a patient is fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The patient receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. The data element specification assesses whether a patient has received TPN during the assessment period. Dignity Health is concerned this data element is not always appropriate in the PAC setting since in cases where patients receive TPN as inpatients prior to a transfer to a PAC providers and urges CMS to provide appropriate guidance to ensure the right provider is held accountable to the care they provide.</p> <p>Vasoactive Medications</p> <p>Vasoactive medications are drugs that increase or decrease blood pressure and/or heart rate. Because patients on these medications can experience extreme changes in blood pressure or heart rate, use of these medications requires close monitoring and observation. The data element assesses if the patient received vasoactive medications during the assessment period. Dignity Health sees the value of including this data element in the assessment, but we are unclear about with collecting this data will restrict the settings in</p>	

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		<p>which these types of medications will be administered and whether additional monitoring of patients that receive the medication will be required. In addition, Dignity Health urges CMS to provide an updated list of vasoactive meds we will be required to report on to ensure compliance.</p> <p>Oxygen (intermittent or continuous) Oxygen therapy provides a patient/ resident with extra oxygen when conditions prevent the patient/ resident from getting enough oxygen from breathing. The data element Oxygen assesses if the patient received oxygen therapy. Dignity Health agrees this data element is important to include in patient/ resident assessment, but we wonder if the element would be better if the assessment also required providers to report the level of oxygen and how it was delivered.</p> <p>BiPAP/ CPAP</p> <p>Continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) are respiratory support devices that prevent the airways from closing by delivering slightly pressured air through a mask continuously or via electric cycling throughout the breathing cycle. A BiPAP/CPAP mask enables the individual to support his or her own respiration by ventilators that “breathe” for the individual. They can be used for sleep apnea or for more serious conditions. Dignity Health agrees this data element is important to include in patient/ resident assessments and urges CMS to include the reason for the use of the device to provide more clarity about the patient/ resident’s condition. For example, using CPAP to address sleep apnea is much different than using the device to address chronic obstructive pulmonary disease (COPD) or respiratory failure.</p> <p>Invasive Mechanical Ventilator: Weaning Status</p> <p>Weaning from mechanical ventilation is the process of reducing ventilator support, ultimately resulting in a patient/ resident breathing spontaneously and being extubated. Many complications associated with invasive ventilation increase in likelihood with duration of ventilation; therefore it is important to wean patients/ residents from mechanical ventilation as quickly as possible. Dignity Health agrees this is an important data element to include in order to support increased staffing needs, especially in SNFs.</p> <p>Suctioning</p> <p>Suctioning is used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of</p>	

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		<p>suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning and suctioning through an artificial airway such as a tracheostomy tube. Dignity Health supports the inclusion of data elements to address suctioning, but urges CMS to consider to also include gastric suction to the measure to more comprehensively address this issue in PAC.</p> <p>CONCLUSION</p> <p>Dignity Health appreciates the opportunity to respond to this request for comments and hopes our input is helpful. If you have any questions, please feel free to reach out to Clara Evans, Director of Public Policy & Fiscal Advocacy at Clara.Evans@DignityHealth.org or at (916) 851.2007.</p>	
RCPC42	9/12/16	<p>Dear Measure Development Team,</p> <p>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.</p> <p>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 2016, the Centers for Medicare & Medicaid Services started phasing in new patient criteria that pays significantly more for 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. LTCHs are paid significantly less (and less than their cost) for caring for cases not meeting the new criteria. Thus, LTCHs are expected to increase their share of patients coming from an intensive care unit and/or on prolonged mechanical ventilation.</p> <p>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.</p>	Lane Koenig PhD President KNG Health Consulting

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		<p>We have carefully reviewed the draft data element specifications for the PAC cross-setting standardized patient assessment data and provide some comments below. While we support the inclusion of many of the data elements, we also have concerns.</p> <p>Cognitive Function and Mental Status</p> <p>CMS is seeking comment on six data elements for use in a standardized clinical assessment of cognitive function and mental status:</p> <ol style="list-style-type: none"> 1. Brief Interview for Mental Status (BIMS) 2. Expression of Ideas and Wants 3. Ability to Understand Others: Understanding Verbal Content 4. Confusion Assessment Method (CAM) 5. Behavioral Signs and Symptoms 6. Patient Health Questionnaire (PHQ) <p>We believe that requiring collection of all six data elements will add significant burden on providers with questionable benefit in terms of potential to improve quality and describing case mix. LTCHs currently report on three data elements: (1) Expression of Ideas and Wants; (2) Ability to Understand Others: Understanding Verbal Content; and (3) CAM. We provide comments for each element below.</p> <p>Brief Interview for Mental Status (BIMS): NALTH views the BIMS as redundant with some of the elements already collected in the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set. Specifically, the use of the BIMS to assess signs and symptoms of delirium are already done through administration of the CAM. Further, recall problems, among other issues, can be identified through the Ability to Understand Others elements. While we recognize that the elements are different, it is our assessment that the added burden of requiring the BIMS in all settings are significant relative to the value of this information for quality improvement and case mix.</p> <p>NALTH is also concerned that the BIMS would not be completed for half or more of LTCH patients upon admission. As noted above, LTCHs increasingly treat patients that are coming from an intensive care unit and/or may be on a ventilator. In many of these cases, we anticipate that the interview would not be attempted because the patient is either unresponsive or unable to make himself or herself understood.</p>	

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		<p>Behavioral Signs and Symptoms: Although not required as part of the CARE Data Set, LTCHs already collect the information that would be captured by the Behavioral Signs and Symptoms data elements. Such information is critical for admission and discharge decisions, as well as the identification of special resources required to care for patients with behavioral issues. NALTH recognizes that the type of information captures in Behavioral Signs and Symptoms is different from the other draft elements in the Cognitive Function and Mental Status domain. Moreover, behavioral issues impair a patient’s ability to improve. Thus, we recognize the potential value of this data element for purposes of potential to improve quality and in describing case mix.</p> <p>Patient Health Questionnaire (PHQ): NALTH does not believe that the Patient Health Questionnaire – either the PHQ-9 or the PHQ-2 data elements – as currently constructed are appropriate for a cross-setting measure. As noted above, LTCHs patients are of high severity and suffering from acute conditions requiring prolonged hospitalization. The majority of these patients will have spent at least 3 days in an ICU prior to coming to the LTCH and/or will be on 3mechanical ventilation. These patients are likely to show depressive symptoms during the two-week period prior to administering the questionnaire since the two-week period would likely include the stay in the intensive care unit.</p> <p>Cognitive Function and Mental Status Comment Summary:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Requiring all six dataelements to be reported by each setting will increase provider burden with questionable value in terms of improving care or differentiating the types of patients treated at each setting. <input type="checkbox"/> LTCHs currently report on three dataelements (Expression of Ideas and Wants; Ability to Understand Others: Understanding Verbal Content; and CAM) and believe these three elements are useful for improving quality and distinguishing the types of cases seen at each settings, and are feasible to collect. <input type="checkbox"/> Because of the types of patients treated by LTCHs, the BIMS and PHQ are not appropriate for use in the LTCH CARE Data Set. <input type="checkbox"/> The Behavioral Sign and Systemselements may add information not captured in the other draft data elements. <input type="checkbox"/> It is important to empirically demonstrate that a particular dataelement adds to our understanding of the resources required to treat patients and expected outcomes. <p>Development and Maintenance of Pain and Impairments of Hearing and Vision NALTH supports the data elements on pain presence and severity and impairments of hearing and vision as many LTCHs are already collecting similar information for patients that are able to verbally respond to the assessment.</p>	

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		<p>Development and Maintenance of Special Services, Treatments, and Interventions For All Special Services, Treatments, and Interventions: For each of the data elements listed for use in a standardized clinical assessment of special services, treatments, and interventions, the specifications allow the assessor a 3-day assessment period to review the patient’s medical history to determine if the patient received a service, treatment or intervention during his or her stay. Instead of an arbitrary 3-day assessment period that can occur at admission when the LTCH has not administered any service, treatment or intervention, NALTH supports modifying the data elements (with the exception of Invasive Mechanical Ventilator: Weaning Status) to specify that the assessment should occur only at discharge and the assessor should review the patient’s medical history to determine if he or she had or had not received any special services, treatments, and interventions at any time during his or her stay. This recommendation will reduce the burden on clinical staff by allowing all assessments to be documented at discharge.</p> <p>Hemodialysis: NALTH supports the data element related to hemodialysis, but recommends that the provision of peritoneal dialysis also be assessed.</p> <p>Oxygen (Intermittent or Continuous): NALTH supports a two-part assessment for the oxygen data element. The first assessment would be to assess whether the patient received oxygen at any time during his or her stay and second, if the patient did receive oxygen, did the patient receive high flow oxygen. The identification of high flow oxygen is important because it is a form of respiratory support commonly used on patients with acute respiratory failure. High flow oxygen requires high oxygen levels that exceeds peak inspiratory pressure in respiratory failure patients thus maintaining higher oxygen saturation. Patients that receive this therapy require specialized equipment and supervision that is usually found in intensive care units and LTCHs.</p> <p>BiPAP/CPAP: NALTH recommends that the data element for BiPAP/CPAP be distinguished as two separate data elements instead of one. NALTH recognizes that BiPAP and CPAP are both respiratory support devices that enables individuals to support his or her own respirations and therefore can be used for sleep apnea or for more serious pulmonary or respiratory conditions. However, while both devices are similar in design and function, BiPAP is historically used for life threatening diseases (e.g., acute respiratory distress syndrome), while CPAP is used for less serious diseases (e.g., sleep apnea). Having two separate data elements will lead to a more comprehensive review of the patient’s medical record to more finely determine the severity of the patient’s condition and thus, the LTCH’s potential for improving quality.</p> <p>Invasive Mechanical Ventilator: Weaning Status: NALTH recommends that the data element for invasive</p>	

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		<p>mechanical ventilator be kept the same as presented in the LTCH CARE Data Set v3.0 to reduce the burden of data collection on LTCHs. In the CARE Data Set, assessment of weaning status is conducted at admission rather than both at admission to and at discharge from the PAC setting as specified in the data element specifications for public comment.</p> <p>Other Special Services, Treatments, and Interventions: NALTH believes that chest tubes should be included in the list of special services, treatments, and interventions.</p> <p>Special Services, Treatments, and Interventions Comment Summary:</p> <p><input type="checkbox"/> With the exception of Invasive Mechanical Ventilator: Weaning Status, NALTH recommends modifying the data elements to specify that the data elements can be collected at discharge from the PAC setting and to ask whether the patient had or had not received any special services, treatments, and interventions at any time during his or her stay.</p> <p><input type="checkbox"/> CMS should collect information on: peritoneal dialysis and chest tubes.</p> <p><input type="checkbox"/> NALTH supports a two-part question to assess whether a patient received oxygen and, if yes, whether the patient received high flow oxygen.</p> <p><input type="checkbox"/> NALTH recommends that the dataelement for BiPAP/CPAP be distinguished as two separate data elements instead of one.</p> <p><input type="checkbox"/> NALTH supports that the dataelement for invasive mechanical ventilator be kept the same as represented in the LTCH CARE Data Set.</p> <p>Thank you for the opportunity to comment on these data element specifications. If you have any questions about these comments, please contact Lane Koenig, PhD, NALTH Director of Policy and Research, at lane.koenig@knghealth.com.</p>	
RCPC43	9/12/16	<p>Dear Barbara Hennessey:</p> <p>On behalf of the nearly 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), thank you for the opportunity to submit feedback on the data elements that CMS has selected to meet the IMPACT Act domains.</p> <p>AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses and other health and spiritual care providers deeply committed to improving quality of life for patients facing serious or life-threatening conditions, as well as their families.</p>	<p>Christian T. Sinclair, MD FAAHPM AAHPM President</p>

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		<p>We applaud the efforts of the CMS to develop a comprehensive assessment tool that would cross post-acute settings. This is an important effort that could greatly improve the quality of care. We have the following suggestions to strengthen this effort and ensure that those with cognitive impairments are not excluded from the denominator.</p> <p>Recommendation #1 – Include a Non-Verbal Pain Scale for Patients/Residents Unable to Self-Report While we appreciate the inclusion of the two pain elements in the uniform assessment, we are concerned that this will not be sufficient for a significant portion of patients or residents in the PAC-LTC settings who may be unable to self-report. These include older adults with advanced dementia, critically ill/unconscious patients, patients in delirium, and patients at the end of life. Studies have shown that between 30-50 percent of people with dementia experience persistent pain, much of which is due to inadequate assessment and treatment.¹ Consequences of untreated pain can include poor appetite and weight loss, disturbed sleep, withdrawal, sadness, anxiety, depression, physical and verbal aggression, and even increased morbidity and mortality. Therefore, the standardized assessment must include both instructions for patients who are unable to self-report, as well as data elements to assess pain for this subpopulation. It is important to ensure that this tool have an appropriate non-verbal scale. The MDS 3.0 approach would be an important addition to this instrument.</p> <p>Recommendation #2 – Collect and Document Patient Goals of Care</p> <p>It is critical to discuss patients’/residents’ goals in order to ensure that the care delivered is appropriate and aligned with their wishes. The standardization of the PAC assessment form across settings presents an unparalleled opportunity to ensure that patients’ preferences are known and honored, regardless of their location. Studies have shown that high quality goals of care conversations 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.^{2,3} But in order to be most effective, these conversations should occur early in the illness trajectory – and certainly before any serious decisions must be made. We suggest that CMS reinstate the MDS 2.0 section on advance directives and orders for life sustaining treatment.</p> <p>The post-acute care patient population includes persons with significant risk of mortality and 30 day re-hospitalizations. Advance care planning and documentation of patient goals of care and wishes is very important in this population. MDS 2.0 had a section that documented advance directives and orders regarding life sustaining treatment. This section was not removed for psychometric reasons, but because it was only used on an annual basis with the concern that, without frequent updating, this information may be</p>	

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		<p>in error. For all the reasons we listed above, we believe it was a mistake to drop the section on advance directives and orders for life sustaining treatment from MDS 3.0, and the IMPACT Act should strongly consider including these measures in their common set.</p> <p>AAHPM continues to appreciate CMS's thoughtful work in the creation of a uniform set of assessment measures. With a few small additions to the data elements, clinicians can gain a more comprehensive understanding of the things that matter most to their patients and residents. This in turn will lead to better, more person-centered care across post-acute settings.</p> <p>Thank you again for the opportunity to provide feedback on the data elements CMS has selected to meet the IMPACT Act domains. We are eager to collaborate with CMS to address the issues discussed here. Please address questions or requests for additional information to Katherine Ast, MSW LCSW, AAHPM Director of Quality & Research, at kast@aaahpm.org or 847-375-4818.</p>	
RCPC44	9/12/16	<p>Cerner Corporation, a leading supplier of electronic health record, clinical and revenue cycle information systems, and EHR vendor for a large contingent of US based hospitals, critical access hospitals, eligible professionals and Post Acute Care (PAC) providers appreciates the opportunity to submit comments on the IMPACT Act as CMS seeks to standardize patient assessment data across settings to improve the patient quality of care and quality of life. As a vendor who supplies solutions across the longitudinal patient care, we find there are many challenges in providing the transitional care data from one provider of care to another, because there is a lack of standardization not just between the PAC venues but also from the acute care to the PAC. We recognize and appreciate the work CMS has invested to mitigate these challenges and we continue to support this work.</p> <p>We are submitting comments to the project titled "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data". The project request for public comment asked to review the proposed data elements for potential in improving quality, validity, and feasibility for use in PAC and utility for describing case mix. Cerner provides solutions for home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long-term acute care hospitals (LTCH) and skilled nursing facilities (SNFs). We gathered multiple representatives from each of these venues to discuss these data elements and their impacts.</p> <p>Overall, we feel these data elements have potential for improving quality in the patient longitudinal care if these data elements were also captured, and shared with the PAC provider, for patients who were also admitted to an inpatient facility prior to the PAC episode of care. These data elements (and others) would serve as a baseline through the transitions of care and upon admission to the post acute venues. We believe CMS will not only find savings in the patient case mix and improvement in the patient quality of care, but</p>	John Travis President and Compliance Strategist, Cerner Corporation

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		<p>also substantiate the discharge planning process and patient case management.</p> <p>We would also like to point out concerns for the inpatient rehabilitation facilities (IRFs) where quality improvement in these measures often may not happen during the IRF stay, but will support the longitudinal overall outcome of the patient care. We caution CMS from tying the IRF reimbursement model to improved outcomes in these areas as the patient length of stay is too short to develop an improvement score during the IRF episode of care. We also found there were areas where the IRF Patient Assessment Information (IRF-PAI) language was more specific than the proposed language in this RFI, and the proposed assessment would not support IRF scoring improvements.</p> <p>We have compiled comments other specific RFI requests, noted below:</p> <p>Brief Interview for Mental Status (BIMS)</p> <p>Overall we feel this is a good cross-setting measure which most venues are already collecting or will be collecting. Assessing the cognitive state of the patient can assist in determining an increased service utilization and a slower healing process for patients who exhibit a decreased mental status.</p> <p><input type="checkbox"/> _Home health (HH) providers are already using the Mini Mental State Exam (MMSE) so we feel this would not be a big change in current processes.</p> <p><input type="checkbox"/> _IRF providers will begin assessing by 10/1/2016, and do not feel this is a burdensome collection</p> <p><input type="checkbox"/> _Skilled Nursing Facilities (SNF) are already assessing at admission, quarterly or when the patient experiences a decline in 2 or more levels of care and would not be a change in the current process. Can you indicate if this would continue to be assessed in this way for the MDS?</p> <p>Expression of Ideas and Wants</p> <p>Overall this is a good cross-setting measure which most venues are already collecting and we urge CMS to consider this as a replacement of the current measures and not to include this in addition to the current assessments.</p> <p><input type="checkbox"/> _IRF providers already collect this information within the Cognitive section of the Functional Independent Measures (FIMs) assessment within the IRF-PAI. This suggested measure is not as sensitive as the components of the current FIM so this could actually make the FIMs less significant, impacting the quality of patient outcomes as well as the accuracy of reimbursement for IRF providers. Patients with a shorter lengths of stay would not benefit from this abbreviated scoring.</p> <p>Ability to Understand Others: Understanding Verbal Content</p> <p>Again, we believe this is another valid cross-setting measure to collect.</p> <p><input type="checkbox"/> _SNF providers do not have objection to changing the naming convention as it makes the responses more understandable.</p>	

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		<p><input type="checkbox"/> _IRF providers do collect this information as a part of the FIMS assessment within the IRF-PAI, but again the scale for this proposed measure is not one that would be applicable to a performance based outcome measure for an IRF. The short stay in an IRF environment doesn't allow for the patient to show an improvement and is inadequate for an outcome measure.</p> <p>Confusion Assessment Method (CAM) We have concerns using this measure as a rate setting measure, but it may be a measure more effective in a longitudinal plan of care where there has been an acute care baseline measurement.</p> <p><input type="checkbox"/> _HHAs already collect data to assess confusion, and requests the removal of the current OASIS confusion assessment elements in favor of these new data elements, if they are identified for use.</p> <p><input type="checkbox"/> _SNF providers are already required to determine confusion from delirium, which is a process done over a long period of time. Making a determination of confusion or delirium on an initial assessment, without an acute care baseline measurement, is inaccurate and will not provide quality results.</p> <p><input type="checkbox"/> _IRF patients do not have a length of stay long enough to determine the difference between confusion and delirium. It will be markedly difficult to assess true patient confusion without an acute care baseline measurement.</p> <p>Behavioral Signs and Symptoms We agree with this data element, except in the case of the patients with trauma induced injuries. Specifically, IRF patients with brain injuries may exhibit these behavioral signs as they were acquired from trauma induced injuries, however, it is not necessarily a behavioral health issue. There should be a way to differentiate between injury acquired conditions and true behavioral health issues.</p> <p>Patient Health Questionnaire (PHQ) We agree with the inclusion of the PHQ-2 as a precursor to initiation of the PHQ-9 for all venues except the IRF which the PHQ-9 is not applicable to short patient stays.</p> <p>Pain Presence and Pain Severity These were listed as two separate data elements, but we suggest a combination into one element. Instead of Pain Presence as Yes/No/Unable to respond and Pain Severity as a level of pain; we recommend rewording to a single question where the patient would respond with the level of pain they have experienced in the last 3 days, with zero being no pain and 10 being the worst pain imagined. Unresponsive patients would only have an entry of 88 in the assessment.</p> <p>Special Services, Treatments, and Interventions</p>	

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		<p>Instead of listing these individually, we comment to these data collection elements as a whole. We agree with the collection of each of the elements CMS has noted in this section:</p> <ul style="list-style-type: none"> <input type="checkbox"/> _Hemodialysis <input type="checkbox"/> _IV (intravenous) Chemotherapy <input type="checkbox"/> _Radiation <input type="checkbox"/> _Central Line <input type="checkbox"/> _Total Parenteral Nutrition (TPN) <input type="checkbox"/> _Enteral Nutrition <input type="checkbox"/> _Vasoactive Medications <input type="checkbox"/> _Oxygen <input type="checkbox"/> _BiPAP/CPAP (bilevel or continuous positive airway pressure) <input type="checkbox"/> _Invasive Mechanical Ventilator: Weaning Status <input type="checkbox"/> _Suctioning <input type="checkbox"/> _Tracheostomy care <p>We believe these elements could be used for case mix grouping, however we do not believe they will provide any additional resource for quality measures as these are Yes/No answers to indicate the patient did/did not require these services. We do believe it will improve the patient transitions of care and encourage the use of this data for that purpose.</p> <p>In conclusion, we appreciate the efforts CMS is spending to more closely align the assessment process in the post-acute venues of care and encourage CMS to also keep in mind the type of care provided in each of these venues as they do have distinct differences. These individual differences mean some outcomes or case-mix groupings may be valid for one venue of care, but may not provide adequate distinction of care in another venue. Specifically, we have concerns in developing outcome based quality measures and case mix distinctions for data elements which require a greater length of time to see positive results and feel it distinctly puts the IRFs at a disadvantage. The IRF venue plays a significant role in stabilizing and preparing patients for their next venue of care and would encourage CMS to find ways to accurately measure the patient quality of care in venues where the average length of stay is significantly less than other LTPAC venues of care.</p> <p>Cerner Corporation hopes these comments will be of value in considering possible update to the cross setting standardization of post-acute care assessment data. We are happy to help clarify any of the comments should you wish to pursue any such conversations with us.</p>	

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RCPC45	9/12/16	<p>Dear Ms. Hennessey:</p> <p>On behalf of the more than 9,000 physiatrists of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), we appreciate the opportunity to submit comments to the Call for Public Comments: Development and Maintenance of Post- Acute Care Cross- Setting Standardized Assessment Data. 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.</p> <p>Physiatrists coordinate, supervise and provide medical rehabilitation services in a wide variety of settings including all of the post- acute care (PAC) settings impacted by these draft specifications. physical medicine and rehabilitation (PM&R) physicians are increasingly present across the post- acute care continuum and are not aligned with any one PAC setting and, as a result, can act as an impartial medical decisionmaker to help direct patients to the most appropriate setting and intensity of rehabilitative care to meet the individual medical and functional needs of patients. General Concerns in the Call for Public Comments: Standardizing patient assessment data amongst Post- Acute Care (PAC) settings is important work that greatly impacts AAPM&R’s members. In an effort 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 as long as 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.</p> <p>In response to your specific comment request, AAPM&R appreciates the opportunity to comment. However, the summary document given for review does not allow itself to critical analysis, especially in the context of dealing with different PAC settings. There was not enough data presented on the assessment instruments. For these reasons, AAPM&R has the following concerns based upon the information that was provided: 1) The document does not speak to how these instruments will be standardized in each of the PAC settings. Timing is extremely important when using a number of these assessments. While we found the data assessment instruments to be reliable, we cannot speak to the validity if they are not executed the same way in each setting. AAPM&R recommends that if using assessment instruments across settings, there should be clear instructions on exactly how to use them and when. 2) Another concern with the information provided,</p>	<p>Thiru Annaswamy, MD Chair, Evidence Based Practice Committee American Academy of Physical Medicine and Rehabilitation</p>

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		<p>was the uncertainty of how one assessment element impacts another. For example, the data element, Expression of Ideas and Wants was tested and when combined with the data element, Understanding Verbal Content, the Expression of Ideas and Wants data has been shown to be reliable. If one of these data elements is used on its own, its validity will come into question. What if Expression of Ideas and Wants, is not used with Understanding Verbal Content? In this request for comments, CMS is asking for comments on each data element as if it stands alone; however, the evidence presented is not consistent across the data elements as stand- alone elements. There needs to be a level of certainty that that the data elements are both reliable and valid on their own before AAPM&R can support this data element. In addition to the general comments above, AAPM&R has the following comments in each category:</p> <p>Cognitive Function and Mental Status Brief Interview for Mental Status <input type="checkbox"/> AAPM&R agrees this is a reliable dataelement and feasible to implement across PAC settings.</p> <p>Expression of Ideas and Wants <input type="checkbox"/> While AAPM&R agrees this dataelement has good reliability, we have concerns with the feasibility of implementation. Expression is extremely variable which could cause problems in different settings. For example, brain injury patients can be more assertive than other patients and may score well in this area; however, this does not always indicate a positive clinical situation.</p> <p>Ability to Understand Others: Understanding Verbal Content <input type="checkbox"/> AAPM&R knows this is an importantelement, however we have major concerns with validity. As we stated previously, since this element is tied to Expression of Ideas and Wants, it may not be valid on its own. Another concern is that this assessment could have huge variations moment to moment depending on when a patient is assessed. This element would be stronger if it took into account other variables that impact a person’s ability to understand, such as if the patient has slept, what medications they are on and when the assessment is taking place.</p> <p>Confusion Assessment Method <input type="checkbox"/> AAPM&R has some concern with this dataelement. Its low kappa value indicates it needs further testing across the settings. Once testing is complete and the data element is found valid, then we believe it would be useful and feasible to use across settings.</p> <p>Behavioral Signs and Symptoms <input type="checkbox"/> This dataelement was extremely difficult to assess with limited information. While it is important for care planning and clinical decision-making, AAPM&R is concerned with the lack of inter- rater reliability.</p>	

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		<p>•AAPM&R also strongly urges treatment refusal be added as a data element. This is a disruptive behavioral response not directed towards others and can provide insight into how individuals react to treatment recommendations. Patient Health Questionnaire</p> <p><input type="checkbox"/> AAPM&R likes the approach of using PHQ- 2 as a gateway to PHQ- 9. It will help reduce data burden on physicians and patients. We also believe it would be feasible across all settings when using this approach.</p> <p>Medical Conditions: Pain</p> <p>Pain Presence and Pain Severity</p> <p><input type="checkbox"/> AAPM&R strongly urges these dataelements be removed and replaced with an element that focuses on how pain impacts an individual's level of function, such as question 9 of the Brief Pain Assessment (BPI): Mark the box beside the number (0- 10) that describes how, during the past 24 hours, pain has interfered with your:</p> <ul style="list-style-type: none"> o general activity o mood o walking ability o normal work (outside the home and housework) o relations with other people o sleep o enjoyment of life <p>Solely asking about the presence of pain does not provide enough information to help an individual's overall quality of life improve. Pain levels may never change, even when the function/ability of the patient does. Therefore, the focus on pain should be on how pain limits function. As you know, opioid abuse is on the rise and the more focus that is solely on pain and not its relationship to function, the more risk of over prescribing and overuse of narcotics. The importance of both Pain Presence and Pain Severity must be assessed by their relationship to function.</p> <p>Impairments of Hearing and Vision</p> <p>Ability to Hear and Ability to See in Adequate Light</p> <p><input type="checkbox"/> AAPM&R agrees both dataelements are important and would improve quality. As we stated in our general comments, these should be collected at a standard time among the various settings.</p> <p>Special Services, Treatments and Interventions</p>	

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		<p>General Comments: AAPM&R agrees that all of the data elements in this category are feasible to collect in the different PAC settings and that they are valid. Due to the nature of these data elements, every positive score will create a larger burden of care, will be tougher to treat and will use more resources. However, we do have concern that these are difficult to assess and monitor quality improvement. For example, if someone requires oxygen during their length of stay and treatment, you cannot improve in that area.</p> <p>Below are our comments on some of the data elements in this category:</p> <p>Hemodialysis</p> <p><input type="checkbox"/> AAPM&R is unsure why peritoneal dialysis was left out and believes that it should be included in this data element.</p> <p>Central Line Management</p> <p><input type="checkbox"/> There was no mention of peripherally inserted central catheters (PIC Line) and AAPM&R believes they should be included here.</p> <p>Oxygen (intermittent or continuous)</p> <p><input type="checkbox"/> In line with our comments in the pain category, AAPM&R urges that the focus on pain should be in relation to function. A better question to ask is, does oxygen requirement/use/supplementation limit the patient's functional ability?</p> <p>BiPAP/CPAP</p> <p><input type="checkbox"/> AAPM&R suggests these data elements need be separated because they deal with two very different types of patients.</p> <p>Invasive Mechanical Ventilator: Weaning Status</p> <p><input type="checkbox"/> AAPM&R would like further clarification of what "weaning" means when used with this data element, since it is not clear in the document provided.</p> <p>We appreciate the opportunity to comment on this request for information. AAPM&R looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Beth Radtke, Manager of Quality and Research Initiatives in the AAPM&R Division of Health Policy and Practice Services. She may be reached at bradtke@aapmr.org or at (847)737- 6088.</p>	

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		<p>APM&R Recommendations on Post-Acute Care Data Standardization and Quality Measurement</p> <p>Background</p> <p>Medicare spending on post-acute care provided by home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals accounted for approximately 10 percent of total Medicare spending in 2013, totaling \$59 billion. The Medicare Payment Advisory Commission (MedPAC) has noted several long-standing problems with the payment systems for post-acute care (PAC) and has suggested refinements that are intended to encourage the delivery of appropriate care in the right setting for a particular patient's condition. Several recent federal laws have affected, or will affect, payments to one or more post-acute care providers, including physicians who provide services in these settings. These federal laws include the Patient Protection and Affordable Care Act of 2010 (ACA), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). However, new legislation is also being considered by lawmakers that may accelerate payment reform of post-acute care, possibly including value-based purchasing.</p> <p>AAPM&R Position on Post-Acute Care Data Standardization and Quality Measurement Data standardization across PAC settings is critical to compare and contrast care episodes in the various PAC settings. Not only will data standardization help facilitate appropriate payment reforms, it is also important to the development of appropriate quality measures that reflect the setting in which rehabilitation care is being provided. AAPM&R supports outcome measures in post-acute care environments that accurately assess patients' functional status, whether the treatment is improving, maintaining, or slowing deterioration of function. AAPM&R cautions, however, that the data collected may be affected by educational level and the professional expertise of the evaluator that will need to be factored into conclusions based on the data.</p> <p>AAPM&R continues to advocate for post-acute care quality measures that are based on sound evidence with fully developed risk-adjusters. The following are requirements extracted directly from the IMPACT Act on data standardization and quality measurement across post-acute care settings in three areas, from high level domains to standardized assessment categories with specific data elements within each. AAPM&R supports these requirements.</p> <p>However, AAPM&R continues to stress to lawmakers and interested stakeholders that risk adjustment is necessary for comparison purposes and needs to be further studied for reliability. IMPACT Act Requirements Supported by AAPM&R</p>	

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		<p>The IMPACT Act of 2014 requires The Secretary to implement specified clinical assessment categories using standardized (uniform) data elements to be nested within the assessment instruments currently required for submission by LTCH, IRF, SNF, and HHA providers. The Act further requires that CMS develop and implement quality measures from five quality measure domains using standardized assessment data. In addition, the Act requires the development and reporting of measures pertaining to resource use, hospitalization, and discharge to the community. These domains and categories are listed below.</p> <p>Through the use of standardized quality measures and standardized data, the intent of the Act, among other obligations, is to enable interoperability and access to longitudinal information for such providers to facilitate coordinated care, improved outcomes, and overall quality comparisons. AAPM&R supports the following measure domains, assessment categories and data elements as specified in the IMPACT Act.</p> <p>I. Quality Measure Domains:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Skin integrity and changes in skin integrity; <input type="checkbox"/> Functional status, cognitive function, and changes in function and cognitive function; <input type="checkbox"/> Medication reconciliation; <input type="checkbox"/> Incidence of major falls; <input type="checkbox"/> Transfer of health information and care preferences when an individual transitions <p>II. Resource Use and Other Measure Domains:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Resource use measures, including total estimated Medicare spending per beneficiary; <input type="checkbox"/> Discharge to community; and <input type="checkbox"/> All- condition risk- adjusted potentially preventable hospital readmissions rates. <p>III. Assessment Categories:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Functional status <input type="checkbox"/> Cognitive function and mental status <input type="checkbox"/> Special services, treatments, and interventions <input type="checkbox"/> Medical conditions and co- morbidities <input type="checkbox"/> Impairments <input type="checkbox"/> Other categories required by the Secretary <p>IV. Data Elements for Each Standardized Assessment Category</p>	

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		<p>In order to compare outcomes across post-acute care settings, specific data elements must be identified and collected for each of the standardized assessment categories. AAPM&R recommends collection of the following data elements in each assessment category.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Functional Status <ul style="list-style-type: none"> o Self-Care <ul style="list-style-type: none"> <input type="checkbox"/> Dataelements of self-care should include eating; showering/bathing; upper body dressing; lower body dressing; toileting and medication management. Depending on the patient’s goals, there may be a need to evaluate more complex abilities (Instrumental Activities of Daily Living) such as cooking, laundry, shopping, driving, money management, and using a telephone and computer. o Mobility <ul style="list-style-type: none"> <input type="checkbox"/> Dataelements of mobility should include measurement of a patient’s unique capacity for mobility, whatever form it takes. Data collected should include bed mobility, the ability to transfer from bed to chair, come from sitting to standing and to complete a car transfer. If a patient is expected to be able to ambulate, data collected should include: distance able to ambulate on level surfaces indoors; go up and down 1 step (curb); 4 steps; 12 steps; and ambulate on uneven surfaces and the use of an assistive device. If a patient is expected to primarily use a wheelchair, data should include safe wheelchair use (e.g., locking the wheelchair before transfer), the distance rolled, the ability to navigate more complex environments (such as turns or uneven surfaces) and the ability to go up and down a ramp. <input type="checkbox"/> Cognitive and behavioral function <ul style="list-style-type: none"> o General Mental status including alertness and orientation o Evaluation of memory, attention, concentration o Evaluation of mood, agitation and pain <input type="checkbox"/> Communication function <ul style="list-style-type: none"> o Ability to understand and express verbal and written information <input type="checkbox"/> Special services, treatments and interventions provided such as <ul style="list-style-type: none"> o Pulmonary treatment/ventilator o Dialysis o Chemotherapy and other intravenous medications o Enteral nutrition o Use of assistive devices (DME, orthotics/prosthetics, communication devices) <input type="checkbox"/> Medical conditions and co-morbidities such as <ul style="list-style-type: none"> o Diabetes 	

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		<ul style="list-style-type: none"> o Pressure Ulcers o Post-surgical or complex wound care o Respiratory failure, tracheostomy o Heart failure, cardiac monitoring <input type="checkbox"/> Impairments o Bowel and Bladder function and level of patient independence o Swallowing function o Visual impairment o Hearing impairment <input type="checkbox"/> Environmental factors o Community and family support o Access to community for basic needs o Access to transportation o Independent living status, with or without long term services and supports o Ability to return to work <p>Future Quality Measurement of PAC Services</p> <p>It is important for PAC settings to move from the current emphasis on process measures and toward a series of outcomerelated measures to compare and contrast between PAC settings and to assess short-and long-term patient status postinjury or illness. This requires data standardization across PAC settings in a series of important domains, as detailed above. Once achieved, quality measurement in the PAC arena needs to expand toward assessment of quality of life and long-term functional outcomes, such as those community-oriented factors described in the International Classification of Function (ICF), including the ability to live independently, return to work (where appropriate), community participation, social interaction, and other factors that indicate the true value of rehabilitative care.</p>	
RCPC46	9/12/16	<p>On behalf of the Visiting Nurse Associations of America (VNAA), thank you for the opportunity to comment on the proposed standardized assessment-based data elements to meet the requirements as set forth under the IMPACT Act of 2014. VNAA advances quality, value and innovation in home-based care and represents mission-driven providers of home and community-based health care, including hospice, across the United States.</p> <p>VNAA members provide high-quality, patient-centered care at home, as well as offer support for family caregivers. They primarily serve the most clinically complex and vulnerable patients¹, who are by definition homebound and who will benefit from having closely integrated health exchange between all members of</p>	Danielle Pierotti, RN, PhD, CENP, AOCN, CHPN Vice President, Quality and Performance Improvement, Visiting Nurse

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		<p>the care team—regardless of the severity of their illness—and serve a mixture of Medicare, Medicaid, privately-insured and uninsured patients. Home health providers continue to provide value and innovation in home-based care and care coordination.</p> <p>Home-based care providers work to improve the management of patients with chronic conditions, thus addressing some of the greatest challenges in health care today, including medication management, uncoordinated transitions of care and high rates of unnecessary hospital and emergency department utilization². In addition, home health provides medically necessary, skilled services in an incredibly efficient manner, providing care at a fraction of the cost of institutional care.</p> <p>Our overarching concern is the need to monitor the time points for assessing and documenting. There are significant differences in the three facility based PACs versus home health agencies and it will be an important consideration. Specifically, when elements which are not documented at admission or discharge from another care setting, home health agencies will need adequate time for documentation and to gather information. Attached is a chart laying out the measures with VNAA’s concerns highlighted. We value the opportunity to provide input on these proposed measures and look forward to further collaboration as well develop consistent and effective measures across all post- acute care settings.</p> <p>Please contact Danielle Pierotti, Vice President of Quality and Performance Improvement at dpierotti@vnaa.org or 571-527-1529 with any questions or concerns.</p> <p>Sincerely, Danielle Pierotti, RN, PhD, CENP, AOCN, CHPN Vice President, Quality and Performance Improvement</p> <p>Appendix</p>	Associations of America
RCPC47	9/12/16	<p>As the RAND/CMS recommendations indicate, this project will add significantly more elements to the Quality Indicator sections of the postacute care assessment instruments (in our case the IRF PAI), with the intent of creating future quality measures for these elements.</p> <p>The issue we have with this project is that the postacute care staff here at the IRF will be required to add these new assessment and documentation requirements to their present work process with the intent of developing reliability for these new elements. The staff will need to continue the current CMS assessment and documentation requirements for the IRF PAI as well as adding these new Quality Indicator elements with no guarantee that these elements will become reliable and the new standard for the IRF PAI. Not only are these new elements not determined as reliable they have also not been determined to be true indicators of</p>	Mini Malhotra MBA, MHA Administrator, Physical Medicine & Rehabilitation Administration, Upstate Medical University

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		<p>quality care. We are not confident that these new elements have the potential for improving quality. Since these new Quality Indicators are becoming mandatory and the present FIM scoring requirements for the IRF PAI will remain mandatory, the significant increase in assessment and documentation time burden on the PAC staff will be excessive. This excessive increase in burden on the staff will undoubtedly negatively impact the clinician’s ability to provide the intensive nursing and therapy needs of the IRF patient. Not only does this project increase the time burden on the staff for assessment and documentation but the amount of time required to train the staff on the new Quality Indicators has also increased. CMS projects an increase in the time required to accomplish the assessment and documentation of the new elements to be 41 minutes. We project the additional time for the PPS Coordinator to populate the new 18 page IRF PAI and insure all the elements are coded to meet requirements, to potentially meet or exceed this projection of 41 minutes. Our projection does not include the additional time that Physical, Occupational and Speech Therapy as well as Nursing staffs will need to accomplish these new elements.</p> <p>The use of the BIMS assessment tool does not comprehensively assess a patient’s cognitive function or mental status since its primary focus is on memory. This assessment tool does not assist the TEAM in developing a comprehensive cognitive treatment plan of care for the patient with cognitive deficits that have barriers for a safe discharge back to a community setting.</p> <p>The BIMS tool may be an assessment that has high validity but since it predominantly focuses on memory we question its potential for improving quality of care.</p> <p>The “Staff Assessment for Mental Status” branch is at best complete guess work by the clinicians and we do not see how this can be valid or have potential for improving quality.</p> <p>The coding in the “Expression of Ideas and Wants” and “Understanding Verbal Content” Section B of the Quality Indicators is actually less specific than the FIM scoring method in the Cognitive section of the current IRF PAI. Since the new Quality Indicators coding is less specific than the current FIM scoring, we do not see how this new process has any potential to improve quality.</p> <p>Total Parenteral Nutrition (Section O) in the new Quality Indicators is to be coded on day 3 per CMS. We feel that TPN should and can be coded on day 1 since a patient is undoubtedly not appropriate for admission to an IRF if their nutritional status is so unstable that they may need to be switched to TPN between days 1 and 3 of their admission. Having to wait until 3 of the admission unnecessarily increases the potential for noncompliant coding by the postacute care TEAM.</p> <p>We feel that the multiple “walk and wheelchair” elements (Section GG0170) will have an excessive number of assessments that will not be able to be accomplished on admission since the patient’s mobility deficits are typically significant. Even though many of these elements cannot be accomplished at admission they must still be coded in the new IRF PAI. This imparts an undo documentation burden on the PAC staff and PPS Coordinator in order to meet the IRF PAI completion requirements.</p>	
RCPC48	9/12/16	Dear Ms. Hennessey and RAND Corporation Representatives:	Sharmila

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		<p>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.</p> <p>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 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.</p> <p>AOTA was pleased that Congress recognized the importance of collecting data on cognitive status, functional status, vision, and pain, 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.</p> <p>Our comments focus on areas where we believe occupational therapy can have a positive impact on the multiple outcomes set as goals by IMPACT. A recent study confirms for us the overall value of occupational therapy in the mix of services provided to patients to achieving systemic goals, such as reducing hospital readmissions.</p>	<p>Sandhu, J.D. Director of Regulatory Affairs American Occupational Therapy Association</p>

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		<p>The article, “Higher Hospital Spending on Occupational Therapy is Associated with Lower Readmission Rates,” was published August 5, 2016 in Medical Care Research and Review (Rogers et al, 2016). The research looked into the relative use and value of specific services in reducing 30-day readmissions to acute hospitals. The study found that out of several services, the direct effect of occupational therapy was seen in patients admitted for heart failure, pneumonia, and acute myocardial infarction.</p> <p>We found that occupational therapy is the only spending category where additional spending has a statistically significant association with lower readmission rates for all three medical conditions. One possible explanation is that occupational therapy places a unique and immediate focus on patients’ functional and social needs, which can be important drivers of readmission if left unaddressed. (Rogers et. al., 2016, p. 1)</p> <p>This pointed conclusion should be considered when looking at service utilization in PAC as well. Occupational therapy as part of the comprehensive plan for patients in acute and in PAC settings can reap significant systemic and patient level benefits. It is critical that the IMPACT Act data elements can appropriately identify medically necessary services for clinical planning, including referral to occupational therapy.</p> <p>AOTA appreciates the opportunity to comment on the RAND Corporation Report on Development and Maintenance of Post-Acute Care Cross Setting Standardized Patient Assessment Data: Data Element Specifications. Our recommendations focus on improving the assessment of cognition, pain and vision.</p> <p>I. Assessment of Cognition</p> <p>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.</p> <p>a. Functional Cognition</p> <p><i>Cognition</i> refers to information-processing functions carried out by the brain that include, attention,</p>	

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		<p>memory, executive functions (i.e., planning, problem solving, self-monitoring, self-awareness) and a range of other abilities. Rather than attempt to isolate specific cognitive functions, occupational therapy practitioners administer assessments and interventions that focus on functional cognition as it relates to the performance and successful completion of everyday life activities.</p> <p>Toward this end, <i>Functional Cognition</i> is how an individual utilizes and integrates his or her thinking and processing skills to accomplish everyday activities in clinical and community living environments. Occupational therapy practitioners believe that cognition can only be understood and facilitated fully within the context of the performance of activities that are needed in the client’s daily life.</p> <p>Why is it important to assess functional cognition? Health care providers need to determine whether and how a client safely and effectively participates in essential human activities of daily living (ADLs), such as personal hygiene behaviors and dressing, and instrumental activities of daily living (IADLs), such as meal planning and preparation and medication management, to guide care planning and implementation within the PAC setting as well as to impact post-acute care transition placement, discharge decisions, and client/caregiver training. As these are all the purposes of IMPACT, assessing functional cognition appropriately will be critical to achieving success for IMPACT.</p> <p>We have conducted a detailed analysis of the Post-Acute Care Payment Reform Demonstration and Continuity Assessment Record and Evaluation (CARE) Element Set. Based on our knowledge of existing assessment procedures and measures, AOTA proposes the development of new measures of functional cognition to be included in the IMPACT Act data element library and utilized in post-acute care settings. AOTA believes there is a significant need to include a measure of functional cognition to fully meet the key domain of the IMPACT Act to measure “functional status, cognitive function and changes in function and cognitive function”. AOTA would like to provide insight into the links between function and cognition, frame a broad understanding of cognition and cognitive performance, and put forward suggestions on how CMS should gather data on and include functional cognitive performance as a key aspect of assessment data, quality measures and also as a component affecting care planning and resource utilization.</p> <p>We believe that new elements could be designed to be simple to administer and score and could be modeled after existing daily life performance based tests. Such measures would have ecological validity and have high face validity and can be developed to be completed quickly by various disciplines working in post-acute care settings.</p> <p>Assessment of functional cognition will strengthen the IMPACT Act assessment data set by filling the gaps that exist with current assessments of cognitive function, the Brief Interview for Mental Status (BIMS) and</p>	

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		<p>the Confusion Assessment Method (CAM). AOTA supports the use of the CAM (Confusion Assessment Method) to identify individuals in delirium and the BIMS (Brief Interview for Mental Status) to identify individuals with severe dementia. However, the BIMS and CAM elements do not capture other constructs of cognition, such as executive function and the capacity to use and integrate thinking and processing skills to accomplish complex everyday activities (i.e., perform ADLs and IADLs). By screening an individual's functional cognition key information about his/her safety, outcome stability, burden of care, resource utilization, and reduced re-hospitalizations can be captured. To that end, AOTA is working in collaboration with content experts in the area of cognition and functional performance to delineate the rationale and scientific support for collecting expanded standardized patient assessment data including functional cognition to bridge the gap in current assessment elements. Expanded elements and processes would assess, evaluate and assure proper treatment of cognition and function to better predict and achieve positive patient post-acute care outcomes.</p> <p>b. AOTA Recommendations on Assessment of Functional Cognition</p> <p>AOTA believes that cognition exists in a hierarchical structure that is best assessed and reported as such. (For example, completing an Instrumental Activity of Daily Living such as grocery shopping requires the combination of several cognitive skills including executive functions and performance in context.) This hierarchical nature lends itself to measures that have skip patterns embedded within them allowing for implementation of additional information gathering without a significant increase in burden on facilities.</p> <p>The CAM and BIMS are effective in screening for delirium and severe dementia, respectively. However, there are individuals with cognitive deficits that are above the ceiling identified by the CAM and the BIMS, but who need assistance to maintain community living without medical deterioration and remain out of the hospital without additional clinical input or support services due to cognitive impairments. AOTA believes that these individuals very often go without identification in the PAC setting which puts them at a higher risk of readmission to the acute hospital or deterioration after PAC discharge. Fortunately, if these beneficiaries are identified at admission to PAC, there are interventions and services that can be provided by the setting to increase the odds of a successful PAC discharge.</p> <p>Due to the ceiling effect of the CAM and BIMS assessment elements, these data elements alone don't separate Medicare beneficiaries into appropriate case mix categories, nor do they identify the ability of a person to integrate cognitive functions into daily life as needed for a successful discharge. In other words, a client can successfully complete the CAM and BIMS, but still have cognitive limitations that can and should be addressed in a PAC setting. Without an additional step in the assessment process, PAC settings are unable</p>	

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		<p>to identify or separate these persons into an appropriate case-mix to describe the resources needed or the clinical planning needed for care and appropriate discharge planning.</p> <p>The missing piece is functional cognition, which describes how an individual utilizes and integrates his or her thinking and processing skills to accomplish everyday activities in clinical, home and community living environments. This additional information can be collected without a significant increased burden on PAC settings by instituting a skip pattern that represents the hierarchical structure of cognition. This data element can be framed from the rich literature of performance based functional cognition assessment, such as the following assessments.</p> <p>The Executive Function Performance Test (EFPT) has been validated in a variety of populations (including stroke, multiple sclerosis, schizophrenia, and traumatic brain injury). The assessment includes five subtests. Internal consistency and interrater reliability have been established for each subtest and for the assessment as a whole. The EFPT demonstrates strong construct validity with one-way ANOVA demonstrating significance with Trails B ($p < 0.001$). Criterion validity has been established with neurological tests known to be measures of executive function (Wolf et al 2010; Baum et al, in press; Cederfeld, et al., 2011; Katz et al., 2007). Interrater reliability has been established in each subtest and for the assessment as a whole. Internal consistency has been established with multiple populations (Baum, et al., in press; Baum, et al., 2008; Kalmar, et al, 2008; Katz, et al., 2007).</p> <p>The Performance Assessment of Self-care Skills (PASS) has also been validated to measure functional cognition and includes 26 core elements, 14 of which directly address 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 elements 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 elements have been more accurate than self-report for predicting home care service needs in a Canadian province population study (Brown & Finlayson, 2013). Rodakowski (2014) found that administration of selected PASS IADL elements can be used to discriminate among older adults with MCI and older adults with normal cognition with 80% accuracy. Thus, several PASS IADL elements (in this case about 15-20 minutes of administration time) are a fair 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 (Chisholm, 2005; Foster, 2014; Holm & Raina, et al., 2006; Rogers, 2008; Rogers, et al., 2001;</p>	

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		<p>Skidmore, et al., 2006). Elements stand alone and can be administered independent of the entire assessment (Chisholm, et al., 2014). The content validity has been established with multiple assessments of functional performance through exploratory factor analysis (Chisholm, et al., 2014).</p> <p>Both the PASS and the EFPT are used by occupational therapists to fully assess functional cognition. A single element from either of these assessments could prove effective and efficient in screening for a deficit in functional cognition to facilitate proper referral for treatment. The elements could be administered by any clinician and scored as a part of a hierarchical cognitive assessment. For additional consideration, experts in the field of functional cognition have designed a quick screen that is currently being validated in multiple populations and is being referred to as The Menu Task. The Menu Task 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 functional cognition that may result in increased resource utilization and failure in community settings. The initial research into the Menu Task is quite promising. The task is typically administered in less than 5 minutes with an average at approximately 3 minutes. In pilot testing, the menu task is highly correlated with the Montreal Cognitive Assessment (0.65) and Trails B (0.61), but is much more straightforward to administer and score. In initial regression modeling, the Menu Task was significant (p=0.002) when modeled with Age, BIMS, and Trails B demonstrating that the Menu Task captured additional variance not captured by the other variables. When modeling with only persons who were found to have no impairment on the BIMS (by only including persons with a score greater than 13), the Menu Task was again significant (p=0.009) demonstrating that the task captured additional information. In each analysis the Menu Task score was a significant predictor of Impairment on the MoCA providing preliminary evidence of predictive validity. (unpublished results).</p> <p>AOTA proposes that the BIMS act as an initial question in the cognition domain with an embedded skip pattern for the additional measure of functional cognition. If the BIMS indicates there is a deficit, the new functional cognition data element would not be administered. However, if the BIMS score does not indicate a deficit, the new data element would be administered to capture information for clinical care planning and resource needs for persons who have impairments in functional cognition and who are not identified by data elements currently used by CMS.</p> <p>AOTA believes that an additional element to capture functional cognition is critical for capturing an accurate representation of the clinical planning and resources needed to care for the population in post-acute care. While this element would not be a full, comprehensive assessment, we believe that implementing a quick element with a skip pattern can provide valuable information with minimum burden on PAC settings.</p>	

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		<p>II. Patient Health Questionnaire for Depression Identification</p> <p>Depression has been found to be underdiagnosed in older adults (Allan, et al., 2014). AOTA believes that identifying depressive symptoms is critically important to plan appropriate care and to understand resources needed for successful post-acute care. While the PHQ-2 and PHQ-9 have both been validated in populations at interest, we are concerned that relying on the PHQ-2 may under-identify persons with depressive symptoms. This is supported in a recent meta-analysis of the PHQ-2 tool (Manea, 2016). AOTA advises against including only the PHQ-2 as a data element.</p> <p>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.</p> <p>III. Assessment of Pain</p> <p>We are concerned that the proposed pain data elements are insufficient as meaningful PAC cross-setting pain element(s). We believe that it is critical not only to measure perceived pain, but also the impact that the pain has on function. This may include differentiating between chronic and acute pain. We also support consideration of a data element to measure pain management, specifically if pain is being managed by pharmacologic, non-pharmacologic, or a combination of both interventions.</p> <p>Using a self-management approach, occupational therapy focuses on helping individuals participate in daily activities in adaptive ways in conjunction with education, functional goal setting, training, and home exercise programs. Pain can significantly impact an individual’s functional recovery, sleep, and ability to engage in rehabilitation treatment sessions during post-acute care. Pain is a key factor that impacts clinical decisions to transition from one site of care to another, or in the case of home health, homebound status.</p> <p>IV. Assessment of Vision</p> <p>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.</p>	

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		<p>The data element “<i>ability to see in adequate light</i>” is proposed to determine whether the patient has visual limitations. AOTA proposes that this element is not strong enough to identify persons who have deficits in vision. The data element includes questions that focus on high contrast acuity and ask questions primarily about reading or viewing pictures and graphics. Although high contrast visual acuity is an important aspect of vision, it is only one component of <i>functional</i> vision—the person’s ability to use vision to complete daily activities and participate in environments (Colenbrander, 2010). Functional vision encompasses a wider range of visual functions including low contrast acuity (e.g., contrast sensitivity) and visual field (Colenbrander, 2010). These two visual functions are critical to the ability to safely navigate environments and have as strong or stronger association to an elevated falls risk as high contrast acuity (Cox et al., 2005, Cummings et al., 1995; Ivers et al., 1998; Lord & Dayhew, 2001; Pedula et al., 2006). The two visual functions are frequently impaired in persons with a normal aging visual system (Brabyn et al., 2002; Jackson & Owsley, 2003), persons with age-related eye diseases and conditions (Colenbrander, 2010; Jackson & Owsley, 2003; Wood et al., 2011); persons with neurological conditions such as stroke (Clatworthy et al., 2013; Rowe et al., 2009; Rowe et al., 2013) and prevalent neurodegenerative diseases such as Parkinson’s Disease (Jackson & Owsley, 2003; Pieri et al., 2000), and Alzheimer’s disease (Jackson & Owsley, 2003; Risacher et al., 2013).</p> <p>AOTA is concerned that the limited scope of the vision data element may potentially overestimate the patient’s ability to use vision functionally and underestimate the patient’s limitations in functional vision unless the vision domain is expanded to address visual field limitations and low contrast acuity.</p> <p>In addition we have concerns about the wording of the current data element in terms of its validity and reliability. We believe that the current data element will have poor inter-rater reliability and validity if utilized in all PAC settings for the following reasons:</p> <p><input type="checkbox"/>_The inherent nature of age-related visual impairment is that functional vision fluctuates throughout the day depending on the visibility of task and environment and is also impacted by comorbidities, medications, fatigue, and other factors. A comment needs to be included with the data element stating that functional visual abilities can vary throughout the day and across environments.</p> <p><input type="checkbox"/>_Using the task of reading various elements of a newspaper as a measurement of acuity.</p> <p>o Concern 1: <i>Validity</i>. Reading visual information is dependent on more than vision. The person may be able to see the printed material but have difficulty reading it due to many factors such as low literacy and</p>	

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		<p>educational attainment, primary language and reading disorders including alexia and dyslexia (Rodriguez & Barton, 2015; Rowe et al., 2013)</p> <p>o Concern 2: <i>Reliability</i>. Newspaper formats are not standardized in font size or typeface. Several factor may determine a patient’s response level and subsequent scoring including the typeface and size of the font; print quality: amount of contrast with paper, uniformity (limb width, print density, contrast), presence of streaks or bands, missing or smudged print and so on) (Legge & Bigelow, 2011).</p> <p><input type="checkbox"/> _Adequate lighting</p> <p>o <i>Reliability</i>: This term is not defined or standardized across settings or assessors. Since the intent of the IMPACT Act is to ensure common data points across settings, this element is inherently limited, as lighting in an institutional settings vs. home setting under home health can differ dramatically. It is unclear how measure reliability will be achieved with the current element.</p> <p>o <i>Validity</i>: Individual access to functional vision can be enhanced or inhibited by various characteristics of lighting and the lighting chosen by the assessor as ‘adequate’ or by the range of lighting options available to the patient in the setting including the intensity of the light and the presence of glare. These elements can be influenced by the temperature (color) of lighting and it’s angle in relation to the page (Eperjesi, Maiz-Fernandez & Bartlett, 2007; Holton et al., 2011)</p> <p><input type="checkbox"/> _These limitations impact the feasibility of using the current assessment in the PAC setting and the <i>potential of data element to be standardized</i>.</p> <p>o In order to remedy the high rate of variability among printed materials, it will be necessary for any included data element assessing visual function be accompanied by a printed page of characters, text, &/or graphics to be used during the assessment of vision.</p> <p>If the intent is to improve the quality of care transitions through a meaningful exchange of data between providers and to improve person-centered care and planning, then it is important that the data element capture the person’s ability to use vision functionally to complete daily activities. The current focus on the “ability to see” is not equivalent to being able to use vision in a functional manner. It is suggested that an alternative wording and focus of the data element be considered that focuses on the patient’s <i>‘ability to use vision to perform functional tasks in their environments.’</i></p> <p>We believe that changing the focus of the data element to assessment of functional vision provides the following benefits:</p> <p>Potential for Improving Quality</p>	

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		<p>The inclusion of a data element signifying a patient’s level of functional vision can greatly improve the quality of care, care planning, choice of pertinent outcomes and ability to achieve targeted, person-centered outcomes</p> <p><input type="checkbox"/> <i>Improving care transitions</i>: Identification of individuals with vision challenges provides meaningful data for expectations during transitions and care planning. This, in turn leads to <i>improved person-center care & care planning</i>.</p> <p>o For example: awareness of vision limitations can trigger adaptations &/or greater assistance upon initial transition to a new setting. The result is two-fold. First, the patient more quickly learns their new environment; decreasing both risk and care needs. Second, the staff is aware & can adjust for additional auditory or physical cuing to enhance interactions/care.</p> <p><i>Quality comparisons</i>. Patients with impaired functional vision perceive fewer environmental cues in typical environments. This frequently necessitates adjusted timeframes to achieve comparable performance levels to their normally sighted peers.</p> <p><input type="checkbox"/> <i>Support clinical decision-making & care coordination</i>. With proper adaptations, interventions, equipment, and resources patients with decreased functional vision can achieve performance and independence levels of their normally sighted peers. For this to occur, staff must be aware of and make effective clinical decisions accommodating for the unique needs of patients with limited functional vision. Furthermore, care coordination must consider additional referrals and inclusion of specialists to the clinical care team to ameliorate deficits created by visual impairment.</p> <p>Feasibility for use in PAC</p> <p><input type="checkbox"/> <i>Clinical appropriateness</i>. Awareness of a patient’s vision impairment and the ability of a setting or staff to mitigate subsequent functional deficits can have a significant impact on outcomes. Effective interventions employed in preceding settings shared during setting transition can be employed to temper resources and level of care.</p> <p><input type="checkbox"/> <i>Relevance to work flow across settings</i>. Patients with vision impairment often require additional time and resources to achieve outcomes. Awareness of a patient’s need can assist with care planning and care transitions.</p> <p>Utility for describing case mix</p> <p><input type="checkbox"/> <i>Use with different payment models</i>. Anticipated outcomes and outcome achievement for patients with visual impairment may be disparate from normal-sighted peers secondary to additional time and resources required to assure adequate adaptations, devices and supports for function at an equivalent level. This</p>	

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		<p>reflects the necessity of patient-centered, quality care for individuals with decreased functional vision.</p> <ul style="list-style-type: none"> o Providers who incorporate a patient’s visual limitations in the care plan influence future levels of necessary intervention and care. Thus addressing visual impairment also demonstrates future cost containment. o Meeting the needs of patients with vision impairment in Post-acute care (PAC) requires the type of team focused approach found in Accountable Care models o Patients with visual limitations require a significant level of adaptation, modification and support to assure positive outcomes. Sharing of this information in patient health records along and among the continuum of care settings in PAC is imperative to care planning, quality patient-centered care and cost containment. <p><i>Measurement of difference in patient severity levels related to resource needs.</i> Individuals with limited visual function may require an increase in care secondary to limited environmental cues/input. At a minimum, these patients will require additional time and training/intervention to achieve maximum independence in daily living tasks that involve significant visual input. Balance, mobility and safety require intensified intervention and prolonged training for mastery of tasks in novel and/or dynamic environments should be anticipated.</p> <ul style="list-style-type: none"> • * * * * • <p>Thank you for the opportunity to comment on assessment of cognition, pain and vision in SNFs, IRFs, HHAs, and LTCHs. 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.</p>	
RCPC49	9/12/16	<p>To Whom It May Concern:</p> <p>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. AMRPA is the national trade organization representing the interests of medical rehabilitation providers. It</p>	<p>Bruce M. Gans, M.D. Chair AMRPA Board of Directors, Executive Vice President and Chief Medical Officer, Kessler Institute for</p>

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		<p>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.</p> <p>AMRPA supports the implementation of the IMPACT Act, and we are thus concerned about the manner in which public comments were requested on these exceptionally important aspects of the Act. The IMPACT Act established a detailed process to collect critical data, analyze, and synthesize them across post-acute care (PAC) settings. The standardized patient assessment data collected under the Act would provide the foundation for significant changes to post-acute payment and quality policies aligned with the triple aims of the National Quality Strategy of better care, smarter spending, and healthier people. Therefore, timely stakeholder engagement and the considerate analysis of these data are essential to developing meaningful data elements that satisfy the statutory requirements.</p> <p>Hence, one immediate concern was the short time period allowed for comments, August 12 to August 26. We applaud CMS for responding quickly to the concerns of the PAC community on this issue and extending the comment period to September 12. A compressed timeframe would ultimately hinder, rather than inform, the data element development process required by the IMPACT Act. Extending the comment period to provide CMS with the requested information with sufficient time to review and respond to proposed elements is important, given the high stakes for the agency, beneficiaries and providers. AMRPA encourages CMS to continue to allow the public a minimum of 30 days to submit comments on proposed data elements and measures (including comments submitted to measure development contractors). Shorter time periods do not afford the public sufficient time to review and respond to proposed elements and their draft specifications.</p> <p>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.” One of these topics is the “potential for improving quality.” The first phase of the IMPACT Act is focused on the development of quality and resource use measures. 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 IMPACT Act</p>	<p>Rehabilitation National Medical Director for Rehabilitation, Select Medical</p>

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		<p>regards standardized patient assessment information as a data collection effort, 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.</p> <p>However, 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 and supporting clinical decision making and care coordination.</p> <p>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 (pain), comorbidities and impairments (hearing and vision), as well as looking at the potential for improving quality, validity, feasibility of use in PAC and utility for describing case mix.</p> <p>Cognitive Function and Mental Status AMRPA believes that it is critically important to assure that patients’ cognitive function is fully assessed and measured. Unfortunately, the IRF prospective payment system (IRF PPS) does not adequately reflect the cognitive status of a large number of patients because the IRF patient assessment instrument (IRF PAI) cognitive elements are not sufficiently sensitive to do so. The RAND Corporation acknowledged this issue in its initial development of the IRF PPS and particularly in the subsequent revisions which were implemented in FY 2006. Hence the payment system actually may not satisfactorily recognize patients with these deficits and may</p> <p>therefore underestimate these patients’ resource use intensity. Our members find that the majority of patients with neurological conditions as well as other conditions present with cognitive impairments. Knowing a patient’s cognitive status leads to better development of a care plan, which in turn: dictates the resources necessary for proper treatment; allows for measurement of change over the period of the stay or longer episode of care which relates to quality; is needed for any transfer of the patient to a new setting (and may perhaps dictate that setting); and many other aspects of care. AMRPA’s specific comments on the individual elements follow:</p> <p>A. Brief Interview for Mental Status (BIMS)</p> <p>As noted, the BIMS is now collected on the Minimum Data Set (MDS) 3.0 and, effective October 1, 2016,</p>	

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		<p>on the IRF PAI v. 1.4. As used in the Post-Acute Care Payment Reform Demonstration (PAC PRD), it had a very high kappa rating. The narrative proposes to change one element which is option 2 for B1b by changing it from “communication disorder” to “unable to make self understood.”</p> <p>1. General Comments</p> <p>Many AMRPA members are pleased that information from the BIMS is now being collected on the IRF PAI. Furthermore, we support that change in the language in Option 2 for B1b in that it states the observation and does not presume there is an underlying disorder. Naturally there is the question of whether any such change would change the interrater reliability which would have to be examined.</p> <p>2. Use as a Quality Measure</p> <p>Our members do not feel this element will necessarily improve quality as defined in the narrative. Instead it would help give an indication of the burden of care for purposes of developing an individual plan of care. It adds additional information so that an interdisciplinary team can make an informed decision about the patient which would also include care coordination, transitions, and inform professionals as they make clinical decisions.</p> <p>3. Validity</p> <p>While the kappa scores for this element were strong, we question if having different assessment periods among the various providers will lead to assessing different levels of cognitive impairment in that, at least in rehabilitation hospitals and units, patients’ clinical status changes rapidly during the first several days of their stay. This point would also apply to other data elements in this section where there are different assessment periods proposed. Perhaps data on this and all elements should be collected within the same time frame such as 48 or 72 hours after admission. Such an assessment period would give a clearer picture of the patient’s true clinical condition.</p> <p>4. Feasibility</p> <p>We believe the measure is feasible for PAC use.</p> <p>5. Describing Case Mix We believe the measure will help assess differences in patient severity related to resource needs. As noted above, it will help determine the burden of care and feed into developing the individual plan of care and therefore the resources needed. It will also help to develop payment models for the same reason—predicting resource use.</p> <p><i>B. Expression of Ideas and Wants</i></p>	

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		<p>We appreciate the proposal to break down the various aspects of cognitive functioning to constituent parts, as this element demonstrates. However, as noted below, AMRPA has some concerns.</p> <p>1. General Comments</p> <p>This element moves away from assessing a patient’s memory to delving into the ability to express oneself. We support an approach that allows for any manner of communication by which patients express themselves or makes it clear that they understand verbal content. However, we are concerned that such an element may be confounded by other variables, such as a patient’s level of assertiveness. Some patients who are clearly able to express their ideas and wants may be reticent to do so for whatever reasons. Furthermore, our members are extremely concerned that such a measure would be used to disqualify people from being referred to rehabilitation, particularly if it is not a valid element. This prompted several questions and concerns from our members, including: To what end will it be used? What happens if a patient does not have the motor or cognitive skills to express themselves? An aphasic patient is one example.</p> <p>2. Potential for Improving Quality</p> <p>This element will provide a more descriptive state of the patient, which can be helpful in care planning and in clinical decision making and possibly care coordination. However, our members do not feel that it would provide an opportunity for developing further quality metrics and subsequent comparisons for various reasons including the concerns about its validity.</p> <p>3. Validity</p> <p>As noted above, the element’s face value may not measure recognition but may only measure assertiveness. One irony is that as brain injury patients progress in their recovery, they often become more assertive if not aggressive, which may be viewed negatively on a metric (vs. element) when it is actually a positive clinical development.</p> <p>4. Feasibility for Use in PAC Given the concerns mentioned above, our members do not think that it is feasible for use in post-acute care.</p> <p>5. Utility for Describing Case Mix</p> <p>While acknowledging the limitations mentioned above, we believe a data element for this purpose would</p>	

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		<p>have utility in describing case mix. However, the element may need extensive refinement first.</p> <p><i>C. Ability to Understand Others: Verbal Content</i> As noted, determining if an individual can comprehend what is to be communicated to them is critical to their ability to understand instructions and benefit from their various therapies and other services. It also raises questions about their safety and is a major factor in placement decisions.</p> <p>1. General Comments</p> <p>Like many aspects of a patient’s recovery, their initial status in performing this element may change over time. For example, the first day of a patient’s admission to IRFs is very busy with the transfer, assessments, medications reconciliation, and assuring all orders are received. Hence some observations made the first day may be moot by the end of the assessment period given how quickly patients may change. The assessment occurs during a three-day period for IRFs, which is helpful but still the element does not get to the root of why the patient doesn’t understand. Assessing hearing and vision as proposed with other impairments will help but not necessarily uncover the core problem. For instance, there may be other factors (psychological, emotional, cognitive, or sociological) contributing to the patient’s lack of comprehension. Furthermore, some of these issues can be resolved if a translator is provided when there is a language barrier which is acknowledged under how the element is collected.</p> <p>2. Improving Quality</p> <p>Our members remain concerned about whether the element would truly add to quality. They do however believe it would help in clinical decision making and care coordination.</p> <p>3. Validity</p> <p>The narrative states that this element was paired with Expression of Ideas and Wants with respect to validity and reliability under the PAC PRD to form a composite communication variable. Hence, on its own, its validity may be unknown.</p> <p>4. Feasibility for Use in PAC</p> <p>It could be standardized across the settings.</p>	

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		<p>5. Utility for Describing Case Mix</p> <p>This element does not give a clear picture of why there is a problem in understanding others pursuant to this element. It will not reveal if the patient is deaf, aphasic, is culturally bound not to respond or other factors. If these details were known, they would add something to determine case mix as opposed to just the burden of collecting the data. While a speech language pathologist (SLP) may be involved in the assessment response, these elements do not delve into the cause for the behavior.</p> <p><i>D. Confusion Assessment Method</i></p> <p>This element seeks to assess overall cognitive impairment and distinguish delirium and reversible confusion from other types of impairments. It is not currently used on the IRF PAI v. 1.4 but is found on the MDS 3.0 and LCDS v. 3.0. It is referred to as the short CAM.</p> <p>1. General Comments</p> <p>This element is quite subjective and it is essentially a screen. Delirium is very uncommon upon admission to IRFs due to the types of patients who qualify for admission to this hospital-level of service. As such, routine screening for delirium makes little sense. While IRF admitted patients are medically complicated with active medical comorbidities requiring daily physician evaluation and management to ensure optimal participation in the rehabilitation program, delirium is not a routine problem seen in IRFs.</p> <p>2. Potential for Improving Quality Generally we do not believe it will improve quality. However, it will help in care planning and clinical decision making.</p> <p>3. Validity We question if the element is valid given its proposed construction. The narrative on page 19 notes that there are different response options between the LCDS and MDS 3.0. Furthermore, it notes that the element as proposed does not include one question that was included in prior testing. Finally, while there is a reference to some research at footnote 3, it appears that research was conducted in the acute, not post-acute, setting. Hence we believe it would need to be retested.</p> <p>4. Feasibility for Use in PAC It could be used across settings once standardized and tested for validity. It may be more useful in some PAC settings versus others.</p>	

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		<p>5. Utility for Describing Case Mix We believe it could assist in determining case mix in highlighting resource needs and therefore care planning.</p> <p><i>E. Behavioral Signs and Symptoms</i></p> <p>These elements seek to determine cognitive impairment or other issues during the assessment period.</p> <p>1. General Comments</p> <p>The narrative states that the behavior is associated commonly “with dementia and other cognitive impairment.” As mentioned above, we note that some brain injury patients become more aggressive as they heal from their injury. This behavior is not a hallmark of dementia or other impairments, but of the brain healing. We would also suggest that there be a more uniform method by which to measure the behaviors in addition to or in lieu of observations by friends and family, staff, etc.</p> <p>In addition, this assessment element does not address patient refusals but focuses only on physical aggression, verbal aggression, and self-injurious behavior. We recommend that the E3 response option be expanded to include “Refusals of treatments/lack of participation” under “Other disruptive or dangerous behavioral symptoms not directed toward others.”</p> <p>2. Potential for Improving Quality</p> <p>We are concerned that the element would not necessarily improve quality. While it is helpful for case mix it may help improve quality in that it feeds into care planning and clinical decision making.</p> <p>3. Validity</p> <p>We recommend that the element be reexamined and improved. As noted on page 22 “because of the low incidence” the PAC PRD did not report interrater reliability. Hence there is an inherent danger in using it for such a critical domain without further testing.</p> <p>4. Feasibility for Use in PAC</p> <p>We do not believe it is feasible to use in its current form across PAC settings. We are concerned that this element could wrongly indicate dementia and other mental health issues rather than other phenomena, such as the issue pertaining to brain injury above.</p>	

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		<p>5. Utility for Describing Case Mix</p> <p>The concept sought to be determined via these elements will be helpful in determining case mix, particularly if the provider has a neuro-behavioral unit or otherwise serves neuro-behavioral patients.</p> <p><i>F. Patient Health Questionnaire (PHQ)</i></p> <p>The PHQ seeks to determine a patient’s mood, and particularly whether or not they are depressed or have been. It involves the two versions: PHQ-2 and PHQ-9.</p> <p>1. General Comments</p> <p>The narrative discusses utilizing a form of skip logic to economize time and reduce burden. We support utilizing the skip pattern. In fact, the entire element could be skipped if a patient is at a certain lower cognitive level. Hence AMRPA supports the use of the PHQ-2 as a gateways data element as described on page 27.</p> <p>Nonetheless, AMRPA members are concerned that the PHQ-9 is a depression screening tool and therefore will miss the substantial percentage of IRF patients with anxiety. Patients who are in need of post-acute care are frequently anxious about their circumstances. Neither the PHQ-2 nor PHQ-9 address issues related to how the presence of anxiety, trauma, or fear may interfere with a patient’s ability to improve. While the assessment element includes depression as a “treatable” condition interfering with behavior, anxiety can be much of an interference and also (perhaps more so) “treatable.” Furthermore, the influence of anxiety on length of stay and burden of care is not captured in the questionnaire.</p> <p>Finally, the assessment element is conducted on a question and answer basis. This method of data collection again poses challenges for assessing patients who are unable to communicate for various reasons, such as a patient who has aphasia.</p> <p>2. Potential for Improving Quality</p> <p>The PHQ 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.</p> <p>3. Validity</p>	

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		<p>The narrative mentions several studies to this effect, however, it is not clear the degree to which either data set has been tested. Hence we believe it to be valid for the purposes stated.</p> <p>4. Feasibility for Use in PAC We believe it is feasible to use this assessment in PAC settings. However, we caution it may pick up various mood disturbances which are not necessarily depressive.</p> <p>5. Utility for Describing Case Mix</p> <p>We believe the PHQ will help ascertain case mix by helping describe severity, the burden of care and therefore resource needs.</p> <p>Medical Conditions</p> <p><i>A. Pain Presence</i></p> <p>1. General Comments</p> <p>Due to the highly intensive nature of therapy services delivered in IRFs, it is not uncommon for some IRF patients to experience some degree of pain. As required under Medicare regulations, patients treated in IRFs must receive an intensive level of therapy services typically demonstrated by the participation in a minimum of 15 hours of therapy a week. This intensity of service is often delivered as three hours of therapy a day five days a week and known in the industry as the “three-hour rule.”</p> <p>2. Potential for Improving Quality</p> <p>Given the intensity of IRF therapy, we do not think that the presence of pain, on face value, has merit as a quality measure for comparison across settings nor does it have the potential to improve quality.</p> <p>3. Validity</p> <p>While the PAC PRD kappa scores for this element are very strong, we question whether this element is truly asking the right question. Reducing suffering is not the always the same as reducing pain and, given the opiate crisis facing our country, perhaps the blanket notion of “presence of pain” should be viewed from a more nuanced perspective. We wonder if rephrasing the question to address pain tolerance, such as “How often did the patient report their pain to be at a tolerable limit?” may be more suited at addressing the core patient concern in this matter.</p>	

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		<p>4. Feasibility for Use in PAC</p> <p>We are unsure that the presence of pain, as proposed, is an appropriate element for PAC use.</p> <p>5. Utility for Describing Case Mix</p> <p>We believe it could assist in determining case mix in highlighting resource needs and therefore care planning.</p> <p><i>B. Pain Severity</i></p> <p>1. General Comments</p> <p>AMRPA members believe this element is particularly subjective due to the fact that no predetermined definitions may be offered to the patient. Pain severity is not meaningful if there is no scale provided to patients when asked to rate their pain on a scale of zero to ten. In addition, we strongly recommend this element be collected at a standard point in time during the post-acute stay. For instance, within a three-day assessment window for a post-operative patient, he or she is much more likely to report a higher level of pain in the first day than in the third day.</p> <p>2. Potential for Improving Quality</p> <p>We do not think this element has adequate merit for comparison across settings nor does it have the potential to improve quality for the reasons stated above.</p> <p>3. Validity</p> <p>Despite the high PAC PRD kappa scores, we are doubtful there is satisfactory validation given the subjectivity of the assessment question itself.</p> <p>4. Feasibility for Use in PAC</p> <p>We are unsure that the presence of pain or its severity is an appropriate element for PAC use as currently</p>	

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		<p>written.</p> <p>5. Utility for Describing Case Mix</p> <p>Elements assessing the presence and severity of pain could assist in determining case mix and highlighting resource needs, particularly if it can be examined with length of stay. Patients who have higher levels of pain are less likely to endure intensive therapy on a given day and may need their stay extended in order to complete their rehabilitative care. However, we believe the assessment of the presence and/or severity of pain would only have demonstrable utility for understanding PAC patient case mix.</p> <p>Impairments of Hearing and Vision</p> <p><i>A. Ability to Hear</i></p> <p>1. Potential for Improving Quality</p> <p>As with almost all patient assessment information, this data element could help improve 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. Knowing a patient’s degree of hearing, because it is readily available in the medical record, could assist providers in creating patient-centered treatment plans and accommodate care coordination as needed. We do not believe this data element could be used for quality comparisons.</p> <p>2. Validity</p> <p>The element is adequately valid on the basis of the “substantial agreement” in PAC PRD kappa scores. However, the assessment period should be standardized across settings; currently, the LCDS has a 7-day assessment period and the OASIS tool does not appear to have an assessment period at all.</p> <p>3. Feasibility for Use in PAC</p> <p>This data element could be used across settings once standardized.</p> <p>4. Utility for Describing Case Mix</p>	

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		<p>It has utility in describing case mix in that it helps determine resource use.</p> <p><i>B. Ability to See in Adequate Light</i></p> <p>1. General Comments</p> <p>We note that this element addresses only a patient’s degree of vision. It does not test a patient’s visual-spatial ability or assess their level of visual-perceptual recovery, which are important clinical considerations for cognitive rehabilitation.</p> <p>We believe there is too wide a range between response option 2 (Mildly to Moderately Impaired) and option 1 (Severely Impaired). This could lead to subjective interpretations of what qualifies clinically as Mildly to Moderately Impaired versus Severely Impaired. Additionally, such a steep increase in the next level of impairment measurement could result in an unrepresentative volume of patients being assessed as Mildly to Moderately Impaired.</p> <p>2. Potential for Improving Quality</p> <p>We do not believe this data element could be used for quality comparisons. However, as with almost all patient assessment information, this data element could help improve quality of care if it is made into an interoperable element and included in information that is shared among a patient’s care providers. Having a patient’s degree of vision in the medical record would assist providers in creating patient-centered treatment plans and accommodating care coordination as needed.</p> <p>3. Validity</p> <p>The element is adequately valid on the basis of the “substantial agreement” in PAC PRD kappa scores. However, the assessment period should be standardized across settings.</p> <p>4. Feasibility for Use in PAC</p> <p>It could be used across settings once standardized.</p> <p>5. Utility for Describing Case Mix</p> <p>It has utility in describing case mix in that it helps determine resource use.</p>	

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		<p>Special Services, Treatments, and Interventions Summarized below are our general comments regarding the twelve data elements specified for the domain of Special Services, Treatments, and Interventions. If applicable, we also include comments and recommendations for specific data elements in the proceeding sections.</p> <p>1. General Comments on Potential for Improving Quality</p> <p>We are not certain these data elements would have a significant impact on quality improvement, outside of the overarching concept that patient assessment information, when collected in a standardized format and made interoperable for medical records, will help inform patient-centered care planning and accommodate care coordination as needed. However, it is unclear how data derived from these elements could be used to develop clinically meaningful and outcomes-based quality measures. In our view, most of the data elements in the domain of Special Services, Treatments, and Interventions focus more on resource use and the intensity of care available in various PAC settings, rather than the quality of care the patient received in those settings. If it is CMS' intention to collect information on resource-intensive practices in PAC, we recommend the Agency additionally evaluate cardiac monitoring services, telemetry, the provision of LifeVestsTM, and special services for transplant patients. These are highly resource-intensive treatments and services that many IRFs provide.</p> <p>2. General Comments on Validity</p> <p>While we believe the data elements are valid for general use given their predominantly binary construct, we reiterate our recommendation that CMS standardize the assessment period so that all providers are collecting this information at the same time during the PAC stay.</p> <p>3. General Comments on Feasibility</p> <p>Much of the information CMS seeks to collect under this domain could be obtained through Medicare claims data and ICD-10 documentation. It seems redundant to require providers to additionally comb through medical records, at admission and discharge, for clinical details solely in order to populate PAC assessment forms. Needless to say, any additional reporting requirements will be administratively burdensome and divert time and resources away from patient care. We respectfully remind CMS that the IMPACT Act requires the Secretary to match claims data with assessment data for the purposes of assessing prior service use and concurrent service use by October 1, 2018, which is the same date that providers need to begin reporting standardized patient assessment data.¹ Thus, we strongly encourage CMS to investigate how it</p>	

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		<p>may be able to glean information on special services, treatments and interventions by utilizing Medicare claims data already at its disposal rather than doing so via additional provider reporting requirements.</p> <p>4. General Comments on Utility in Describing Case Mix We believe these elements will help assess differences in patient severity related to resource needs.</p> <p>5. The following are comments and recommendations for specific data elements in the proceeding sections.</p> <p>A. Hemodialysis We recommend CMS consider collecting information on peritoneal dialysis in addition to hemodialysis. Patients on peritoneal dialysis will also have special needs and different considerations at post-acute discharge than patients who do not need any type of dialysis.</p> <p>B. Central Line Management We recommend CMS include peripherally inserted central catheters (PICCs) to meet the data element for central line management and to be clear in its implementation instructions to providers on this element. CMS should also clarify if midline IVs are included in this element and if not, consider a separate category for midline IVs.</p> <p>C. Total Parenteral Nutrition This element is already collected on the IRF PAI and we support its standardization across other PAC settings.</p> <p>D. Enteral Nutrition This information is already collected on the IRF PAI and we support its standardization across other PAC settings.</p> <p>E. Vasoactive Medications We recommend that only use of intravenous vasoactive medications would qualify a patient to meet this data</p>	

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		<p>element.</p> <p><i>F. BiPAP/CPAP</i></p> <p>We recommend CMS separate BiPAP and CPAP into two different data elements. The burden of care for patients who require BiPAP (e.g., patients with CO2 retention due to COPD, obesity hypoventilation, or central hypoventilation) is higher than for patients who most commonly use CPAP (e.g., obstructive sleep apnea).</p> <p><i>G. Invasive Mechanical Ventilator: Weaning Status</i></p> <p>We recommend CMS clarify further how data elements for this assessment element will be collected. Does the element reflect the clinical intent to wean the patient from the ventilator over a specific measurement timeframe, or does it reflect evidence that the patient is being weaned during the measurement period? We question how the data element will be used if the weaning process is temporarily interrupted due to medical factors.</p> <p>With respect to the following elements under the domain of Special Services, Treatments, and Interventions, we do not have additional comments:</p> <ul style="list-style-type: none"> • IV Chemotherapy • Radiation • Oxygen • Suctioning • Tracheostomy Care <p>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 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 Government Relations and Policy Associate (mzhang@amrpa.org) at 202-223-1920.</p>	
RCPC50	9/12/16	<p>Dear RAND/Barbara Hennessey:</p> <p>The National Association for the Support of Long Term Care (NASL) is a national trade association representing suppliers of ancillary services and providers to the long term and post-acute care (LTPAC)</p>	Cynthia K. Morton, MPA Executive Vice President

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		<p>settings. NASL members include therapy companies that employ more than 64,000 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, skilled nursing and ancillary care and services. Other NASL members deliver assisted living, skilled nursing and ancillary care and services, such as clinical laboratory services, portable x-ray/EKG and ultrasound, complex medical equipment and other specialized supplies for the LTPAC sector. NASL also is a founding member of the Long Term & Post-Acute Care Health Information Technology Collaborative (LTPAC Health IT Collaborative), which formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders.</p> <p>The National Association for the Support of Long Term Care (NASL) appreciates the opportunity to provide our comments on these standardized data elements. For many years, NASL members have been actively engaged in the development and review of statutory and policy proposals, assessment of tools, processes, measures and clinical protocols, especially as it relates to the IMPACT Act. NASL members also have provided extensive technical contributions, such as serving on technical expert panels, to facilitate quality care for Medicare beneficiaries and compliance with statutory requirements. We have always been ready to assist the Centers for Medicare and Medicaid Services (CMS) and its contractors when needed on the application of policy in the long term and post-acute care (LTPAC) setting.</p> <p><i>Cognition</i></p> <p>NASL assembled a team of clinicians who are experts in post-acute care settings (PAC) including speech language pathologists, occupational therapists and physical therapists to review the document: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment (RAND document) as released by CMS on August 12, 2016.</p> <p>In looking at the various cognitive assessment elements and tools under consideration in the RAND document, it becomes clear that no one single element is sufficient to identify a beneficiary’s cognitive status, as each elements focuses on a different aspect (memory and orientation, presence of delirium, presence of depressions, ability to communicate and understand). Further, there are important assessment considerations not captured, such as simple and complex problem-solving, ability to follow directions, and the ability to plan and sequence tasks are excluded. This point was made in NASL’s comment submission</p>	National Association for the Support of Long Term Care

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		<p>for the <i>Proposed Rule, Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection; Proposed Rule. Federal Register, Vol. 80, No. 75, April 20, 2015 CMS-1622-P</i> which we have incorporated into these comments.</p> <p>In looking at the various PAC assessment tools and process, NASL has considered the key intent of the tools and expectations regarding process, in particular:</p> <ul style="list-style-type: none"> <input type="checkbox"/> The key intent to identify areas of concern that must be further assessed and then more comprehensively considered in care planning, discharge planning, and coordination of care/transitions. <input type="checkbox"/> The need for data element assessment tools or elements that could be reliably executed by trained, qualified health care professionals of various disciplines <input type="checkbox"/> The need for brief, screening-type data element assessment tools or elements <input type="checkbox"/> The need for sufficient data elements that are sensitive enough to capture potentially impactful functional issues for even those with less obvious mild to moderate impairments <input type="checkbox"/> Scoring methodologies (interval, ordinal, or nominal) that support reliable and valid reporting and interpretation for the purposes of care planning and for the purpose of measuring quality of care and outcomes <p>In looking at the differences across settings, it also becomes clear that in addition to the data elements themselves, the lookbacks and the sequence of the data elements are important considerations that must be consistently applied across the PAC settings. For example, since tools such as the BIMS require verbal responses, it would be necessary to first identify a beneficiary's ability to understand and communicate. Further, temporary conditions such as delirium may affect a beneficiary's ability to reliably respond to the interview questions, thus use of the CAM may be beneficial before the BIMS. Additionally, the logic for the variations in lookback periods must be examined further so consistent, relevant, and reliable timeframes can be established for all of the PAC assessment tools. The BIMS is still a screening tool for memory and really a gateway to additional and necessary assessment, not a full scale cognitive assessment. Assessing a beneficiary's cognition has far reaching implications including ability to return to their home and implications for independence, no one screening can fully assess. NASL understands the need to accurately assess cognition and we would consider much of what is proposed in the RAND document to be interim measures.</p> <p>NASL recognizes that the IMPACT Act imposes implementation timelines that create challenges in terms of assuring sufficient time and resources to explore alternatives and assure that potentially useful data element</p>	

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		<p>tools and elements are adequately standardized and tested for validity, reliability, case-mix applicability, and predictive nature. From this perspective, NASL supports an interim use of the existing tools, given consideration of the sequence and timeframes noted above, while other potentially useful data element tools and elements are vetted.</p> <p>In addition, NASL members have voiced the need for clarification with regard to the manner in which the data elements will be translated/transitioned/developed from process to outcomes for the quality measure purposes mandated by the IMPACT Act.</p> <p>In addition to the above comments regarding cognition, the following information is offered regarding the noted areas in need of assessment:</p> <p>Impairments of Hearing and Vision</p> <p><i>Ability to Hear</i></p> <p><input type="checkbox"/> Potential for Improving Quality. This element 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 element should be included in a valid data set. Feasibility for Use in PAC – With respect to MDS element C1d. We should indicate if the resident normally uses a hearing aid or hearing appliance. Such as, “Is it present, operational and ultimately used at time of interview?”</p> <p><input type="checkbox"/> We believe this statement is misleading: <i>“A code of 1 is assessed if the patient/resident fails to comprehend conversational speech...”</i> This appears to be verifying the ability to comprehend rather than hear.</p> <p><input type="checkbox"/> Unable to assess 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.</p> <p><i>Ability to See</i></p> <p><input type="checkbox"/> Potential for Improving Quality– This element does have potential to provide improved quality care as well as accurately measuring the patient’s condition</p> <p><input type="checkbox"/> Validity-- To assure accuracy of patient information, this element should be included in a valid data set.</p> <p><input type="checkbox"/> Feasibility for Use in PAC– with respect to MDS element C1c., we should indicate if glasses or other visual appliances are used. Such as, <i>“Are they present, operational and ultimately used at time of interview?”</i></p> <p><input type="checkbox"/> The <i>“ability to identify objects”</i> in the instructions is misleading as we are measuring ability to see, not</p>	

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		<p>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.</p> <p><input type="checkbox"/> Unable to assess 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.</p> <p>Special Services: Treatments and Interventions <i>Hemodialysis</i></p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Some patients may be receiving hemodialysis but not in the past 3 days due to scheduling reasons, illness or perhaps they are only on a 2 day/week schedule. It is important to consider for describing case mix and potential for improving quality, but we are concerned about the time period of 3 days applied in the measure.</p> <p><input type="checkbox"/> In the spirit of trying to meet their new time frame consistent across all settings, we would suggest having 2 checkboxes: “<i>Did the patient receive it in the last 3 days prior to admission and again in the last 3 days?</i>” (similar to the current MDS but using a 3 day versus 7 day)</p> <p><input type="checkbox"/> This data is important to capture.</p> <p><input type="checkbox"/> This demonstrates demand on coordination of services, clinician skill level, and resident acuity.</p> <p><input type="checkbox"/> It is a useful covariate.</p> <p><i>IV Chemotherapy</i></p> <p><input type="checkbox"/> We agree with only coding IV chemotherapy versus oral and IV chemotherapy. Experience shows that oral chemotherapy is usually a maintenance dose – but it still is chemotherapy. The patient is certainly affected, but we do not believe the effects of IV chemotherapy and oral chemotherapy would be the same. Chemotherapy does significantly affect patients’ condition and case mix.</p> <p>o Data collection of both is optimal.</p> <p><input type="checkbox"/> We would presume IV chemotherapy would affect case mix/condition more than oral chemotherapy.</p> <p><input type="checkbox"/> We think it is important to consider for describing case mix and potential for improving quality, but we are concerned about the time period of 3 days applied in the measure.</p> <p><input type="checkbox"/> In the spirit of trying to meet the new time frame consistent across all settings, we would suggest having 2 checkboxes, “<i>Did the patient receive it in the last 3 days prior to admission and then again in the last 3 days?</i>” (similar to the current MDS but using a 3 day versus 7 day).</p> <p>o This data is important to capture.</p> <p><input type="checkbox"/> We question whether this includes chemotherapy done in AND out of facility – e.g., as an outpatient service?</p>	

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		<p>o This is a useful covariate. <input type="checkbox"/> This demonstrates demand on coordination of services, clinician skill level, and resident acuity.</p> <p><i>Radiation</i></p> <p><input type="checkbox"/> We agree with including to give evidence of quality care. it. <input type="checkbox"/> We believe it is important to consider for describing case mix and potential for improving quality, but we are concerned about the time period of 3 days applied in the measure. Assessment periods and/or “lookbacks” need to be consistent. <input type="checkbox"/> In the spirit of trying to meet the new time frame consistent across all settings, we would suggest having 2 checkboxes, “Did the patient receive it in the last 3 days prior to admission and then again in the last 3 days?” (similar to the current MDS but using a 3 day versus 7 day).</p> <p>o This data is important to capture. o This is a useful covariate. <input type="checkbox"/> This demonstrates demand on coordination of services, clinician skill level and resident acuity.</p> <p><i>Central Line Management</i></p> <p><input type="checkbox"/> We agree with including it to give evidence of quality care. <input type="checkbox"/> We believe it is important to capture.</p> <p><input type="checkbox"/> <input type="checkbox"/> We question whether this defines management. <input type="checkbox"/> We question whether this includes inAND out of facility? <input type="checkbox"/> This demonstrates demand on coordination of services, clinician skill level and resident acuity.</p> <p><i>Total Parenteral Nutrition</i></p> <p><input type="checkbox"/> We agree with including it to give evidence of quality care. <input type="checkbox"/> We believe it is important to capture. <input type="checkbox"/> We believe it demonstrates demand on coordination of services, clinician skill level and resident acuity.</p> <p><i>Enteral Nutrition</i></p> <p><input type="checkbox"/> We agree with including it to give evidence of quality of care. <input type="checkbox"/> We believe it is important to capture. <input type="checkbox"/> We believe it demonstrates demand on coordination of services, clinician skill level and resident acuity.</p> <p><i>Vasoactive Medications</i></p> <input type="checkbox"/> We agree with including it to give evidence of quality of care.	

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		<p><i>Oxygen</i></p> <p><input type="checkbox"/> We agree with including it, but the 3 day limits the collection of data on those patients who have orders for PRN oxygen. If they have orders for PRN oxygen it does indicate their level of medical stability and the acuity of their condition and therefore it should be considered. I would encourage a longer look-back period so that we can capture that aspect of case mix.</p> <p><input type="checkbox"/> We think it is important to consider for describing case mix and potential for improving quality, but we are concerned about the time period of 3 days applied in the measure.</p> <p><input type="checkbox"/> In the spirit of trying to meet the new time frame consistent across all settings, we would suggest having 2 checkboxes, <i>“Did the patient receive it in the last 3 days prior to admission and then again in the last 3 days?”</i> (similar to the current MDS but using a 3 day versus 7 day).</p> <p>o The data is important to capture.</p> <p><input type="checkbox"/> This does reflect resident acuity.</p> <p><input type="checkbox"/> This is a useful covariate.</p> <p><input type="checkbox"/> This does have potential to support rehab intervention and effect on condition especially if weaned.</p> <p><i>BiPAP / CPAP</i></p> <p><input type="checkbox"/> The data is important to capture.</p> <p><input type="checkbox"/> This does reflect resident acuity.</p> <p><input type="checkbox"/> This is a useful covariate.</p> <p><input type="checkbox"/> This does have potential to support rehab intervention and effect on condition especially if weaned.</p> <p><i>Invasive Mechanical Ventilator: Weaning Status</i></p> <p><input type="checkbox"/> We agree with including it, but the 3 day limits the collection of data on those patients who have recently been weaned which does give some insight into their level of medical stability and the acuity of their condition and therefore it should be considered. We would encourage a longer look-back period so that you can capture that aspect of case mix.</p> <p><input type="checkbox"/> We think it is important to consider for describing case mix and potential for improving quality, but are concerned about the time period of 3 days applied in the measure.</p> <p><input type="checkbox"/> In the spirit of trying to meet the new time frame consistent across all settings, we would suggest having 2 checkboxes, – <i>“Did the patient receive it in the last 3 days prior to admission and then again in the last 3 days?”</i> (similar to the current MDS but using a 3 day versus 7 day).</p> <p><input type="checkbox"/> This data is important to capture.</p> <p><input type="checkbox"/> With respect to adding a D16 Ventilator weaned during or by end of stay– but may be captured on</p>	

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		<p>discharge assessment by answering they are not receiving the treatment when they were in the beginning.</p> <ul style="list-style-type: none"> <input type="checkbox"/> This reflects coordination of services. <input type="checkbox"/> This does reflect resident acuity. <input type="checkbox"/> This does reflect clinician skill level. <input type="checkbox"/> This is a useful covariate. <p><i>Suctioning</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> We agree with including it, but the 3 day limits the collection of data on those patients who have recently required suctioning which does give some insight into their level of medical stability and the acuity of their condition and therefore it should be considered. We would encourage a longer look-back period so that you can capture that aspect of case mix. <input type="checkbox"/> We believe it is important to consider for describing case mix and potential for improving quality, but we are concerned about the time period of 3 days applied in the measure. <input type="checkbox"/> In the spirit of trying to meet the new time frame consistent across all settings, I would suggest having 2 checkboxes, – <i>“Did the patient receive it in the last 3 days prior to admission and then again in the last 3 days?”</i> (similar to the current MDS but using a 3 day versus 7 day). <input type="checkbox"/> This data is important to capture. <input type="checkbox"/> This does reflect clinician skill level. <input type="checkbox"/> This does reflect resident acuity. <input type="checkbox"/> This is a useful covariate. <p>###</p> <p>We have constructed a chart found in the Addendum Section of this document that shows the assorted tools used for cognition and communication in the post-acute settings and identifies the differences in core content. Although a particular area or functional skill may appear to be addressed in each setting, upon a closer analysis of the elements, on a setting by setting basis, there is inconsistency in the content, scoring process, and intended calibration of each tool.</p> <p>Cognition is the sum total of many skills. Each settings’ cognitive assessment includes a different set of those skills for measurement. The results of the findings across settings do not avail themselves a valid comparison of a client’s cognitive function because different elements were scored to determine cognitive function.</p> <p>The second table continues this analysis into the domain of Self Care to show that, again, the element-</p>	

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		<p>specific requirements for each large topic area do not align in the assessment tools throughout the post-acute settings. Additionally, to promote consistency across the post-acute care settings, consideration should be given to the following aspects of the various setting-specific assessment tools:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Allowing for consistency of the assessment look back periods: Currently, the look back times vary. For example, for self-care and mobility elements, the MDS has a 7-day look back, the IRF has a 3-day look back, and the LTCH proposes a 3-day look back. Specifically, in regard to the MDS, Section G uses a 7-day look back and the proposed Section GG parameters use a 3-day look back period. In light of an October 1, 2016 implementation of MDS Section GG, the alignment and validity of the patient’s status for functional mobility and self-care are yet to be determined. <input type="checkbox"/> Providing instructions, timing requirements, and metrics to minimize the risk of inaccuracies: The current MDS functional elements (Section G) evaluate a resident’s greatest dependence on three or more occasions, using ratings based on self-performance and ADL support provided. This contrasts with the proposed Section GG which proposes to evaluate an individual’s “usual” performance at the time of admission and at the time of discharge for goal setting purposes, using a 6-point Safety and Quality of Performance rating scale. These differences must be carefully considered, as they have potential to impact the manner and accuracy of data collection, as well as interpretation of these data points when assigning ratings for each element. <input type="checkbox"/> Ensuring that daily fluctuations in patient status are consistently accounted for: Patient status can fluctuate based on the time of day of data collection. For instance, patients with cardiopulmonary conditions may exhibit variations in activity tolerance at different times of the day. In addition, cognitive function is not often accurately determined based on how someone responds/functions at one point in time. Some patients are alert and oriented in the morning and at “sundown,” becoming confused in the late afternoon. <input type="checkbox"/> The depth and functional applicability of the cognitive assessment elements: Cognition is not currently measured in a consistent manner across all post-acute settings. For instance, the BIMS and CAM are used in the SNF; the FIM and the BIMS in IRF settings and the CAM is used in the LTCH setting. HH currently uses reported or observed status. Further, the proposed MDS assessment of cognition appears to focus primarily on memory, using the BIMS screening tool. Other areas of cognitive function, such as simple and complex problem-solving, ability to follow directions, and ability to plan and sequence tasks are excluded, creating potential for absence throughout post-acute care. Without an accurate foundational knowledge of the patient’s true and overall cognitive status, the questions of patient safety, social/interpersonal functioning, and ability to transition to other post-acute settings are difficult to effectively address. <input type="checkbox"/> The BIMS (usually administered by nursing and is the cognitive test used on the MDS) uses recall on most elements, although one element is orientation which also relates to memory, and another question relates to decision making. 	

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		<p><input type="checkbox"/> The BIMS is completed in 2-4 minutes, usually 2 minutes.</p> <p><input type="checkbox"/> Research does not support the correlation of this score to the prediction of function.</p> <p><input type="checkbox"/> Use of BIMS seems in part driven by reliability data that shows high reliability (k-values) NASL suggests the development of data elements and measures across settings that are based on a cognitive assessment that supports comprehensive care and discharge planning via use of a standardized, public-domain cognitive assessment tool that provides a wider assessment of cognition. We understand that such an effort would require exploration and testing of available assessment tools.</p> <p>Thank you for the opportunity to provide these comments. If you have further questions or need clarifications, they can be addressed to cynthia@nasl.org.</p>	
RCPC51	9/12/16	<p>Dear Ms. Hennessey:</p> <p>Thank you for this opportunity to comment on the report titled “Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment,” dated August, 2016. The Illinois HomeCare & Hospice Council is a trade association representing providers and suppliers of home care services in Illinois.</p> <p>While IHHC members generally support the approach that CMS and Rand are taking to comply with the IMPACT Act, members repeatedly find that the thinking behind the measures overlooks the very real differences between the home health setting and the commonalities among the other three settings involved in these efforts. Unlike skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs) and long-term care hospitals (LTCHs), home health services are delivered via relatively short visits to patient’s homes. Home health personnel do not have the luxury of institutional equipment, 24 hour access to their patients, or 24 hour control over the delivery of care, treatments and services.</p> <p>The home environment is unpredictable and patient and caregiver behavior is difficult to control. These factors seem to be escaping the notice of CMS and its contractors in this endeavor. Perhaps the most striking example of this lack of understanding was the addition for 2017 of the height and weight measurement to the OASIS data collection tool. While IHHC members recognize that these are critical elements in the care of some patients, the data is not easy to collect in the home environment. IHHC’s recommendation that a response be added to the choices available that conditions prohibit the collection of the information was ignored.</p> <p>Elements that Require A Three Day Assessment Period</p>	Sheila Guither, RN, MSN, CWOCN, COS-C IHHC President

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		<p>IHHC members’ primary concerns relate to the elements that require collection of data over a three day time period. These include C1610 (the CAM) and the Behavioral Signs and Symptoms element. Home health agency personnel often do not see patients on a daily basis, though it is much more common early in care than around the time of discharge. While it is possible to interview family and caregivers (as suggested in the Report) who may have had much more intensive contact with the home health patient over the designated time period, the findings will be much less reliable than will those collected in an inpatient setting. We know this from extensive experience in collecting OASIS data over the past 15 years. It is also not always possible to schedule a home visit when the most reliably observant family member is available to be interviewed, again particularly toward the end of care.</p> <p>Recommendations: IHHC and Rand should work to develop employ mechanisms for measuring confusion and behavioral signs and symptoms that do not require the collection of data over a three day time period that then results in an answer that identifies typical behavior. IHHC members believe the proposed approach results in an arbitrary answer and one that is difficult to implement in the home setting.</p> <p>Expression of Ideas and Wants</p> <p>IHHC members have concerns about element C1b. A similar element exists in OASIS (M1230) that measures the patient’s ability to use language and verbal expression to communicate. Both elements err on the side of mixing physical, cognitive and emotional factors together in a single element designed to evaluate a patient’s ability to communicate. IHHC members believe that the OASIS element does a better job of capturing the complexity of the issues faced by a patient (though hardly perfectly) than does the proposed element.</p> <p>Recommendation: CMS and Rand should consider using M1230 from OASIS rather than C1b. Alternatively, CMS could take a more sophisticated approach to measuring patients’ abilities to communicate their needs and wants by separating the assessments of physical, cognitive and emotional abilities to do so into multiple elements.</p> <p>Ability to Understand Others</p> <p>IHHC members have similar concerns about C1a and the similar OASIS element M1220 as those described above regarding C1b and M1230. However, in this instance, IHHC members find little difference between the two elements.</p>	

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		<p>Patient Health Questionnaire</p> <p>IHHC support the proposal to use the PHQ-2 as a screening tool for employing the PHQ-9. While the PHQ-9 is not appropriate for every home health patient, it does potentially provide much more information about the symptoms of depression and other affective disorders than only using PHQ-2. This is an aspect of the needs of home health patients that has not historically received sufficient attention, though use of the PHQ-2 in OASIS has moved the industry forward.</p> <p>Pain</p> <p>IHHC members do not object to proposed elements G2 and G3 as they are less complex than the similar OASIS elements M1240 and M1242. M1240 collects information both on whether a standardized pain scale has been administered, and whether it showed that the patient has pain defined as severe. M1242, however, collects important information for the home setting which is whether the patient’s pain level interferes with his or her ability to engage in activity or movement. This seems to us to be an important aspect of the OASIS elements to retain and perhaps address in the other settings.</p> <p>Recommendation: IHHC supports replacing M1240 with G2 And G3, but recommends that M1242 be used in all four post-acute settings.</p> <p>Hearing</p> <p>IHHC supports the use of proposed C1d as it is identical to the OASIS element M1210.</p> <p>Vision</p> <p>IHHC members have concerns about the proposed C1c titled Ability to See in Adequate Light. The concept of “adequate light” is troublesome to standardize across all of these settings, and may be difficult to come by in the home health setting. Home lighting is not like that in inpatient settings. It seems that if we are going to have a cross-setting measure it should remove external factors that interfere with reliability and validity. In addition, neither the proposed C1c nor the OASIS element M1200 clearly assesses vision, though IHHC believe the OASIS element comes closer. Both of these elements mix vision and reading into the same element—both are critical to post-acute success, but they are not at all equivalent. In fact, in IHHC’s view, a cross-settings measurement should be able to distinguish between vision, the ability to recognize numbers and other symbols, and actual literacy.</p>	

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		<p>Recommendation: At a minimum, CMS and Rand should remove the notion of adequate lighting from the element as it is not a concept that contributes to reliability or validity. And, home and institutional environments are not comparable in this regard. CMS and Rand should strive for measures that separate physical ability (vision) from levels of cognitive ability (ability to recognize symbols) from literacy (e.g., reading).</p>	
RCPC52	9/12/16	<p>On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the nearly one thousand postacute care (PAC) facilities (IRFs, SNFs, and LTCHs) we provide services to, we are pleased to present our comments related to the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data.</p> <p>We appreciate CMS’s continuing efforts to allow stakeholders to comment on elements and tools to assist in measuring quality in healthcare, with an emphasis on developing standardized and interoperable measures within PAC settings. UDSMR strongly believes that CMS and its contractors should focus on identifying elements that</p> <ul style="list-style-type: none"> • have a long history of being reliable and valid, • are in use or have been used by providers in all PAC venues, and • are predictors of quality, cost, and payment or are currently used in an existing quality measurement or payment system. <p>UDSMR has the following overall comments and concerns related to the elements provided by RAND to address the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data:</p> <ol style="list-style-type: none"> 1. The environmental scan of the evidence as part of the development of standardized data elements failed to include elements or measures that measure the domains noted and meet the various topics for comment. Numerous elements or measures were not identified that are currently collected by PAC providers, that are used to define case-mix and measure quality, and whose consideration would minimize burden of data collection on providers. 2. The elements detailed in the RAND document provide little or no evidence that they are reliable and valid and that they improve quality. 3. Although adding more assessment elements may provide an enhanced opportunity to potentially 	<p>Fran Hagerty Associate Director</p> <p>Carol Harper, COTA/L Manager of Education, Training, and Consultation</p> <p>Troy Hillman Manager, Analytical Services</p> <p>Kathleen Conboy Manager, Sales and Client Services</p> <p>Brigid Greenberg, PT, MHS Manager of Postdischarge</p>

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		<p>define or describe case-mix, the RAND document does not provide any evidence to suggest that the addition of these elements will provide any benefit toward explaining patient severity or cost alongside existing assessment elements.</p> <p>In terms of feasibility, although certain elements may be clinically appropriate for certain populations and capable of being standardized across PAC settings, the burden of data collection that will be placed on providers is extensive and will further reduce the time available for actual patient care in favor of completing administrative tasks.</p> <p>The remainder of this letter provides additional detail related to these concerns.</p> <p>1. The environmental scan of the evidence as part of the development of standardized data elements failed to include elements or measures that measure the domains noted and meet the various topics for comment. Numerous elements or measures were not identified that are currently collected by PAC providers, that are used to define case-mix and measure quality, and whose consideration would minimize burden of data collection on providers.</p> <p>In relation to the IMPACT Act’s domain of cognitive function, the FIM[®] instrument embedded in the existing IRF-PAI contains five elements (Comprehension, Expression, Social Interaction, Problem Solving, and Memory) that specifically address various aspects of cognitive function. CMS has a royalty-free license to utilize these elements in their current form, and IRFs have collected data on these five cognitive elements for Medicare patients as part of the IRF PPS since 2001, where they are currently used to differentiate case-mix and payment within the stroke and traumatic brain injury populations. In addition, IRFs, SNFs, and LTCHs have been collecting FIM[®] data to measure the functional status of patients for over twenty-five years. Given these five elements’ history of reliability and validity and their use in an existing case-mix/payment system, we ask that RAND/CMS consider using these elements rather than create an additional burden on providers by requiring the collection of data elements that may duplicate the measurement of the same domain or construct.</p> <p>As part of the public comment, CMS specifically asked for feedback as to whether the elements have the potential for improving quality, are reliable and valid, are feasible for use within each PAC setting, and can be used to describe case-mix.</p> <ul style="list-style-type: none"> • Potential to improve quality: The five cognitive FIM[®] elements are collected at both admission and discharge, and reports have been and can be produced that show not only the difference in values at both admission and discharge, but also the amount of change for each individual element and the total of all 	<p>Services and Appeals</p> <p>Paulette Niewczyk, MPH, PhD Director of Research</p>

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		<p>five. PAC providers have used these values to show the progress made by patients with a variety of impairments, thereby tracking the quality-of-life improvements their services have provided to the patient.</p> <ul style="list-style-type: none"> Validity: These elements have proven to be reliable and valid, as required for any element implemented for use in a CMS payment system. Additional studies have been published documenting the inter-rater reliability of not only these cognitive elements, but also all eighteen FIM[®] elements. Feasibility: These elements are feasible for use in all PAC settings, as (1) CMS already has a royalty-free license to use the FIM[®] instrument and (2) training materials for these elements are available, as currently documented in <i>The IRF-PAI Training Manual</i>. Describing case-mix: As stated previously, the sum of the five cognitive elements is currently used to describe case-mix and payment for stroke and traumatic brain injury populations. Additional analyses can be provided that will show the differentiation for each of the five cognitive elements for patients within all impairments, allowing the potential for further definition of patient severity based on individual element performance. <p>In making this request for consideration of the five cognitive FIM[®] elements, we are not suggesting that these are the only elements needed to define a patient’s mental status or other cognitive abilities. We are only asking CMS/RAND to consider including these elements alongside other elements as part of evaluating and producing cross-setting standardized assessment data related to cognitive function and mental status.</p> <p>2. The elements detailed in the RAND document provide little or no evidence that they are reliable and valid and that they improve quality.</p> <p>The overwhelming majority of elements refer only to inter-rater reliability statistics based on PAC-PRD data. Inter-rater reliability measures the extent of agreement on an element or a set of elements among data collectors; it does not indicate whether the element or set is a valid measure of what it is supposed to measure.</p> <p>Given the differences in assessment periods, wording, and responses in the various elements, the selection of these elements is highly unlikely to produce a standardized data element that can be used in a valid and reliable manner. In the interest of producing valid data elements and quality measures that can be used to improve quality and describe case-mix, we strongly recommend that any differences in the elements be standardized to minimize any variability caused by the timing of assessments or by differences in verbiage. With respect to improving quality, although the collection and exchange of more information has the</p>	

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		<p>potential to improve care transitions, care coordination, and clinical decision-making, we do not recommend using any of these elements to compare quality. A number of these elements will soon be implemented for data collection among PAC providers, but they will initially be used as risk-adjustment factors for the various functional outcome measures or for other assessment-based quality measures. In reviewing the quality measure specifications that use these risk-adjustment factors, we have determined that a number of these elements that identify cognitive impairment reduce expectations for patients identified with moderate or significant cognitive impairment.</p> <p>We agree that patients with cognitive impairment typically experience less-than-standard outcomes, but we question whether lowering their expectations will improve their quality of life.</p> <p>Additionally, a number of these elements will not be completed for certain patients and therefore will provide little or no information for use in care transitions, care coordination, and clinical decision-making. For example, the Brief Interview for Mental Status (BIMS) will not be completed for patients who are rarely or never understood, who cannot respond verbally or in writing, or for whom an interpreter is needed but not available. Similarly, the “Expression of Ideas and Wants” and “Ability to Understand Others” elements provide the opportunity to code responses of “unable to assess” or “unknown” without explaining why the information could not be obtained.</p> <p>Finally, although we recognize that cognitive and mental deficits affect the cost of providing care to these patients and the ability of PAC providers to provide such care, we must ask whether the proposed assessment elements truly produce more information than existing assessment elements.</p> <p>For example, PAC providers currently use ICD-10 codes to record comorbidities or complications, which are based on a different series of clinical assessments and documentation of patient behavior. The Confusion Assessment Method (CAM) is supposed to screen “for overall cognitive impairment as well as features to distinguish delirium or reversible confusion from other types of cognitive impairments.” Is there any evidence that the CAM will provide information for quality purposes beyond that provided by an ICD-10 code for delirium or another cognitive impairment?</p> <p>UDSMR would like CMS/RAND to provide additional analyses related to these elements and their ability to produce reliable and valid results than can lead to improved quality.</p> <p>3. Although adding more assessment elements may provide an enhanced opportunity to potentially define or describe case-mix, the RAND document does not provide any evidence to suggest that the addition of these elements will provide any benefit toward explaining patient severity or cost alongside existing assessment elements.</p> <p>Other elements in existing PAC assessments already capture a construct or domain that is supposed to be measured by a number of the elements identified in the RAND document. From the cognitive function</p>	

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		<p>elements of the FIM[®] instrument to the opportunities to code various diagnoses in the available comorbidity and complication fields of the various assessment instruments, we believe that CMS/RAND needs to demonstrate how the burden of collecting these elements will enhance case-mix definitions and will further explain the variance in program costs. For example, the RAND document states that the BIMS is predictive of costs, but if the BIMS is considered along with primary impairment (such as stroke) and other patient characteristics (such as motor function), what does it add to predicting cost or defining patient severity?</p> <p>UDSMR asks CMS/RAND to provide additional analyses related to these elements and their ability to define or describe case-mix when combined with common patient factors such as primary impairment, age, and other functional characteristics.</p> <p>4. In terms of feasibility, although certain elements may be clinically appropriate for certain patient populations and capable of being standardized across PAC settings, the burden of data collection that will be placed on providers is extensive and will further reduce the time available for actual patient care in favor of completing administrative tasks.</p> <p>As part of the call for public comments, CMS/RAND indicated that a data element's relevance to the workflow should be considered when assessing its feasibility. In the past two years, as part of the introduction of the IRF QRP and the requirements identified in the IMPACT Act, CMS has introduced nearly two hundred new assessment elements to the IRF-PAI, taking the assessment form from four pages to eight pages to eighteen pages on October 1, 2016. These changes have required providers to spend considerable time, money, and resources on education, training, and implementation within their clinical and technological systems, often requiring staff to spend more time completing documentation for assessment requirements instead of providing direct patient care. Furthermore, some of the quality elements introduced and implemented by CMS have resulted in the measurement of very limited populations, calling into question the burden of collecting data on every patient. For example, less than 1% of all IRF patients have been identified as having new or worsened pressure ulcers.</p> <p>UDSMR asks CMS/RAND to consider the data collection burden on providers and to determine whether additional data collection will truly improve the quality of care.</p> <p>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.</p>	

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RCPC53	9/12/16	<p>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.</p> <p>In general, NAHC believes the proposed standardized data set elements under the domains for cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments have potential for improving quality, meet validity criteria, are feasible for use in the home health care setting, and are important elements for determining case mix. However, NAHC has concerns regarding the potential for duplication and/or overlap with current OASIS assessment elements and the implications for replacing or altering OASIS elements.</p> <p>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 elements 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. The risk adjustment model and/or measure specifications for the impacted measures will need to be revised.</p> <p>NAHC is also concerned that elements will continue to be added to the OASIS data set instrument to meet the requirements of the IMPACT Act, which could result in a lengthy assessment tool that will become very burdensome for agencies to administer.</p> <p>Cognitive Function and Mental Status: Brief Interview for Mental Status (BIMS)</p> <p>The BIMS overlaps with the OASIS element M1710 – Cognitive Functioning. The overlap results in duplication in assessing for cognitive function. In addition, maintaining the OASIS elements along with the proposed new elements adds unnecessary burden for the agency and risks inconsistency in the assessment.</p> <p>Recommendation: CMS should consider replacing or aligning OASIS element M1700 with an assessment element that uses the BIMS. CMS must also consider the impact on current measure calculations and risk adjustment with replacing the OASIS element M1700.</p>	Mary K. Carr Vice President for Regulatory Affairs, National Association for Home Care and Hospice

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		<p>Expressing of Ideas and Wants and Ability to Understand Others</p> <p>The OASIS data set contains elements that are very similar to the proposed element. OASIS element M1230 – Speech and Oral (Verbal) Expression of Language measures the patient’s ability to express ideas and wants and OASIS element M1220 – Understanding of Verbal Content measures the patient’s ability to understand others.</p> <p>Recommendation: NAHC recommends that either the proposed elements or the current OASIS elements be used to measure expression of ideas and ability to understand others in order to avoid duplication. However if CMS chooses to use the proposed elements, CMS must also address the impact replacing these elements will have on the current risk adjustment model for the home health quality measures.</p> <p>Confusion Assessment Method (CAM) and Signs and Symptoms of Delirium and Behavior Signs and Symptoms</p> <p>The first portion of CAM element asks whether there has been an acute onset and/or fluctuation in behavior. Home health agencies will likely be required to complete this portion of the element based on caregiver response rather than direct observation that would typically occur in a facility. Therefore, comparison of this element between PAC settings may not be accurate. This element appears to be different enough from the CAM element that was included in the CARE tool during the PAC PRD that the inter-rater reliability conducted during the PAC-PRD may not be applicable. In addition, both of the CAM and Behavior Signs and Symptoms elements overlap with OASIS element M1740-Cognitive, Behavior, and Psychiatric Symptoms. Including these elements would be duplication for assessing behaviors.</p> <p>Recommendations: NAHC recommends CMS not adopt the CAM and Behavior Signs and Symptoms. The CAM may not be a valid cross setting measure as propose and the Behavior Signs and Symptoms element is not as robust as the OASIS element M1740 in that it only requires a yes/no response rather than a selection of six options related to behaviors. In addition, M1740 is used to calculate the potentially avoidable event quality measure for “Discharge to Community with Behavior Problems” and as a risk adjuster for other quality measures. Therefor, it should remain in the OASIS assessment data set.</p> <p>Patient Health Questionnaire</p> <p>NAHC believes the burden of requiring the PHQ-9 out weights any added benefit. The PHQ-2 is currently used to screen home health patients for depression. The instructions in M1730 allows the agency to choose a</p>	

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		<p>second screening tool, or the agency may contact the physician for further interventions if the PHQ-2 indicates depression.</p> <p>Medical Conditions: Pain</p> <p>Pain Presence</p> <p>Pain Severity</p> <p>The proposed elements for pain assessment overlap with M1240 – Has this patient had a formal Pain Assessment using a standardized, validated pain assessment tool. It is unclear how CMS intends to use the proposed pain assessment elements in relation to the existing OASIS elements for pain.</p> <p>Recommendation: NAHC recommends CMS consider the implications for overlap by incorporating these elements into the OASIS assessment. CMS must also consider the impact on risk adjustment if the M1240 is eliminated.</p> <p>Impairment of Vision and Hearing</p> <p>Ability to Hear and Ability to See in Adequate Light</p> <p>The proposed data elements duplicates OASIS element M1210 – Ability to Hear and OASIS element M1200- Vision</p> <p>Recommendation: NAHC does not have a preference as to which of these elements should be included in the assessment, the current OASIS element or the proposed element. However, If CMS chooses to use the proposed elements, the impact on risk adjustment for the quality measures must be addressed.</p> <p>Special Services, Treatment and Interventions</p> <p>NAHC supports incorporating the services, treatments, and interventions into the assessment to identify resource use intensity.</p> <p>NAHC has the following recommendations regarding several of the listed service, treatments and interventions.</p>	

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		<p>Recommendations: Eliminate the 3 day assessment time frame. This time frame does not align with the assessment time frame required to complete the OASIS assessment.</p> <p>Hemodialysis: NAHC recommends that the intervention should be dialysis to included peritoneal dialysis. A home health patient receiving peritoneal dialysis often requires training, education, and direct assistance with peritoneal dialysis, which yields more resource utilization than a patient receiving hemodialysis that would typically be provided in an outpatient setting. IV Chemotherapy: NAHC recommends including oral chemotherapy. Resource use related to oral chemotherapy is similar to IV chemotherapy. For example, monitoring and intervening on adverse effects, and ensuring compliance with an oral medication regimen. It is not so much the route of the chemotherapy that dictates the resource utilization, but the substance administered and its potential toxicity.</p> <p>Invasive Mechanical Ventilator: Weaning Status: NAHC recommends weaning status be removed from the element. The description for this element addresses resource utilization related to weaning a patient from a mechanical ventilator. However, in the coding instruction this element is checked whether the patient is weaning, or not, from a mechanical ventilator. In addition, it is very unlikely a patient would be weaned from a mechanical ventilator in the home health setting. Thank you for the opportunity to submit comments. If you need further information, please do not hesitate to contact me.</p>	
RCPC54	9/12/16	<p>To Whom It May Concern:</p> <p>On behalf of Adventist Health System (AHS), the nation’s largest not-for-profit Protestant health care provider, we appreciate the opportunity to comment on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data. Our organization includes 46 hospital campuses, one Long Term Acute Care Hospital (LTCH), 15 Skilled Nursing Facilities (SNFs) and 22 Home Health and Hospice Agencies located across 10 states. AHS provides inpatient, outpatient and emergency room care for four million patient visits each year.</p> <p>AHS operates in a variety of settings, ranging from rural Appalachia to urban teaching hospitals. We believe this broad perspective enables us to provide reality-based and sound policy advice. Our comments below are divided into two sections: general comments on the project and specific comments on each data set. Our specific comments assess, as requested by CMS, the following factors:</p> <p><input type="checkbox"/> _Potential for Improving Quality</p> <p><input type="checkbox"/> _Validity</p>	Richard E. Morrison Vice President, Government & Public Policy Adventist Health System

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		<p> <input type="checkbox"/> _Feasibility for Use in PAC <input type="checkbox"/> _Utility for Describing Case Mix General Comments The <i>Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014</i> requires the development of standardized assessment-based data. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data Call for Public Comment seeks feedback on data elements that meet the IMPACT Act domains of: </p> <p> <input type="checkbox"/> _Cognitive Function and Mental Status <input type="checkbox"/> _Special Services, Treatments and Interventions <input type="checkbox"/> _Medical Conditions and Comorbidities <input type="checkbox"/> _Impairments </p> <p> AHS believes that the standardization of data collection across the PAC continuum will lead to improvements in care. However, we are concerned that a “one-size-fits-all” approach may be problematic. One challenge is that terminology is not common across all settings. Another challenge is that licensure and data collection requirements differ across the various PAC settings. We recommend a “modular” approach to standardized patient assessment data elements. The standardized elements could form a baseline “lingua franca” that is common across all settings yet is aligned with additional data collection efforts that may occur in different settings so as to avoid unnecessary duplication of efforts. We also recommend that the data elements be specified in a manner that can be integrated with Electronic Health Records (EHRs). It is our hope that much of the specified data can be populated from data that is already gathered, and documented in patients’ medical records, as part of normal care processes. </p> <p> Data Elements by Category Cognitive Function and Mental Status Brief Interview for Mental Status (BIMS) <i>Potential for Improving Quality</i> AHS believes that the potential for improving quality is high. Specifically, if CMS were to decrease the assessment period to two days for all settings of care this would provide more real-time data. This is critically important for quality improvement. Moreover, within the OASIS instrument, there is not a task for measuring cognitive function. This would provide a more objective way of measuring, which we believe is important. </p> <p> <i>Validity</i> While we believe that this is a valid form of assessment, we believe that there needs to be an option for a patient’s refusal to participate in the interview. </p> <p> <i>Feasibility for Use in PAC</i> </p>	

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		<p>We believe that this is highly feasible.</p> <p>Expression of Ideas and Wants <i>Potential for Improving Quality</i> AHS believes that the changes to this data element are clearer than in their current form within MDS 3.0. This will allow assessors to collect more pertinent data. Therefore, we believe that the data collected from this will help lead to better quality outcomes. <i>Feasibility for Use in PAC</i> AHS believes that this is highly feasible.</p> <p>Understanding Verbal Content <i>Potential for Improving Quality</i> AHS believes that the changes to this data element are clearer than in their current form. This will allow assessors to collect more pertinent data. We believe that the data collected from this will help lead to better quality outcomes. <i>Feasibility for Use in PAC</i> AHS believes that this is highly feasible.</p> <p>Confusion Assessment Method (CAM) <i>Potential for Improving Quality</i> AHS believes that the proposed form will better evaluate the level of consciousness of the patient/resident. This will allow for a more detailed plan of care and, therefore, has potential for improving quality. <i>Validity</i> AHS believes that the proposed changes accurately captures the patient/resident attributes. <i>Feasibility for Use in PAC</i> Feasibility varies depending on the care setting. Within the SNF setting, we believe this is highly feasible. In the home health setting there is only one visit and not an experience over an entire day. Therefore this comparative measure would not be applicable in a home care setting.</p> <p>Behavioral Signs and Symptoms <i>Validity</i> Captures attributes. <i>Feasibility for Use in PAC</i> While this may be feasible in a SNF setting, signs and symptoms are not applicable to measure over a 3-day period in a certified home health delivery episode. It would be unrealistic to go back each day if there was not a clinical need to assess a change. Therefore, within the home health setting this is not feasible.</p> <p><i>Utility for Describing Case Mix</i> It is used in different models today and therefore has demonstrated utility for describing case mix.</p> <p>Patient Health Questionnaire PHQ-9 <i>Potential for Improving Quality</i> While the PHQ-9 is currently used in MDS for SNFs, OASIS uses the PHQ-2. PHQ-9 is rather extensive. Unless the patient has a known psychiatric diagnosis, we believe that PHQ-2 is sufficient for the home health setting and therefore the PHQ-9 will not provide additional quality improvement.</p>	

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		<p><i>Validity</i> Captures attributes. <i>Feasibility for Use in PAC</i> Feasible. <i>Utility for Describing Case Mix</i> Is used in different models today. PHQ-2 <i>Potential for Improving Quality</i> We believe this has the potential to improve quality because it does not inundate the resident with too many questions. This could help increase resident participation. <i>Validity</i> Does not capture enough. <i>Feasibility for use in PAC</i> Feasible. <i>Utility for Describing Case Mix</i> It can be used and may lead to greater resident participation.</p> <p>Medical Conditions: Pain Pain Presence <i>Potential for Improving Quality</i> We believe this has the potential to improve quality because we think that a two day period will provide more accurate information than a five day period. <i>Validity</i> Pain can be a difficult measure to assess as pain can be subjective. The OASIS tool does a good job of phrasing this question: Does your pain interfere with your daily activity or movement? The OASIS pain frequency measurement is also helpful. AHS believes pain assessments should determine whether or not patients have pain that is interfering in their daily life. <i>Feasibility for use in PAC</i> Feasibility varies based on care setting. Within the home health setting, a measure that spans multiple days is not feasible. It would be unrealistic to go back each day if there is not a clinical need to assess a change. <i>Utility for Describing Case Mix</i> Not very useful since pain is subjective and the mix will vary with each resident pain threshold.</p> <p>Pain Severity <i>Potential for Improving Quality</i> We believe this has the potential to improve quality because we think that a two day period will provide more accurate information than a five day period.</p>	

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		<p><i>Validity</i> We are concerned that responses may vary depending on the circumstances of the assessment. We find that variables such as who is the assessor and when the assessment takes place may influence response. For example, a male patient may be hesitant to tell a female clinician his true pain level. Pain is very subjective and very individualized.</p> <p><i>Feasibility for use in PAC</i> Highly feasible.</p> <p><i>Utility for Describing Case Mix</i> Low.</p> <p>Ability to See in Adequate Light <i>Potential for Improving Quality</i> Opportunity to document “unable to assess” and at present that is not on the MDS.</p> <p><i>Feasibility for use in PAC</i> Highly feasible.</p> <p><i>Utility for Describing Case Mix</i> High.</p> <p>Hemodialysis <i>Potential for Improving Quality</i> We support a tool that identifies a patient receiving dialysis.</p> <p><i>Feasibility for use in PAC</i> Feasible.</p> <p><i>Utility for Describing Case Mix</i> We believe this will be useful for describing case mix.</p> <p>Special Services, Treatments, and Interventions</p> <p>Chemotherapy <i>Validity</i> Very easy to duplicate.</p> <p><i>Feasibility for use in PAC</i> For some settings this is highly feasible. However, within the home health setting, the term ‘resident’ is not appropriate. If this language is eliminated this could be more appropriate for the home health setting.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Radiation</p>	

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		<p><i>Potential for Improving Quality</i> Provides simpler assessment with shorter time frame of 14 days to three days.</p> <p><i>Feasibility for use in PAC</i> Highly feasible.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Central Line Management</p> <p><i>Potential for Improving Quality</i> No, this will only be done at admission and at discharge. At present there is nothing on the MDS to acknowledge it. It just has IV meds on the MDS. This addition is more specific to central line not just IV meds. Furthermore, within the home health setting, OASIS asks a broader question set and does not limit this to just central lines. We believe it is important to know about all of the lines and not just the central line. This question is too narrow.</p> <p><i>Feasibility for use in PAC</i> Feasible.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Total Parenteral Nutrition (TPN)</p> <p><i>Potential for Improving Quality</i> AHS believes this information should be collected at a regular interval, not just at admission and discharge. An example would be if the patient received TPN four days prior to discharge then the 3-day assessment would not capture that information which would be valuable to other providers along the patient's care continuum.</p> <p><i>Feasibility for use in PAC</i> Not feasible for all entities. Only collecting this data at admission and discharge, this does not meet one of the components within the feasibility definitions described as it related to the relevance to the workflow settings.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Enteral Nutrition</p> <p><i>Potential for Improving Quality</i> Do not think this is a good change. It should be on every assessment not just admission and at discharge.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Vasoactive Medications</p>	

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		<p><i>Potential for Improving Quality</i> Currently MDS is just IV medications. This is proposing you identify specific IV meds (Vasoactive). It is not a good change if it is just vasoactive IV meds.</p> <p><i>Feasibility for use in PAC</i> Not feasible for all entities. Does not meet the component of clinical appropriateness under feasibility as it only addresses one class of IV medication. Currently the MDS collects data for any IV medication within the lookback period, which is important because of the risks associated with IV access. However, within the LTCH setting, we believe that this has high feasibility.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Oxygen</p> <p><i>Potential for Improving Quality</i> We believe the assessment needs to be made on regular intervals. We are concerned that limiting the assessment to just admission and discharge may yield incomplete information. Furthermore, this element only addresses one method of oxygen delivery, high concentration. We believe data should be collected for any method of oxygen delivery.</p> <p><i>Feasibility for use in PAC</i> Highly feasible.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>BiPAP/CPAP</p> <p><i>Potential for Improving Quality</i> No.</p> <p><i>Feasibility for use in PAC</i> Highly feasible.</p> <p><i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Invasive Mechanical Ventilator</p> <p><i>Potential for Improving Quality</i> No, assessments should occur on regular intervals in addition to at admission and discharge.</p> <p><i>Feasibility for use in PAC</i> While this may be feasible in some PAC setting it is not feasible within the home health setting. OASIS does not address the weaning or non-weaning of the ventilator. It only addresses if it is at night or continuous. In home health settings, patients are not typically weaned off of the respirator therefore this is not applicable to</p>	

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		<p>this particular setting. <i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type. Suctioning <i>Potential for Improving Quality</i> No. <i>Feasibility for use in PAC</i> Highly feasible. <i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type. Tracheostomy <i>Potential for Improving Quality</i> No, assessments should occur on regular intervals in addition to admission and discharge. <i>Feasibility for use in PAC</i> Highly feasible. <i>Utility for Describing Case Mix</i> This will greatly assist with the separation of levels of care by acuity and patient type.</p> <p>Thank you for the opportunity to comment. We are happy to work with CMS and RAND on any of the issues discussed above. Please do not hesitate to contact me, if you would like to discuss further.</p>	
RCPC55	9/12/16	<p>Background</p> <p>Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment</p> <p>AHCA/NCAL appreciates the opportunity to comment on the Data Element Specifications for Public Comment that were issued as part of the RAND Corporation’s work on the CMS contract Development and Maintenance of Post-Acute Care Cross- Setting Standardized Patient Assessment Data. We also appreciate the extension of the original comment period to provide us the opportunity to vet the proposed data elements more thoroughly so that we can provide more thoughtful and comprehensive comments.</p> <p>AHCA/NCAL 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</p>	<p>Daniel E. Ciolek Associate Vice President, Therapy Advocacy American Health Care Association</p>

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		<p>that care, and inform and contribute to the development of more appropriate payment models.</p> <p>We note that Section 2(a) of the IMPACT Act includes the following categories of data to be included in the standardized patient assessment data:</p> <p>“(i) Functional status, such as mobility and self care at admission to a PAC provider and before discharge from a PAC provider. “(ii) Cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia. “(iii) Special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition. “(iv) Medical conditions and co-morbidities, such as diabetes, congestive heart failure, and pressure ulcers. “(v) Impairments, such as incontinence and an impaired ability to hear, see, or swallow. “(vi) Other categories deemed necessary and appropriate by the Secretary.</p> <p>Upon review of the data elements specifications document we have been asked to comment on, it appears that the scope of these comments include only a subset of these categories of data. Specifically, we are being asked to comment on the categories of 1) Cognitive Function and Mental Status, 2) Medical Conditions: Pain, 3) Impairments of Hearing and Vision, and 4) an array of 12 specific Special Services, Treatments, and Interventions.</p> <p>The following comments are organized into two sections. First, AHCA provides general comments that apply to most if not all the proposed elements contained in the proposed data element specifications. Next, AHCA provides detailed comments pertaining to the individual proposed PAC cross-setting data elements.</p> <p>A - General Comments</p> <p>Page 6 of the proposed data element specifications document, states the following:</p> <p>“Standardizing assessment data elements across PAC settings has important implications for patients/residents, families, providers, and policymakers. At the patient/resident level, standardized data elements may ensure the collection of high quality, reliable information that will aid in improving person-centered outcomes and goals, guide the choice of PAC providers, and improve care coordination.”</p> <p>“At the provider level, standardized assessment data elements may promote data exchangeability, thus</p>	

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		<p>enhancing efficiency through data sharing.”</p> <p>“At the national level, standardized assessment data elements will make it possible to measure and compare quality, outcomes, patient acuity, and resource use consistently across PAC settings and longitudinally, guiding policies and PAC payment reform based on patient/resident populations.”</p> <p>We fully support moving towards these objectives 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 elements are considered within the context those elements are currently utilized in the respective PAC settings. For example, as we discuss in the Detailed Comments below (see Section B), many of these proposed data elements exist in some form in the current SNF Minimum Data Set (MDS) 3.0 patient assessment instrument. 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.</p> <p>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 most if not all of the proposed data elements are 1) the alignment of PAC assessment window durations, and 2) potential impacts on provider burden.</p> <p>A.1.1 - Alignment of PAC assessment window durations</p> <p>The data element specification document proposes to standardize the assessment window across PAC settings to a uniform 3-day 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, as described in our detailed comments below (see Section B), the SNF MDS 3.0 elements that would be impacted by the proposed data elements typically require a 5-, 7-, or 14 day assessment lookback period. Many of these elements are currently linked to Medicare and Medicaid payment case mix and quality</p>	

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		<p>measures that may require recalibration if the proposed data elements were adopted with a 3-day assessment window.</p> <p>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 elements for all long- and short-stay residents with a 3-day assessment window. We are concerned that there may be disconnects between Medicare and non-Medicare assessments.</p> <p>Furthermore, if the MDS is proposed to maintain its longer duration assessment reference date structure, would the 3-day assessment elements reflect the three days just prior to the assessment reference date, or would a separate (additional) assessment reference date be necessary for the 3-day elements? We believe that the proposed data elements would better represent the patient’s status at admission if the reference date was during the first three days of admission, while the same information collected on discharge should represent the last three days of the stay.</p> <p>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.</p> <ul style="list-style-type: none"> • Please provide a thorough mapping of the Medicare and Medicaid case mix groups that would be impacted by adopting a standard PAC 3-day assessment window for the proposed data elements1. • Please provide a thorough mapping of the PAC quality measures that would be impacted by adopting a standard PAC 3-day assessment window for the proposed data elements2. • Please clarify how the proposed data element 3-day assessment windows would align with or require significant changes to the existing MDS reporting schedules for short- and long-stay SNF residents. <p>A.1.2 - Provider burden</p> <p>Any change to the SNF MDS 3.0 assessment data elements would 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 that would be necessary so that assessors would understand how to properly enter the element information would represent a temporary burden increase and would vary depending on the</p>	

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		<p>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 elements require a separate assessment reference and data entry date, as this could introduce staff effort and risk for reporting errors.</p> <p>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) 3 that reflects current SNF documentation burden associated with MDS 3.0 assessments. We believe that any proposed assessment instrument element specification changes should identify and quantify the provider burden impact.</p> <p>Figure 1. NAC SNF MDS 3.0 Time Study</p> <p>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 elements 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 elements 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.</p> <p>For example, the legacy MDS 3.0 Section G -Functional Status elements include numerous mobility and self-care elements that are used in part for the SNF PPS case-mix payment system as well as several quality measures. However, in order comply with the IMPACT Act standardized PAC cross-setting data reporting implementation deadlines, they required SNFs to also report on elements 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 used for reporting purposes only. CMS has cited that due to the legacy payment and quality purposes of the Section G – Functional Status elements, 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 element reporting requirements from the MDS as they added the new Section GG</p>	

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		<p>reporting requirements for the similar clinical domain.</p> <p>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.</p> <ul style="list-style-type: none"> • 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 the current PAC patient assessment instrument data elements that could potentially be duplicated if CMS is unable to retire the legacy elements due to existing element linkage to payment case mix and/or quality measures. <p>B - Detailed Comments</p> <p>This section contains detailed comments related to each of the proposed cross-setting data elements in the order they were presented in the Data Elements Specification document under the categories of 1) Cognitive Function and Mental Status, 2) Medical Conditions: Pain, 3) Impairments of Hearing and Vision, and 4) an array of 12 specific Special Services, Treatments, and Interventions. The AHCA comments related to the individual data elements are intended as stand-alone element-specific comments and are generally structured as follows: 1) summary of the proposed data element, 2) AHCA’s position on the cross-setting importance of the data element domain, 2) components of the proposed data element that AHCA supports, 3) AHCA’s impression of the impact of the proposed data element on SNF MDS 3.0 reporting, 4) AHCA’s recommendation for next steps for the proposed data element before we can support it, and 5) AHCA’s rationale for the recommended next steps.</p> <p>B.1 - Cognitive Function and Mental Status</p> <p>AHCA believes that cognitive function and mental status are domains that represent an array of factors that are critically important and that impact patient care, resource use, and outcomes related to the probability of their ability to function independently. As such, PAC cognitive function and mental status assessment must incorporate elements related to determining a person’s potential at being discharged back to the community, or whether long term care services will be necessary. Overall we support the inclusion of data elements associated with the six cognitive function and status domains, but have some concerns related to specific details for each proposed element that are described in Sections B.1.1-B.1.6 below.</p> <p>In addition, we believe that there are PAC patients with cognitive deficits that are clinically significant, not</p>	

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		<p>identified in elements proposed, but who require skilled interventions to restore or maintain function. We believe that these individuals and their cognitive needs are often overlooked in PAC settings which lead to reduced rates of return to the community, higher readmission rates, and higher healthcare costs. We believe that the missing piece is a data element associated with “functional cognition”, which would describe how an individual utilizes and integrates his or her thinking and processing skills to accomplish everyday activities in facility and community living environments. We understand that the American Occupational Therapy Association (AOTA) has been developing and offering potentially feasible data element specification options related to the “functional cognition” data element domain, possibly as a hierarchical data element that would only be completed if no cognitive deficits are identified by the other lower sensitivity cognitive function data elements. Additionally, the American Speech-Language-Hearing Association (ASHA) has been developing other cognitive measure elements.</p> <p>AHCA encourages that these options for a “functional cognition” or other cognition-related data elements be considered for further development and potential implementation.</p> <p>B.1.1 - Brief Interview for Mental Status (BIMS)</p> <p>The data element specifications document proposes to include a 9-element Brief Interview of Mental Status (BIMS) to assess cognition, with a focus on learning and memory at admission to the PAC setting. The proposed data element specifications document did not list a proposed assessment period duration for the BIMS element</p> <p>We believe that the BIMS element set is important information to share across the care continuum to facilitate care coordination related to a patient’s cognition, particularly related to learning and memory as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 elements C0100-C0400C. Specifically, the proposed BIMS elements would 1) add an element indicating reasons that the interview was not attempted; and 2) reverse the order of the response options in elements C0200-C0400C.</p> <p>We agree that the proposed element B1b indicating reasons that the interview was not attempted would be a beneficial addition, and that using the proposed response option 2 – “unable to make self understood would help to clarify the reason that the interview was not attempted.</p>	

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		<p>AHCA recommends that the proposed BIMS element set be further evaluated, and that CMS continues to use the existing MDS 3.0 C0100-C0400C element set definitions until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed BIMS element would create a burden associated with training and assessment scheduling (if the assessment period differs from the current SNF 7-day window) and could only be supported if the following AHCA concerns were first resolved.</p> <p>We are uncertain about the coding requirements if a patient is unable to respond in the proposed BIMS (individual elements). We seek further clarification of response options to resolve this.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to possibly 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the MDS 3.0 BIMS C0200-C0500 elements lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs BA-BB) and various Medicaid payment systems, as reflected in Appendix A. We are also concerned about the potential downstream impacts of changing the MDS 3.0 BIMS C0200-C0500 elements lookback period on quality measures as described in our comments in section A.1.1 above. For example, BIMS is currently used as a variable in several existing CMS Nursing Home Compare Quality Measures including: short stay rehospitalization, ER visits, discharge to community, short stay improvement in function; long stay ability to move independently; pain management, and bowel and bladder function.</p> <p>B.1.2 - Expression of Ideas and Wants</p> <p>The data element specifications document proposes to include one Expression of Ideas and Wants element with six response options to assess whether the patient/resident is able to express him/herself with verbal or nonverbal forms of communication at admission and discharge from the PAC setting. The data element specifications document did not list a proposed assessment period duration for the Expression of Ideas and Wants element.</p>	

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		<p>The data element specification document proposes to combine this data element with the proposed “Ability to Understand Others” element (see Section B.1.3) to form a composite “communications” variable that had substantial inter-rater reliability in the PAC-PRD.</p> <p>We believe that the Expression of Ideas and Wants element is important information to share across the continuum to facilitate care coordination related to a patient/resident is able to express him/herself with verbal or nonverbal forms of communication, as a number of underlying conditions and treatment approaches can influence this variable. We also believe that combining this element with the proposed Ability to Understand Others data element would add value.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element B0700 – Makes Self Understood. Specifically, the proposed Expression of Ideas and Wants elements would expand and significantly revise the response options phrasing.</p> <p>AHCA recommends that the proposed Expression of Ideas and Wants element be further evaluated, and that CMS continues to use the existing MDS 3.0 B0700 – Makes Self Understood element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Expression of Ideas and Wants element would create a burden associated with training and assessment scheduling (if the assessment period differs from the current SNF 7-day window) and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Expression of Ideas and Wants response options provide better and more meaningful descriptors than the current B0700 – Makes Self Understood response options, we request further details of how to code Option 8 – Unable to assess, and Option 9 – Unknown. We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to possibly 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the MDS 3.0 B0700 – Makes Self Understood element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs BA-BB) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>B.1.3 - Ability to Understand Others: Understanding Verbal Content</p>	

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		<p>The data element specifications document proposes to include an Ability to Understand Others element with six response options, to assess whether the patient/resident is able to comprehend direct person-to-person verbal or nonverbal forms of communication at admission and discharge from the PAC setting. The data element specifications document did not list a proposed assessment period duration for the Ability to Understand Others element.</p> <p>The data element specification document proposes to combine this data element with the proposed “Expression of Ideas and Wants” element (see Section B.1.2) to form a composite “communications” variable that had substantial inter-rater reliability in the PAC-PRD.</p> <p>We believe that the Ability to Understand Others element is important information to share across the care continuum to facilitate care coordination related to a patient/resident is able to express him/herself with verbal or nonverbal forms of communication as a number of underlying conditions and treatment approaches can influence this variable. We also believe that combining this element with the proposed Expression of Ideas and Wants data element would add value.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element B0800 – Ability to Understand Others. Specifically, the proposed Ability to Understand Others element would expand and revise the response options phrasing.</p> <p>AHCA recommends that the proposed Ability to Understand Others element be further evaluated, and that CMS continues to use the existing MDS 3.0 B0800 – Ability to Understand Others element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Ability to Understand Others element would create a burden associated with training and assessment scheduling (if the assessment period differs from the current SNF 7-day window) and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Ability to Understand Others response options provide better and more meaningful descriptors than the current B0800 – Ability to Understand Others response options, we request further details of how to code Option 8 – Unable to assess, and Option 9 – Unknown. We reiterate our comments in Sections A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to possibly 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We</p>	

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		<p>caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.1.4 - Confusion Assessment Method (CAM)</p> <p>The data element specifications document proposes to include one Confusion Assessment Method (CAM) element with six yes/no response options to distinguish delirium or reversible confusion from other types of cognitive impairments during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the Confusion Assessment Method (CAM) element is important information to share across the care continuum to facilitate care coordination related to distinguishing delirium or reversible confusion from other types of cognitive impairments, as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element C1310 - Signs and Symptoms of Delirium (from CAM©). Specifically, the proposed Confusion Assessment Method (CAM) element would 1) reorganize the CAM response options, 2) revise the response option wording related to Inattention, Disorganized thinking, and Altered level of consciousness, and 3) reduce the assessment lookback period for the MDS 3.0 from 7 days to 3 days.</p> <p>AHCA recommends that the proposed Confusion Assessment Method (CAM) element be further evaluated, and that CMS continues to use the existing MDS 3.0 C1310 - Signs and Symptoms of Delirium (from CAM©) element until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Confusion Assessment Method (CAM) element would create a burden associated with training and assessment scheduling, and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Confusion Assessment Method (CAM) response options generally provide better and more meaningful descriptors than the current C1310 - Signs and Symptoms of Delirium (from CAM©) response options, we disagree with the language in the proposed C1610E2 describing “Vigilant” as “hyperalert.” We recommend that the Confusion Assessment Method (CAM) element instead use the current MDS 3.0 response terminology</p>	

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		<p>which describes “Vigilant” as “startled easily to any sound or touch”.</p> <p>We reiterate our comments in Sections A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.1.5 - Behavioral Signs and Symptoms</p> <p>The data element specifications document proposes to include one Behavioral Signs and Symptoms element with three yes/no response options to assess the presence of behavioral verbal, physical, and other disruptive symptoms that may indicate cognitive impairment or other issues during a 3-day assessment period at admission to the PAC setting.</p> <p>We believe that the Behavioral Signs and Symptoms element is important information to share across the care continuum to facilitate care coordination related to assess the presence of behavioral verbal, physical, and other disruptive symptoms that may indicate cognitive impairment or other issues, as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>We agree that the proposed Behavioral Signs and Symptoms response options generally provide better and more meaningful descriptors than the current MDS 3.0 E0200 - Behavioral Symptom - Presence & Frequency response options, and with the elimination of the frequency response options.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element E0200 - Behavioral Symptom - Presence & Frequency. Specifically, the proposed Behavioral Signs and Symptoms element would 1) reorganize the response options, 2) revise the response option wording related to physical, verbal, and other behavioral symptoms, 3) eliminate the frequency response options, and 4) reduce the assessment lookback period for the MDS 3.0 from 7 days to 3 days.</p> <p>AHCA recommends that the proposed Behavioral Signs and Symptoms element be further evaluated, and that CMS continues to use the existing MDS 3.0 E0200. Behavioral Symptom - Presence & Frequency element until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Behavioral Signs and Symptoms element could create a burden</p>	

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		<p>associated with training and assessment scheduling, and could only be supported if the following AHCA concerns were first resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the MDS 3.0 E0200 - Behavioral Symptom - Presence & Frequency element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs BA-BB) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>We are also concerned about the potential downstream impacts of changing the MDS 3.0 lookback period on quality measures as described in our comments in section A.1.1 above. For example, the MDS 3.0 E0200 - Behavioral Symptom - Presence & Frequency element is used as a variable in the SNF Prevalence of Behavior Symptoms Affecting Others (Long Stay) quality measure.</p> <p>B.1.6 - Patient Health Questionnaire (PHQ)</p> <p>The data element specifications document is soliciting comment on the use of the Patient Health Questionnaire (PHQ) to be collected at admission and discharge form the PAC setting. The PHQ is commonly used to identify signs and symptoms of depression.</p> <p>The PHQ-2 consists of the first two questions of the PHQ-9 identifying the presence and frequency of 1) little interest or pleasure in doing things, or 2) feeling down, depressed, or hopeless. The PHQ-9 includes seven additional depression symptom elements, identifying presence and frequency that provide more precision in identifying depression. The specifications document is soliciting comment on the advantages and limitations of the various versions of the PHQ for purposes of assessment data standardization, and the feasibility of using a combined data element that would utilize the PHQ-2 as a “gateway” to the PHQ-9.</p> <p>We believe that the Patient Health Questionnaire element set is important information to share across the care continuum to facilitate care coordination related to assess the presence depression as a number of underlying conditions and treatment approaches can influence this variable.</p>	

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		<p>With respect to the SNF, the PHQ-9 element set has been used in the MDS 3.0 D0200 - Resident Mood Interview (PHQ-9©) section when a resident is able to respond to the questions and D0500 - Staff Assessment of Resident Mood (PHQ-9-OV4) reflecting staff observations over a two week period if D0200 was not completed (e.g., the resident is not able to respond to the PHQ questions).</p> <p>AHCA recommends that the PHQ-9 element set as proposed be further evaluated, and that CMS continues to use the existing MDS 3.0 D0200. Resident Mood Interview (PHQ-9©) section element set until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>AHCA strongly recommends rejecting the proposed use of PHQ-2 as a stand-alone element set or as a “gateway” element set to the PHQ-9.</p> <p>We have significant concerns, supported by recent publications⁵ and statements by the Centers for Disease Control and Prevention (CDC)⁶ that depression is underdiagnosed in older adults. We believe that the proposal to consider using the simpler PHQ-2 as opposed to the more comprehensive PHQ-9 already in use on the SNF MDS 3.0 would represent a step backwards clinically and reduce cross-setting communications of important data associated with identifying and managing depression. Similarly we do not believe that using the PHQ-2 as a “gateway” to the PHQ-9 is an acceptable tradeoff due to the clinical significance of depression on care quality and outcomes.</p> <p>We believe that changing the element set to PHQ-2 or introducing PHQ-2 as a “gateway” to the PHQ-9 element set would create a burden associated with training and assessment scheduling.</p> <p>We would like to see further clarification as to the staff observation questions if the resident/patient is unable to respond.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to 3 days) or changing the element set to PHQ-2 or introducing PHQ-2 as a “gateway” to the PHQ-9 could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period or element set for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the MDS 3.0</p>	

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		<p>D0200 - Resident Mood Interview (PHQ-9©) section element lookback period, or removing the mandated reporting of the complete element set, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs CA-CE) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>We are also concerned about the potential downstream impacts of changing the MDS 3.0 lookback period on quality measures or changing the element set to PHQ-2 or introducing PHQ-2 as a “gateway” to the PHQ-9 as described in our comments in section A.1.1 above. For example, the MDS 3.0 D0200 - Resident Mood Interview (PHQ-9©) section element is used as a variable in the SNF Percent of Residents Who Have Depressive Symptoms (Long Stay) quality measure.</p> <p>B.2 - Medical Conditions: Pain</p> <p>We believe that data pertaining to pain presence and severity are important to share across the care continuum to facilitate care coordination as a number of underlying conditions and treatment approaches can influence these variables.</p> <p>However, we believe that for person-centered care, pain cannot be evaluated in isolation. We believe that a primary reason for assessing pain in PAC is its impact on function as the ability to sleep and tolerate movement/activity/exercise is a primary determinant of clinical decisions to transition from one site of care to another, or in the case of home health...to determine homebound status. We are concerned that the proposed pain elements are insufficient as meaningful PAC cross-setting pain element(s). We are also interested in identifying whether there should be an indicator if/how pain is being managed with pharmacologic vs non pharmacologic interventions.</p> <p>Specifically, we are recommending the addition of a cross-setting PAC data element similar to the MDS 3.0 J0500 - Pain Effect on Function element set that asks the patient if during a set number of days 1) about the impact that pain has on his/her ability to sleep , and 2) if the pain has limited his/her day-to-day activities.</p> <p>B.2.1 - Pain Presence</p> <p>The data element specifications document proposes to include a Pain Presence element to assess the presence of pain during a 3-day assessment period at admission to the PAC setting.</p> <p>We believe that the Pain Presence element is important information to share across the care continuum to</p>	

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		<p>facilitate care coordination related to assess the presence of pain symptoms as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed title definition of this measure differs from the existing MDS 3.0 element J0300 - Pain Presence. Specifically, the proposed Pain Presence element would reduce the assessment lookback period for the MDS 3.0 from 5 days to 3 days.</p> <p>AHCA recommends that the proposed Pain Presence element be further evaluated, and that CMS continues to use the existing MDS 3.0 J0300 - Pain Presence element until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Pain Presence element would create a burden associated with training and assessment scheduling, and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Pain Presence response options, although slightly different from the current MDS 3.0 element J0300 - Pain Presence responses, they generally provide better and more meaningful descriptors than the current response options. However, we would appreciate a more complete description of the parameters of the “Unable to answer or no response” option.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures, especially as the PAC-PRD results were based on a 2-day lookback period. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>We are also concerned about the potential downstream impacts of changing the MDS 3.0 lookback period on quality measures as described in our comments in section A.1.1 above. For example, the MDS 3.0 J0300 - Pain Presence element is used as a variable in the SNF Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay), Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay), and The Percentage of Residents on a Scheduled Pain Medication Regimen on Admission Who Self-Report a Decrease in Pain Intensity or Frequency (Short Stay) quality measures.</p>	

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		<p>B.2.2 - Pain Severity</p> <p>The data element specifications document proposes to include a Pain Severity element to assess whether the patient/resident is responding to pain medication regimens and/or non- pharmacological interventions during a 3-day assessment period at admission to and at discharge from the PAC setting.</p> <p>We believe that the Pain Severity element is important information to share across the care continuum to facilitate care coordination related to assess the patient/resident response to pain medication regimens and/or non-pharmacological interventions as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed title definition of this measure differs from the existing MDS 3.0 element J0600 - Pain Intensity. Specifically, the proposed Pain Presence element would 1) Only include MDS 3.0 option A of J0600, the Numeric Rating Scale (00-10), and would change definition of the exclusion option from the MDS “Enter 99 if unable to answer” to “Enter 88 if patient does not answer or is unable to respond,” 2) exclude the MDS 3.0 option B of J0600, the Verbal Descriptor Scale which asks the resident to describe pain as mild; moderate; severe; or very severe, horrible (or to indicate if the resident is unable to answer, and 3) reduce the assessment lookback period for the MDS 3.0 from 5 days to 3 days.</p> <p>AHCA recommends that the proposed Pain Severity element be further evaluated, and that CMS continues to use the existing MDS 3.0 J0600. Pain Intensity element until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Pain Severity element would create a burden associated with training and assessment scheduling, and could only be supported if the following AHCA concerns were first resolved.</p> <p>We recommend that the Verbal Descriptor scale continue to be used as an alternative in cases where a resident is unable to respond to the 0-10 Numeric Rating Scale. We are very concerned that the management of pain needs for many PAC patients could be overlooked if they are not able to express pain intensity on a numeric rating scale, and thus are recorded with a response of “88 – patient does not answer or is unable to respond,” but are able to express pain on a valid scale that can be cross-walked to the numeric rating scale..</p>	

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		<p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures, especially as the PAC-PRD results were based on a 2-day lookback period. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>We are also concerned about the potential downstream impacts of changing the MDS 3.0 lookback period on quality measures as described in our comments in section A.1.1 above. For example, the MDS 3.0 J0600 - Pain Intensity element is used as a variable in the SNF Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay) quality measure.</p> <p>B.3 - Impairments of Hearing and Vision</p> <p>We believe that impairments of hearing and vision elements are important information to share across the care continuum to facilitate care coordination related to a patient/resident. This is particularly true if the impairment is of recent onset or reflects recent change, as this may significantly impact the prognosis and timeline for restoring functional loss or developing compensatory function-related strategies in the PAC setting.</p> <p>B.3.1 - Ability to Hear</p> <p>The data element specifications document proposes to include one Ability to Hear element with five response options to assess the patient/resident level of hearing impairment at admission to the PAC setting. The data element specifications document did not list a proposed assessment period duration for the Ability to Hear element.</p> <p>We believe that the Ability to Hear element is important information to share across the care continuum to facilitate care coordination related to a patient/resident hearing impairment as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element B0200 – Hearing. Specifically, the proposed Ability to Hear elements would expand and significantly revise the response options phrasing.</p>	

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		<p>AHCA recommends that the proposed Ability to Hear element be further evaluated, and that CMS continues to use the existing MDS 3.0 B0200 – Hearing element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Ability to Hear element would create a burden associated with training and assessment scheduling (if the assessment period differs from the current SNF 7-day window) and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Ability to Hear response options provide better and more meaningful descriptors than the current B0200 – Hearing response options, we request further details of how to code Option 8 – Unable to assess, and Option 9 – Unknown.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to possibly 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.3.2 - Ability to See in Adequate Light</p> <p>The data element specifications document proposes to include one Ability See in Adequate Light element with five response options to assess the patient/resident level of visual impairment at admission to the PAC setting. The data element specifications document did not list a proposed assessment period duration for the Ability See in Adequate Light element.</p> <p>We believe that the Ability See in Adequate Light element is important information to share across the care continuum to facilitate care coordination related to patient/resident vision impairment as a number of underlying conditions and treatment approaches can influence this variable.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element B1000 – Vision. Specifically, the proposed Ability See in Adequate Light elements would collapse the two current “Impaired” and “Moderately impaired” B1000 – Vision element response options into a single “Mildly to Moderately Impaired” element response option, and significantly revise the response options phrasing.</p>	

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		<p>AHCA recommends that the proposed Ability See in Adequate Light element be further evaluated, and that CMS continues to use the existing MDS 3.0 B0200 – Hearing element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Ability See in Adequate Light element would create a burden associated with training and assessment scheduling (if the assessment period differs from the current SNF 7-day window) and could only be supported if the following AHCA concerns were first resolved.</p> <p>While we agree that the proposed Ability See in Adequate Light response options provide better and more meaningful descriptors than the current B1000 – Vision response options, we request further details of how to code Option 8 – Unable to assess, and Option 9 – Unknown.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to possibly 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. For example, the MDS 3.0 B1000 – Vision element is used as a variable in the SNF Percent of Residents Who Declined in Independence in Locomotion (Long Stay) quality measure. We caution against proceeding with a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.4 - Special Services, Treatments, and Interventions</p> <p>We believe that the need/delivery of certain special services, treatments, and interventions elements represent important information to share across the care continuum to facilitate care coordination related to a patient/resident as a number of underlying conditions and treatment approaches can influence these variables. Additionally, while many of these elements are furnished infrequently, they frequently represent significant per- individual ancillary care delivery costs, and can serve as an important patient characteristic case-mix risk-adjustment variable for payment and quality purposes.</p> <p>While we support the direction most of the proposed data elements are heading, once potential downstream impacts on payment case mix and quality measures are addressed, we have serious concerns about the proposed removal of certain patient treatment parameters from the Hemodialysis and IV Chemotherapy</p>	

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		<p>elements (see Sections B.4.1 and B.4.2), as well as the need to carve out Vasoactive Medications (see Section B.4.7) as a separately reported data element.</p> <p>B.4.1 - Hemodialysis</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Hemodialysis during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of dialysis services, regardless of delivery method and site of care or during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element O0100J – Dialysis. Specifically, the proposed Hemodialysis element would 1) eliminate the site of service delivery differentiation, 2) exclude peritoneal dialysis, and 3) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p> <p>AHCA recommends that the proposed Hemodialysis element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100J - Dialysis element title and definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Hemodialysis element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>We disagree with the proposed removal of peritoneal dialysis from the definition for several reasons. First, while patients requiring hemodialysis may be more resource intensive, removing peritoneal dialysis delivery method from reporting could have a real impact on the quality of care due to the clinical impact on infection risk related with this delivery method. Second, as discussed in Section A.1.1 above, we are concerned about the downstream impact on corrupting existing case mix weights in SNF PPS (e.g., Medicare RUGs CA-CE and LB-LE) and various Medicaid payment systems as reflected in Appendix A. Third, we are concerned</p>	

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		<p>about the potential downstream impacts on quality measures as described in our comments in section A.1.1 above. For example, in an August 2016 TEP summary document, the CMS contractor charged with developing PAC functional outcomes measures under the IMPACT Act indicated they are proposing the presence of dialysis as a risk-adjustment factor for SNF7, and reference the presence of dialysis in existing in NQF endorsed quality measures # 2613 – CARE: Improvement in Self-Care, #2634 – IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients, and #2636 – IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.</p> <p>Additionally, we reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as possibly some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.4.2 - IV Chemotherapy</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received IV Chemotherapy during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of chemotherapy services, regardless of delivery method and site of care or during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element O0100A – Chemotherapy. Specifically, the proposed IV Chemotherapy element would 1) eliminate the site of service differentiation; 2) exclude oral administered chemotherapy; and 3) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p>	

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		<p>AHCA recommends that the proposed IV Chemotherapy element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100A - Chemotherapy element title and definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed IV Chemotherapy element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>We disagree with the proposed removal of oral administered chemotherapy from the definition for several reasons. First, while patients requiring IV Chemotherapy may be more resource intensive, removing oral administered chemotherapy delivery method from reporting could have a real impact on the quality of care due to the clinical impact related with this delivery method. Second, as discussed in Section A.1.1 above, we are concerned about the downstream impact on corrupting existing case mix weights in SNF PPS (e.g., Medicare RUGs CA-CE) and various Medicaid payment systems as reflected in Appendix A. Third, we are concerned about the potential downstream impacts on quality measures as described in our comments in section A.1.1 above. For example, in the CMS MDS 3.0 Quality Measures User’s Manual⁸, the Percent of Short- or Long-Stay Residents Assessed and Appropriately Given the Pneumococcal Vaccine measures, and the Percent of Short- and Long-Stay Residents Who Did Not Receive, Due to Medical Contraindication, the Pneumococcal Vaccine measures rely on the current MDS 3.0 O0100A – Chemotherapy element.</p> <p>Additionally, we reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.4.3 - Radiation</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Radiation during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of Radiation services, regardless of site of care or during the look-back period,</p>	

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		<p>is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element O0100B – Radiation. Specifically, the proposed Radiation element would 1) eliminate the site of service differentiation; and 2) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p> <p>AHCA recommends that the proposed Radiation element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100B - Radiation element title and definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Radiation element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the O0100B - Radiation element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs CA1-2 and LB-LE) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>B.4.4 - Central Line Management</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Central Line Management during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence Central Line Management services, with the broad scope of services beyond</p>	

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		<p>medication administration as defined in the proposed data element specifications, would be beneficial to add to the MDS 3.0 element set, and that it is important information to share across the care continuum to facilitate care coordination.</p> <p>AHCA recommends that the proposed Central Line Management element be further evaluated until identified MDS 3.0 element conflicts and downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Central Line Management element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>One point of concern is that the data element specifications document suggests that there is no same or similar MDS 3.0 data element; however, AHCA would like to point out that existing MDS 3.0 element O0100 – IV Medications is the element where SNFs currently report central line management as it pertains to medication delivery. It is also unclear if the proposed Central Line Management element is intended to replace, or be in addition to the existing O0100 – IV Management MDS 3.0 element. If not, is the intent that the existing O0100 – IV Management MDS 3.0 element would serve as a gateway question leading to coding they type of IV (e.g., through a central line)?</p> <p>Our main concern is that the administration of medications through a central line is currently reported on the SNF MDS 3.0 assessment as one of a range of services within the definition of the O0100H – IV Medications element (which includes a 14-day lookback period). The IV Medications element is used in the SNF PPS case mix system (RUGs CA- CE) as well as some Medicaid RUG payment models (see Appendix A). The proposed introduction of the Central Line Management element with only a 3-day assessment period would require CMS to also redefine the existing O0100H IV Medications element, as well as adjust the case mix weights associated with removing the Central Line Management components of the existing IV Medications element.</p> <p>We are also concerned about the potential downstream impacts of introducing the proposed Central Line Management element as well as the introduction of any modifications to the O0100H 0 IV Medications element to accommodate the introduction of the new Central Line Management element to the MDS 3.0.</p> <p>B.4.5 - Total Parenteral Nutrition (TPN)</p>	

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		<p>The data element specifications document proposes to include a check box to report whether the patient/resident received Total Parenteral Nutrition during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of Total Parenteral Nutrition services, regardless of site of care during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>AHCA recommends that the proposed Total Parenteral Nutrition element be further evaluated, and that CMS continues to use the existing MDS 3.0 K0510A – Parenteral/IV feeding element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Total Parenteral Nutrition element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element K0510A – Parenteral/IV feeding. Specifically, the proposed Total Parenteral Nutrition element would 1) eliminate the site of service differentiation; 2) change the name of the element, and 3) reduce the assessment lookback period for the MDS 3.0 from 7 days to 3 days. Similar to the IV medication administration issue pointed out pertaining to central line management in section A.1.1 above, a central line could be used to deliver TPN. As such, it is also unclear if the proposed Total Parenteral Nutrition element is intended to replace, or be in addition to the existing O0100 – IV Management MDS 3.0 element. If not, is the intent that the existing K0510A – Parenteral/IV feeding MDS 3.0 element or the proposed Total Parenteral Nutrition element would serve as a gateway question leading to coding they type of nutrition delivery (e.g., through a central line)?</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example,</p>	

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		<p>we are concerned about the downstream impact of changing the K0510A – Parenteral/IV feeding element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs CA1-2 and HB-HE) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>B.4.6 - Enteral Nutrition</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Enteral Nutrition during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of Enteral Nutrition services, regardless of site of care during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element K0510B – Feeding tube – nasogastric or abdominal (PEG). Specifically, the proposed Enteral Nutrition element would 1) eliminate the site of service differentiation; 2) change the name of the element, and 3) reduce the assessment lookback period for the MDS 3.0 from 7 days to 3 days.</p> <p>AHCA recommends that the proposed Enteral Nutrition element be further evaluated, and that CMS continues to use the existing MDS 3.0 K0510B – Feeding tube – nasogastric or abdominal (PEG) element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Enteral Nutrition element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 7 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the K0510B – Feeding tube – nasogastric or</p>	

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		<p>abdominal (PEG) element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs HB-HE and LB-LE) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>B.4.7 - Vasoactive Medications</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Vasoactive Medications during a 3-day assessment period at admission and discharge from the PAC setting. The data element specifications document suggests that a subset of the existing MDS 3.0 element O0100 – IV Medications is the element where SNFs currently report patients who receive vasoactive medications. It is unclear if the proposed Vasoactive Medications element is intended to replace or be in addition to the existing O0100 – IV Medications MDS 3.0 element.</p> <p>AHCA recommends that the proposed Vasoactive Medications element be rejected for the following reasons.</p> <p>We do not believe that there is enough clinical significance in PAC settings to isolate the reporting of vasoactive medications as proposed. Research indicates that the greatest risk of error is administration of IV in acute and not PAC care. For example, a SNF-specific study indicates that the most cited long-term care medication errors are for antipsychotics, antidepressants, sedatives/hypnotics, and anticoagulants – not vasoactive medications⁹. We believe that vasoactive medications administration is a less significant PAC clinical issue, and would already be captured in the existing O0100H - IV Medications SNF MDS 3.0 element to facilitate communication across the continuum.</p> <p>In addition, we are concerned that since the administration of vasoactive medications are currently reported on the SNF MDS 3.0 assessment as one of a range of services within the definition of the O0100H – IV Medications element, that includes a 14-day lookback period, could negatively impact existing case mix methodologies. For example, The IV Medications element is used in the SNF PPS case mix system (RUGs CA-CE) as well as some Medicaid RUG payment models. The proposed introduction of the Vasoactive Medications element with only a 3-day assessment period would require CMS to also redefine the existing O0100H IV Medications element, as well as adjust the case mix weights associated with removing the Vasoactive Medications components of the existing IV Medications element.</p>	

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		<p>We are also concerned about the potential downstream impacts of introducing the proposed Vasoactive Medications element as well as the introduction of any modifications to the O0100H - IV Medications element on SNF quality measures to accommodate the introduction of the new Vasoactive Medications element to the MDS 3.0.</p> <p>B.4.8 - Oxygen (intermittent or continuous)</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Oxygen (intermittent or continuous) during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of oxygen delivery services, regardless of site of care during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element O0100C – Oxygen therapy. Specifically, the proposed Oxygen (intermittent or continuous) element would 1) eliminate the site of service differentiation; 2) change the name of the element, and 3) reduce the assessment lookback period for the MDS 3.0 from 7 days to 3 days.</p> <p>AHCA recommends that the proposed Oxygen (intermittent or continuous) element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100C – Oxygen therapy element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Oxygen (intermittent or continuous) element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in</p>	

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		<p>lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the O0100C – Oxygen therapy element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs CA-CE) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>We are also concerned about the potential downstream impacts of changing the O0100C – Oxygen therapy element lookback period on quality measures as described in our comments in section A.1.1 above. For example, in the CMS MDS 3.0 Quality Measures User’s Manual, the Percent of Residents Who Declined in Independence in Locomotion (Long Stay) measure relies on the current MDS 3.0 O0100C – Oxygen therapy element.</p> <p>B.4.9 - BiPAP/CPAP</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received BiPAP/CPAP during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of BiPAP/CPAP delivery services, regardless of site of care during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element O0100G – BiPAP/CPAP. Specifically, the proposed BiPAP/CPAP element would 1) eliminate the site of service differentiation; and 2) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p> <p>AHCA recommends that the proposed BiPAP/CPAP element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100G – BiPAP/CPAP element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed BiPAP/CPAP element would create a burden associated with training and assessment scheduling and could only be supported if the following AHCA concerns were first</p>	

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		<p>resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved.</p> <p>B.4.10 - Invasive Mechanical Ventilator: Weaning Status</p> <p>The data element specifications document proposes to include two check boxes to report whether the patient/resident received ongoing (non-weaning) ventilator support services, or were in the process of reducing ventilator support (weaning) during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of ventilator support services, regardless of the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We believe that reporting the status of ventilator support (weaning or non-weaning) would be beneficial for care delivery, PAC care coordination, and case mix purposes.</p> <p>With respect to the SNF, the proposed title and definition of this measure differs from the existing MDS 3.0 element O0100F – Ventilator or respirator. Specifically, the proposed Ventilator – Weaning and Ventilator – Non-Weaning element would 1) split the patient population currently reported by SNF to the status of ventilator support; 2) change the name of the element, and 3) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p> <p>AHCA recommends that the proposed Ventilator – Weaning and Ventilator – Non- Weaning elements be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100F – Ventilator or respirator element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p> <p>We believe that the adoption of the proposed Ventilator – Weaning and Ventilator – Non- Weaning elements would create a burden associated with training and assessment scheduling and could only be supported if the</p>	

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		<p>following AHCA concerns were first resolved.</p> <p>We reiterate our comments in Section A.1.1 above regarding our global concerns that reducing the MDS 3.0 lookback period for this element (from 14 to 3 days) could corrupt that basis of the current payment case mix models for the SNF PPS and some Medicaid payment systems, as well as some quality measures. We caution against proceeding with such a change in lookback period for this element until the potential downstream impacts on payment case mix and quality measures are identified and resolved. For example, we are concerned about the downstream impact of changing the O0100F – Ventilator or respirator element lookback period, which could corrupt the existing case mix weights in the SNF PPS (e.g., Medicare RUGs RUX-RLX, RUL-RML, and ES1-ES3) and various Medicaid payment systems, as reflected in Appendix A.</p> <p>B.4.11 - Suctioning</p> <p>The data element specifications document proposes to include a check box to report whether the patient/resident received Suctioning (other than oral) during a 3-day assessment period at admission and discharge from the PAC setting.</p> <p>We believe that the presence of Suctioning services, regardless of site of care during the look-back period, is important information to share across the care continuum to facilitate care coordination.</p> <p>We do agree that eliminating the requirement to report whether the service was furnished while a resident or not would reduce an unnecessary reporting burden that currently serves no clinical or quality purpose.</p> <p>With respect to the SNF, the proposed definition of this measure differs from the existing MDS 3.0 element O0100D – Suctioning. Specifically, the proposed Suctioning element would 1) eliminate the site of service differentiation; and 2) reduce the assessment lookback period for the MDS 3.0 from 14 days to 3 days.</p> <p>AHCA recommends that the proposed Suctioning element be further evaluated, and that CMS continues to use the existing MDS 3.0 O0100D - Suctioning element definition until identified downstream impacts on payment case mix and quality measures are addressed.</p>	
RCPC56	9/12/16	While the National Association for Home Care & Hospice (NAHC) will be submitting comments related directly to the measures and their applicability to home health, we have also reviewed them more broadly with consideration of their potential for use in hospice care. While hospice is <u>not</u> currently one of the	Theresa M. Forster VP for Hospice

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		<p>provider types included in the Post-Acute Care Cross-Setting Standardized Patient Assessment initiative, CMS has indicated that it plans to create a comprehensive patient assessment instrument for hospice care; additionally, CMS has with increased frequency referenced hospice as a post-acute care provider type. Given these circumstances, we believe it prudent at this time to also consider these measures for their potential applicability, usefulness and impact on hospice, as well.</p> <p>Post-acute care covers a wide range of services that facilitate continued recovery with a focus on restoring medical and functional capacity to enable the patient to return to the community and preventions of further medical deterioration¹. The post-acute care provider types that are currently part of the cross-setting standardized patient assessment initiative do not have all, or even the majority, of their patients during their end of life. Hospices admit patients who have been served previously in the acute care and post acute care settings; when the transition to hospice occurs relatively soon after the acute or post-acute care phase, the availability of standardized data from the cross-setting measures will support a smooth transition from one setting to another. Specifically, the BIMS could be helpful to hospices admitting a patient if the information coming from the PAC provider is recent. We do caution that as time passes the data may become less useful due to the nature of patients changing functional status with increased frequency toward the end of life.</p> <p>In addition, we believe as CMS moves forward with work in the hospice area, it must give thorough consideration to whether use of any of the cross-setting measures is appropriate in hospice. Some of the tools would lose their value if they were to be utilized by hospice providers in a comprehensive assessment. For instance, the BIMS could not be utilized with many hospice patients as many are non-verbal/unable to self-report and could not be asked to remember three words. The volume of hospice patients who are unable to self-report is great enough that CMS decided to stop using quality measure NQF #209 in the hospice quality reporting program (HQRP) due to this reason.</p> <p>We appreciate the opportunity to provide these general comments and look forward to continued work with CMS as it considers a comprehensive patient assessment instrument for the hospice setting. If you have any questions or comments, please contact Katie Wehri at Katie@nahc.org and me at tmf@nahc.org.</p>	<p>Policy & Programs National Association for Home Care & Hospice</p>
RCPC57	9/12/16	<p>Dear Ms. Barbara Hennessey:</p> <p>On behalf of Gundersen Health System, I write in response to the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data project plan. Our comment letter outlines specific feedback and identifies issues and concerns with proposed assessment data.</p> <p>Gundersen Health System provides integrated care for patients in predominantly rural areas along the Mississippi River in western Wisconsin, northeast Iowa, and southeast Minnesota. As the largest employer</p>	<p>Deborah Head Rehab Program Manager Gundersen Health System</p>

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		<p>in the La Crosse, Wisconsin region with over 6,000 employees, Gundersen provides integrated healthcare services including: clinical care, level II trauma care, medical education, and air and ground ambulance services. Gundersen has consistently achieved top national rankings in many areas of medical excellence including being named as a Healthgrades Top 50 hospital in overall care, many clinical specialty services, and patient experience.</p> <p>We appreciate the opportunity to provide feedback on the Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data project. In addition to meaningful input, we also seek clarification and identify concerns, as detailed in the following sections, regarding a number of provisions in the project.</p> <p>Feedback Overview</p> <p>Several of the elements within the Assessment Data document do not appear to be useful for inpatient rehabilitation services. It appears several lend themselves to a home-based, long-term living or care setting and not for the short term, intensive and goal directed rehabilitation for a primarily acute illness or injury. In essence, forcing the use of these factors just to meet the purpose of collecting data across all PAC venues and not necessarily aligning with better care, is not in the best interest of patients and providers and does not contribute to improved quality or efficiency of care.</p> <p>At Gundersen Health System, our inpatient rehabilitation services are unit-based within an integrated healthcare system. By nature of being a unit based inpatient rehabilitation facility (IRF) within a hospital, we already follow the hospital level care guidelines related to pain, and have a thorough knowledge of their special services, treatments and interventions. The vast majority of our patients have been seen, screened and assessed within the acute care setting prior to coming to rehab services for some of the basic issues outlined within the collection of data elements. This will add burden for the patient and the caregivers without much benefit.</p> <p>Overall, we agree the outlined concepts are valuable to understand cognitive, behavioral issues, pain control and general health issues to appropriately treat the patient as a whole person, and not just a specific ailment. As an integrated healthcare delivery system, this approach to patient care is embedded within our system and the elements proposed to replace our current structure will give us less value-laden information that will not add to quality improvement or decrease the cost of care. Unnecessary additional data assessment will diminish the value of our outcome data and does not match the function of the IRF setting in our opinion. There is current data which the Functional Independence Measure (FIM) tool used within IRFs that allows far better use of data and outcome potential than proposed for Medicare quality reporting and improvement</p>	

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		<p>initiatives.</p> <p>Cognitive Function and Mental Status Comment: Gundersen believes the Cognitive FIM elements would be considered to meet the domain of "cognitive function and mental status." Staff can utilize appropriate standardized assessments based on that patient's needs along with observation and assign a FIM rating that more accurately assesses cognition and has the means to measure improvement.</p> <p><i>3-day assessment window:</i> Gundersen believes the 3-day assessment window become much more difficult given the language on some of these proposed cognitive elements. Having to do some cognitive assessment elements "prior to intervention" while others are to be collected throughout the 3-day window is going to be administratively burdensome. The measure parameters using varying time frames for each setting and differing timeframes is challenging. Assessing one element to the next within one setting makes for significant burden to manage, monitor, and comply with so many varied time frames for assessments, documentation requirements, (providers and staff) and reporting requirements.</p> <p>We would suggest that the Cognitive FIM elements (Comprehension, Expression, Social Interaction, Problem Solving, and Memory), would be considered to meet the domain of "cognitive function and mental status." The FIM tool already meets the criteria for potential to measure improved quality, validity and is already used by CMS for describing case mix. We feel the FIM tool meets the ability to be used across PAC settings.</p> <p>Expression of Ideas and Wants Comment: Within this section, Gundersen Health System suggests this element will provide a more descriptive state of the patient which can be helpful in care planning and in clinical decision making and possibly care coordination. However, we do not feel that it would provide an opportunity for developing further quality metrics and subsequent comparisons for various reasons including the concerns about its validity. This element is very vague and subjective and would not allow for outcome comparison for individual cases let alone from setting to setting. Once again CMS is already using the FIM Comprehension and Expression within the current IRF Patient Assessment Instrument (PAI) and it is established as meeting the criteria of potential for measuring improved quality, validity, and use in describing case mix and we feel it can be used across PAC settings.</p> <p>Confusion Assessment Method (CAM) Comment: The CAM instrument may indeed screen for delirium, however we disagree that it is a useful</p>	

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		<p>tool to assess overall cognitive impairment. It is a subjective screen and the nature of the questions for Inattention, Disorganized Thinking and Altered Level of Consciousness can be closely related to other cognitive impairments that are not Delirium.</p> <p>However, we believe it is also important to note acute onset of Delirium in all settings. It would be important that the tool does not serve as a tool to represent overall cognitive impairment as reflected in the Data Element Specifications document. The evidence of delirium would be rare in the IRF setting however impaired cognition is common and this tool would not be an appropriate tool to measure quality improvement related to impaired cognition or in determining use of resources. There is the potential for staff to erroneously rate the questions based on cognitive dysfunction and not delirium and they are two separate and clinically different presentations and have different treatment protocols and resource use. This can be noted with regard to an altered level of consciousness E1 and E2. – a “yes” answer to this element clumps very different clinical circumstances together and again making it difficult to compare quality or in determining use of resources. Both elements are critical to value-based care approaches.</p> <p>Patient Health Questionnaire (PHQ) Comment: The Resident Mood Interview (PHQ-9) can be a tool that is appropriate for use within a long term living setting, either home health or SNF, and not in an acute setting caring for an acute injury or illness. The time frame refers to the last two weeks, not congruent with assessment in an acute setting. The questions asking: feeling down, trouble falling or staying asleep, feeling tired or little energy, trouble concentrating, can also be answered affirmatively following any major illness or injury. These are screening questions to be asked when patients see primary care providers or in a long-term living setting. IRFs address this issue with more in-depth Rehab psychology assessment that fully assesses these matters in a much better way. This would not be a useful method of gauging quality, outcome or resource utilization.</p> <p>Medical Conditions: Pain Comment: Due to the intensity of IRF therapy, Gunderson opposes measuring the presence of pain. This measure doesn’t merit as a quality measure for comparison across settings nor does it have the potential to improve quality. For Gunderson Health System, pain management is a vital part of our care planning and essential to positive outcomes; however, the way this question is asked will not demonstrate reflective quality improvement or outcomes across settings.</p> <p>Impairments of Hearing and Vision Comment: The project plan indicates impairments of hearing and vision are only to be collected at admission and would suggest that they are to be utilized for risk-adjustment; however the plan fails to state</p>	

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		<p>which measures these elements may impact. In other words, these may become elements to be collected that add burden but never amount to usable information.</p> <p>In regards to the feasibility for use in PAC, it seems that CMS is trying to group all 4 PAC settings into the same mold with similar data and be able to compare various PAC settings against each other. We strongly caution this approach when each of the settings have a very different focus or purpose for the patients we serve. Comparing two home settings, such as home health and SNF to an intense acute rehab or a lengthy medical recovery setting within the long term acute care hospital (LTCH) does not effectively correlate. Despite some adjustments to try to accommodate differences among settings, clumping all data together does not make policy, clinical, or operational sense. The only meaningful outcome is added, unnecessary burden onto caregivers, meaning increased cost with little value for comparative data use.</p> <p>Conclusion On behalf of Gundersen Health System, we appreciate the opportunity to comment on this project. We strongly support an improved value-based healthcare delivery system and appreciate efforts by CMS to achieve these goals. However, value-based models need to include useful data compared across similar settings of care. Collecting and comparing data from very different PAC providers will be skewed and useless to providers and patients. Please consider these responses and thoughts as we work together to improve healthcare, in a thoughtful and evidence-based manner</p>	
RCPC58	9/12/16	<p>Dear Ms. Hennessey,</p> <p>The National Hospice and Palliative Care Organization (NHPCO) is pleased to provide comments on the draft Post-Acute Care standardized patient assessment tool and data element specifications. NHPCO is the largest membership organization representing the entire spectrum of not for profit and for profit hospice and palliative care programs and professionals in the United States. We represent over 4,000 hospice locations and more than 70,000 hospice professionals in the United States, caring for the vast majority of the nation's hospice patients. The organization is committed to improving end-of-life care and expanding access to hospice care with the goal of creating an environment in which individuals and families facing serious illness, death, and grief will experience the best that humankind can offer.</p> <p>NHPCO is pleased to provide comments on several draft data elements as well as missing data elements.</p> <p>1. Pain</p> <p>We note that there are data elements for the presence and severity of pain. In each case, the questions are</p>	J. Donald Schumacher President and CEO, National Hospice and Palliative Care Organization

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		<p>designed to solicit responses from patients who have the ability to respond. However, many patients who receive services in a PAC setting may be unable to self-report, for reasons of dementia, stage of illness, or at the end of life. The literature shows that many of these patients experience pain and may not have it adequately addressed or treated. We believe that the standardized assessment must include data elements to assess pain in the population of patients who may not be able to respond verbally. We strongly encourage CMS to review the published options available to collect and document pain for the non-verbal patient.</p> <p>We note that the MDS 3.0 does have a data element (J0800 – Indicators of Pain or Possible Pain) to measure non-verbal indicators of pain. This data element should be considered for inclusion in the PAC data elements for pain.</p> <p>NHPCO Recommendation: Consider the inclusion of pain assessment and documentation for patients who are non-verbal. One option is to use the MDS 3.0 data element J0800 – Indicators of Pain or Possible Pain for other PAC settings.</p> <p>2. Patient Goals of Care</p> <p>NHPCO notes that in this draft patient assessment tool, there are no data elements that reference the patient/resident’s goals of care. We believe that collecting and documenting goals of care is essential to guiding the care that is provided and ensuring that it is aligned with patient wishes. Goals of care conversations have increased in importance as CMS continues to focus on patient-centered care. New physician fee schedule codes have been adopted to encourage, and pay for, physician and NPP conversations with patients about advance care planning. There is mounting empirical evidence that goals of care conversations can be linked to better patient outcomes, increased patient and family satisfaction with care, as well as reductions in hospital readmissions and unnecessary treatments. Conversations about goals of care is not a “once and done” discussion, but rather occurs at various points in the disease trajectory and should be encouraged by all post-acute care providers. There are multiple tested and effective resources available to providers to guide and structure these goals of care discussions.</p> <p>Two options from the MDS could be incorporated into this PAC patient assessment tool:</p> <ul style="list-style-type: none"> o <i>Advance Directive</i> (MDS 2.0, full assessment, Section A., Element 10). o <i>Section Q: Participation in Assessment and Goal Setting</i> <p>NHPCO Recommendations:</p>	

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		<p>a. <i>Advance directive – MDS 2.0, Section A, Element 10</i> – We recommend that this data element should be reinstated and included in all assessment tools.</p> <p>b. <i>Participation in Assessment and Goal Setting (MDS 3.0 Section Q)</i> – We recommend the addition of language about patient goals of care which are not focused on the “discharge to the community” goal but still address goals of care across settings. In this section, we also propose that a question be added to this section which states: “Would a referral to hospice be appropriate for this patient/resident?”</p> <p>3. Hospice Consult and/or Referral to Hospice</p> <p>While hospice is not considered, for purposes of the IMPACT Act, a post-acute care provider, hospice services should be considered, when needed, for this seriously ill patient population. There is no reference to a hospice consult, nor is there reference to a hospice referral, as appropriate. In the MDS 3.0, hospice is listed in the section on <i>Special Treatments, Procedures and Programs</i> as Section O, (00100)(K). A hospice consult or referral should be considered for each PAC provider, as is listed in the MDS 3.0.</p> <p>NHPCO Recommendation: NHPCO recommends that there be an additional entry in the <i>Special Services, Treatments, and Interventions</i> section of the PAC standardized assessment tool, to ensure that the availability of hospice is considered as appropriate in this patient population.</p> <p>NHPCO stands ready and willing to work with Rand and other CMS contractors on the further development and refinement of the data elements for the PAC standardized patient assessment tool. For more information, please contact Judi Lund Person, Vice President, Regulatory and Compliance at NHPCO at jlundperson@nhpco.org or 703-837-3122 .</p>	
RCPC59	9/12/16	<p>Dear Ms. Hennessey:</p> <p>On behalf of the Rehabilitation Institute of Chicago (“RIC”), we appreciate the opportunity to comment on the RAND Corporation’s report <i>Development and Maintenance of PostAcute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment (August 2016)</i> (“Data Element Report”). We appreciate your attention to our comments and recommendations.</p> <p>RIC operates a research-based health care system specializing in providing comprehensive rehabilitation services to the physically disabled through an array of diagnostic and therapeutic services. Its mission is rooted in its dedication to providing the highest quality patient care and outcomes through integrated</p>	<p>Peggy Kirk Senior Vice President, Chief Clinical Operating Officer, Rehabilitation Institute of Chicago</p>

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		<p>research, scientific discovery, and education. As part of this system of care, RIC currently operates a 182-bed licensed inpatient rehabilitation facility (“IRF”) hospital and provides a wide scope of outpatient services from its primary location at 345 E. Superior Street in Chicago, Illinois as well as multiple additional locations through wholly-owned or other alliance structures with other hospital systems throughout Illinois and in northwest Indiana.</p> <p>Over the years, RIC has earned an international reputation for excellence in patient care, medical research, and professional training. In 2016, for the twenty-sixth year in a row, RIC was ranked by U.S. News & World Report as the leading rehabilitation hospital in the United States. In fact, RIC is the only hospital in the country of any kind that has earned this ranking for twenty-five consecutive years.</p> <p>RIC is also the Northwestern Feinberg School of Medicine’s Department of Physical Medicine and Rehabilitation psychiatry residency program, which is one of the largest and most sought after programs of its kind in the country. RIC has eight federally designated research programs, including designations as: a Rehabilitation Research & Training Center; a National Center for Medical Rehabilitation Research; the Midwest Regional Spinal Cord Injury Care System; a Rehabilitation Engineering Research Center dedicated to stroke research; the nation’s only Outcomes Rehabilitation Research & Training Center; a Rehabilitation Engineering Research Center for technologies for children with orthopedic disabilities; a Rehabilitation Engineering Research Center for manipulation and mobility technologies; and a Rehabilitation Engineering Research Center for computers and robots in therapy.</p> <p>The Center for Medicare and Medicaid Services (“CMS”) has requested public comment on the Data Element Report. RIC thanks CMS for the opportunity to provide the following comments, which relate ... set forth in the Data Element Report. RIC supports the effort to establish standardized assessment data elements in order to “measure and compare quality, outcomes, patient acuity, and resource use consistently across PAC settings...” (Data Element Report at 6.) RIC believes that guiding principles for establishing standardized assessment data elements should take into account the severity of disease and a risk adjustment process that accounts for disease severity; care management and cost; and functional status outcomes.</p> <p>Brief Interview for Mental Status (“BIMS”) The BIMS is a “performance-based cognitive assessment that assesses repetition, recall with and without prompting, and temporal orientation.” (Report at 10.) BIMS is a useful and well-regarded screening tool to assess the level of cognitive status. RIC’s comments on this assessment are as follows:</p>	

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		<p><input type="checkbox"/> In the responses to Question B1b (“indicate reasons hat the interview was not attempted”), the answer “Unable to make self understood” should be revised to “Patient unable to make self understood.”</p> <p><input type="checkbox"/> An additional response to Question B1b should be added, “Behavioral impairment,” which would reflect that the interview was not attempted for behavioral reasons, such as severe agitation or psychosis.</p> <p>Expression of Ideas and Wants</p> <p>The Expression of Ideas and Wants data element “assesses whether the patient/resident is able to express or communicate requests, needs, opinions, and to conduct social conversation in his or her primary language, whether in speech, writing, sign language, gestures, or a combination of these.” (Report at 13.) The Report offers six (6) proposed responses. Suggested changes to two of the responses are as follows:</p> <ul style="list-style-type: none"> • “Unknown”: It is unclear why a clinician would mark this data element with “Unknown.” Its purpose should be clarified, or the response should be removed. • “Unable to assess”: Similarly, this response should be clarified, or additional options should be provided. There are a variety of reasons for not being able to assess a patient’s expression of ideas and wants, including language barriers, behavioral impairments. The response should be clarified further. <p>Ability to Understand Others (Excluding Language Barriers)</p> <p>RIC supports revising the title of this data element, to indicate that language barriers should not be a consideration in this context for determining whether a patient can understand others.</p> <p>RIC also recommend changes to two of the responses, “Unknown” and “Unable to Assess”, for the same reasons mentioned above.</p> <p>Confusion Assessment Method (“CAM”)</p> <p>The Report states that the CAM is “an instrument that screens for overall cognitive impairment as well as features to distinguish delirium or reversible confusion from other types of cognitive impairments.” (Report at 19.) However, while this instrument has been validated in certain populations, many patients with psychiatric conditions and traumatic brain injuries have fluctuating mental status not related to delirium or to reversibility. This screening tool could be very misleading when used with such patients while their mental status is in flux. We recommend revising the CAM so that it takes such mental status fluctuations</p>	

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		<p>appropriately into account.</p> <p>Additionally, Section E of the CAM is titled “Altered Level of Consciousness,” and includes a response “Vigilant (hyperalert)” as a possible response. However, vigilance does not represent an altered level of consciousness. The phrasing of the title may cause some confusion, and should be reconsidered.</p> <p>Patient Health Questionnaire (“PHQ”)</p> <p>The PHQ-2 and PHQ-9 inquire about a patient’s depressed mood. RIC supports using the PHQ-2, which is a shorter instrument, as a gateway to the more comprehensive PHQ-9.</p> <p>Additionally, consideration should be given to the recommendation of the U.S. Preventive Services Task Force on Screening for Depression in Adults, that “Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.” 1 CMS may wish to consider whether all PAC sites of care have such systems in place for the benefit of their patients who are screened.</p> <p>Ability to Hear and Ability to See</p> <p>For each proposed data element, we recommend changes to the response “Unknown,” for the same reasons mentioned above.</p> <p>IV Chemotherapy</p> <p>This proposed data element would capture patient/resident use of intravenous (“IV”) chemotherapy specifically, and not include oral chemotherapy.</p> <p>The consequences of chemotherapy are primarily related to the agent rather than the mode of delivery. We recommend revising the data element to all chemotherapy, but then include specific exclusions that reflect lower cancer acuity rather than to only include IV chemotherapy.</p> <p>Vasoactive Medications</p> <p>This proposed data element would capture patients who received vasoactive medications during the assessment period.</p>	

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		<ul style="list-style-type: none"> • Since many medications have vasoactive properties, CMS should clarify the specific vasoactive medications that qualify. • CMS also should clarify what is meant by “continuous medication for pulmonary edema.” For example, many patients with heart failure are on continuous maintenance oral dose of Lasix. Would this regimen qualify? <p>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.</p>	
RCPC60	9/12/16	<p>RE: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data</p> <p>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 medical complexity 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 developmental delays.</p> <p>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).</p> <p>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.</p> <p>DATA ELEMENT COMMENTS:</p> <p>Cognitive Functioning and Mental Status: The data elements identified in this area fail to appropriately</p>	<p>Patricia Budo Association President, Pediatric Complex Care Association Lisa Bierly Executive Director, Pediatric Complex Care Association</p>

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		<p>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 many of the proposed data elements. More importantly, a standardized assessment instrument for children should utilize a pediatric developmental and cognitive assessment tool such as the Denver Developmental Screening Test and the Bayley Scales of Infant and Toddler Development. Use of these proposed elements will not improve quality and is not of utility for describing case mix in the population served by specialized pediatric healthcare facilities.</p> <p>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 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.</p> <p>Impairments of Hearing and Vision: While these proposed data elements are appropriate for children with medical complexity, the methods described for collecting the data regarding ability to hear and ability to see in adequate light are not applicable to this population. Because many of the children our members serve are not able to respond verbally to questions about what they see or hear, specialized testing by optometrists/ophthalmologists or audiologists is required to determine the level of hearing and sight each child may have.</p> <p>Special Services, Treatments, and Interventions: These data elements are appropriate for use with children with medical complexity in specialized pediatric healthcare facilities. To ensure appropriateness of care and support care transitions and to identify resource use intensity by capturing medical complexity, we suggest that the following data elements be included: (1) palliative care, and (2) multiple system co-morbidities including extensive congenital cardiac and neurological defects requiring a higher level of ongoing nursing monitoring at a minimum of every 1-2 hours. This may include but is not limited to ongoing assessment of signs and symptoms of adequate tissue perfusion, fluctuating ventilator effort as well as changes in levels of hydration, level of consciousness and vital sign variations. The intensity of nursing hours is not currently captured to adequately illustrate the acuity level of the child and nursing resources required to meet the child's needs.</p>	

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		<p>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 individuals 21 and under.</p> <p>Prior to the implementation of MDS 3.0 over twelve 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.</p> <p>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 LBierly@PediatricComplexCare.org.</p>	
RCPC61	9/12/16	<p>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.</p> <p>Across the post-acute care settings, physical therapists provide physical therapy 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</p>	Sharon L. Dunn, PT, PhD President, American Physical Therapy Association

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		<p>of care to achieve the goals and outcomes of improved function.</p> <p>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 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.</p> <p>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.</p> <p>Overall, APTA supports the standardized assessment data as proposed for the areas of cognitive function and mental status, medical condition: pain, impairments of hearing and vision, and special services, treatments, and interventions. 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 post-acute care settings. We do have several comments regarding the specific elements and concerns which we outline below.</p> <p>APTA is pleased to see the elements on pain presence and severity as we agree that pain is frequently under-recognized, under detected, and under treated in the post-acute care settings. While the presence and intensity of the pain provides some information about the pain a patient is experiencing, it does not provide information on how the pain effects the patient. We recommend that data on pain interference be considered for this domain as this would provide a clearer picture of how the pain is impacting a patient’s function, including mobility and activities of daily living. Several tools are available to collect this data from PROMIS (Patient-Reported Outcomes Measurement System).</p> <p>APTA supports the use of PHQ-2 as a gateway element to the PHQ-9. We believe using PHQ-2 as a gateway element would balance the reporting burden with the ability to collect more in-depth information about depression in patients, using the PHQ-9 in cases in which the patient scored beyond a threshold level indicating signs and symptoms of possible depression. While APTA supports the use of patient reported data elements, such as the PHQ-2 and PHQ-9, we have concerns about the use of these tools in patients with cognitive deficits. Patient reported data elements and tools may not be able to accurately detect or reflect issues such as depression in patients with cognitive functional issues.</p>	

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		<p>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.</p> <p>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 do have some concerns about the use of these data elements to construct outcomes measures that will be used to determine payment. We would encourage CMS to continue to work with stakeholders in the development of future quality measures for the post-acute care settings.</p> <p>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, and MPH, director of quality, at-703/706-3140 or heathersmith@apta.org.</p>	
RCPC62	9/12/16	<p>Dear Ms. Hennessey:</p> <p>The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 186,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. We appreciate the opportunity to offer comments on the document entitled, "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data: Data Element Specifications for Public Comment." ASHA members work in all four of the post-acute care settings affected by the Improving Post-Acute Care Transformation (IMPACT) Act, which requires standardized patient assessment data. Our members have a role to provide many services related to the data</p>	Jaynee A. Handelsman, PhD, CCC-A 2016 ASHA President

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		<p>elements identified in the document, including: cognitive function and mental status; ability to hear; as well as several of the special services categories, such as: enteral nutrition; weaning status for invasive mechanical ventilation; and tracheostomy care. As a result, we believe it is critically important that this data accurately reflects clinical practice for audiologists and speech-language pathologists (SLPs) who work in home health, skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs).</p> <p>Potential for Improving Quality: Outcomes versus Assessment Data</p> <p>Overall, ASHA acknowledges that the IMPACT Act requires a tremendous effort on behalf of the staff of the Centers for Medicare & Medicaid Services (CMS) and those with whom they contract, in a relatively short amount of time. We appreciate the progress made to date and the efforts to engage stakeholders through technical expert panels and comment opportunities. ASHA has made—and will continue to make—every effort to engage with the Agency as it implements the requirements of the law. We recognize that CMS needs to strike a balance between improving care for Medicare beneficiaries, complying with the requirements of the law, and minimizing provider burden, which likely drive the selection of many of the assessment elements outlined in this document. ASHA is supportive of the overall approach to harmonize data elements across all four PAC settings and supports the use of the specific data elements in this document to screen beneficiaries for cognitive and communication impairments. Based on the results of the initial piloting of these measures, some of these data elements may also prove useful for case-mix adjustment. However, ASHA is extremely concerned that any of these data elements might be considered for use as outcome measures.</p> <p>It is ASHA’s assertion that none of these data elements pertaining to cognition or communication are suitable to be used as outcome measures. First, they were developed to screen for the presence of a cognitive or communication impairment, not to diagnose or to track change. The scales are too limited to be used to track change with sufficient sensitivity. Second, the constructs being measured by the cognitive and communication data elements are not the constructs that are typically the focus of therapy. For example, if short-term memory is impaired, speech-language pathologists will likely determine which compensatory strategies are needed to facilitate the patient’s functioning given the memory impairment and teach the patient and family members how to best employ these strategies. One would not expect the patient’s Brief Interview for Mental Status (BIMS) score to improve with treatment; thus, the BIMS would be a very poor choice of data elements by which to measure outcomes. None of the proposed cognitive or communication data elements should be used to assess the patient’s functional status at any point during the episode of care to determine if there was an improvement in that status.</p> <p>Similarly, many of these data elements are inappropriate for measuring the quality of care. For example, in</p>	

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		<p>the data element specifications for ventilator weaning it simply asks if the patient is weaning or non-weaning. This element is relevant from a case mix perspective, but does not differentiate those patients who may not be candidates to be weaned from the ventilator; therefore, it should not be used as an outcome measure. For suctioning, the presence or absence of suctioning is grossly relevant to case mix adjustment, but the frequency of suctioning would be much more informative with respect to staff time and the functional impact on a patient’s ability to speak and swallow. It is critical to understand whether the patient is a candidate to wean from the ventilator, if the patient is successfully weaned from the ventilator, and the outcome of the weaning in terms of the patient’s functional abilities.</p> <p>Because of the limitations of the proposed data element specifications, CMS may find it difficult to accurately measure outcomes, improvements in the quality of care, or to accurately capture the range of services necessary to treat Medicare beneficiaries with these conditions and/or health care needs. As a result, we have outlined (in the chart below) areas for consideration as CMS further develops these data element specifications.</p> <p>TABLE</p> <p>Assessing Cognition: Use of the CARE-C Element Set</p> <p>We were also disappointed that the document did not allude to a recommendation that ASHA has made on numerous occasions, both to CMS staff in face-to-face meetings and in formal comments in response to comment and rulemaking. Specifically, ASHA has recommended that to measure change in cognitive function, communication, and swallowing, the specific elements from the CARE-C data set should be adopted in each of the four post-acute care settings. Our proposal is detailed below for your reference.</p> <p>As RAND and CMS are well aware, the IMPACT Act requires that one of the domains that must be standardized across post-acute care settings includes cognitive function and changes in cognitive function. ASHA recognizes the tremendous amount of work that has been done to date and that remains to be completed as required under this law. While CMS has made significant progress in implementing measures of function (e.g., such as self-care and mobility and other domains of quality specified by the IMPACT Act), to date little progress has been made associated with cognitive function, including communication. We believe that appropriate assessment of cognitive function is critical to determine the status, needs, and outcomes of individuals with stroke, traumatic brain injury, dementia, and other neurological disorders. As a result, ASHA has proposed to CMS the use of elements from the CARE-C tool as a mechanism for CMS to comply with the IMPACT Act. We have included the details of our proposal in responseto all four proposed payment rules for the post-acute care settings issued in 2016. We note that in the final rules for IRFs, SNFs,</p>	

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		<p>and LTCHs, CMS acknowledged our proposal, but has elected not to proceed with measures and data associated with cognitive function for fiscal year 2017.</p> <p>Our proposal (detailed below) is based on a desire to more fully assess cognition, rather than using the screening tools currently under consideration by CMS for the purposes of complying with the IMPACT Act. For example, the BIMS is a valid test of short-term memory, but it is inadequate as a proxy for all of cognition. We believe that at a minimum assessment of cognition should include problem-solving, memory, and attention. The CARE-C Tool includes these elements. We have provided the specific elements in Appendix A of this comment letter for CMS’s reference. To ensure elements associated with cognitive function are only completed when necessary based on patient presentation, CMS should consider using a screening tool, such as the Montreal Cognitive Assessment (MoCA) or a similar screening tool, to determine the need for these services. If the results of the screening tool indicate that the patient needs cognitive treatment, then the suggested elements from the CARE-C would be completed. The CARE-C elements are appropriate outcome measures that meet the purpose of the IMPACT Act as they would provide an indication of treatment outcomes, which screeners or intake elements cannot.</p> <p>ASHA supports the use of elements from the CARE-C tool for use in the post-acute care assessment tools. The use of CARE-C is supported by the extensive use of similar measures via National Outcomes Measurement System (NOMS) and their adaptation and testing through the Developing Outpatient Therapy Payment Alternatives (DOTPA) project as described in more detail below. The use in both NOMS and DOTPA demonstrate the psychometric strength of these elements. We recognize that the addition of the CARE-C elements may increase the length of the various assessment tools that are currently being used by the four PAC settings, but these data elements are the only elements of which we are aware of that could appropriately be used to measure outcomes. Given the statutory mandate, we think this presents a workable solution for all stakeholders.</p> <p>NOMS is the primary outcomes tool used by SLPs across all PAC settings. Developed by ASHA in 1998, NOMS is a nationally aggregated data collection system, utilization, and benchmarking tool used in various speech-language pathology treatment settings. The key to NOMS is the use of Functional Communication Measures (FCMs); a series of disorder-specific rating scales designed to describe the change in an individual’s functional communication and swallowing ability over time, from admission to discharge. Severity of the patient’s disability is measured with a 7-point scale, each with discrete gradations of change designed to gauge progress in the areas most commonly addressed by SLPs. The FCM scales are ordinal and designed specifically for the measurement needs of a given disorder area and do not represent a standardized percentage of functionality. However, all FCMs were designed to set level 5 as the anchor representing the</p>	

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		<p>point at which the patient is able to transition to independent functioning, relative to activities for which that disorder was being treated. The FCMs are not dependent upon administration of any particular formal or informal assessment measure, but are based on clinical observations provided by the SLP of the patient’s communication and/or swallowing abilities to be addressed in an individualized treatment plan. The NOMS FCMs and the 7-point scale was the model used by CMS when developing the functional limitations and status for speech-language pathology services (i.e., G-codes), and are very familiar to speech-language pathologists.</p> <p>The DOTPA project resulted in NOMS-derived measures being included in the CARE-C and CARE-F tools and these data elements provide more appropriate and meaningful information about functional status involving swallowing, communication, and cognition than was in the original CARE tool or the current version under review. In addition, under the “Impairments” section, the CARE-C and CARE-F tools include new elements on cognitive status and communication that not only measure the severity of these impairments, but also capture the amount of assistance that is needed. Separate levels to account for severity and assistance make these scales parallel to the rating scale that has long been in use for scoring self-care and mobility elements on the CARE tool. For those patients with cognitive and/or communication impairments, any less sensitive scoring provides insufficient information to assess the quality of their outcomes. These measures would only be scored when those impairments are being treated, and they would only be scored by professionals treating those impairments in order to assure reliability.</p> <p>In summary, we have worked with other rehabilitation stakeholders to review this proposal and have introduced it to CMS staff as well. We believe that it strikes an appropriate balance between the need to have standardized patient assessment data across the four PAC settings—as required by law—while capturing clinically relevant data that can improve the quality of care for Medicare beneficiaries. We believe this proposal minimizes stakeholder burden to the greatest extent practicable.</p> <p>Validity and Utility for Describing Case Mix Upon review of the standardized data element specifications associated with several of the categories of services—including cognition, hearing, trach care, enteral nutrition, and vent weaning—ASHA has determined that these elements would be more effective as screening mechanisms to determine if a more detailed assessment is necessary. As noted above, it is possible that these elements could be used for case mix purposes, but ASHA is seeking clarification before we can endorse these elements for case mix adjustment. For example, RAND and CMS requested feedback on several standardized clinical assessments of cognitive function and mental status, including the BIMS, Expression of Ideas and Wants, Ability to Understand Others: Understanding Verbal Content, Confusion Assessment Method (CAM), Behavioral</p>	

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		<p>Signs and Symptoms, and the Patient Health Questionnaire (PHQ). These screening tools could not be used for outcomes measurement because the scales used are limited and have not been validated as being sensitive to change. Further, the constructs that these screening elements measure are not typically the constructs that therapists are trying to change.</p> <p>Pending analyses of preliminary data, it may be possible that some of these screening data elements could be validly used for case-mix adjustment. We would like to better understand how these measures would be evaluated for their ability to contribute to case-mix risk adjustment. Some questions that we would pose, include:</p> <ol style="list-style-type: none"> 1. How will the validity of these screening measures be established for use in case-mix risk adjustment? 2. What will be used as the "gold standard" to determine how well the screening elements accurately and sensitively detected the problem that the measures were designed to probe—with respect to expression, comprehension, and cognition? 3. What degree of false positives and false negatives will be acceptable? <p>In closing, ASHA appreciates your attention to our comments and recommendations. We remain interested in assisting the Agency as it implements the requirements 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.</p>	
RCPC63	9/12/16	<p>Dear Ms. Hennessey,</p> <p>On behalf of the Association of Rehabilitation Nurses (ARN) – representing more than 5,400 rehabilitation nurses and more than 13,000 Certified Registered Rehabilitation Nurses (CRRNs) that work to enhance the quality of life for those affected by physical disability and/or chronic illness – we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and RAND Corporation’s (RAND) Development and Maintenance of Post-Acute Care (PAC) Cross-Setting Standardized Assessment Data.</p> <p>Rehabilitation nurses take a holistic approach to meeting patients’ nursing and medical, vocational, educational, environmental, and spiritual needs. Rehabilitation nurses begin to work with individuals and their families soon after the onset of a disabling injury or chronic illness. We continue to provide support and care, including patient and family education, which empowers these individuals when they return home, or to work, or school. Rehabilitation nurses often teach patients and their caregivers how to access systems</p>	Cheryl Lehman, PhD RN CNS- BS RN-BC CRRN President, Association of Rehabilitation Nurses

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		<p>and resources.</p> <p>Rehabilitation nursing is a philosophy of care, not a work setting or a phase of treatment. We base our practice on rehabilitative and restorative principles by: (1) managing complex medical issues; (2) collaborating with other specialists; (3) providing ongoing patient/caregiver education; (4) setting goals for maximum independence; and (5) establishing plans of care to maintain optimal wellness. Rehabilitation nurses practice in all settings, including freestanding inpatient rehabilitation facilities (IRFs), hospitals, long-term subacute care facilities/skilled nursing facilities (SNFs), long-term acute care facilities (LTCHs), comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), and private practices.</p> <p>ARN supports efforts to ensure people with physical disability and chronic illness have access to comprehensive quality care in whichever care setting is most appropriate for them. Specifically, as a part of its mission, ARN stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that promote maximum independence for people living with physical disability and/or chronic illness, particularly among the Medicare population.</p> <p>Overview of Rehabilitation Nursing and the Care Transition Process Rehabilitation nurses are key contributors to the care of individuals with chronic conditions and disability and they are uniquely prepared to lead team-based care coordination, including transitional care. Rehabilitation is provided by professionals who collaborate with each other and the patient and family to develop patient-centered goals and objectives. This team approach values all members of the team, with the patient and family in the center of the team. It is critical that individuals with chronic and disabling conditions are served in a PAC setting that includes the provision of services that will optimize health outcomes and quality of life.</p> <p>Rehabilitation nurses appreciate the available PAC levels and have a thorough understanding and knowledge of the resources available at each PAC level. Additionally, rehabilitation nurses are highly knowledgeable health care professionals that can educate patients on HHA, SNF, IRF, and LTCH data on quality and resource use measures, appropriately weigh a patient’s treatment needs and preferences, and guide a patient through a successful care transition.</p> <p>The care transition process often is confusing and stressful for patients and families. Ensuring patients receive rehabilitation education will result in more appropriate care transitions and has the potential to reduce 30-day readmission rates and the unnecessary utilization of limited health care resources.</p>	

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		<p>Additionally, prior to a patient’s transition to a PAC setting, the primary care physician should be required to consult with the rehabilitation interprofessional team, specifically the rehabilitation nurse, to ensure successful care coordination. ARN’s white paper, <i>The Essential Role of the Rehabilitation Nurse in Facilitating Care Transitions</i>, emphasizes this lack of coordination in current practice. The white paper alludes that care is fragmented, disorganized, and guided by factors unrelated to the quality of care or patient outcomes, and decision-makers often lack the information needed to adequately render the best decision during care transition planning. Appropriate care transitions promote the greatest value and the most effective and efficient care for individuals with chronic conditions.</p> <p>Data Elements by Category Given the scope and limitations of current measurement instruments, including the Functional Independence Measure (FIM) and the Continuity Assessment Record and Evaluation (CARE) tools, often it is difficult to measure the impact of the care furnished to patients. Tools such as the FIM and CARE are narrow in scope and fail to accurately capture the tangible progress of many of our patients. It is imperative that future assessment tools capture – in a meaningful way – patients’ outcomes and the cost effectiveness of medical interventions.</p> <p>Cognitive Function and Mental Status</p> <p>Brief Interview for Mental Status (BIMS) ARN supports the utilization of the BIMS in evaluating a patient’s cognitive status and believes it is valid and reliable in its assessment. Given the relatively low burden of administering the assessment and its ability to generally predict a cognitive impairment, we believe clinicians should be encouraged to administer the assessment on a regular basis as a means to evaluate whether there are changes in the patient’s cognition.</p> <p>However, ARN has concerns regarding the BIMS’ limitations. The BIMS has been shown to be unable to differentiate between patients with a mild cognitive impairment and those with no cognitive impairment;² further, it cannot provide a completely clear picture of a patient’s cognitive status. We urge CMS and RAND to clarify what, if any, additional tools will be used to detect potential cognitive impairment or dementia, such as collecting information from the patient’s family or caregivers to confirm or provide supplemental data.</p> <p>Behavioral Signs and Symptoms Behavioral signs and symptoms could indicate a patient has a cognitive dysfunction or is uncomfortable and needs assistance. The development of an individualized, person-centered care plan depends on accurate</p>	

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		<p>assessment and preventative methods. As members of interdisciplinary teams, nurses collaborate with physicians, social workers, psychologists, therapists, and case managers. Because of these relationship and interactions, nurses are well-equipped to identify and respond to patients with potential behavioral issues.</p> <p>ARN recognizes the need to monitor and assess behavioral signs and symptoms in an effort to better inform a patient's treatment plan. We have concerns, however, that the scope of the Behavioral Signs and Symptoms assessment is limited and may be ineffective for increasing quality of care and improving patient outcomes. The assessment does not capture subtle signs or symptoms, such as agitation or anxiety, which could indicate a cognitive impairment. If a patient exhibits such symptoms, it is unlikely to be referenced in the assessment, which could lead to the development of a care plan that does not fully reflect the patient's condition. Specific questions that help the clinician/assessor identify subtle behavioral signs or symptoms should be included in this assessment to assist in the development of a patient's care plan.</p> <p>Patient Health Questionnaire (PHQ) ARN is supportive of the PHQ and believes the PHQ-2 and PHQ-9 are useful, valid clinical tools. Both questionnaires assist clinicians in determining the severity of symptoms upon admission and throughout the delivery of care in the PAC setting. ARN recommends that the PHQ should initially be presented to patients in the most basic form (PHQ-2), and then administered in its more thorough form if these initial screening questions are positive. Upon admission into a PAC facility, patients are overwhelmed, creating a situation in which some individuals may not feel comfortable with a more invasive mental health screening. Utilizing a shorter form will reduce the burden experienced by clinicians in collecting assessment data.</p> <p>While we appreciate CMS's efforts to limit the administrative burden on patients and providers by proposing to utilize the PHQ-2 as an initial screen for depression, potentially eliminating the need for conducting the PHQ-9 in some circumstances, we have concerns the PHQ-2 is unable to identify the more subtle signs and symptoms of depression. Should CMS move forward with adopting the PHQ-2 as a gateway tool for the PHQ-9 across PAC settings, we recommend CMS utilize a low threshold level for the PHQ-2, to ensure clinicians do not miss those patients who require further evaluation.</p> <p>Medical Conditions: Pain Rehabilitation nurses play a critical role in assessing and managing acute and chronic pain. The goal of pain management for rehabilitation patients is to maximize the level of functioning and the quality of living and to treat pain with appropriate, patient-centered interventions and compassion. As pain is addressed in settings throughout the continuum of care, rehabilitation nurses may play a role in pain management in any health care setting.</p>	

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		<p>In this role, the rehabilitation nurse serves as a coordinator of care and a patient advocate to facilitate a self-management plan; provides pain management information and educates patients and families to promote wellness in order to improve functional abilities; and has a clinical understanding of physiological, pathophysiological, and psychosocial factors and uses pharmacological and non-pharmacologic methods to prevent, identify, and alleviate pain. Moreover, specialized advanced practice nursing roles in pain management can influence and educate best practices for rehabilitation nurses.</p> <p>Pain Presence The accurate assessment of the presence of pain is the first step in developing a successful pain management plan of care. Inadequately managed pain can lead to adverse physical and psychological patient outcomes for patients and their families.⁵ Unfortunately, it often is difficult to adequately assess the presence of pain in patients, particularly in those with cognitive dysfunctions.</p> <p>We recommend that CMS revise the pain presence data element. Upon admission, should the patient be unable to self-report the presence of pain due to dementia or another cognitive condition, the clinician should be prompted to question family members/caregivers, as well as to observe patient behavior. Discussions with those who know the patient, in addition to further investigation or observation, is likely to lead to improved patient outcomes and increased patient satisfaction. Additionally, it is imperative that a pain assessment is conducted after the administration of each treatment, to evaluate the effect of the intervention and determine whether a modification to the treatment plan is necessary.</p> <p>Pain Severity The treatment of PAC patients is difficult due to the presence of multiple comorbidities and chronic conditions, in addition to the number of medications they may have. While we support the use of the numeric rating scale to measure a patient’s level of pain, given its simplicity of use and sensitivity to minor changes in pain, we have concerns that the use of the numeric rating scale with patients who have cognitive impairments or hearing/language issues will lead to inaccurate results. We encourage CMS to modify the pain severity tool to allow for the use of the Wong-Baker Faces Pain Rating Scale and other visual scales with such patients. Additionally, more communicative, articulate patients, or patients for whom it is difficult to quantify pain using the numeric scale, will be better served by expressing to the clinician their level of pain. For such patients, we encourage the use of the verbal descriptor scale. ARN recommends CMS modify the Pain Severity assessment to account for the different capabilities and characteristics of PAC patients.</p> <p>Conclusion</p>	

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		<p>ARN very much appreciates the opportunity to provide comments to CMS and RAND on the Development and Maintenance of PAC Cross-Setting Standardized Assessment Data. We are available to work with you, your colleagues, the rehabilitation community, and other stakeholders to develop and implement payment policy changes that ensure access to quality care for Medicare beneficiaries with physical disabilities and/or chronic disease. If you have any questions, please contact me or have your staff contact our Health Policy Associate, Kara Gainer (kara.gainer@dbr.com or 202-230-5649). We thank you for your consideration of our concerns, recommendations, and requests.</p>	
RCPC64	9/12/16	<p>Dear Ms. Hennessey:</p> <p>The Healthcare Association of New York State (HANYs), on behalf of our 500 member non-profit and public hospitals, nursing homes, home health agencies, and other healthcare providers, welcomes the opportunity to comment on the Data Element Specifications for Post-Acute Care Cross-Setting Standardized Patient Assessment Data.</p> <p>HANYs appreciates the opportunity to provide feedback on the proposed Standardized Patient Assessment Data elements to be collected from post-acute care (PAC) providers using the assessment instruments that the Centers for Medicare and Medicaid Services (CMS) currently requires for use by home health agencies, inpatient rehabilitation facilities, long-term acute care hospitals, and skilled nursing facilities.</p> <p>HANYs agrees data elements in these various domains help clinicians to identify and address the person-centered needs of patients in PAC settings; however, we have concerns about the feasibility of use for some of these data in PAC settings and the potential added burdens the data present to patients and providers.</p> <p><u>Feasibility of Data</u></p> <p>PAC providers currently conduct their own screens for these patient data in their preadmission process to determine a referral patient's appropriateness for admission. Based on those screen results and clinical necessity, they again, in a more comprehensive way, conduct assessments during post-admission and care planning processes. The Confusion Assessment Method (CAM) instrument and the Patient Health Questionnaire (PHQ) are examples of this <i>Confusion Assessment Method</i></p> <p>Patients are routinely screened for confusion and mental status prior to a PAC admission, and especially for rehabilitation. A vital component of rehabilitation is the patient's ability to actively participate in his or her treatment plan. PAC providers recognize the importance of conducting a behavioral health assessment as part of the pre-admission screening process to determine recommendations for PAC admission and develop an individualized plan of care. Required testing after admission would be duplicative and presents an additional burden to the patient and provider.</p>	<p>Debora LeBarron, RN BS Sr. Director Continuing Care HANYs</p>

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		<p>HANYS urges CMS to eliminate CAM from the proposed list and allow current clinical practice to continue, which would include CAM screening when and if it is found to be medically necessary in the PAC setting.</p> <p><i>Patient Health Questionnaire</i> As RAND Corporation noted in its report, there are two commonly used versions of the PHQ: the PHQ-9 and the PHQ-2. Both are clinically meaningful and reliable tools, but they are very different in length and comprehensiveness.</p> <p>As with CAM, PAC providers include mental outlook in their clinical pre-admission screening process, as it is an important factor in predicting patients’ level of participation in their plan of care. HANYS believes that a required comprehensive assessment after admission, in the absence of clinical indicators identified in a screen, would be duplicative and present an additional burden to the patient and provider.</p> <p>HANYS urges CMS to eliminate PHQ-2 and PHQ-9 from the proposed list and allow current clinical practice to continue, which would include PHQ-2 screen when and if it is found to be medically necessary in the PAC setting.</p> <p><i>Special Services, Treatments, and Interventions</i> Because inpatient rehabilitation services are elective and non-urgent, patients are routinely screened for intensity and type of service needed, and the facility’s capacity to provide such services is also evaluated. Patient medical needs are re-assessed on admission, and are documented in providers’ histories and physicals, and in nursing assessments.</p> <p>In addition, RAND noted the Post-Acute Care Payment Reform Demonstration (PAC PRD), and the uniform patient assessment instrument, called the Continuity Assessment Record and Evaluation (CARE) tool. The use of the CARE tool across settings in the PAC-PRD provided much data on the medical status of patients. However, the RAND report makes no reference to those data and the insight provided on the utility of special services, treatments, and interventions for describing case mix.</p> <p>HANYS asks that CMS provide additional information as to the need for the special services, treatments, and interventions checklist.</p> <p><u>Provider Burden</u></p>	

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		<p>In addition to conducting patient screens, assessments, and care plan development, PAC providers are currently required to report a significant amount of patient data to the Centers for Medicare and Medicaid Services (CMS) on Medicare’s setting-specific assessment instruments.</p> <p>RAND’s report compares standardized data to that of the same or similar data already collected and reported by specific PAC settings as part of their completion of required Medicare assessment instruments. However, the RAND report does not discuss how this standardized data would be collected and reported by providers going forward, in light of many existing similar or same data already reported to CMS. HANYS is very concerned that collecting and reporting standardized data can present an additional burden to patients and providers.</p> <p>HANYS urges that the final cross-setting standardized data elements used to meet the Improving Medicare Post-Acute Care Transformation (IMPACT) Act domains not add new requirements to providers for conducting patient assessments and reporting data in PAC settings.</p> <p>Again, thank you for the opportunity to comment on these data specifications. If you have any questions regarding our comments, please contact me at dlebarro@hanys.org, or at (518) 431-7702.</p>	
RCPC65	9/12/16	<p>To Whom It May Concern:</p> <p>Thank you for the opportunity to submit feedback on the data elements CMS has selected to meet the IMPACT Act domains.</p> <p>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, setting of treatment, or state of the disease. The Association of Professional Chaplains (APC) advocates for quality chaplaincy care of all persons in health care facilities, correctional institutions, long-term care units, rehabilitation centers, hospice, the military, and other specialized settings. Palliative care is an interdisciplinary, team-based model of care that emphasizes care coordination, pain and symptom management, shared decision making, and patient-centered goal-setting. It is appropriate for any patient with serious illness or functional impairment, regardless of diagnosis or prognosis.</p> <p>Earlier this year, CAPC submitted comments in response to CMS’s request for input on the IMPACT Act Uniform Assessment. In these comments we noted that post-acute care (PAC) providers are the ones often taking care of the population that can benefit most from palliative care, and that the goals of the IMPACT Act are very much aligned with the goals of palliative care. In addition to the medical status, functional status, cognitive status and social support categories proposed, we recommended that the standardized</p>	<p>Diane E. Meier, MD Director Center to Advance Palliative Care</p> <p>Patricia F. Appelhans JD Chief Executive Officer Association of Professional Chaplains</p>

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		<p>assessment include elements to:</p> <ol style="list-style-type: none"> 1. Fully assess pain and symptom burden; 2. Screen for depression; 3. Collect and document patient goals of care; 4. Assess caregiver burden; 5. Collect additional information for potential risk-stratification; and 6. Collect and document wishes concerning life-sustaining treatment. <p>We are very pleased to see some of these recommendations incorporated into the draft Data Element Specifications. In particular, we applaud the inclusion of the PHQ-9 to detect signs and symptoms of depression, as well as the two elements looking at presence and severity of pain. That being said, there are still critical gaps in the standardized assessment which, if left unaddressed, could lead to needless suffering in the PAC population.</p> <p>Recommendation #1 – Include a Non-Verbal Pain Scale for Patients/Residents Unable to Self-Report While we appreciate the inclusion of the two pain elements in the uniform assessment, we are concerned that this will not be sufficient for a significant portion of patients or residents in the PAC-LTC settings who may be unable to self-report. These include older adults with advanced dementia, critically ill/unconscious patients, and patients at the end of life. Studies have shown that between 30-50 percent of people with dementia experience persistent pain, much of which is due to inadequate assessment and treatment.¹ Consequences of untreated pain can include poor appetite and weight loss, disturbed sleep, withdrawal, sadness, anxiety, depression, physical and verbal aggression, and even increased morbidity and mortality. Therefore, the standardized assessment must include both instructions for patients who are unable to self-report, as well as data elements to assess pain for this subpopulation. Possible assessment tools include:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pain Assessment in Advanced Dementia Scale (PAINAD) <input type="checkbox"/> Checklist of Nonverbal Pain Indicators (CNPI) <input type="checkbox"/> Certified Nursing Assistant Pain Assessment Tool (CPAT) <input type="checkbox"/> Mahoney Pain Scale <p>Alternatively, we suggest that CMS to consider incorporating an additional data element from the MDS 3.0 to assess for additional indicators of pain (including non-verbal sounds):</p> <p>TABLE</p>	

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		<p>Recommendation #2 – Include Data Elements to Assess Non-Pain Symptoms</p> <p>In addition to pain, there are a number of other symptoms that can cause significant distress in older adults and those with serious illness, including breathlessness, nausea, constipation, drowsiness, and fatigue. We reiterate the need to assess patients/residents for the presence and severity of these symptoms in order to arrange treatment, and recommend that CMS review the following instruments for relevant data elements:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Condensed Memorial Symptom Assessment Scale (CMSAS) <input type="checkbox"/> Edmonton Symptom Assessment Scale (ESAS) <p>Recommendation #3 – Collect and Document Patient Goals of Care</p> <p>We also reiterate from our previous letter that it is critical to discuss patients’/residents’ goals in order to ensure that the care delivered is appropriate and aligned with their wishes. The standardization of the PAC assessment form across settings presents an unparalleled opportunity to ensure that patients’ preferences are known and honored, regardless of their location. Studies have shown that high quality goals of care conversations 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.^{2,3} But in order to be most effective, these conversations should occur early in the illness trajectory – and certainly before any serious decisions must be made. To that end, we urge CMS to reconsider the resources proposed in our previous letter:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Five Wishes, a tool to support patients and families to define their wishes for medical treatment, comfort levels, decision-making, and legacy. Five Wishes is a product of Aging with Dignity and can be accessed at www.agingwithdignity.org. <input type="checkbox"/> The Center for Bioethics has published a guide for patients and families to have conversations and reflect on their values and preferences. The full guide can be accessed at http://practicalbioethics.org/files/caring-conversations/Caring-Conversations.pdf. <input type="checkbox"/> The Serious Illness Care Project from Ariadne Labs at Harvard has developed both a screening tool and a documentation template that can be accessed at https://www.ariadnelabs.org/areas-of-work/serious-illness-care/resources/ <p>If these options are infeasible, we urge CMS to consider incorporating at least one of the following elements from the SNF instrument:</p> <p><i>Advance Directives</i> (MDS 2.0, full assessment, Section A., Element 10). While the evidence is mixed as to whether that inclusion of this element in the MDS has increased completion of advance directives or improved related care planning, this may have been due to the fact that the information has not been</p>	

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		<p>consistently collected across care settings.</p> <p>TABLE</p> <p><i>Resident's Overall Satisfaction</i> (MDS 3.0, full assessment, Section Q., Element 0300). We agree with the experts' opinion in the MDS 3.0 Final Report that a data element assessing residents' goals of care for their stay is an improvement over indicating the presence of an advance directive (which in practice becomes a checkbox measure rather than a catalyst for a meaningful discussion). We recognize that the element "Expects to be discharged to the community" might not be appropriate for those receiving services from HHAs; however, we would be happy to partner with CMS to adjust this element or select a new measure that reflects the overall concept (soliciting patients' goals and preferences) so that it can be used across settings.</p> <p>TABLE</p> <p>Conclusion CAPC and APC continue to appreciate CMS's thoughtful work in the creation of a uniform set of assessment measures. With a few small additions to the assessment, clinicians can gain a more comprehensive understanding of the things that matter the most to their patients and residents. This in turn will lead to better, more person-centered care across post-acute settings. Thank you again for the opportunity to submit our recommendations. Please do not hesitate to contact us or Stacie Sinclair, Policy Manager at Stacie.Sinclair@mssm.edu if we can provide any additional detail or assistance.</p>	
RCPC66	9/12/16	<p>Dear Ms. Hennessey:</p> <p>I am writing on behalf of the Pennsylvania Homecare Association to comment on RAND Corporation's development of post-acute care cross-setting standardized assessment data on behalf of CMS. Home health providers are excited to soon have access to cross-setting data under the IMPACT Act that will allow agencies to better compare their performance with their post-acute care (PAC) partners and plan for innovations in care delivery. However, home health agencies (HHAs) often operate on very slim financial margins with limited reimbursement from Medicare that is shrinking with each year, so it is important that new data collection activities do not place an undue administrative burden on providers or become a barrier to patient care.</p> <p>In addition, it is important for RAND and CMS to keep in mind the unique nature of home health care as compared to other facility-based PAC providers. Home-based care involves a one-to-one relationship</p>	Vicki Hoak, CEO Pennsylvania Homecare Association

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		<p>between the patient and each member of the HHA’s interdisciplinary team who visits the patient in their home a few times a week. Unlike our facility partners, we do not have constant access to the patient to monitor for data elements such as a change in behavior. By its very nature and by regulation, home health care is meant to be intermittent and short term. PHA hopes RAND will keep this aspect of homecare in mind as it seeks to establish a measure set that can be broadly applied to all PAC providers.</p> <p>Cognitive Impairment</p> <p>Some measures in the cognitive impairment domain do not fit into the home health model for the reasons discussed above. For instance, the Confusion Assessment Method and Behavioral Signs and Symptoms measures call for a 3-day assessment period during which the patient is observed in a variety of situations and staff across all “shifts and disciplines” are interviewed to determine if the patient exhibited any behavioral symptoms in the past 3 days. PHA providers predict they will not be able to collect the information called for by these measures because they are not in the patient’s home to interact with them in person every day as facility providers do.</p> <p>Home health care plans call for nursing or therapy visits only a few times per week. Therefore, there will be many instances where a patient is not observed by HHA staff over a continuous 3-day period. PHA suggests instead measuring based on the last 3 <i>encounters</i> with the patient in order to accommodate the nature of home-based care.</p> <p>We would also like to point out that patient cognition can change when the PAC setting changes. Some patients experience a decline in cognitive function, whether temporary or long-term, when they enter a facility setting such as a nursing home. The data collected under this domain should be able to account for that shift in settings and measure the impact on a patient when they are transferred between PAC settings.</p> <p>Medical Conditions: Pain</p> <p>PHA supports the incorporation of data elements that are already being collected on the OASIS regarding pain assessment and supports the expansion of the OASIS elements to standardize pain assessment information across settings.</p> <p>Unfortunately, this measure domain also contemplates the same 3-day assessment period as the Cognitive Impairment measures discussed above. We reiterate our concern that HHAs will not be able to accurately capture this information given that home health orders are for intermittent care rather than the 24/7 custodial</p>	

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		<p>care that is provided by a PAC facility.</p> <p>Remaining Domains</p> <p>PHA supports the measures outlined in the remaining two domains: Impairments of Hearing and Vision and Special Services, Treatments and Interventions. We appreciate the efforts by RAND and CMS to incorporate existing data collection elements on the OASIS that will fit into these domains rather than requiring extensive additional reporting by providers.</p> <p>We thank CMS and RAND for the opportunity to provide feedback on these measures and others being developed under the IMPACT Act. PHA member agencies would be glad to participate in any further discussion or testing on these measures as this project moves forward.</p>	