Standing Technical Expert Panel (TEP) for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets

Summary Report

July 16 and 18, 2024

September 2024

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Executive Summary

Under contract with the Centers for Medicare and Medicaid Services (CMS), Acumen, LLC and Abt Global, LLC convened two Technical Expert Panels (TEPs) to solicit on the development of cross-setting measure concepts for the long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs) and home health agencies (HHAs)in the areas of pain, depression, and Falls with Major Injury (FMI). This effort aimed to address some measurement gaps with the CMS' Universal Foundation[1] measures. In preparation for the cross-setting TEP, Acumen, LLC and Abt Global, LLC, together referred to as the Team, gathered the Patient and Family Partners (PFP) perspective through a listening session on June 20, 2024. Subsequently, the Team solicited feedback from the TEP over the course of three topic-driven sessions;

- pain and depression measure concepts on July 16, 2024 and
- falls with major injury measure concept on July 18, 2024.

During these sessions, panelists voiced their thoughts on the utility, feasibility, and validity of adding these measure concepts to the Post Acute Care (PAC) and Hospice Quality Reporting Program (QRP) to fill measurement gaps in the following CMS' Universal Foundation domains of behavioral and mental health and pain management. The FMI measure respecification is proposed as a means of responding to several analyses, including a recent report published by the Office of Inspector General (OIG) as well an independent peer-reviewed journal publication, that recommended CMS consider taking steps to improve the measure's accuracy by incorporating data from claims. [2,3] During each session, panelists discussed the

[1] Centers for Medicare & Medicaid Services. "Aligning Quality Measures Across CMS – The Universal Foundation" in *CMS National Quality Strategy* (CMS, Accessed April 2024), https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation

[2] Department of Health and Human Services Inspector General. Home Health Agencies Failed To Report Over Half of Falls with Major Injury and Hospitalization Among Their Medicare Patients (HHS, Accessed June, 2024), https://oig.hhs.gov/documents/evaluation/2950/OEI-05-22-00290-Complete%20Report.pdf

[3] Sanghavi, P., Pan, S., & Caudry, D. (2020). Assessment of nursing home reporting of major injury falls for quality measurement on nursing home compare. Health services research, 55(2), 201-210.

appropriateness of the potential new measure concepts, setting-specific considerations, data sources, and other topics tailored to each measure area.

During the depression measure concept discussion, panelists provided feedback on three depression measure concept options modeled after the CMS' Universal Foundation measure Merit-based Incentive Payment System (MIPS) Measure #134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan. Each measure concept uses available assessment items as the basis for specifying a different approach to reporting a depression measure and follow-up measure concept. Most panelists preferred the measure concept option that reports the screening and the follow-up plan as two separate measure components. Some panelists raised concerns around exclusions and unplanned discharges, length of stay issues, and a patient being unresponsive. Some panelists expressed concern about the guidance that will be provided to address the issue of follow up. Specifically, would be considered as a valid follow up. Further, these panelists emphasized the follow-up is not so targeted that it doesn't address follow ups that may already be in play. For example, monitoring that is already implemented. Some panelists expressed concern that the guidance will need to be applicable for the post-acute care settings in general. PFPs shared that assessing for depression is important and interventions to mitigate depression are extremely important.

During the pain measure concept discussion, panelists provided feedback on pain interference (how much of the time) versus pain intensity (how much) with a patient. There was a broad understanding of the distinction between pain interference relative to the concept of pain intensity. There were differing groups of panelist thoughts as to whether to use the item J0510 (Pain Effect on Sleep) and/or the item J0530 (Pain Interference with Day-to-Day Activities). Most thought the items shouldn't be combined into a single measure, because they are different concepts that require different clinical intervention to impact improvement. Some panelists asked about a third assessment item (Pain Interference with Therapy Activities) and were reminded that the December 2023 TEP suggested not using it. Some panelists were concerned maintenance or improvement of pain interference could be contrary to goals related to functional improvement for patients undergoing intensive therapy. Robust therapy care plans may help facilitate functional improvement but may also result in high pain scores for

many patients. This could result in patients scoring successfully on the functional improvement measures but poorly on the pain interference measure concept. This dynamic was particularly of concern in the IRF setting, where intensive therapy is common. Some panelists felt only using the sleep item (J0510) may be a way to get around this issue. Multiple panelists raised the idea that different types of patients may have different pain assessment needs (e.g. spinal injury patients, amputee phantom limb pain). Some mentioned the importance of risk adjustment and correlation to comparable factors such as acuity, functional status, and medication-seeking behaviors. Overall, panelists seemed to prefer the Pain Interference Maintained or Improved at Discharge measure concept.

At the start of the FMI measure respecification discussion, panelists shared how they would weigh the benefit of improving the accuracy of the respecified measure by incorporating claims data against the cost of greater data lag. In general, panelists agreed that improving the accuracy of the measure is an important goal but expressed concern that the resulting reporting lag associated with adding claims data would be significant, from their perspective. The discussion then turned to how a major injury should be defined. Although some panelists noted that different PAC settings may have different requirements for sending patients to a higher level of care following an FMI event, most agreed that if a fall resulted in a major injury, it would necessitate an escalation of care. Similarly, most panelists also agreed with broadening the definition of a major injury to include other injuries not explicitly mentioned in the current J1900C (Fall resulted in Major Injury) assessment item.

When the topic of attribution entered the discussion, panelists were reluctant to attribute an FMI event to PAC settings for patients who have an injury code from a subset of the major injury diagnoses clinically determined to have resulted from a fall, on their claims data. Panelists were concerned that this approach would introduce too many false positives into the measure. Even so, panelists had the opportunity after the TEP to reflect on the list of diagnoses proposed for this approach. Panelists were more comfortable using the J1800 (Fall indicated) and J1900C assessment items as in the current measure specification, and the J1800 assessment item in conjunction with any major injury code on the claim. However, some panelists voiced general skepticism towards using any information from the claims data, and

suggested further analysis be part of the ongoing respecification effort to ensure proper attribution. For the Home Health setting specifically, panelists stated the claims should occur within the stay.

Lastly, panelists were open to adding risk adjustment to the measure. None of the panelists proposed any additional exclusions, and the Patient Family/Partner representative stated that there should be no exclusions for the measure.

Acronym List

The following list defines acronyms used during the TEP and included in this report:

- ACA – Patient Protection and Affordable Care Act
- ADLs – Activities of Daily Living
- AHRQ – Agency for Healthcare Research and Quality
- AMA – Against Medical Advice
- CBE – Consensus Based Entity
- CDC – Centers for Disease Control and Prevention
- CMS – Centers for Medicare & Medicaid Services
- COVID-19 – coronavirus disease 2019
- ECHO – Experience of Care and Health Outcomes
- EOC – Experience of Care
- FMI – Falls with Major Injury
- FFS – Fee-for-Service
- HCP – Healthcare Personnel
- HCPCS – Healthcare Common Procedure Coding System
- HH – Home Health
- HHA – Home Health Agency
- HQRP – Hospice Quality Reporting Program
- ICD-10 – International Classification of Diseases, Tenth Revision
- IMPACT Act of 2014 – Improving Medicare Post-Acute Care Transformation Act of 2014
- IP/OP – Inpatient/Outpatient
- IRF – Inpatient Rehabilitation Facility
- IRF-PAI – Inpatient Rehabilitation Facility Patient Assessment Instrument
- LOS – Length of Stay
- LTCH – Long-Term Care Hospital
- MA – Medicare Advantage
- MBHO – Managed Behavioral Healthcare Organization
- MCO – Managed Care Organization
- MDS – Minimum Data Set
- MIPS – Merit-based Incentive Payment System
- NHSN – National Healthcare Safety Network
- NIH – National Institutes of Health
- OASIS – Outcome and Assessment Information Set
- OBRA '87 – Omnibus Budget Reconciliation Act of 1987
- OIG – Office of Inspector General
- PAC – Post-Acute Care
- PCP – Primary Care Provider
- PFP – Patient and Family Partners
- PFCC – Patient and Family Centered Care (Contractor)
- PHQ – Patient Health Questionnaire

- PPS – Prospective Payment Systems
- PROMs – Patient Reported Outcome Measures
- PROMIS – Patient Reported Outcomes Measurement Information System
- QRP – Quality Reporting Program
- SNF – Skilled Nursing Facility
- SSM – Summary Survey Measure
- TEP – Technical Expert Panel
- VBP – Value-Based Purchasing

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Introduction

1.1 Project Context

The Centers for Medicare and Medicaid Services (CMS) develops and maintains quality measures (QMs) for Post-Acute Care (PAC), composed of the long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs) and home health agencies (HHAs) and Hospice Quality Reporting Programs (QRPs). Abt Global and Acumen, LLC, together referred to as the Team, support CMS in these efforts.

- Abt Global develops and maintains Home Health (HH) and Hospice QRP measures, and
- Acumen, LLC develops and maintains Inpatient Rehabilitation Facility (IRF), Long-Term Care Hospital (LTCH), and Skilled Nursing Facility (SNF) QRP measures.

Measures included in the PAC and Hospice QRPs (HQRP) are designed to improve care quality and to enable Medicare beneficiaries and their caregivers to make informed choices when selecting health care providers. CMS routinely evaluates and refines the PAC and HQRP measure sets to ensure they remain parsimonious while still addressing key clinical services and dimensions of quality in each setting, as care practices change and CMS priorities evolve over time. CMS identified measurement gap areas for future measure development and maintenance using a systematic approach that relies on four principles: (i) actionability, (ii) comprehensiveness and conciseness, (iii) a focus on provider responses to payment systems, and (iv) alignment with statutory requirements and CMS initiatives such as the Universal Foundation of measures.[4] In their role, the Team convenes a standing Technical Expert Panel (TEP) to gather input on utility, feasibility, validity, and cross-setting alignment of measurement concepts. The first TEP meeting occurred in December 2023; and this cross-setting TEP will reconvene annually, or on an as-needed basis, to support the evaluation, development, and maintenance of the PAC and HQRP measurement sets until 2028. For the July 2024 TEP

[4] Centers for Medicare & Medicaid Services. "Aligning Quality Measures Across CMS – The Universal Foundation" in *CMS National Quality Strategy* (CMS, Accessed April 2024), https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation

meetings, the Team convened the TEP to discuss measure concepts that could be used to fill two of the four measurement gap areas in the PAC and HQRPs; specifically, behavioral and mental health and pain management. Respecification has been recommended for the Falls with Major Injury (FMI) measure on the basis of several analyses presented in a peer-reviewed journal publication and a report from the OIG, both of which documented substantial underreporting in the current measure. [5, 6]

1.2 Panelists

The PAC and HQRP Cross-Setting TEP included seventeen stakeholders from the PAC and hospice settings. The panelists represent a broad range of perspectives across healthcare, from physicians, administrators, policy experts, to patients and families/caregivers. Table 1-1 below provides the name, organizational affiliation, setting(s) of expertise, and conflict of interest disclosures for each panelist. Additionally, while their names are not provided in this report, the TEP included two patient and family/caregiver advocates (PFPs) who provided their unique perspectives.[7]

[5] Department of Health and Human Services Inspector General. Home Health Agencies Failed To Report Over Half of Falls with Major Injury and Hospitalization Among Their Medicare Patients (HHS, Accessed June, 2024), https://oig.hhs.gov/documents/evaluation/2950/OEI-05-22-00290-Complete%20Report.pdf

[6] Sanghavi, P., Pan, S., & Caudry, D. (2020). Assessment of nursing home reporting of major injury falls for quality measurement on nursing home compare. Health services research, 55(2), 201-210.

[7] The term "panelist(s)" is used throughout this report and is meant to represent all panelists including the PFPs. However, this report occasionally refers specifically to PFPs in order to amplify their unique perspective on particular subjects.

Table 1-1: TEP Composition

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Setting(s) of Expertise	Conflict of Interest Disclosure
Bruce A. Pomeranz, MD, MMM Chief Quality Officer	Select Medical/Kessler Institute for Rehabilitation West Orange, NJ	IRF, Quality Measurement, Clinical Researcher	No
Joseph E. Daly, PT, MBA, MHA, FACHE Executive Director	Stanford Health Care, Palo Alto, California	LTCH, IRF, SNF/NH, Acute Care Hospital, HH	No
Rebecca Montross, MS, GCAS Assistant Vice President	Allied Services Integrated Health Systems Tunkhannock, Pennsylvania	IRF, HH, Hospice, Quality Measurement	No
Janet P. McMillan, DSN, APRN, PMHNP-BC Psychiatric Nurse Practitioner/QAPI Coordinator	Forrest General Home Care and Hospice Hattiesburg, Mississippi	Acute Care Hospital, HH, Hospice, Rural Practice, Quality Measurement, Measurement Developer, Clinical Researcher	No
Barbara "Barb" Hansen, MA, RN CEO and Executive Director	Oregon Hospice and Palliative Care Association Marylhurst, Oregon	SNF/NH, HH, Hospice, Rural Practice	No
Sireesha Koppula, MD, MPH, MBA, CPE, CMQ Associate Professor of Nephrology	University of New Mexico Albuquerque, NM	LTCH, IRF, SNF/NH, Acute Care Hospital, HH, Hospice, Quality	No
Michele Cournan, DNP, RN, CRRN, ANP-BC, FNP, FARN Director of Quality Improvement	Association of Rehabilitation Nurses Chicago, IL	IRF	No

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Setting(s) of Expertise	Conflict of Interest Disclosure
Edward W. Martin, MD, MPH, FACP, FAAHPM Chief Medical Officer	HopeHealth Providence, RI	LTCH, SNF/NH, HH, Hospice	No
Jennifer L. Kennedy, EdD, MA, BSN, RN, CHC Vice President, Quality and Standards	Community Health Accreditation Partner (CHAP) Arlington, VA	HH, Hospice, Quality Measurement	No
Chloe Slocum, MD, MPH Medical Director for Quality and Safety and Attending Physician, and Assistant Professor and Director of Health Policy	Spaulding Rehabilitation – Mass General Network, and Harvard Medical School Charlestown, MA	LTCH, IRF, SNF/NH, Quality Measurement	No
Robert J. Rosati, PhD Vice President of Research and Quality	Visiting Nurse Association Health Group Holmdel, NJ	HH, Hospice, Quality Measurement, Clinical Researcher	No
Eugene A. Gonsiorek, PT, NHA, PhD Vice President of Clinical Regulatory Standards	PointClickCare Baltimore, MD	SNF/NH, Quality Measurement, Measurement Developer, Clinical Researcher	No
Amy J. Stewart, MSN, RN, RAC-MT, RAC-MTA, DNS-MT, QCP-MT Chief Nursing Officer	American Association of Post-Acute Care Nursing Denver, CO	SNF/NH, Quality Measurement	No
April Diaz RN, BS Vice President of Clinical Services	Marquis Companies Milwaukie, OR	SNF/NH	No
Rebecca Cartright, FACHE Chief Medical Officer	Midlands Regional Rehabilitation Hospital Elgin, SC	IRF, Acute Care Hospital, HH, Hospice, Rural Practice	No

Meeting Overview

2.1 Structure

The PAC and Hospice Cross-Setting TEPs addressed in this report consisted of three meetings held July 2024, see (Table 2-1). First, the Team, in coordination with Patient and Family Centered Care (PFCC) partners,[8] held a one-hour listening session with PFPs on June 20, 2024. This listening session included participants with experience as patients or caregivers in PAC and hospice settings. The session covered types of services provided by each PAC and hospice care setting and participants responded to questions relevant to quality measurement. Participants also provided feedback on the utility of the Universal Foundation measures in the PAC and HQRPs. Next, the Team held a July 16, 2024, four-hour TEP meeting to cover the Depression and Pain Interference measure area. Finally, on July 18, 2024, there was a four-hour TEP covering the FMI respecification.

[8] PFCCpartners is an organization which utilizes a network of healthcare providers, administrators, patients and caregivers in order to convene focus groups and listening sessions to design policies and programs that improve patient health and the patient experience. More information on PFCCpartners and their work can be found at: https://pfccpartners.com.

Table 2-2: Overview of Pre-TEP Meetings and TEP Agenda

Topic	Section
Patient and Family Caregiver Listening Session (June 20, 2024)	
Introductions	--
PAC and Hospice Care Goals by Setting	3.1
Discussion and Input on Future Measure Concepts and Universal Foundation Measures	3.1
Next Steps/Closing Remarks	--
Cross-setting Depression Screening and Follow-Up /Pain Interference Measures TEP Meeting (July 16, 2024)	
Welcome and Introductions	--
Overview and Background	--
Depression Quality Measure	4.1
Pain Interference Quality Measure	4.2
Wrap-up and Review	--
Cross-Setting Falls with Major Injury (FMI) Measure Respecification TEP Meeting (July 18, 2024)	
Welcome and Introductions	--
Background/Motivation	--
Considerations when Adding Claims Data Sources	4.3
Identifying FMI Events	4.3
Investigating Risk Adjustment and Additional Exclusions	4.3
Setting-Specific Considerations	4.3
Next Steps	--

2.2 Meeting Materials

Last year at the inauguration of the TEP, panelists reviewed the TEP Charter, which outlined the purpose of the TEP, and the level of commitment expected for participation (see Appendix B). For the July 2024 TEP meetings the Team distributed presentation slides for each of the two meeting dates. In addition, they distributed an FMI TEP meeting handout, and post-TEP homework including a measure exclusion review document related to the PAC Depression Screening and Follow-up Plan QM and FMI Post-TEP Workbook. The panelists were expected to complete their review within two weeks after the TEP meetings. The panelists also received a PowerPoint summary of ongoing Hospice QRP measure development work, noting that a hospice only TEP meeting is planned for fall 2024.

Summary of Pre-TEP Meetings

3.1 Listening Session with Patient and Family Centered Partners

During this hour-long listening session on June 20, 2024, the Team met with a group of nine Patient and Family Partners (PFPs) convened by PFCCpartners to gather PFP inputs on three measure concepts – i) Falls with Major Injury (FMI), ii) Screening for Depression and Follow-Up Plan, and iii) Pain Interference.[9] Participants included PFPs from different regions of the country with experience as PAC and/or hospice patients, family members of patients, caregivers, and/or healthcare volunteers. This session was held to obtain PFPs' thoughts and opinions about these measure concepts, as well as to prepare those PFPs who would be participating in the upcoming TEP meeting. First, the PFPs first received a brief introduction, where the Team shared how CMS plans to use feedback from PFPs in the future, followed by descriptions of the three measure concepts under discussion, and care goals for each PAC setting and hospice. Following the introductory presentation, PFPs attended one of three breakout sessions, predetermined by their area of interest and/or experience. Three PFPs attended the FMI session, two attended the Screening for Depression and Follow-Up Plan session, and the remaining five attended the Pain Interference session. The sessions were moderated by PFCCpartners representatives, and PFPs were asked tailored questions regarding potential measures for the specific topic of their breakout room. These questions included the importance of the quality dimension, feasibility and usability considerations for publicly reported data, and measure specification considerations.

Section 3.2 lists the key findings of the discussion, and Section 3.3 provides more detail including the introduction, specific questions asked, and subsequent discussions.

3.2 Key Discussion Takeaways

Falls with Major Injury:

[9] PFCCpartners staff who organized and led the listening session include Libby Hoy (Founder/CEO), Brittany Jackson (Community Connection Coordinator), and Lindsey Galli (VP of Programs).

- All three PFPs considered a provider's score for falls resulting in a major injury important to know before choosing a provider. One PFP explained this score would allow patients to narrow down which providers to choose from and help them select a provider(s) that would improve their desired health outcomes.
- All three PFPs supported incorporating data sources beyond provider-reported information to identify falls. One PFP emphasized that adding broader sources of information could potentially help capture fall events that happen in between services or during transfers between PAC settings.
- All three PFPs expressed support for the proposed definition of a major injury: 1) need for immediate care, 2) has the potential to result in a permanent injury or poses a risk of death, 3) results in a major reduction in function.

Screening for Depression and Follow-Up Plan:

- Both PFPs supported having providers ask questions related to mental health, including a screening for depression and follow-up plan measure. They would still be supportive even if the measure results for many providers would not be publicly available.
- Both PFPs felt existing mental health support and follow-up practices are insufficient and requested additional support for patient/residents during and after their time in PAC or Hospice.

Pain Interference:

- The majority of PFPs expressed concerns with medication management related to pain and highlighted the importance of holistic care plans.
- The majority of PFPs identified additional areas of pain interference, for which information would be useful to include in an assessment item.

3.3 Listening Session Discussion Details

To begin the session, the Team provided a brief introduction. Then, PFCCpartners split PFPs into topic-specific virtual breakout rooms. Two PFPs participated in the Depression and Follow-

up discussion, five PFPs participated in the Pain Interference discussion, and three PFPs participated in the FMI discussion.

3.3.1 Background

An overview was presented to PFPs in advance of topic specific breakout sessions that indicated how CMS plans to use PFP feedback, description of the three topic areas under discussion, and care goals by setting for PAC and Hospice.

3.3.2 Falls with Major Injury

Question 1: Would you consider a provider's score for falls resulting in a major injury a useful piece of information when selecting a provider?

- All three PFPs considered a provider's score for falls resulting in a major injury important to know before choosing a provider.
- One PFP explained, to them, a better score indicates that a provider's staff are well trained and experienced. Therefore, this score would support patients as they consider their options for PAC providers and select a provider that will improve their health outcomes.
- Another PFP, who experienced a fall that they did not think was recorded, emphasized the importance of increased provider transparency regarding this issue.
- Two of three PFPs supported developing quality measures that assess the fall prevention training provided to staff.

Question 2: The current FMI measure only uses information reported by providers about whether a fall with a major injury occurred under their care. We have observed this source of information does not capture a notable number of these events, which can raise concerns about the accuracy of the measure.

Given this observation, do you believe it would be meaningful to use additional sources of information to identify falls if CMS determines this increases the accuracy of the measure?

- All three PFPs supported incorporating additional sources of information to identify falls.

- One PFP said that gathering information related to follow-up services, including physical and occupational therapy and from the PAC setting itself, is important in identifying the extent of the injury after a fall.
- Another PFP added that sources of information need to be broader and potentially capture patient falls that happen between HH provider visits or during transfers between PAC settings.

Question 3: We define an injury as "major" if it results in one or more of the following:

a. ***Need for immediate care, which requires the skills of a physician or other services, that are usually delivered in an emergency department or hospital***
b. ***Has the potential to result in a permanent injury or poses a risk of death***
c. ***Results in a major reduction in function, such as affecting somebody's ability to walk***

Do you agree with this definition of a major injury? Are there other types of injuries that you would consider major?

- All three PFPs expressed support for this definition of a major injury and did not suggest further criteria for a major injury.

3.3.3 Screening for Depression and Follow-Up Plan

Question 1: When receiving care in a post-acute care setting, would you want a provider to ask you questions about your mood and mental health status?

When discussing your mood and mental health status, what would you like the provider to ask you about?

When, and how often, would you want this discussion to happen?

If a provider determined that a patient has signs of depression, is it important to you that the provider develop a follow-up plan for the appropriate treatments or necessary action?

- Both PFPs were supportive of having a provider ask questions about their mood and mental health status.

- One PFP highlighted the importance of asking these questions given many patients/residents have recently transitioned into a new environment and are facing uncertainty about their future.
- Both PFPs recommended specific approaches to gauge patients'/residents' mental health status.
- One PFP discussed the importance of asking patients/residents about any recent changes in their mental health status.
- The other PFP agreed, and requested providers ask targeted questions of patients/residents, including questions about difficult topics like suicidal thoughts. This PFP added that without these targeted questions, some patients may deliberately avoid these subjects.
- Another PFP suggested additional training for providers.
- One PFP requested healthcare providers assess patients'/residents' mental status every 24 to 36 hours to determine if it has changed, or if there is anything the provider can change to help support them.
- Both PFPs shared general concerns regarding the depth of follow-up patients/residents receive, and offered several recommendations regarding how patients/residents should be supported.
- One PFP highlighted the importance of identifying a support individual who is visiting the patient/resident, and the role visitors can have in improving their mood. This PFP requested providers track this information, and if a patient/resident does not have anyone who will visit, that the provider could arrange for someone to visit.
- Another PFP shared that even though many patients may receive a follow-up plan, they expressed frustration that there is rarely any additional follow-up beyond creating and sharing that plan. This PFP continued by stressing the importance of having additional

support and asking a patient/resident about their mental status after their time in acute care.

- The second PFP agreed and added the importance of each patient/resident having a multidisciplinary care team with clear follow-up and patient/resident activities to help support their mental health while in a facility.

Question 2: Based on our initial analyses, many providers would not have results for a measure that shows information about whether they developed a follow up plan. This is because a large number of providers would not have enough patients with depression to publish providers' scores on Care Compare.

Is it still important to you to have some information, even if it is only for a small fraction of all providers?

- Both PFPs agreed it was important to have this information.
- One PFP focused on the importance of having this measured, as the reporting of any program or measure is likely to help improve the situation.
- The second PFP reiterated the importance of comprehensive follow-up to support patients/residents as they manage their depression.

Question 3: As we develop this measure, if it only told you that the provider developed a follow-up plan would that be helpful?

- Both PFPs felt strongly that this would not be sufficient information.
- One PFP began the discussion by stating that plan development alone is not enough, and strongly expressed their view that current follow-up practices are insufficient to meet patient/resident needs. The second PFP agreed.

Question 4: When a provider creates a follow-up plan to address signs of depression, what do you think is important for them to consider?

- PFPs shared several specific components to include in follow-up plans, how to best interact with patients/residents,' and concluded by discussing the importance of mental health and appropriate treatment.
- One PFP recommended follow-up plans contain information on overall goals and an implementation strategy.
- Another PFP added follow-up plans should also include discussions of additional support outside of the patients'/residents' care teams, and address payment for any interventions. This PFP also shared an anecdote about the difficulty an individual faced accessing mental health care due to a clerical issue and re-iterated the importance of additional support beyond the care team.
- The first PFP then brought up the importance of how providers ask patients/residents questions about their mental health. This PFP stressed the significance of trauma-informed care, including how questions are phrased, how answers are presented, and that many patients/residents may not be truthful if the interview is not conducted in private.
- Both PFPs closed the discussion by re-affirming the importance of mental health and treatment overall, and how it is often overlooked.

3.3.4 Pain Interference

Question 1: When selecting a provider, what is important to you about how providers manage pain? What distinguishes high-quality and low-quality care when it comes to pain?[10]

- Four of five PFPs shared indicators of high-quality care: provider behaviors, specific pain management approaches, holistic care plans, and transparency in the pain management approaches providers offer.

[10] Please note that the question, "What distinguishes high-quality and low-quality care when it comes to pain?" was added during the session by the facilitator to clarify the first question.

- Two of the five PFPs highlighted other markers of high-quality care, including making patients/residents feel understood and that their providers have a genuine interest in their health outcome.
- Four of five PFPs mentioned that thorough and holistic care plans with coordination between different types of providers would distinguish high-quality care from low-quality care.
- Finally, two of five PFPs mentioned that they would like to have access to information on a provider's pain management approaches prior to a visit.
- All PFPs shared examples of care practices they believe to be indicative of low-quality care, and this discussion was primarily focused on issues of medication management. Examples included overreliance on medication (particularly opioids) without exploring other options or identifying the root cause of the pain, challenges with filling and refilling prescriptions, and a lack of empathy with patients' concerns.
- In addition, two of five PFPs recommended that providers allow for more flexibility in their medication regimens depending on the amount of expected activity in a day.

***Question 2: What types of treatments do you find helpful when you have pain? (*Due to time constraints, the facilitator did not ask this question.)**

Question 3: Would you consider a provider's score about reducing pain interference to be a useful piece of information when selecting a provider? (Due to time constraints, the facilitator did not ask this question.)

Question 4: Have any of you experienced pain interference while either being in, or caring for someone in pain in one of the post-acute care settings that were described during the opening session?[11]

- Three of five PFPs shared concerns about how pain interference is addressed in post-acute care, focusing primarily on issues with medications.

[11] Please note that the facilitator asked this question to guide the conversation towards the PAC settings discussed during the introduction session.

- One PFP raised a concern about how pain medications are taken away from patients upon admission to inpatient settings.
- A second PFP mentioned that getting treatment for pain is difficult in these settings without having family advocating on behalf of the patient. This PFP mentioned that there is often a stigma associated with pain medication, which can result in providers not doing enough to address pain.
- A third PFP shared this concern and added that the response to the opioid epidemic may be unintentionally making access to pain treatments more difficult.

Question 5: Currently we have information from patients on how often pain interfered with sleeping, therapy sessions, and day-to-day activities, and we could use this to develop a quality measure about pain interference.

(i) Do you think these three areas represent the full impact that pain interference could have on a person's daily life?

(ii) If this is the only information we can use to develop measures in the short term, would this level of information be helpful to you?

In response to part (i) of this question:

- Four of five PFPs provided examples of activities where pain often interferes, and which would be useful to include in an assessment.
- One PFP highlighted sleep, bathing, preparing meals, and sitting comfortably in the evening. This PFP, along with another, discussed pain interference with getting dressed as a possible assessment item.
- One of these PFPs also mentioned pain interference with transportation and provided the example of not being able to ride in a car due to pain.
- A third PFP mentioned being forced to make tradeoffs in activities due to pain, such as choosing between attending a family event and bathing.
- Two PFPs also mentioned pain interfering with relationships as useful to include in an assessment item.

- Finally, one PFP added that pain interference with carrying in groceries and preparing food would be important areas to assess.

Two PFPs responded to part (ii) of this question:

- Both focusing on the kinds of questions providers ask patients.
- When asked by the facilitator, one PFP confirmed that a more comprehensive pain interference measure would be preferred, even if it takes longer to get the information.

***Question 6: Some types of post-acute care settings provide intensive rehabilitation to patients with painful conditions (e.g., hip fractures). Do you think these providers should be able to reduce the impact of pain on day-to-day activities and on sleep for these patients? (*Due to time constraints, the facilitator did not ask this question.)**

***Question 7: Not all patients treated in post-acute care settings are able to respond to questions themselves. Should we allow a proxy to answer the question for the patient? (*Due to time constraints, the facilitator did not ask this question.)**

Summary of TEP Presentation and Discussion

4.1 Depression Measure Concepts

4.1.1 Summary of Presentation

The Team began this session by providing justification for the development of behavioral and mental health measures. First, depression is prevalent in post-acute care. Estimates among home health patients range from 11.1% to 23% for any depression and from 8.5% to 13.5% for major depression[12], and 28% in PAC sample[13]. Depression impacts quality of life and health status, risk for adverse outcomes including hospitalization and re-hospitalization in home health patients.[14] Some evidence suggests disparities in screening, diagnosis, and treatment of depression among racial and ethnic minority home health care patients.[15] Further evidence indicates interventions can achieve reduction in depressive symptoms or remission, and improvement in other functional and health outcomes.[16][17]

The Team then introduced background information about previous depression measures used in PAC settings, as well as the need to fill a measurement gap in the CMS' Universal Foundation area of behavioral and mental health. Experts and PFPs from prior sessions agreed that behavioral health is often overlooked in PAC; and supported measure development – including screening for depression. The PFPs from a June 20, 2024, listening session strongly supported screening and assessment, with a defined plan for follow-up, and evaluation after interventions are provided. The HH QRP previously assessed how often patients were screened

[12] Xiang X, Daniolovich MK, Tomasino KN & Jordan N. Depression prevalence and treatment among older home healthcare service users in the United States. Arch Geron Geriatr, April 2018; 75:151-157. Depression prevalence and treatment among older home health services users in the United States – ScienceDirect

[13] Siconolfi D, Edelen MO, McMullen TL et al. Standardized assessment of depression symptoms in post-acute care: A screening threshold approach. JAGS, 2022; 70(4):1023-1034. https://doi.org/10.1111/jgs.17646

[14] Lohman MC, Scherer EA, Whiteman KL, Greenberg, RL and Bruce ML. Factors associated with accelerated hospitalization and re-hospitalization among Medicare home health patients. Journals of Gerontology: Medical Sciences J Gerontol A Biol Sci Med Scie, 2018, 73(9):1280-1286. https://doi.10.1093/gerona/glw335

[15] Pickett, YR, Bazelais, KN, Greenberg, RL, and Bruce, ML. Racial and ethnic variation in home healthcare nurse depression assessment of older minority patients. Int J Geriatr Psychiatry, 2014 Nov; 29(11):1140-1144. https://doi.org/10.1002/gps.4001

[16] Choi NG, Sirey JA, Bruce ML. Depression in homebound older adults: recent advances in screening and psychosocial interventions. Curr Tran Geriatr Gerontol Rep (2013):2:16-23. Doi:10.1007/s13670-012-0032-3 ChoiEtAl2013-Depression-homebound-screening-interventions.pdf

[17] Bruce ML, Lohman MC, Greenberg RL, Boa Y, Raue PJ. Integrating depression care management into Medicare home health reduces risk of 30- and 60- day hospitalization: the Depression Care for Patients at Home Cluster-Randomized Trial. JAGS, 2016; 64(11):2196-2203. https://doi.org/10.1111/jgs.14440

for depression at start of care. The measure was topped out and removed from the HH QRP via the CY19 HH PPS Final Rule.[18] With the data elements needed for screening being required items for completion, a measure that reports only the percentage of patient/resident stays in which a depression screening was completed will be topped out quickly.

The Team also summarized input received from a prior PFP listening session (November 2023), and TEP meeting (November/December 2023) to address PAC and Hospice measurement gaps. The key goals for the meetings were to solicit feedback on (1) considering priority measurement gaps for PAC and Hospice and (2) develop of cross-setting measures for PAC and Hospice settings. The PFPs and panelists generally supported the depression and follow-up measure concept, noting that burden to patients in assessment needs to be offset with value to care. The TEP also stressed that measures should use standardized data elements where feasible. Further, the panelists shared that assessment items addressing mental and behavioral health need to be beneficial to patients and contribute value to their overall care. The PFPs shared that any added burden to participate in assessment should be beneficial to patients and contribute value to their overall care.[19]

The Team then reviewed the current assessment items on the PAC assessments. Table 4-1 shows the standardized Patient Health Questionnaire (PHQ) 2 to 9 item while Table 4-2 shows item D0160, total severity score, which was added to the PAC instruments in 2022 and 2023 to align across the four PAC settings. This is a patient interview (proxy responses are not allowed) that identifies the presence and frequency of depressive symptoms.

Table 4-1 – D0150 Patient Mood Interview (PHQ-2 to 9)

[18] CY 2019 Home Health PPS Final Rule: https://www.federalregister.gov/documents/2018/11/13/2018-24145/medicare-and-medicaid-programs-cy-2019-home-health-prospective-payment-system-rate-update-and-cy

[19] Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report, December 15, 2023. https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf-2

Item	Question	Response Values		Setting(s)
D0150. Patient Mood Interview (PHQ-2 to 9)	"Over the last 2 weeks, have you been bothered by any of the following problems?" Little interest or pleasure in doing things Feeling down, depressed, or hopeless Trouble falling or staying asleep, or sleeping too much Feeling tired or having little energy Poor appetite or overeating Feeling bad about yourself-or that you are a failure or have let yourself or your family down Trouble concentrating on things, such as reading the newspaper or watching television Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual Thoughts that you would be better off dead, or of hurting yourself in some way	Column 1. Symptom Presence 0. No 1. Yes 9. No response	Column 2. Symptom Frequency 0. Never or 1 day 1. 2-6 days 2. 7-11 days 3. 12-14 days	IRF, LTCH, SNF, HH

Table 4-2 – Total Severity Score Calculation

D0160. Total Severity Score	
Enter score	Add scores for all frequency responses in Column 2, Symptom Frequency. Total score must be between zero and 27. Enter 99 if unable to complete interview (i.e., Symptom Frequency is blank for 3 required items)

On the HH OASIS instrument (Table 4-3), the OASIS item M2401 - Intervention Synopsis captures if depression interventions are on the physician-ordered plan of care and implemented, since the most recent start of care or resumption of care assessment. This item may be used to identify follow-up when patients/residents screen positive for depressive symptoms. The not applicable response is selected only if the patient has no diagnosis of depression, and every screening conducted at or since the most recent start/resumption of care indicates the patient either has no symptoms of depression or has some symptoms but does not meet the criteria for further evaluation. This item currently only exists on the OASIS assessment tool. If a cross-setting measure for screening and follow-up is developed, this item would be adopted or modified for use in all the PAC settings.

Table 4-3 – M2401. Intervention Synopsis

M2401. Intervention Synopsis At the time of or at any time since the most recent SOC/ROC assessment, were the following interventions BOTH included in the physician-ordered plan of care AND implemented? (Mark only one box in each row)				
Plan/Intervention	No	Yes	N/A	
c. Depression intervention(s) such as medication referral for other treatment or a monitoring plan for current treatment				Patient has no diagnosis of depression AND every standardized, validated depression screening conducted since the most recent SOC/ROC assessment indicates the patient has: 1. No symptoms of depression; or 2. Has some symptoms of depression but does not meet

M2401. Intervention Synopsis At the time of or at any time since the most recent SOC/ROC assessment, were the following interventions BOTH included in the physician-ordered plan of care AND implemented? (Mark only one box in each row)				
				criteria for further evaluation of depression based on screening tool used.

The Team then reviewed three depression measure concepts (Table 4-4) with differing measure reporting calculations and the pros and cons related to each measure reporting option. The options are:

- **Option 1** reports the percentage of patients who screened positive for depression as well as had a follow-up plan, among all patients.
- **Option 2** reports the percentage of patients with follow-up among the patients who screened positive for depression.
- **Option 3** reports separately the percentage of patients screening positive for depression and percentage of patients who screened positive and had follow-up documented.

The Team sought input from the TEP regarding any clarifying questions to understand each measure option and to understand preferences between the three measure specification options presented.

Table 4-4 – Three Options for Depression Measure Reporting Calculation

Option 1	Option 2	Option 3
Reports Percent Screened and Percent Follow-up combined	Reports Percent Follow-up of those who Screen Positive	Reports Percent Screening and Percent Follow-up Separately
One score reported	One score reported	Two scores reported
Denominator is all patients	Denominator is patient screened for depression.	Part one score: Percent of patients screened for depression
Percent of total patients who screened positive for depression plus the percent who had follow-up for a positive screen.	Among patients who screened positive, the percent with follow-up	Part two score: Percent of patients who screened positive, with follow up.
PRO		
Pro: Since it includes a component of follow-up, it would not be completely topped out initially.	Provides more information in one measure	Retains the Universal Foundation measure concept which is reporting both screening for depression and documenting follow up in the plan.
CON		
Most patients screen negative for depression in PAC, which would influence the measure performance Combines two actions together (screening and follow-up) that could be difficult to interpret, including for consumers Measure may quickly top out in most PAC settings	Many providers will not have enough cases to screen positives to report the measure (must have at least 20 eligible cases for public reporting) No information on screening rates at the provider level Measure scores can change dramatically over time with small sample size	Preliminary testing in the HH/IRF/LTCH settings indicate low reportability for the second aspect of the measure.

4.1.2 Key Discussion Takeaways

- Most panelists preferred the measure concept option that reports the screening and the follow-up plan as two separate measure components (Option 3).
- Some panelists raised concerns around exclusions and unplanned discharges, length of stay issues, and a patient being unresponsive.
- Some panelists expressed concern about what is considered the guidance that will be provided to address the issue of follow up in terms of what is considered valid follow up, and that ensuring that it's not so targeted that it doesn't address follow ups that may already be in play - monitoring, for example, already implemented.
- Some panelists expressed concern that the guidance will be applicable for the post-acute care settings in general.

4.1.3 Panelist Discussion Details

The following questions were posed to the panelists:

1. ***Given the options presented, what information do you think is most important to know?***
    a. ***That a screening for depression is completed?***
    b. ***That when screening is positive for depression, follow-up is completed? (Depression interventions are on the physician-ordered plan of care, and implemented)***

2. ***Is this measure a good reflection of quality of care for addressing symptoms of depression? Why? Why not?***

3. ***What are the potential benefits and drawbacks of reporting the information one way or another?***

4. ***Do you have suggestions for how this information might be reported?***

5. ***Is this measure suitable for the hospice population?***

Review of Three Measure Options

Overall, panelists expressed support for developing the Option 3 measure concept that provides both information for screening and depression as well as a standalone component

that reflects a valid follow up, acknowledging potential challenges and the need for setting-specific considerations such as unplanned discharges.

Panelists raised concerns that option 1 and 2 mixed depression screening and follow up in the way the results would be reported, which could make interpreting the results confusing. Others noted that since the rate of screening in care settings could be over 95%, a focus on highlighting the rate of follow up for those who screened positive for depression was important. Other panelists affirmed this position via chat or in the group discussion. Option 3 was viewed as the option that would be most easily understood by the broader public. Some panelists shared that there is good precedent in the PAC settings for a measure having two components that would be reported such as the LTCH Spontaneous Breathing Trials (SBT) Measure discussed during the TEP discussion. Another panelist shared that option 3 offered the best option for ensuring screening rates would remain high while also focusing on follow up for patients who screened positive.

When the Team presented preliminary quality measure concept analyses to approximate provider-level reportability for a potential follow-up component of the measure concept, other challenges related to reporting options 1 and 2 were presented. The potential reportability of the follow-up component was approximated by assessing how many providers had at least twenty cases of patients who screened positive for depression since those who screened positive for depression are the denominator for the follow-up component of the measure concept. An approximate reportability was presented since only the OASIS assessment currently collects the M2401 follow up item. The approximate reportability statistics from 2023 national results for HH, IRF, LTCH, and SNF ranged from as low as 12% for LTCH and as high as 41% for SNFs nationally. These relatively low proxy reportability statistics for the second component was seen by panelists as additional information that reinforced the benefits of option 3.

Lack of Mental Health Care Resources

Multiple panelists noted that there are behavioral health provider capacity issues in rural and urban areas, which may affect valid follow up interventions. As such, patient accessibility to

these interventions is a factor too. One panelist raised an issue related to the national primary care shortage and its effects on PAC. They also noted that not all PAC providers have training in behavioral health. Others shared that wait times to receive treatment can be very lengthy regardless of which provider setting is requesting care for patients.

Measure Applicable to Hospice

Some panelists shared concern about whether the screening tool used in the PAC assessments would be appropriate for Hospice. They noted that the length of stay for Hospice care is relatively short and that adding the PHQ-2 to 9 would be burdensome for patients and families. One suggestion was to consider if the measure could be applicable to Hospice patients who would only have longer lengths of stay. Another panelist felt the measure was inappropriate for the Hospice setting due to the nature of end-of-life goals.

Issues Related to Screening for Depression

One panelist raised the concern about confounding factors that could affect the screening results of the PHQ-2 to 9 tool. They referenced several clinical issues that patients present with that could be confused for depression symptoms such as lack of sleep, issues with appetite, and cognitive challenges because of a health crisis. The screening tool could pick up these issues even though the main health issue is not depression.

Related to this concern, another panelist wondered if it was appropriate to screen the full provider population for depression. They asked about the potential burden of this practice and whether having most providers with very high rates of screening was useful. Many panelists in response to this issue emphasized the importance of screening the full population of patients to ensure that there was information related to this issue that could be then addressed.

Guidelines for Meeting Measure Requirements for Follow-up

Panelists discussed some considerations around how to define follow-up after a positive screening for depression. One panelist inquired if there would be a re-screening of the patients that screened positive for an intervention. The Team clarified that the focus for follow up was

on the initial follow up after screening positive instead of follow-up focused on determining the outcome of whatever care requirement was offered.

One panelist was concerned that the short PAC episode timing for some settings may inadvertently push pharmacological interventions only or in place of other evidenced based practices such as talk therapy or peer-based groups. The Team noted that the M2401 item in home health captures whether depression interventions are on the physician ordered plan of care and if they were implemented at any time during the episode. The item does not restrict what constitutes follow up to be focused on interventions that utilize medications. It was further clarified that an intervention need not be completed to be considered appropriate follow-up. Referral for care with a psychologist or psychiatrist for depression would be considered a positive outcome for this measure.

Some panelists were concerned that given wait times for patient receiving care can be as long as eight months, follow up could not be verified before the end of an episode of care. The Team clarified that the documented initiation of a referral would be sufficient to meet the criteria of follow up. The Team again emphasized that the follow up didn't require completion of an intervention. One panelist in response to this concern shared that providers can initiate behavioral care plan to support patients with a positive depression screening even while waiting for referral to a primary care provider or mental health specialist to further address a patient's needs.

Another panelist raised a concern about how to address follow up for a patient that had previously screened positive for depression and already has a plan of care in place. They were interested in determining if a new plan would be required. The Team noted that the current guidelines for the OASIS M2401 item state that continuing to monitor an active plan of care and continuing with the execution of that plan would constitute appropriate follow-up. The M2401 item explicitly refers to monitoring a plan for current treatment as an appropriate follow up. These guidelines would need to be carefully considered for application across PAC assessments, should the item be considered for use in IRF, LTCH, and SNF.

Exclusion Considerations

Multiple panelists raised the issue of PAC episode timing being too short to allow for successful monitoring and completion of the process of putting in place a clinician order for intervention related to the positive depression screen. Scenarios were discussed where providers may not realistically have the time to confirm a follow up plan was in place such as a case in which a patient is unexpectedly discharged. The group discussed that short episode may be an appropriate measure exclusion. Another scenario panelists considered for exclusion was when a patient is discharged against medical advice (AMA).

A panelist stressed that transitional hand offs and care management are extremely important to mitigate this concern.

The Measure Exclusions Review

The PAC Depression Screening and Follow-up Plan QM document was reviewed as well as current PAC setting specific exclusions and feedback requested. Multiple panelists concurred with the following exclusions:

Patient is rarely/never understood.

Given the current coding guidance, "If the patient is rarely/never understood verbal, in writing or using another method, Code D0150A1 as 9, end the interview, and skip D0160" (D0160 = ^), these stays would already not be included in the denominator.

Most panelists supported the exclusion. It was noted that although there should be this exclusion, clarity is needed regarding the measure is not a language exclusion but rather an exclusion related to a medical condition such as expressive/receptive aphasia, low level cognitive state (coma), advanced dementia, etc. Another panelist noted if the measure used the staff interview for the MDS, then the staff interview would be considered when the patient is rarely/never understood.

Length of stay (LOS < 3 days).

Length of stay (LOS) considers the Discharge Function Score measure excluding patients with a LOS of less than three days. This may depend on how "follow-up" is defined.

Panelists expressed varied support for this exclusion. Panelists supporting unplanned discharge without depression screening and follow-up noted that the patient could have a depression screening that is positive but left the facility before follow-up could occur because follow-up often takes days and weeks. It was noted that when a length of stay is shorter than three days, screening for depression should be completed by referral or communication to primary care physician to follow-up. Another panelist recommended a five day LOS for depression screening and follow-up responses. This metric may require more days than the DC function score to be a reasonable measure based on higher complexity and sensitivity of the metric overall. Support for the exclusion was also expressed as conditional depending on if AMA and LOS were to be measured together.

Patient leaves against medical advice (AMA).

Currently, should a patient leave against medical advice (AMA), the IRF-PAI is the only assessment instrument that collects this information. The AMA plus LOS could be considered.

Supporters of this exclusion measure recommended in SNF setting to add to the MDS an AMA option in the unplanned DC. This would allow for exclusion application more consistently, not only in the depression screening, but in other metrics used for SNF part A, such as TOH to patient, for example. Also noted was how the exclusion would only apply if the patient leaves AMA in the first 24 hours of stay. Follow-up could only be via communication to PCP. Another panelist also noted that should assessment occur at discharge, all unplanned transfers should also be considered for exclusion (AMA, short stay, acute care, etc.).

4.2 Pain Interference Measure Concepts

4.2.1 Summary of Presentation

In 2023, CMS organized a TEP (November/December 2023) to address PAC measurement gaps. When considering the use of standardized data elements, the TEP supported focusing on items that addressed pain interfering with activities of daily living for the patient/resident's intensity of pain. A panelist suggested that it was important to educate the individuals administering questions about pain to elicit information for pain interference with activities rather than just the level of pain. This would be a valuable step in ensuring a consistent measure. When assessing pain interference in daily activities, a panelist suggested there would be value in providers understanding the change in score between the beginning and the end of a stay. Another panelist noted that for some patients/residents, the goal of no pain is not expected or reduction in pain may not be a linear process that would be captured in a scale. It is important to measure if the pain is disruptive. The TEP noted that there is value in considering the use of pain scales but that scales are less appropriate for use in the creation of measures. At that meeting there were three key takeaways that informed our development of the pain interference measure concept:

- Panelists favored pain management measures that focused on addressing issues around pain's effect on daily activities.
- Any pain management measure should use standardized data elements where feasible while also considering setting-specific patient/resident population needs.
- Developing pain management measures should be pursued with a focus on measures that address patient goals around pain management instead of unrealistic targets of all patients experiencing no pain.

During the July 16, 2024 TEP, the Team began the pain interference measure concept session by providing justification for the development of a pain management measure. Pain is common for patients in post-acute care; it negatively affects quality of life, health care

spending, treatment outcomes and transitions in care;[20] pain interference, depression and functional limitations are related, leading to negative health outcomes, particularly among community-dwelling older adults[21]; and Interventions (virtual and in-person) that target pain interference and sleep disturbance are successful in decreasing pain interference, and can improve health outcomes[22,23,24].

The measure concept uses pain interference versus pain intensity. The panelists provided feedback on pain interference (how much of the time) versus pain intensity (how much) with a patient. There was a broad understanding of the distinction between pain interference relative to the concept of pain intensity.

The Team reviewed the current assessment items on the PAC assessments. The measure concept relies on assessment items that reflect frequency of pain interference relating to sleep (J0510. Pain Effect on Sleep) and day-to-day activities (J0530. Pain Interference with Day-to-Day Activities) that were strongly supported by panelists at the December 2023 TEP (See Table 4-5). One panelist asked why the third item (J0520. Pain Interference with Therapy Activities) wasn't used in the measure concept. The Team reiterated that the December 2023 TEP findings indicated that the TEP thought the that third item, the one that talks about pain interference with therapy activities, shouldn't be part of this measure because the interference was different than what would be assessed with these two items.

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[20] Dunbar, M. S., Edelen, M. O., McMullen, T., Bruckenthal, P., Ahluwalia, S. C., Chen, E. K., ... & Saliba, D. (2022). Development and testing of a standardized pain interview assessment for use in post-acute care. *Journal of the American Geriatrics Society*, *70*(4), 1035-1046. https://doi.org/10.1111/jgs.17653

[21] Smith, P. D., Becker, K., Roberts, L., Walker, J., & Szanton, S. L. (2016). Associations among pain, depression, and functional limitation in low-income, home-dwelling older adults: An analysis of baseline data from CAPABLE. *Geriatric Nursing*, *37*(5), 348-352. https://doi.org/10.1016/j.gerinurse.2016.04.016

[22]Brintz, C. E., Polser, G., Coronado, R. A., French, B., Faurot, K. R., & Gaylord, S. A. (2024). Are Formal and Informal Home Mindfulness Practice Quantities Associated With Outcomes? Results From a Pilot Study of a Four-Week Mindfulness Intervention for Chronic Pain Management. *Global Advances in Integrative Medicine and Health*, *13*, 27536130241236775. https://doi.org/10.1177/27536130241236775,

[23] Dumain, M., Jaglin, P., Wood, C., Rainville, P., Pageaux, B., Perrochon, A., ... & Billot, M. (2022). Long-Term efficacy of a home-care hypnosis program in elderly persons suffering from chronic pain: a 12-month follow-up. *Pain Management Nursing*, *23*(3), 330-337. https://doi.org/10.1016/j.pmn.2021.06.005

[24] Znidarsic, J., Kirksey, K. N., Dombrowski, S. M., Tang, A., Lopez, R., Blonsky, H., ... & Golubić, M. (2021). "living well with chronic pain": integrative pain management via shared medical appointments. *Pain Medicine*, *22*(1), 181-190. https://doi.org/10.1093/pm/pnaa418

Table 4-5: Standardized Pain Items added to PAC Assessments

Item	Question	Response Values	Setting(s)
J0510. Pain Effect on Sleep	"Over the past 5 days, how much of the time has pain made it hard for you to sleep at night?"	1 = Rarely or not at all 2 = Occasionally 3 = Frequently 4 = Almost constantly 9 = Unable to answer	IRF, LTCH, SNF, HH
J0530. Pain Interference with Day-to-Day Activities	"Over the past 5 days, how often have you limited your day-to-day activities (excluding rehabilitation therapy sessions) because of pain?"		

The Team reviewed preliminary item level statistics. The Team reviewed two pain interference measure concepts (Table 4-6) with differing measure specifications.

The Option 1 measure concept was called "same as or better than expected at discharge." For the Option 1 measure concept, we would use statistical modelling to predict an expected level of pain at discharge for each episode (controlling for patient characteristics, clinical characteristics, the level of pain at the start of the episode, and other factors). We would then compare the observed pain at discharge with the expected pain at discharge. The final measure would reflect the percentage of patients for each provider whose pain interference was the same as or better than expected level at discharge.

The Option 2 measure concept was called "maintained or improved compared to start of care." The Option 2 measure concept reflects whether patients reported maintained or improved pain interference at end of care, relative to start of care. Providers would be scored based on the proportion of patients that maintained or improved their pain during the episode. The measure would be risk adjusted to allow an apples-to-apples comparison across providers.

Table 4-6 – Two Options for Pain Intervention Measure Specifications

Pain Interference Measure Option 1: Same as or Better than Expected at Discharge		
Description	Percent of patients whose pain interference with sleep and day-to-day activities is at or below the expected level at discharge.	
Sample Calculation	Out of 100 patients, 80 had pain interference at discharge that was similar to or better than the expected pain interference at discharge, while the other 20 had a pain interference at discharge that was worse than expected.	
	This facility would have a score of 80% on this measure.	
Example	IRF Measure of Discharge Mobility	
	Percentage of patients who are at or above and expected ability to move around at discharge *Higher percentages are better*	39% National average 61.4%

Pain Interference Measure Option 2: Maintained or Improved Compared to Start		
Description	How often patients had pain interference with sleep and day-to-day activities that got better or was the same.	
Sample Calculation	Out of 100 patients, 70 patients had less pain interference when they went home, 5 had the same amount of pain interference, and 25 had more pain interference.	
	This provider would have a score of 75% on this measure	
Example	HH measure of patient improved mobility	
	How often patients got better at walking or moving around *Higher percentages are better* This measure was included in the quality star rating calculation	78.8% National average: 61.4% California average: 83%

Pain Interference Measure Option Comparisons	
Option One: Better than Expected Pain Interference at Discharge	Option Two: Pain Interference Maintained or Improved at Discharge
Pro	
QM reflects performance relative to expected improvement, maintenance, and decline QM allows for variability in pain frequency and takes advantage of the ordinal nature of the pain interference scale, which may lead to better-fitting risk-adjustment model Does not exclude patients who were unable to respond at admission/SOC/ROC	QM reflects improvement and maintenance, a priority outcome for CMS Directly incorporates change in pain during the episode Easier to explain maintenance and improvement rather than an expected score
Option One: Better than Expected Pain Interference at Discharge	Option Two: Pain Interference Maintained or Improved at Discharge
Con	
More difficult to explain and understand the outcome	Does not take advantage of variability in pain frequency, which may lead to less well-fitting risk-adjustment model Excludes patients who were unable to respond at admission/SOC/ROC

4.2.2 Key Discussion Takeaways

- Overall, panelists seemed to prefer (Option 2) Pain Interference Maintained or Improved at Discharge measure concept.
- Some panelists had concerns about using these items together in a measure.
- Some panelists were concerned maintenance or improvement of pain interference could be contrary to goals related to functional improvement for patients undergoing intensive therapy. Robust therapy care plans may help facilitate functional improvement but may also result in high pain scores for many patients. This could result in patients scoring successfully on the functional improvement measures but poorly on the pain interference measure concept. This dynamic was particularly of concern in the IRF

setting, where intensive therapy is common. Some panelists felt only using the sleep item (J0510) may be a way to get around this issue and the importance of sleep to pain levels.

- Some panelists mentioned the importance of risk adjustment and correlation to comparable factors such as acuity, functional status, and medication-seeking behaviors

4.2.3 Panelist Discussion Details

The following questions were posed to the panelists:

1. ***Does the TEP have feedback about using both J0510 pain effect on sleep and J0530 pain interference with day-to-day activities in a combined measure, instead of just one item?***
2. ***What feedback does the TEP have on these two measure options (Option 1 – Better than expected Pain Interference QM or Option 2 - maintained or improved Pain Interference QM)?***
3. ***Are there any additional pros and cons for the two options presented?***
4. ***What challenges to interpreting the measure score does each option present?***
5. ***Does the TEP have other ideas for measuring pain interference?***

Combining pain interference with sleep and pain interference with day-to-day activities

Some panelists had concerns about using the items for pain interference with sleep and pain interference for day-to-day activities together in a single combined composite measure. One panelist noted that these two components of somebody's day (sleep and day-to-day activities) can be drastically different. Combining them would make interventions challenging, because interventions will be different for those sleep and day-to-day activities. Two other panelists concurred. One stated that it would be helpful to see the measures shown separately, because interventions could possibly have opposing effects (with a net effect cancelling each other out). This panelist also suggested that, if measures provided duplicative information in the longer run, one could be dropped.

Relevance of pain interference for patients receiving rehabilitation therapy

Some panelists were concerned maintenance or improvement of pain interference could be contrary to goals related to functional improvement for patients undergoing intensive therapy. Robust therapy care plans may help facilitate functional improvement but may also result in high pain scores for many patients. This could result in patients scoring successfully on the functional improvement measures but poorly on the pain interference measure concept. This dynamic was particularly of concern in the IRF setting, where intensive therapy is common. Some panelists felt only using the sleep item (J0510) may be a way to get around this issue and the importance of sleep to pain levels. Some panelists through sleep as the pinnacle of importance to patients getting better.

Specifically, one panelist noted that pain interference with day-to-day activities may not be as relevant for patients in PAC receiving intensive rehabilitation therapy and where they may be in a context where they will not engage in their normal day-to-day activities. Another panelist noted that when a patient is engaged in rehabilitation therapy, such as what is commonly offered in the inpatient rehabilitation facility setting, some pain can be expected/common with the rehabilitation provided; because patients are encouraged to participate in rehabilitation therapy when able. A third panelist worried that a positive outcome on this measure (i.e., reduced pain during the PAC episode) could work against other goals consistent with quality in PAC , such as functional improvement.

Following the conversation above, the Team asked the TEP whether concerns about pain interference in PAC or the IRF setting might be different for pain interference with sleep and pain interference with day-to-day activities. Two panelists noted that pain interference with sleep would likely be more similar to the other settings, and that their concerns were more for pain interference with day-to-day activities.

One panelist wondered why the item for pain during rehabilitation therapy sessions was excluded from the measure. They believed it was important for pain to be controlled enough so that patients can participate meaningfully in rehabilitation. The panelist was surprised not to see the item for pain during rehab therapy sessions as included. The Team clarified that during the December 2023 TEP, it was conveyed the item on pain interference with therapy activities

should not be part of this measure. They recommended to focus on pain interference with activities outside of therapy. The intent of the pain interference measure concept is to focus on pain interference activities outside of therapy activities since some pain interference with therapy activities would be expected. Some panelists suggested that there may be challenges differentiating pain interference with therapy activities versus day-to-day activities in PAC, since working on therapy activities isn't limited to designated therapy time.

Importance of Risk Adjustment

Multiple panelists mentioned the importance of risk adjustment and correlation to comparable factors, such as acuity (diagnoses/ICD-10), functional status (diagnoses/ICD-10, assessment items), medication-seeking behaviors (SUD diagnoses/ICD-10).

For example, one panelist encouraged the Team to investigate differences in pain interference with day-to-day activities disaggregated data by condition. This panelist gave the example of some conditions, such as strokes and certain spinal cord injuries, where patients are expected to have pain.

Panelists expressed a preference for Option 2

Overall, the TEP expressed support for developing the Option 2 measure concept Pain Interference Maintained or Improved at Discharge. Specifically, one panelist noted that option one is like the discharge function score, which many providers have struggled to understand. The panelist further explained that, from the provider perspective, when performing quality improvement activities, it's important to understand why measures may go up or down. Another panelist noted that, when these quality measures are reported on care compare, the public needs to understand them as well. This panelist noted that the risk adjustment process, as applied in the discharge function measure, makes it hard for consumers to understand what they're actually reading.

4.3 Falls with Major Injury Measure Concepts

This section summarizes discussion regarding the cross-setting respecification of the FMI measure in the PAC and Nursing Home settings. Section 4.3.1 summarizes the content presented to the panel during this session to facilitate the discussion, Section 4.3.2 lists the key takeaways from the discussion, and Section 4.3.3 covers the TEP discussion in greater detail, including the questions presented and a summary of the responses.

4.3.1 Summary of Presentation

After providing general background and the current specifications of the FMI measure, the Team began the presentation by discussing motivation for its respecification. Three key reasons were discussed;

- First, there is some ambiguity as to what constitutes a "major injury" resulting from a fall. Respecification provides a chance to bring further clarity to this aspect of the measure.
- Second, evidence from several independent analyses points to substantial underreporting - by as much as 50% - in the current measure. On this issue, respecification provides the opportunity to incorporate other data sources such as claims information, to address underreporting.
- Third, the current measure does not have any form of risk-adjustment, since falls are considered a "never event." Never events (NEs) are a subset of patient safety incidents that are preventable and so serious that they should never happen[25]. However, recommendations from previous technical meetings have encouraged implementing risk-adjustment in the future, and therefore, respecification of the measure provides a time to explore this possibility.

After this introduction, the Team discussed tradeoffs to consider when adding claims data into the current measure. The key benefit of introducing information from claims data is that it

[25] Identifying a list of healthcare 'never events' to effect system change: a systematic review and narrative synthesis - PMC (nih.gov)

can address data accuracy concerns such as underreporting. Specifically, claims data can resolve this by capturing cases in which the provider filling out the assessment is unsure or unaware of the severity of an injury sustained from a fall or could be choosing to not report an FMI to avoid a poor score on the measure. However, when introducing information from claims there are other considerations, including which patient populations should be represented from this data source. Restricting to a narrower set of patient populations, such as only Medicare Fee-for-Service (FFS) beneficiaries, could reduce the number of stays captured when compared to a broader set of patients represented in the existing measure. In turn, this could impact provider-level reportability for the measure. However, reflecting a more extensive set of patient populations, such as Medicare Advantage (MA) and Medicaid enrollees, could impose additional data lags to when the measure results become publicly available, since claims on these beneficiaries takes longer to become available for analysis.

Next, the Team discussed several factors regarding how best to identify FMIs through the combination of assessment and claims data that would be available with a respecified measure. This was broken up into two sections.

1. **The first section focused on the "major injury" component of an FMI.**
   After a conceptual discussion to gather input on what the requirements should be for defining a major injury resulting from a fall, the Team presented two options for consideration. Option 1 would be to stay with a narrower definition focusing only on the types of injuries explicitly mentioned in the assessment item used to construct the current measure: bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematoma. Option 2 would be to develop a more comprehensive definition that would include the injuries listed in Option 1 as well as other injuries, including non-fracture bony injuries, organ trauma, crush injuries, spinal injuries, lacerations and open wounds, and soft tissue trauma (e.g., compartment syndrome and rhabdomyolysis). The key benefit of the comprehensive definition is that it would acknowledge clinically severe injuries that are not currently explicitly included

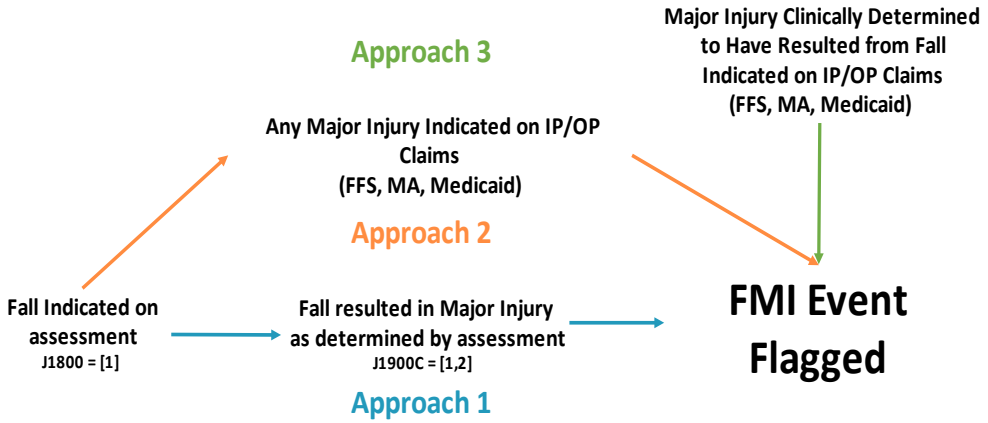
in the current assessment item, although it would require further work to refine the current assessment item, including additional education and outreach.

2. **The second section focused on the "Fall" component of an FMI.**

   The Team presented results from several analyses showing that the initial proposal for how to identify an FMI on claims data – requiring both a major injury diagnosis *and* an external cause of injury code indicating a fall – would be impeded by poor coding practices of falls codes within the inpatient/outpatient setting. Since PAC facilities have no control over the coding done by other providers, relying on the falls code to be present on the claim could unfairly penalize certain facilities through no fault of their own.

Thus, due to the unreliability of falls coding on claims data, the Team recommended several alternative approaches for incorporating information from this data source to identify an FMI. These are presented in Approaches 2 and 3 in Figure 1 below.

Figure 1: Potential Approaches for Identifying a Falls with Major Injury (FMI) Event



Approach 1, described in Figure 1 above, reflects the current FMI specification. Approach 2 proposes to use the claim to identify a major injury, and use the "any fall" item on the assessment (J1800 = [1]) to identify that a fall occurred. This would have the advantage of

capturing a number of additional FMI events currently not included under Approach 1, and in a manner that would be unlikely to identify "false positives" (cases in which an FMI didn't actually occur). However, because Approach 2 would still be relying on the assessment, it would likely undercount the true number of FMIs to some extent, particularly in cases where the provider was intentionally choosing not to report the event.

The Team then presented Approach 3 which proposes to count a subset of major injuries as an FMI whenever the diagnosis is present on the claim, regardless of whether or not a fall was indicated on the assessment. This would have the benefit of having a higher rate of capturing FMIs. However, this approach does have some drawbacks. In particular, it could be challenging to come to consensus on the subset of diagnoses to be included within this approach, and even with consensus on the subset of diagnoses, there would still likely be instances of false positives.

The Team stressed these approaches should be considered in an additive manner, rather than mutually exclusive: Approach 2 would also include FMIs identified under Approach 1, and Approach 3 would also include FMIs identified under Approach 1 and Approach 2. This section concluded with discussion from the panelists regarding the three approaches.

For the next section of the presentation, the Team touched on several other factors for TEP input. This included whether to explore risk adjustment, whether to consider additional exclusions for the measure, and whether the Home Health (HH) setting should factor in a distinct set of timing considerations given the additional challenges associated with attribution in this setting.

Finally, the Team concluded the presentation with a discussion of next steps, including future analyses it will conduct and present at future TEP meetings based on the feedback from this TEP discussion. The Team also alerted the panelists to a workbook that was sent after the meeting where they could provide additional input on the more detailed sets of codes used for the claims-based definition of an FMI.

4.3.2 Key Discussion Takeaways

- When introduced to the concept of incorporating claims information as part of a respecified FMI measure, several panelists voiced concerns related to the increased lag in public reporting that would likely be imposed. Although there was recognition that the measure's accuracy was vitally important for the measure's aim of making cross-provider comparisons, any decision that leads to an increase lag in reporting should not be taken lightly.
- When asked to conceptualize the necessary elements for a fall to have resulted in a "major injury," there were no substantial objections to the three concepts presented by the Team. Panelists seemed to agree that instances which required an "escalation in care" were a good starting point since subsequent functional limitations directly attributable to the fall may be more difficult to identify. Repeatedly, panelists generally approved the decision to broaden the definition of a major injury to include other injuries not explicitly mentioned in the current J1900C assessment item, although there was a sense that some of the categories such as soft tissue trauma would need to be selectively refined. The Team previewed the workbook to be completed after the TEP meeting which would allow for panelists to provide more detailed feedback on specific ICD-10 diagnoses to be included in the major injury definition.
- The issue of attribution to the PAC facility when incorporating claims information was a key discussion point throughout the meeting. Several panelists brought up issues with hospital coding practices related to external cause of injury codes that aligned with the Team's suggestion not to rely on the presence of these on acute care claims. However, for some panelists this seemed to translate to general skepticism about using any information from claims data. They suggested additional information documenting analysis steps taken to ensure appropriate attribution may be beneficial as part of the ongoing work for respecification. A broader group was more skeptical about using the Approach 3, although some of the concerns could be allayed once panelists had the opportunity to refine the set of diagnoses to be utilized under this approach. The decision during the meeting was to allow panelists to reflect further on the approaches

proposed by the Team. The post-TEP workbook provides panelists the opportunity to rank the approaches in the order of their preference.

- On the issue of adding risk-adjustment to the measure, panelists were widely receptive to exploring this refinement and proposed several clinical factors to consider in addition to the preliminary list suggested by the Team.
- When asked, none of the panelists posed any additional exclusions to the measure. The Patient Family/Partner representative strongly stated there should not be any exclusions for the measure.
- Panelists representing the HH setting strongly felt there should not be a window allowed between an episode's end and a claim indicating a major injury, as was posed by the Team. Rather, they believed a brief period at the beginning of the episode should be considered exempt for reporting an FMI, since this is often a period where services such as patient education are only just beginning to be implemented

4.3.3 Panelist Discussion Detail

The following questions were posed to the panelists:

1. ***When considering incorporating MA and Medicaid claims on top of Medicare FFS, do the benefits in addressing underreporting while capturing a broader patient population outweigh potential additional reporting lags?***
2. ***Are there other considerations for conceptualizing what constitutes a "major injury" resulting from a fall, particularly with regards to patients in a nursing home or PAC setting?***
3. ***Are panelists comfortable with adopting a more comprehensive definition of a major injury? And are there other categories of injuries that could be incorporated?***
4. ***At a high-level, which of the three approaches for calculating an FMI that were presented seems most attractive to panelists?***
5. ***Does the TEP agree with the recommendation to explore risk adjustment? If so, are there are particular patient characteristics that should be specifically considered?***
6. ***Are there other exclusions that should be considered, either in the numerator or denominator? If so, could these instead be worked in to a potential risk adjustment model?***
7. ***Should additional time between the start date of an IP/OP claim and the end of the stay apply in the HH setting?***

Concerns with Additional Data Lags

There appeared to be broad consensus among panelists that the current situation with lags in public reporting is already a concern, so introducing additional lags by adopting claims into a hybrid measure would be costly. Issues such as a patient having incorrect information on a facility that has been making improvements, or an insurer using outdated data when it sets rates, were both cited.

On the possibility of selectively including some sets of claims data where additional lags would not be so severe, such as using only Medicaid FFS, there was concern from at least one panelist, who cited the growing share of the population covered by Medicare Advantage as a reason to not selectively omit this patient population from a hybrid measure.

However, it was notable that as the conversation began to shift towards existing inaccuracy in the measure from issues of underreporting, some providers began to reconsider the strength of their initial objections. Although, others still appeared skeptical of the finding of broad underreporting in the current measure, stating their belief that there were few "bad apples" and that most providers would go back and submit a corrected assessment if appropriate. These panelists generally remained resistant to the idea that claims data would be able to provide sufficient benefit in addressing underreporting and improving the measure's accuracy that would be worth the cost of additional data lags.

Attribution of a Fall to the PAC Provider

The main concern panelists voiced with bringing in claims information when constructing the measure was the issue of attribution to the PAC facility. The conversation initially focused on coding of falls on claims data through external cause of injury codes (although the Team did clarify that it agreed with not using these codes). Nevertheless,

there were several possibilities mentioned where attribution could still be challenging, such as cases where the PAC provider discovers a previously undiagnosed injury that existed prior to the patient's fall. Despite the PAC and Hospice QRP pointing to the additional pathway under Approach 2 as a solution to issues of attribution with claims, along with using only those diagnosis codes that reflect an initial encounter for an injury, several panelists continued to voice skepticism that attribution could be appropriately dealt with in a hybrid measure.

When considering attribution to HH providers and the addition of time between HH discharge and admission to an IP/OP setting, panelists were not in favor of this approach since claims data might be linked with a HH episode even when the IP/OP claim period did not overlap with the actual HH episode dates. Rather, they suggested that an exclusion period might be more appropriate. For example, if a claim with a major injury was found during the first several days of a HH episode, it might be more appropriate not to count it as an FMI against the HH provider, since the first few days of an episode reflect the gradual process of establishing services, interventions, and patient education. Panelists noted that it would not be reasonable to expect that these early interventions could immediately prevent a fall.

One suggestion related to attribution was the development of a pre-reporting confidential feedback process whereby facilities could challenge cases in which an FMI was identified through the claim and remove the event from the measure calculation.

At least one panelist voiced doubts that the measure complexities that would be introduced by claims data might outweigh the benefits that the simplicity of the original assessment-based measure offers.

Concerns About False Positives

When presenting the approaches for how to introduce claims information to the measure, a number of panelists expressed concerns with methodological changes that would introduce false positives to the measure, particularly given its current low prevalence. This issue could be especially magnified for small providers that have low case

counts in the denominator and false positives could cause the measure to fluctuate wildly across reporting periods. However, at least one panelist did note that the error in the current measure could occur in both directions, suggesting there may already be false positive to consider with the assessment-based Approach 1.

Regarding Approach 2, one possibility raised by a panelist was if a fall with a non-major injury occurred, followed by a subsequent event causing a major injury that resulted in a hospital stay. Another panelist felt that given these possibilities, Approach 2 should be modified to require the fall to be reported on both the assessment and the claim. However, the bulk of concern with false positives appeared to lay with the additional pathway specified under Approach 3, since it did not utilize any information about a fall, and that the impact of non-fall exclusions (e.g., disease-related fractures or motor vehicle accidents) appears small. Although many of these concerns brought up by panelists could be dealt with by refining the major injury and the diagnoses included in Approach 3 (e.g., excluding pathological fractures from consideration), the Team reiterated that panelists would have the opportunity to provide final input on this concern when they were asked to rank the three approaches.

Meeting the Threshold of "Major Injury"

Most panelists were receptive to the conceptual requirements for an injury resulting from a fall to be considered "major." Specifically, if the injury results in a need for immediate care, the injury has the potential to result in an irreversible deficit or death, and the injury results in a major deficit in function. Several panelists were initially open to the idea of only immediate care being required, but others noted that there could be inconsistency in how PAC providers make this determination, where some will send a patient out immediately for testing after a fall out of abundance of caution, while others will try to treat certain types of injuries in place. The group began to coalesce around the idea that a fall resulting in some sort of escalation of care would be a reasonably good starting point (assuming this resulted in a "positive finding" of major injury during this care).

Panelists seemed largely receptive to the idea of adopting a more comprehensive definition that would consider issues like spine injuries, crush injuries, and others as "major" in nature. There was more skepticism about the broader category of Soft Tissue Injury and there was brief discussion about diagnoses such as compartment syndrome and rhabdomyolysis. The Team again noted that panelists would have the opportunity to further refine this category, or ultimately drop it altogether, in the Post-TEP workbook.

The Patient Family Advocate in attendance argued that any fracture should be considered major in nature, citing a personal experience where a minor fracture resulted in a deficit in function, and many of the other panelists signaled agreement with this viewpoint.

On the question of whether multiple minor injuries could be considered major, the group agreed in theory that this could be a possibly, assuming it resulted in the outcomes put forth in the conceptual definition of major injury. However, operationalizing this through claims, and in a manner that would be consistent across settings, appeared to be a challenge, with several IRF and HH providers noting that multiple bruises and a skin tear could be a frequent outcome that might or might not lead to an escalation in care.

Adopting Risk Adjustment, but not Additional Exclusions

Despite general agreement that FMIs should be considered as a "never event," panelists were broadly supportive about the suggestion to include risk adjustment for the measure, agreeing with the assertion that FMIs are more likely to happen to particular sets of patients. There did not appear to be concern about whether or not to include social risk factors in a risk adjustment model, but at least one panelist mentioned they would like to see prior history of fall included, even though it was flagged as not possible in the LTCH measure.

Several additional covariates were mentioned as worth considering in a risk adjustment model: medications (i.e., a dichotomous measure of "receiving 5 or more"), signs and

symptoms of delirium, having a visual deficit, and being an amputee with phantom limb sensations.

There were no suggestions for additional excisions, and the Patient Family Advocate stated his belief that no patients should be excluded.

Next Steps

The input provided by these TEP meetings will help CMS and the Team prioritize next steps in specifying or respecifying the Pain Interference, Depression and Follow-up, and Falls with Major Injury measure concepts.

Appendix

Appendix A: Cross-Setting TEP Team

The Team is multidisciplinary and includes individuals with knowledge and expertise in the areas of measure development, payment policy, health economics, clinical practice, public reporting, pay-for-performance, value-based purchasing, and quality improvement. The following individuals from the project team attended the TEP:

Acumen Team:

- Sri Nagavarapu, Co-Project Director
- Stephen McKean, Co-Project Director
- Sana Zaidi, Project Manager
- Ellen Strunk, Clinical Lead
- Kris Mattivi, Clinical Lead
- Nathaniel Anderson, Policy Associate
- Josh Coopersmith, Data and Policy Analyst
- Lidya Tadesse, Data and Policy Analyst
- Hugh O'Connor, Data and Policy Analyst

Abt Team:

- Amy Cowell, Project Director
- Alrick Edwards, Home Health Project Manager
- Jennifer Riggs, Home Health Clinical Lead
- Nicole Keane, Home Health Clinical Lead
- Mariana Sarango-Cancel, Home Health and Hospice Health Equity Lead
- Sean McClellan, Home Health Quality Measure Development and Analytic Lead
- Marisa Roczen, Home Health Data Analytic Associate
- Derek Hoodin, Home Health Data Analytic Associate
- Eric Lammers, Home Health Data Analytic Associate
- Zinnia Harrison, Hospice Project Manager
- Brenda Karkos, Hospice Clinical Lead
- Thomas (T.J.) Christian, Hospice Quality Measure Development and Analytic Lead

Appendix B: TEP Charter

All panelists formally ratified the TEP Charter, which outlines the TEP objectives, requirements, scope of responsibilities, and estimated meeting schedule. The full text of the TEP Charter is below:

Project Title:

Standing Technical Expert Panel (TEP) for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets

TEP Expected Time Commitment and Dates:

Selected nominees will serve on a standing committee to support the evaluation and maintenance of PAC QRP measurement sets for the Inpatient Rehabilitation Facility (IRF), Long-Term Care Hospital (LTCH), Skilled Nursing Facility (SNF), Home Health (HH) and Hospice settings. Selected nominees can expect to be contacted on an annual, or as needed, basis for up to five years.

Selected nominees will be expected to attend the first TEP meeting in November 2023 (specific dates to be determined) and a pre-TEP webinar approximately 1-2 week(s) prior to meeting date. All meetings will be held virtually.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC and Abt Associates Inc. (hereafter referred to as Acumen and Abt) to support the development, evaluation, and maintenance of quality and cost measures for use in the Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) and Nursing Home Compare as mandated by the Patient Protection and Affordable Care Act (PPACA) of 2010 and the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Acumen's contract name is "Quality Measure & Assessment Instrument Development & Maintenance & QRP Support for the Long Term Care Hospital, Inpatient Rehabilitation Facility, Skilled Nursing Facility, Quality Reporting Programs, &

Nursing Home Compare." The contract number is 75FCMC18D0015, Task Order 75FCMC19F0003. Abt's contract name is "Home Health and Hospice Quality Reporting Program Quality Measures and Assessment Instruments Development, Modification and Maintenance, & Quality Reporting Program Oversight Support." The contract number is 75FCMC18D0014, Task Order 75FCMC19F0001.

As part of its measure development process, Acumen and Abt convene groups of stakeholders and experts who contribute direction and input during measure development and maintenance.

Project Objectives:

PAC QRPs aim to characterize provider performance across various dimensions of care. With the support of Acumen and Abt, CMS refines and develops QRP measures to ensure that (a) Medicare beneficiaries and their caregivers have high-impact, meaningful performance data to assist in making informed healthcare decisions; and (b) providers have actionable information to guide performance improvement efforts without being overburdened by reporting requirements. Acumen and Abt are convening this TEP to evaluate the measurement sets across the IRF, LTCH, SNF, HH, and Hospice setting, with a focus on identifying measurement gaps, and ensuring measures align with CMS program requirements and goals. Acumen and Abt will organize a panel of stakeholders from a broad base of expertise (e.g., clinical, policy and program, measure development, technical, etc.) and solicit their input regarding the PAC and Hospice QRP measurement sets and future measure concepts. This input will be used to inform new measure development and maintenance of PAC and Hospice quality measures.

Technical Expert Panel (TEP) Objectives:

The TEP will provide input and guidance on the evaluation of the PAC and Hospice QRP measurement sets and inform new measure development and maintenance of PAC and Hospice quality measures. Specifically, we will seek guidance on the following:

- *Input on the framework used to assess PAC and Hospice Measurement gaps;*
- *Input on new measure domains and future measure concepts identified;*

- *Input on the alignment of the PAC and Hospice QRPs and Hospice QRPs with the Universal Foundation Measures*

TEP Requirements:

A TEP of approximately 12-15 individuals will provide guidance on concepts related to the evaluation of the PAC measurement sets and new measure development and maintenance of PAC and Hospice quality measures. The TEP will be composed of individuals with differing areas of expertise and perspectives, including but not limited to:

- *Clinical experts with knowledge or experience working in the IRF, LTCH, SNF/NH, HH and Hospice settings;*
- *Other subject matter experts or independent researchers with expertise or working knowledge of IRF, LTCH, SNF/NH, HH and Hospice settings;*
- *Clinical experts or independent researchers with expertise in healthcare disparities;*
- *Independent researchers or representatives from consumer stakeholder organizations;*
- *Measure development experts;*
- *Quality improvement specialists;*
- *Patient/Family (Caregivers) who received care in a PAC and Hospice setting;*
- *Clinical experts or independent researchers with expertise using the assessment tools or Medicare claims data.*

Scope of Responsibilities

The TEP's role is to provide input and advice to Acumen and Abt on the evaluation and maintenance of the PAC and Hospice quality measurement sets, new measure development and maintenance of PAC and Hospice quality measures. Holding a TEP allows Acumen and Abt to leverage the panelists' experience, which increases the clinical and face validity of the measures and helps to maximize the number of critical dimensions of care being addressed. As such, panelists are expected to attend all meetings and to notify Acumen and Abt should circumstances change where they no longer wish to participate. Acumen and Abt will work with panelists to schedule meetings at least one month in advance. In the case of last-minute

scheduling conflicts, Acumen and Abt ask panelists to provide any feedback or thoughts on the materials and discussion questions for Acumen and Abt to share with the panel. In some circumstances, a panelist may designate a temporary replacement from their organization. Any substitute is subject to approval, as we strive to ensure a balanced and diverse composition.

If a panelist is no longer able to meet membership commitments, Acumen and Abt will identify a replacement from the nominees from the most recent call for nominations or by working with the panelist's affiliated professional society to nominate another panelist. Upon identification of an appropriate alternate panelist, any TEP obligations will transfer to the replacement panelist.

Guiding Principles:

Participation as a panelist is voluntary and the measure developer records the participant's input in the meeting minutes, which the measure developer will summarize in a report that they may disclose to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. TEP organizers will answer any questions about confidentiality.

All potential panelists must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, there is no intent for the disclosure requirement to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other panelists, and CMS about the source of panelists' perspectives and how that might affect discussions or recommendations.

Input, advice, and recommendations by panelists will be considered by the measure developer. An appointed TEP chair will help facilitate discussion and build consensus.

Estimated Number and Frequency of Meetings:

Selected nominees can expect to be contacted on an annual, or as needed, basis for up to five years.

The first TEP will be scheduled to meet virtually in ***October and November 2023:***

- ***One-hour*** *pre-TEP webinar in* ***October 2023*** *(specific date to be determined). This meeting serves as an orientation and will be held approximately 1-2 week(s) prior to the TEP meeting date.*
- ***Two four-hour*** *TEP Meetings in* ***November 2023*** *(specific dates to be determined based on availability of selected panelists.)*
- *If necessary and feasible, follow-up webinars will be held to present decisions made on TEP input.*

Date Approved by TEP:

TBD

Panelists*:*

Bruce A. Pomeranz, MD, MMM, Chief Quality Officer

Joseph E. Daly, PT, MBA, MHA, FACHE, Executive Director

Rebecca Montross, MS, GCAS, Assistant Vice President

Janet P. McMillan, DSN, APRN, PMHNP-BC, Psychiatric Nurse Practitioner/QAPI Coordinator

Barbara "Barb" Hansen, **MA, RN,** CEO and Executive Director

Sireesha Koppula, MD, MPH, MBA, CPE, CMQ, Associate Professor of Nephrology

Michele Cournan, DNP, RN, CRRN, ANP-BC, FNP, FARN, Director of Quality Improvement

Edward W. Martin, MD, MPH, FACP, FAAHPM, Chief Medical Officer

Jennifer L. Kennedy, EdD, MA, BSN, RN, CHC, Vice President, Quality and Standards

Chloe Slocum, MD, MPH, Medical Director for Quality and Safety and Attending Physician, and Assistant Professor and Director of Health Policy

Robert J. Rosati, PhD, Vice President of Research and Quality

Eugene A. Gonsiorek, PT, NHA, PhD, Vice President of Clinical Regulatory Standards

Amy J. Stewart, MSN, RN, RAC-MT, RAC-MTA, DNS-MT, QCP-MT, Chief Nursing Officer

April Diaz, RN, BS, Vice President of Clinical Services

Rebecca Cartright, FACHE, Chief Medical Officer