Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting

Project Title:

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

Dates:

• Feedback on materials presented at November 27, 2018 meeting were asked to be sent to SPADEForum@rand.org by February 1, 2019 in order to be included in this compilation.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the RAND Corporation to develop standardized assessment-based data elements to meet the requirements as set forth under the IMPACT Act of 2014, Section 2(a). The contract name is "Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data." The contract number is HHSM-500-2013-13014I. As part of its data element development process, CMS encourages interested parties to submit input on the materials presented at the Noveemer 27, 2018 meeting, available here: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Forum-Slides_Early-Findings-from-the-RAND-IMPACT-National-Beta-Test.pdf

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 risk, 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.

About this Document:

RAND received nine emails with comments from 17 organizations (including trade and professional associations, PAC providers, and consulting organizations). Verbatim comments are listed below, along with the name and organization of the commenter.

Name, Credentials, and Organization of Commenter	Date Received	Text of Comments
Alyssa Keefe	1/14/19	Dear Ms. Mandl and Ms. Pratt:
Vice President,		
Federal Regulatory		On behalf of our more than 400 member hospitals and health systems, including approximately 300 hospital-based
Affairs		post-acute care providers, the California Hospital Association (CHA) appreciates the opportunity to provide feedback
California Hospital		on RAND's national beta test of candidate standardized patient assessment data elements (SPADEs).
Association		CHA supports the objectives of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, including the development of SPADEs as well as data collection across all levels of post-acute care to ensure high-quality patient care. We agree that such data collection and standardization, when performed correctly and consistently, will better align Medicare payments for services with beneficiaries' clinical characteristics. CHA appreciates the Center for Medicare & Medicaid Services' (CMS) efforts to release early findings of the national beta test for stakeholders' review and discussion. This input has been key throughout measure development and testing, and has brought shared understanding to this process. We applaud CMS for providing multiple engagement opportunities over the past several years and we urge CMS to continue this dialogue as we move forward. CMS should build on the steps it has taken to date and allow access to the data set that was developed as part of the national beta test. CHA urges CMS to make the SPADE data set available — and update it as appropriate — so that other external parties and stakeholders may not only replicate CMS' analysis, but also offer additional analysis for consideration.
		While not a nationally representative data set, it contains tremendous information. Allowing all parties access will lead to a richer and more informed policy discussion going forward. Releasing the data set as early as possible would benefit CMS in that through additional third-party analysis, stakeholders will be able to more fully understand the potential impact on their organizations, leading to more informed and robust comments. A technical appendix in support of this data set would also be helpful to stakeholders. We also appreciate CMS' efforts to return data to the organizations that have participated so that they can benefit from those learnings. This administration has been committed to transparency of data, and continues to release information across many areas on an ongoing basis. We believe our request aligns with the agency's overall priorities and goals. Further, absent a fully transparent process, it is nearly impossible to provide meaningful input on such significant changes. Change is difficult, but it is made even more challenging when providers are not given adequate information to make informed strategic and operational decisions. Unfortunately, in many areas of payment and coverage policy, CMS woefully underestimates the time providers need make the cultural and organizational changes that are being

requested — especially while simultaneously ensuring beneficiary access is not limited. Therefore, CHA urges CMS to look for additional ways — outside a very limited rulemaking process — to engage providers as we continue on this transformation journey. We acknowledge that this is a time-consuming and difficult task. However, we believe it is critical and fundamental as CMS proceeds. Resources and personnel should be dedicated to this process. CHA stands ready to work with CMS to help inform next steps.

As previously mentioned, CHA appreciates CMS' efforts to engage stakeholders. However, we hope the agency will provide additional opportunities prior to implementation of the SPADEs. When given the opportunity, CHA and our member organizations have been actively engaged in developing the SPADEs. This has included participation in technical expert panels, open door forums, previous public comment periods and the national beta test. However, while CHA member organizations participated in the national beta testing in the California markets, we are unaware of any field staff focus groups held with those organizations, as discussed in the November meeting. We see this as a missed opportunity to solicit provider feedback on their experiences with the candidate SPADEs and would welcome an opportunity to assist in a future convening.

In addition, as stated in our comments on the federal fiscal year (FFY) 2019 inpatient rehabilitation facility prospective payment system final rule, we continue to urge CMS to create a multi-disciplinary technical advisory group representing the full continuum of post-acute care providers to advise the agency on the technical, strategic and operational implications that should be considered as these changes go forward. To date, stakeholder input for measure development and testing has been approached within each setting type, limiting the opportunity for comparison across settings. Not only is such an approach counterintuitive to the overall goal of increasing alignment across settings, but — in our view — it also limits the scope and value of the input received.

Finally, CHA supports many of the design elements of the national beta test, including steps to better test reliability across settings and data elements. However, our members — particularly those that participated in the beta test — are increasingly concerned that the data do not adequately recognize the frequency of cognitive and communication impairments or their impact on the care process. Patients with significant communication or cognitive impairments were omitted from the study, due to their inability to participate in the interview process. This omission causes providers great concern.

The presence of a cognitive or communicative impairment will significantly impact the care process and associated resource use. For example, in a case where two patients have similar levels of functional mobility but only one has a cognitive impairment, the patient with deficits in comprehension, memory or safety awareness will require significantly more intervention.

		The limited assessment of cognitive and communication impairments, as well as the elimination of many patients from the data collection process, undermines both the comparability of the patients assessed to the general population cared for in post-acute settings and the ability to draw conclusions about the use of these measures in clinical post-acute care. We urge CMS to consider these implications as it reviews the national beta test findings. Additionally, we understand that the testing did not include non-English speaking patients, who represent a significant portion of the population at many of our member organizations. Their omission from the testing process limits our ability to assess the value of the measures in a diverse patient population, and brings into question the measures' validity. CHA looks forward to additional discussion on these important matters. Thank you for the opportunity to provide comments on the early findings of the beta test. If you have any questions, please contact me at akeefe@calhospital.org or (202) 488-4688. Sincerely, /s/ Alyssa Keefe Vice President, Federal Regulatory Affairs
Jeremy Furniss, OTD,	1/15/19	Dear Dr. Edelen & the RAND SPADEs Team:
OTR/L, BCG		
Director of Quality The American Occupational Therapy Association		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). 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. AOTA appreciates the opportunity to comment on the RAND IMPACT National Beta Test of Candidate Standardized
		Patient Assessment Data Elements (SPADEs) and appreciates the work that RAND and CMS have done to ensure high quality, highly reliable data elements. I. Cognitive Status AOTA thanks RAND for separating the cognitive status and mental status elements in discussion as they are separate
		I. Cognitive Status

and Confusion Assessment Method (CAM); however, AOTA remains concerned that there are significant and important domains of cognition that are not captured by these data elements. Specifically, these items cannot identify persons with mild cognitive impairment (MCI). AOTA supports the addition of performance based data elements to identify MCI. This is an important construct for care planning, resource use, and beneficiary outcomes. We refer RAND to a more thorough discussion of cognitive status in our letter submitted to impactpubliccomment@rand.org on June 26, 2017. During the November 27, 2018 "Early Findings from the IMPACT National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs)" meeting, RAND and CMS staff acknowledged that more work needs to be done to address cognitive status. AOTA looks forward to working with CMS and contractors on this issue in the future.

II. Mental Status

Identifying symptoms of depression is a major concern for post-acute care settings, and we appreciate that the PHQ-2 to 9 maintains very high reliability. However, the lookback periods for the PHQ and PROMIS items tested for mental status may be problematic in the PAC setting. RAND noted that the assessor feedback demonstrated that the two week lookback period on the PHQ was difficult. AOTA believes the seven day lookback on PROMIS items may also prove difficult. Many times the preceding hospital stay was unplanned—for many beneficiaries, their lives were very different one to two weeks from the admission into a PAC setting. A major life event, hospitalization, and at least one (if not more) facility transfers have happened in the past two weeks. AOTA does not believe that this necessarily negates the use of the items, but requests that RAND consider and address the lookback periods for each of the items in any final reports or recommendations.

AOTA is pleased to see RAND testing PROMIS measures for use in PAC. We emphatically support the inclusion of patient reported outcomes in post-acute care. We also believe that accurately capturing patient report and responding appropriately via care planning and interventions is critical. We defer to the research team to determine if PROMIS depression and anxiety are the best measures to include in this setting.

III. Medical Conditions: Pain

AOTA strongly supports the consistent measurement of pain related items. We are excited to see that the pain items yielded excellent reliability for both percent agreement and kappa scores. We appreciate that the questions look beyond the presence or absence of pain and to the activities that are limited or hindered by the pain. We encourage CMS to finalize these items.

IV. Impairments

A. Vision and Hearing

		AOTA compared the condition of the allowants and consents that CMC to the first of
		AOTA supports these data elements and suggests that CMS include these items at the beginning of the assessment to
		identify the needs of the beneficiary before the reimaging assessment items are administered and to support clinical
		decision-making, care coordination, and care transitions.
		B. Continence
		AOTA supports these data elements.
		V. Other Categories
		A. Care Preferences
		AOTA believes that this is a great first step to ensuring that patients are involved in their own care planning and that
		options are made available and explained to them when patients want to be involved.
		B. Global Health
		AOTA supports a global patient reported outcome measure that examines the change in global health. Our comments above related to the PROMIS Mental Status elements also apply to the PROMIS Global Health elements. Many of the questions are specific to the past seven days which for many beneficiaries will include a vast array of unusual, unexpected life situations. These questions ask a beneficiary to rank their global health considering a premorbid status, acute care and potential emergency services, and transfer to post-acute care. Consideration for these factors should be addressed in final recommendations. Although PROMIS was not tested in this way, from a clinical perspective, more meaningful information would be: (1) the global health rating prior to acute care admission, (2) the global health rating at PAC admission, and (3) the global health rating at PAC discharge. Unfortunately, as stated, this measure asks the beneficiary to create an answer based on the combination of (1) and (2). * * * * *
		Thank you for the opportunity to comment on the SPADEs National Beta Test. Please contact me at
		jfurniss@aota.org or (240) 800-5986 if you have any questions about AOTA's feedback.
Michael J. Barnett, JD NASL Manager of	1/15/19	Dear Ms. Mandl:
Legislative &		The National Association for the Support of Long Term Care (NASL) is a trade association representing suppliers of
Regulatory Affairs		ancillary services and providers to the long term and post-acute care (LTPAC) sector. NASL members include therapy
,		companies that employ more than 300,000 physical therapists, occupational therapists and speech-language
		pathologists who furnish rehabilitation therapy to hundreds of thousands of Medicare beneficiaries in nursing
		facilities as well as to beneficiaries in other long term and post-acute care settings. NASL members also include both
		vendors of health information technology (IT) that develop and distribute full clinical electronic medical records
		(EMRs), billing and point-of-care IT systems and other software solutions that serve the majority of LTPAC providers
		of assisted living, skilled nursing and ancillary care and services. Additional services and products provided by NASL
	ı	,

members include clinical laboratory services, portable x-ray/EKG and ultrasound, complex medical equipment and other specialized supplies for the LTPAC sector. NASL is a founding member of the Long Term and Post-Acute Care Health Information Technology Collaborative (LTPAC Health IT Collaborative), which was formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders.

NASL appreciates the opportunity to participate in the November 27, 2018, briefing on the candidate standardized patient assessment data elements and submit additional comments toward a finalized set of data elements for standardized assessment in post-acute care settings. NASL members are aware the intended use of these elements is to facilitate compliance with the IMPACT Act provision for patient standardized assessment. This letter provides the SPADEs Project Team with NASL's ongoing concerns regarding application of a standardized assessment process using several components of the information presented during the November 27, 2018, briefing entitled, *Early Findings from the RAND IMPACT National Test of Candidate Standardized Patient Assessment Data Elements* (*SPADEs*). Although NASL's concerns are generalized for all four post-acute settings, the following comments are particularly focused on Skilled Nursing Facilities (SNFs) where there appears to be potential for the largest beneficiary impact. Using the data presented in the *Nursing Home Data Compendium 2015 Edition* (Department of Health and Human Services https://www.cms.gov/Medicare/Provider-Enrollment-and-CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf), the following comments are shared in an effort to encourage ongoing collaboration between CMS, RAND, and NASL members that will assure the most accurate assessment of beneficiary needs throughout the post-acute environment upon initial

1. SAMPLE TYPE

Geographic and Population Mix

As noted on slide 10 of RAND's November 2018 presentation¹, the guiding principles for the evaluation of candidate SPADEs is to identify potential for improving quality, assure validity and reliability, determine feasibility for use in

implementation and as standards of practice continue to evolve.

¹ Early Findings from the RAND IMPACT National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs) slides from the November presentation are available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Forum-Slides Early-Findings-from-the-RAND-IMPACT-National-Beta-Test.pdf

PAC settings and utility for describing case mix (including use in payment models). Based on this information, we believe it is important to consider the composition and quantity of SNF settings involved in the Beta Test.

While the referenced HHS compendium (Figures 1.1 through 1.9) shows the largest number of certified SNF beds for those over 65 years of age located in the central part of the United States and nursing home occupancy is known to be in excess of 80%, the Beta Test locations appear to exclude a very significant portion of the Medicare population (SPADEs presentation – slide 16). Even though the sample was randomly chosen, essentially it appears there is no data capture for the north central portion of the United States as well as the northwest regions. In addition, the sample came only from providers who after being randomly chosen, did volunteer to participate in the Beta Test. As such, we believe that this sample is not truly random. NASL understands that the only alternative to this volunteer approach would be to mandate participation or provide additional incentives for providers to participate. As such, NASL encourages RAND to invite stakeholders to provide, specifically, what incentives would be helpful in gathering more volunteers.

From a researcher point of view, we see how a random sample is optimal; but, because the SPADEs are going to be used to assess patients that face obstacles and environmental factors that may be missed from a random selection, NASL members are concerned that the Beta Test results have not accounted for the geographic and seasonal challenges as well as the very rural population residing in a large portion of the United States.

Throughout the November presentation and the HHS 2015 compendium, a noted absence in these discussions is consideration of Medicare beneficiaries with limited English proficiency. Despite several Beta Test Markets being in known locations for cultural diversity and a significant number of residents who do not have English as a primary language, there is no mention of how these citizens are to be included in a standardized assessment process. In the stakeholder briefing, we believe that it was clarified that non-English speakers were excluded from assessments. Not only is there concern regarding access to appropriate care when a beneficiary may be misunderstood, there is significant concern that erroneous assessment of patient needs could be an unintended consequence. This observation facilitates concern that the assessment process could be structured to not meet Medicare rules of participation to equitably serve all beneficiaries, as well as causing non-compliance to the IMPACT Act due to the lack of a standardized assessment for all the beneficiaries being served.

NASL members have concerns as to whether this Beta Study is truly reliable and valid as to the true Medicare population. NASL members are concerned that the Beta Test results have omitted a significant segment of the Medicare beneficiary population who reside in culturally diverse areas and are not fully proficient with the English language.

By failing to account for, or even mention this non-English speaking population, one could infer that RAND is excluding this population from their random sample altogether, and thus calling into question the reliability and validity of the entire study sample. Providers treat limited English-speakers and non-English speakers, and assessing and treating this population requires more resources in time, and money to treat this population.

Furthermore, on July 18, 2016, HHS implemented the final rule for the anti-discrimination provisions of Section 1557 of the Affordable Care Act (ACA) (81 FR 31376, 45 C.F.R. Part 92), through directives from the Office of Civil Rights (OCR) related to health care provider communication of civil rights, including a mandated use of a notice of non-discrimination with language assistance taglines in several languages. Exclusion of the limited English-speakers and non-English speakers does not lend support to these important initiatives from HHS and the OCR. If RAND is excluding this non-English speaking population from the study, NASL questions how CMS plans to incorporate the impact of this population on the SPADEs when they are implemented. This is a point of particular relevance with recent focus on decreasing administrative burden and increasing transparency. In the alternative, NASL offers the suggestion to consider "limited English" as an exception in the future.

2. SAMPLE SIZE

Equitable Samples

During the RAND briefing, RAND staff indicated that they had to extend the recruitment period to obtain more providers for testing. The HHS Nursing Home Compendium, 2015 Edition indicates there are over 14,000 SNFs throughout the nation. Slide 18 of the November 2018 presentation² indicates a total of 60 SNFs participated in the Beta Test. This information appears to indicate that significantly less than one-half of one percent of the SNFs in this country were included in the Beta Test. This is concerning when, for comparison, approximately 2% (23) of the Inpatient Rehabilitation Hospitals in the United States participated in the Beta Test. We are concerned that the overall sample of post-acute providers does not represent the distribution of post-acute providers in the nation.

² Early Findings from the RAND IMPACT National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs) slides from the November presentation are available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Forum-Slides Early-Findings-from-the-RAND-IMPACT-National-Beta-Test.pdf

NASL members are concerned that the small SNF sample of participating providers is not accurately representative of the number of SNFs in the nation overall, and comparatively smaller than the number of IRFs chosen for the Beta test. Instead of repeating the Beta test with a more representative sample, NASL recommends that CMS introduce some of these items into the assessment instruments to test them live. The items tested should be those that have shown very high results from the Beta Test. While being tested, the items would not be part of the SNF Quality Reporting Program calculations or other quality program calculations. In other words, there would be no risk to the provider that the item would impact their results. This is similar to standardized aptitude testing (SAT) for prospective college students. SAT exams include some test questions that are being tested for potential future use. These test questions are included in the student's exam but are not scored as part of the student's overall grade.

We also observe that only "Communicative Assessments" are reported. When we look to the SNF contribution in these numbers, we find that approximately 37% of the communicative assessments were completed in a SNF.

Compendium reported information indicates that approximately 44% of the SNFs across the nation have between 100 and 200 beds. The Beta Test sample indicates that a total of 1167 SNF Communicative Assessments were completed. This could suggest that if each average size SNF in the country had only one patient per bed per year, Beta data would have captured less than 15% of the communicative patients admitted. If we expand to have a more realistic extrapolation, we could readily find that far less than one half of one percent of communicative patients were Beta Tested. As often discussed and reported, the SNF population often consists of many more non-communicative patients than any other post-acute setting. Unfortunately, the process appears to have predetermined that a non-communicative patient on admission may never be capable of rehabilitation to a communicative status as the admission assessment process discounts non-communicative patients for a communication status at discharge. This combination of data and observations give cause for concern regarding the reliability of findings for the SNF population currently required to be comprehensively serviced. It also creates significant burden on providers, in addition to creating concern regarding the equitability of the overall testing process across all four post-acute settings.

NASL members are concerned that the limited data for communicative assessments paired with the absent non-communicative assessment data is not fully reflective of the SNF setting, nor does it allow for data capture of a quality outcome for the Medicare beneficiary who may initially test as non-communicative and may have rehabilitated to be communicative at discharge. Non-communicative testing was limited (slide 23, two assessments). This testing was not particularly positive (slide 24).

3. COGNITIVE ASSESSMENT

Assessment. However, the overall volume of positive assessments found positive for cognitive deficits has not been reported. In addition, the question and answer portion of the November update revealed the Beta Test indicated more work is needed to assure reliability and overall confidence in cognitive assessment. It was also noted that another CMS project was working on this very topic. When we look to the HHS SNF Compendium findings (figure 3.1), we see that in 2014 approximately 61% of the SNF residents were found to have moderate to severe cognitive impairments. For the remaining 39%, the patients were grouped as having "none to mild" cognitive impairment. Unfortunately, this indicates no historic capture of, or baseline for, mild cognitive impairment. Current standards of practice give evidence to positive outcomes for those identified and treated with mild cognitive impairments while, unfortunately, Medicare continues to be unable to identify this population and lacks historic data of servicing this beneficiary population. This assessment gap does not appear to assure potential for improving quality, nor does it assure valid and reliable patient identification, support of efforts to improve outcomes, including decreasing the risk of preventable hospital readmissions, or to be feasible in all PAC settings and/or adequately describe case mix. We also wish to reiterate a comment that we submitted back in June of 2017, that the PROMIS items were designed for non-institutional patients only.

NASL members are concerned the inability to reliably identify patients with all levels of cognitive impairments (mild through severe) continues to inadequately identify a patient population to assure access to care.

4. POST-IMPLEMENTATION REVIEW AND REVISION

Of particular note, slide 24 of the November presentation³ gives evidence to the varying findings for the assorted data elements in the test. The chart shows that darker elements showed more positive results. About a third or less of the squares are dark, which clearly demonstrates that only some elements indicate more reliability across all project guiding principles than others. While the number of more positive data elements is noted, it appears there is significant potential for improvement in many areas. The briefing did not indicate that, based on the findings of this Beta Test, that there is any plan for future retesting on these elements. We believe it would be beneficial and in the best interest of the patients being served, if a more granular plan is developed and shared with stakeholders. Patient

³ Early Findings from the RAND IMPACT National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs) slides from the November presentation are available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Forum-Slides Early-Findings-from-the-RAND-IMPACT-National-Beta-Test.pdf

assessment is being used for very important facets of patient's care, including quality measurement, compassed in the settings, payment, burden measurement, care transitions, etc. As clinical evidence and practice standards of the settings are settings.	
settings, payment, burden measurement, care transitions, etc. As clinical evidence and practice standards e	
seems best to assure a plan is in place to allow for improvements in patient assessment. In addition, during	
briefing, slides were included that showed the support and challenges that were encountered with each of	
data elements. It would be helpful to engage stakeholders in discussions to further assess the potential imp	act of
these findings and ways in which the challenges may be addressed.	
NASL members are concerned that study results showed more work is needed in an overwhelming number of	of the
elements, as illustrated on slide 24. We are concerned regarding the absence of a plan for ongoing review, r	evisions
and refinement of the standardized assessment elements and processes and recommends this be included a	s an
essential part of the final plan for implementation.	
CONCLUSION	
On behalf of the members of NASL, I thank you for the opportunity to provide these comments. Please do r	not
hesitate to be in contact should more information or detail be needed.	
Devon Seibert-Bailey 1/15/19 To Whom It May Concern and those involved with the SPADE FORUM at Rand:	
Vice President ,	
Strategic Health Care As a group of not-for-profit, long-term acute care hospitals (LTCH) encompassing several regions across the	United
States, we appreciate the opportunity to comment on the National Beta Test of candidate standardized pat	
Asheville Specialty assessment data elements (SPADE) that RAND is currently conducting on behalf of the Centers for Medicard	
Hospital Medicaid Services (CMS).	
Asheville, NC	
Aultman Specialty As such, we believe following the completion of the assessment phase of the Improving Medicare Post-Acu	te Care
Hospital Transformation Act of 2014 (IMPACT Act), standardized data submitted by post-acute care providers –LTCH	
Canton, OH nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and home health agencies (HHAs) will prom	ote the
Continuing Care creation of an effective, evidence-based, unified payment system if these key data are analyzed. That said,	
Hospital, assessment phase of the IMPACT Act, is of critical importance. We believe the assessment and standardized	
KentuckyOne Health reporting must be inclusive of an array of acuity and risk of mortality elements.	
Lexington, KY Representatives from the LTCH organizations represented here are key stakeholders within the post-acute	care (PAC)
Craig Hospital community. In review of the tested data elements we find the project as presented very interesting, althou	
Denver, CO clinical elements necessary to adequately and appropriately measure the needs of the high acuity post-acu	-
Gaylord Specialty patient.	
Healthcare	
Wallingford, CT	

Henry Ford Allegiance CareLink Jackson, MI Presence Holy Family Medical Center Des Plaines, IL Regional Hospital for Respiratory and Complex Care CHI Franciscan Seattle, WA Shepherd Center Atlanta, GA Collectively, the members contend that it is imperative to include several key data elements to better stratify the patient population appropriately.

We propose the following risk stratifications for inclusion into the SPADE project:

- Patients' severity-of-illness (SOI) using the 3M model (four different acuity levels),
- Four supplemental acuity measures; o Risk of mortality (ROM) using the 3M model (four risk of death levels),
- o Time (measured in days) spent in the Intensive Care Unit (ICU) (three or more days is baseline),
- o Average number of major complications and comorbidities (MCC), and
- o Average number of complications and comorbidities (CC) (may be reported as either MCC, CC or MCC/CC).

Attached for your review you will find three charts (Attachment 1, Attachment 2 and Attachment 3, labeled as 3A and 3B for ease of review) providing the above detailed risk stratification for ALL PAC settings by license designation (MedPAR 2016 data). This data clearly illustrates that different PAC settings have significantly different acuity and risk of death mixes of patients. As such, the best place for any given patient post-ICU may vary given these risk strata (SOI as it crosses with ROM, etc.).

Analysis Interpretation

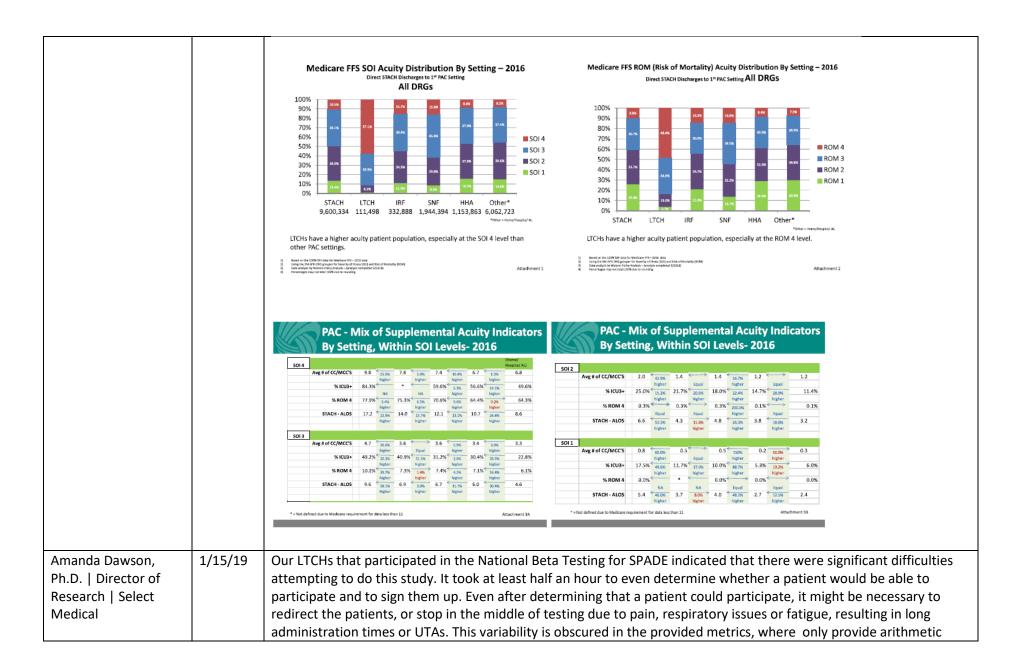
From these attached data tables, we concluded that:

- a. There are meaningful variances between settings when acuity is crossed with risk of mortality. Understating this prior to ICU discharge could lead to more appropriate PAC disposition to gain best patient outcomes
- b. Acuity as determined by co-morbidities must be factored into the expected levels of defined outcomes. Realization that a more critically ill patients or patients with more severe co-morbidities impact the ability to heal, are a determinant in the level and frequency of care provided at a given PAC, and at least impact the length of time required to making *meaningful* or *significant* gains.

Again, we support effectively setting expected levels of performance along with the standardized collection of assessment data only when the complete array of necessary factors are applied. If SOI, ROM and MCC/CC factors are applied to all patients, then these SPADE data will be appropriate, actionable and lead to both cost savings as well as improved healing of these fragile patients.

We appreciate your work on this important project and are grateful for your attention and consideration of our suggestions.

See Slides.



means of administration times were provided and no measures that would indicate the range of administration times experienced.

Regardless of the time estimates provided for the administration of individual instruments, our staff indicated that, cumulatively, the study was "very time consuming." Even when two staff members were assigned to the study, they indicated that "it took up the majority of our time." These concerns were raised with the research nurse that was assigned to each facility, but we did not receive any feedback about the concerns at that time, nor were they appropriately reflected in the presentation on early findings from the SPADE Beta Test. Further, in one of our hospitals, we experienced a change in the research nursing staff from one individual to another, and our clinical staff reported major differences in approach between the two. It is unclear how you pooled data and accounted for differences within that facility, and then how you accounted for variance between the different facilities, both within a single type of provider and between different provider types, in order to be able to present aggregate results near universally across measures.

Based on the inclusion criteria, the majority of our patients were unable to participate in this trial, resulting in data that represents only a small subgroup of patients treated in the LTCH. A large proportion of the excluded LTCH patients were responsive but couldn't communicate. Based on a long history of administering similar scales measuring health-related quality of life, depression, anxiety, cognitive function and delirium, our network of 100 LTCHs has a firm understanding of which instruments are appropriate for our patients, the reasons why patients may not be able to respond, which alternative instruments should be used, and the amount of time it takes to administer them. The time data collected in this Beta Test does not mirror our own data collected during time studies. Based on our experience, and based on the high number of UTAs reported in the alpha test of these measures in LTCHs, we assert that in order to assess feasibility of the instruments, it is critical to report the breakdown in scores and the proportion of excluded/UTA patients for each measure at admit and discharge and by post-acute provider type, as well as the provision of measures of patient and facility-level variation.

It should be noted that the reliability estimates provided apply only to scoring of the instruments. The research nurse relied on staff member administration of the instruments. Only scoring the responses occurred independently. Thus, we do not know whether staff can reliably administer the instruments across individuals or hospitals, nor do we know that the instruments can reliably capture patient characteristics upon reassessment. Even scoring could have been influenced based on the way in which the staff member administered the response, e.g., the way in which the staff member frames the patient's response in their verbalizations with the patient, and their attempts to follow-up on a provided response.

For some measures, only percent agreement was provided and not Kappa for inter-rater reliability. Percent agreement is not sufficient to establish inter-rater reliability because it doesn't take chance agreement into account, tends to overestimate the level of agreement, and is not robust to multiple raters (which was often the case in hospitals). Sample sizes should be provided for the kappa estimates, and it should be made clear whether the ranges provided are the confidence interval. Further, to understand the magnitude of the kappa coefficient, it is necessary to understand the prevalence of the attribute being assessed by the instrument, e.g., classifying a patient as being negative or positive on the CAM. It is also necessary to present the actual results obtained on measures in order to inform us as to the need for adjust the kappa, and thereby, the assess the feasibility of the instrument. LTCH patients are on most of the medications listed in the medication reconciliation form. It seems unlikely that there were no setting differences in the time to completion between settings. In particular, because only 17% of the participating facilities were acute care hospitals, the arithmetic mean of time assessments may be skewed by the higher proportion of lower acuity post-acute care facilities and patients. This would be particularly aggravated for measures like medication reconciliation. Again a breakout by facility type would answer this question for participants, as well as some assurances that the study was powered to detect differences amongst the different provider types. Lastly, if CMS has LTCHs submit this data with one of the assessment tools that has to be done in 7 or 14 days, does

Lastly, if CMS has LTCHs submit this data with one of the assessment tools that has to be done in 7 or 14 days, does this changes the admission assessment completion/submission timeframe? Will there be an additional admission assessment submitted, or will the info get submitted with the discharge assessment? Likewise, the admission assessments currently in use are reflective of the data collected on the day of admission or by the second calendar day. Would that apply to these assessments? It does not seem feasible to administer all of these questions to patients within 2 days. It would also seem to be challenging to collect all of this data again prior to discharge. Some of the tools also refer to treatments patients received during a time window that could predate admission. The time window for assessment will need to disentangle this issue of attribution.

Mimi Zhang
Senior Policy and
Research Analyst
American Medical
Rehabilitation
Providers Association
(AMRPA)

Richard Kathrins, PhD

Dear Dr. Edelen:

These comments are submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA) with respect to the above captioned Request for Stakeholder Input. We welcome the opportunity to offer feedback on the development of standardized patient assessment data elements (SPADEs) 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.

Chair, AMRPA Board of Directors President and CEO, Bacharach Institute for Rehabilitation

Suzanne Kauserud, FACHE, MBA, PT Chair, AMRPA Quality Committee Vice President, Continuing Care Division - Inpatient Carolinas Rehabilitation / Atrium Health AMRPA is the national trade association representing more than 625 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals (referred to as inpatient rehabilitation facilities (IRFs) by Medicare), outpatient rehabilitation service providers, and several long-term care hospitals (LTCHs) and skilled nursing facilities (SNFs). Inpatient rehabilitation hospitals and units (IRH/Us) provide hospital-level care, which is significantly different in intensity, capacity, and outcomes from care provided in non-hospital post-acute settings. 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.

With our Quality Committee and member clinicians, AMRPA has reviewed the SPADEs national beta test preliminary results presented by RAND and CMS staff at the November 27, 2018 stakeholder forum. Our following comments are divided into two sections:

I. General comments and recommendations regarding the development of the SPADEs, and II. Specific questions pertaining to RAND's presentation slides from the stakeholder forum. AMRPA appreciates CMS' continued transparency and willingness to engage post-acute care (PAC) stakeholders in developing the SPADEs. We look forward to reviewing the forthcoming summary report on this work.

I. General Comments

A. Setting-Specific Findings

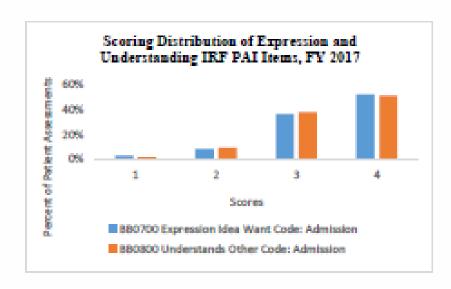
While the data presented in November were highly informative, they were overall results aggregated across all four post-acute care settings. **AMRPA requests that CMS/RAND make setting-specific beta test results and data available.** It would be helpful for stakeholders to see feedback from the participant sites on the items' potential for improving quality, and particularly an item's clinical relevance to PAC or value added to existing care practices.

B. Quantifying SPADEs' Utility to Describe Case Mix

One of the criteria used to evaluate the candidate SPADEs is "Utility for describing case mix." It appears that RAND's evaluations of this criterion so far have been qualitative in nature, *i.e.*, derived from stakeholder input and beta test assessor surveys and focus groups. **AMRPA recommends that RAND quantitatively assess the SPADEs' utility in differentiating patient case mix**. It would be very worthwhile to see if any of the items are actually able to differentiate patients within one PAC setting or among PAC settings. AMRPA has a strong appreciation for CMS' view that SPADEs are being developed for multiple purposes not limited to payment-setting or resource utilization, such as facilitating clinical information transfer and improving care coordination. Nonetheless, CMS and RAND should methodologically evaluate the merits of the candidate items especially with regard to their ability to distinguish casemix within and among PAC settings.

This analysis should also examine whether the SPADEs items are psychometrically sound and look at potential floor or ceiling effects. To illustrate, several beta test SPADEs are already being reported by all IRH/Us on the IRF PAI, including the Expression and Understanding Cognitive Status items. Based on FY 2017 data however, these items show a ceiling effect when used for IRH/U patients, with more than half of all patients scoring at the highest-functioning level for these items (see data below).1 Assessment items that exhibit a ceiling effect for inpatient rehabilitation patients, such as these, are ill-suited for patient classification and case-mix purposes. AMRPA recommends that RAND rigorously analyze candidate SPADEs' utility for case-mix purposes and include this assessment in its overall evaluation of each item's suitability for future use.

IRF PAI Scoring Distribution, FY 2017				
	N			
Scores	1	2	3	4
IRF PAI Item BB0700: Expression of Ideas and Wants	9,958	30,616	135,731	193,085
Percent of all patients	2.7%	8.3%	36.7%	52.2%
IRF PAI Item BB0800: Understands Other Code	6,109	34,438	140,227	188,616
Percent of all patients	1.7%	9.3%	37.9%	51.0%



C. Cognitive Status

With regard to cognitive status, many PAC patients are somewhere between the extremes of severely cognitively impaired and highly cognitively functional. Although the Brief Interview for Mental Status (BIMS), Confusion Assessment Method (CAM), and other candidate Cognitive Status SPADEs might distinguish between highly

functional or severely impaired cognitive status, AMRPA and our members have significant reservations that these items are able to capture the *full range* of PAC patients' cognitive impairment. As described above, the Expression and Understanding items show a ceiling effect for rehabilitation hospital patients. Similarly, for the BIMS, AMRPA remains concerned that it is not sensitive enough to capture the range of cognitive impairments exhibited by IRH/U patients. Our members report that many patients who score the highest/most functional score on BIMS in fact have mild to moderate cognitive deficits which are not being captured by the BIMS.

As designed for the Continuity Assessment Record and Evaluation (CARE) Item Set used in the Post-Acute Care Payment Reform Demonstration (PAC PRD), the BIMS is a gateway item for the CAM, which is triggered when responses to the BIMS suggest the presence of cognitive impairment.2 Currently, IRH/Us only report the BIMS on the IRF PAI. As AMRPA has expressed to CMS previously, we do not think the BIMS alone is sufficiently sensitive to measure the cognitive deficits of inpatient rehabilitation patients.3 We recommend that RAND examine if using the BIMS in combination with the CAM (as done in the beta test) produces a more sensitive cognitive assessment tool. We are particularly interested in seeing this data, and all Cognitive Status SPADEs data, specific to IRH/U patients.

We appreciate RAND's recognition, as expressed during the stakeholder forum, that the cognitive status items used and tested to date may be too simplistic to capture the full range of cognitive functional deficits seen in PAC. Unfortunately, this important domain remains an inadequately captured aspect of patients' clinical profiles. AMRPA and our members welcome the opportunity to continue working with CMS to improve how cognitive status is captured by providers and addressed by Medicare.

D. Assessment Time

As AMRPA has commented to CMS before, we do not think that the beta test's results for time spent on each SPADE are representative of what it will actually take the average PAC provider to conduct these assessments. The beta test participants have benefitted from highly specialized training by CMS and RAND staff, been provided with an electronic assessment tool (a tablet), and could readily turn to CMS/RAND staff as resources for any questions that arose during assessments. Furthermore, it is highly likely that the staff chosen by beta test sites to be the assessors were the facilities' more experienced staff members. These are simply not the conditions that PAC providers would actually face in their day-to-day operations. The assessment times from the beta test's relatively controlled testing environment do not necessarily reflect the provider burden if SPADEs were collected as part of PAC patient assessment instruments (PAIs). We ask CMS to be cognizant of these factors should it consider adding SPADEs to PAIs.

E. Burden on Patients and Fatigue

Finally, we remind CMS and RAND to be mindful of the impact that numerous assessments or patient-reported questions could have on the patient-provider relationship. We believe this aspect has been an unevaluated, yet critical, component to the successful implementation of PAC assessment items. Would patients be receptive to the breadth of information being collected from them and on them? To some patients such as the elderly, frail, and those with cognitive deficits, so many questions can seem intrusive and patients may respond negatively to an exhaustive battery of assessment minutiae. Our members also report seeing some patients, such as those with cognitive impairments, lose focus after being asked so many questions. This may also muddle the accuracy of patient-reported data.

II. Questions Regarding the November 27, 2018 Presentation Slides⁴

The following are questions pertaining to specific slides from the stakeholder forum. We would appreciate clarification and/or additional information from RAND on these topics.

Slide 18: There appears to be a much lower percentage of completed discharge assessments compared to admission assessments, and differences in completion rates across settings. What are the factors contributing to these results? How does the low volume of discharge assessments impact the completeness of test results?
 Slide 24, "Overall Evaluation of Candidate SPADEs" colored grid: How did RAND conduct this evaluation? Was it based on beta test participant feedback or RAND staff's impression of the SPADEs? We would appreciate more background information about how this grid was developed.

② Slide 69: Based on assessor feedback, the Special Services, Treatments, and Interventions (SSTI) SPADEs were of "low clinical utility in IRFs." What does CMS or RAND intend to do with items that do not have high utility to PAC providers? AMRPA urges that only assessment items that demonstrate clear utility to PAC providers and add value to existing practices be considered for any future standardization across settings.

Conclusion AMRPA appreciates the opportunity to provide input on the development of cross-setting PAC standardized patient assessment data elements. We seek to ensure that 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, Senior Policy and Research Analyst (mzhang@amrpa.org) at 202-591-2469.

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⁴ Early Findings from the RAND IMPACT National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs) slides from the November presentation are available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Forum-Slides Early-Findings-from-the-RAND-IMPACT-National-Beta-Test.pdf

		Richard Kathrins,
Deb Head Rehab Program Manager Gundersen Health System	11/27/18	I understand, appreciate and support the goal of standardized data across all PAC settings. With that being said my interest is in the fact that the base data collected is essential for all patients if it is being asked of all patients regardless of their individual circumstances. There is no argument that all of the elements currently outlined have significant implications for some patients. We are in an era of trying to reduce cost of care and ensure quality individualized care. I wonder if it we risk moving away from clinically driven assessment based on individual care needs to heightened response of fill in the required boxes to meet regulatory needs regardless of the individuals circumstances. When a care provider has limited amount of time however is required to fill out a laundry list of questions (some very important to some patients, and maybe less important for others) we risk making a one size fits all and ultimately leading to a size that fits no one. In line with "patients over paperwork" – is there consideration for reducing the number of cross setting standard
		elements instead of continuing to increase the number? Make the most of a handful of items that make the most sense and target just those few items applicable to all patients.
		You could list out every possible critical issue and make a case for including all because it is vital for the care of this or that patient. But that is not individualized care nor is it using the clinical expertise of those trained to provide care. Cognitive dysfunction and Dementia have different clinical implications — within the number of interview assessments, are you differentiating long term dementia from cognitive dysfunction that have different levels of clinical intervention that directly can influence long term outcomes? The resource use will vary and ultimately it may be important if indeed the information is tied to case mix and reimbursement. Will there be appropriate weighting for resources needed to improve clinical function when clinical function can potentially be improved as it relates to cognitive dysfunction due to injury or illness?
Jennifer Nguyen, MPP Research Associate KNG Health Consulting, LLC	1/8/19	We would like to request an extension of the January 15 deadline to comment on the RAND IMPACT National Beta Test of Candidate SPADE testing. With two major federal holidays falling during the comment period, we are requesting this extension because we need more time to provide detail comments and fully analyze the results of the beta test and its impacts on LTCHs.
Lane Koenig, Director of research and policy, National Association of Long Term Hospitals	2/1/19	Dear Measure Development Team: The National Association of Long Term Hospitals (NALTH) is pleased to submit comments on the early findings from the Improving Medicare Post-Acute Care Transformation (IMPACT) National Beta Test of Candidate Standardized Patient Assessment Data Elements (SPADEs). NALTH is the only hospital association devoted exclusively to the needs of severely ill patients who require services provided by long-term acute care hospitals (LTCHs). We hope the measure development team finds the information below helpful.

General Comments

LTCHs provide services for a select group of patients requiring an extended hospital stay. Often these patients have conditions, such as respiratory failure or severe wounds, that require special equipment (e.g., mechanical ventilation) and staff with specialized training. The severity of patients discharged to LTCHs are considerably higher than in other settings. In a study for NALTH by KNG Health Consulting, LLC (KNG Health), the researchers found that LTCH patients have three times the average number of major complications or comorbidities as inpatient rehabilitation facility/skilled nursing facility (IRF/SNF) patients (2.2 for LTCHs vs. 0.6 for IRFs/SNFs). During the 90-day period prior to post-acute care (PAC), LTCH patients spent an average of 18 days in a short-term acute care hospital (STACH) compared to 11 days for IRF/SNF patients. Finally, LTCH patients spent an average of 7 days more in an intensive care unit (ICU) than IRF/SNF patients (11 days for LTCHs vs. 4 days for IRFs/SNFs). We see little added value in the candidate data elements to either improve quality or describe case mix, particularly in light of LTCH patient complexity.

It is unclear how some of the data elements are providing value in the LTCH setting. Many LTCH patients are on a ventilator at the time of admission and spent time in an intensive care unit (ICU) before being admitted to the LTCH. We anticipate that item sets with interviews would not be attempted in many circumstances because the patient is either unresponsive or unable to make himself or herself understood. Feedback from the assessors recognized this challenge as they note "many questions not applicable to patients/residents who are truly non-communicative." We ask that the Centers for Medicare & Medicaid Services (CMS) and RAND Corporation (RAND) consider these comments when assessing the data elements.

Cognitive Function and Mental Status

NALTH recognizes the importance of capturing cognitive function and mental status as these issues can impair a patient's ability to improve. However, it is our assessment that the burden of reporting the data elements are significant relative to the value of the information for quality and case mix. The assessors' feedback agreed with our assessment as they indicated challenges with some of the data elements, specifically PHQ-2 to 9 and PROMIS®, as "burdensome for staff and patients/residents."

• **PROMIS®:** It is unclear why CMS would need to assess the frequency of these symptoms in the LTCH setting. As we noted earlier, patients in the LTCH setting are severely ill, often coming from an ICU in a STACH and require an extended inpatient stay. It is not uncommon for patients to be suffering from mental stress and depression.

Other Categories

Medication Reconciliation: NALTH recognizes the importance of reconciling medications to ensure quality of care. However, we question the length of time needed to complete the medication reconciliation data element, particularly for the LTCH setting. The assessors' feedback indicated that the assessment burden for the data element is high, but note that it takes 3.2 minutes to complete the data element. We suspect that for some settings, such as LTCHs who treat severely ill patients, the time to complete the data element is much higher. NALTH requests that RAND clarify the length of time needed to complete the data element for each PAC setting.

Global Health: It is unclear the relevance of these questions to an LTCH population, as also indicated by the assessors who noted the inappropriateness or irrelevancy of the questions to a PAC population.

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. RAND should provide clarity on the length of time spent on completing the data elements for all measures. We question how the data elements could be completed in the time reported when the assessors are experiencing challenges that could increase the amount of time to complete the data elements. We request that RAND report the length of time to satisfactorily complete the data element for all measures by PAC setting.

NALTH thanks RAND for the opportunity to share our input on the data elements being considered by RAND and CMS. LTCHs provide specialized care to severely ill patients who are high-need and high-resource users. Nontherapy ancillary services including drugs, respiratory care, ventilator services, and other miscellaneous ancillary services account for 35 percent of LTCH stay costs compared to 13 percent for SNFs and IRFs.1 LTCHs must meet the conditions of participation for acute care hospitals and have an average length of stay of 25 days or more. We believe that many of the data elements are not relevant for the LTCH, but would significantly add to provider reporting burden. Feedback from the assessors agrees with our assessment. Therefore, we ask that CMS demonstrate flexibility in its regulatory requirements and only require a data element in a setting for which it is relevant. Clearly it is important to have a common set of elements, but there are some elements that are not appropriate for all settings. Without evidence that the data improves quality or describes case mix, NALTH does not support the addition of candidate data elements to quality reporting requirements.