



**Falls with Major Injury Measure  
Public Comment Summary Report  
Including Verbatim Comments**

**Outcome and Assessment  
Information Set (OASIS) Quality  
Measure Development and  
Maintenance Project  
Option Year 1**

November 14th, 2016

*Prepared for:*  
**Centers for Medicare &  
Medicaid Services**  
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## Project Title:

IMPACT Act of 2014 Cross-Setting Quality Measure: Falls with Major Injury

### Dates

- Dates of public comment period: September 19, 2016 through October 14, 2016
- The public comment summary was made on November 14, 2016.

### Project Overview

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 was signed into law on October 6, 2014.<sup>1</sup> This Act requires Post-Acute Care (PAC) providers to report standardized patient assessment data and quality measure data to the Secretary.

The Centers for Medicare & Medicaid Services (CMS) is aligning quality measurement with PAC assessment instruments. Current federal assessment instruments are setting-specific and contain assessment items with varying concepts, definitions, and measurement scales. The move towards standardized assessment data elements facilitates cross-setting data collection, quality measurement, outcome comparison, and interoperable data exchange.

The Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates to develop a cross-setting post-acute care measure for the quality measure domain – incidence of major falls. The contract name is Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (contract number HHSM -500-2013-13001I, Task Order HHSM-500T0002).

In this measure, “Falls with Major Injury” is defined as:

The percentage of patients who experience one or more falls with major injury (defined as bone fractures, joint dislocations, and closed-head injuries with altered consciousness, or subdural hematoma) during the home health stay.

### Project Objectives

- Introduce falls with major injury data elements for capturing data for a falls with major injury measure in the incidence of major falls domain for home health patients.
- Refine measure specifications.
- Identify setting-specific needs/concerns/barriers for capturing falls with major injury information using the data elements. Gather feedback on importance, feasibility, usability and potential impact of adding falls with major injury data elements for quality measurement as new items to the OASIS item set.
- Identify additional guidance required for the implementation in home health (HH).

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<sup>1</sup> <https://www.govtrack.us/congress/bills/113/hr4994>

## Information About the Comments Received

- Web site used: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>
- Public comments were solicited by the following methods:
  - Posting on CMS Public Comment website
  - Email notification to relevant stakeholders and stakeholder organizations
- Volume of responses received: CMS received 21 comment letters in total (the vast majority of letters contained more than one point). These comment letters represent a mix of perspectives, including providers and clinicians in the home health (HH), those in academic/research organizations with technical expertise in quality measurement and advocacy groups representing HH areas.

## Stakeholder Comments—General and Measure Specific

### Clinical Importance

Multiple commenters expressed support for a cross-setting falls measure. Commenters cited the issue of falls as an important concern and noted that the impact and burden of falls and fall-related injuries among patients enrolled in home health settings contribute to increased hospitalization, morbidity, and mortality. One commenter noted that falls are the leading cause of fatal and non-fatal injuries for older adults and that falls can adversely affect safety and independence and generate economic and personal costs.

**Response: CMS appreciates the commenters' support for the clinical importance of the quality measure concept and the goals of measurement in this domain.**

### Setting-specific Comments

Numerous commenters noted that the HH setting is one in which patients may be alone for long periods of time when the clinician isn't in the home. Many commenters noted that community-based care such as HH is different than facility based care, making it difficult to assessing patient falls.

#### 1. Unwitnessed Falls

Five commenters noted that unwitnessed falls occur when the HHA staff are not in the home. One questioned if these would be captured in the Falls measure and whether they should be counted in the Falls measure.

#### 2. Home Health is not a 24/7 service

Four commenters noted that the HHA isn't with the patient around the clock, unlike facility-based care. Additionally, one commenter noted that the average amount of time that a home health agency is in the home is only 30 days, depending on the clinical, functional and service needs of the patient, adding that this short period of time also limits the scope of falls prevention strategies that could be implemented. Numerous commenters felt that HH clinicians' responsibility is to assess the patient's environment as is.

**Response:** CMS appreciates the commenters' feedback regarding the nature of patients in the HH setting. To examine fall risk and prevalence among the cohort of home health patients targeted for this measure, we conducted analysis using 2015 OASIS data. In nearly 32% of the 5.3 million episodes with relevant data, the patient had a history of falls, defined as two or more falls, or any fall with an injury, in the previous 12 months. For the more than 6.1 million episodes where the patient received a multi-factor falls risk assessment using a standardized, validated assessment tool, the patient was found to have falls risk 93% of the time. Additionally, there were nearly 100,000 instances documented where a patient required emergency care for an injury due to a fall. Currently, no HH measure exists to capture the falls with major injury. Falls resulting in a "major" injury are currently defined as bone fractures, joint dislocations, and closed-head injuries with altered consciousness, or subdural hematoma. This type of injury would require treatment in other levels of care (doctor's office, emergency room, hospitalization). Our environmental scan found that implementing effective falls prevention interventions can positively impact emergency department use and readmission.

### 3. Burden

Multiple commenters requested for existing OASIS items to be removed if new items are to be added to the assessment set, to minimize burden.

**Response:** CMS appreciates the commenters' concerns about the impact of the changes to OASIS on HHAs and vendors. The implementation and reporting of measures to support the requirements of the IMPACT Act are defined within the Act. For HHAs, data collection to support the cross-setting Falls measure must begin on or before 1/1/19. CMS intends to make the changes to OASIS regarding the items used in the Falls measure as part of a scheduled OASIS update and make the guidance on new items available before the update to allow providers and vendors preparation time. Additionally, CMS will use rule-making to propose any changes to the existing HH Quality Reporting Program, and OASIS, and to specify the timeline for any measure set changes, including IMPACT Act measures.

### 4. No mandated Home Health Falls Policy

One commenter offered that there is no federally-mandated HH policy for a uniform process of reporting patient falls by an HHA, adding that agencies vary with regard to their policies on completing occurrence reports for falls.

**Response:** CMS appreciates the commenter's note about HH policy. There is precedence for measure data collection without a federal-wide policy dictating the scope.

## Risk Adjustment

Ten commenters suggested the need for risk-adjusting the measure. Several commenters suggested that there may be unintended consequences without risk adjustment such that HHAs may be hesitant to accept higher falls' risk patients for fear of the financial impact. In turn, this may potentially limit the value of comparison amongst HHAs. One commenter noted that, while measuring the number of falls without risk adjustment would enable clear understanding of the incidence of falls, it is critical to bear in mind that provider incentives will be affected because CMS plans to begin public reporting of this measure in January 2021.

Five commenters offered variations of the following variables to be included in a risk adjustment model:

- Age
- Comorbidity
- Disability
- Diagnosis
- Functional ability/number of therapy visits
- Cognition
- Vision and Hearing
- Caregiver support
- Patient's living environment
- HHA size

According to one commenter, without risk adjustment, the measure could present a distorted correlation between the rate of major injuries related to falls and the quality of care provided by the agency. This would limit comparisons among home health agencies.

Additionally, multiple commenters suggested risk stratification and HHA (confidential) feedback reports to allow for quality improvement.

**Response: CMS appreciates the commenters' concerns about risk adjustment. The application of risk adjustment, as stated by the IMPACT Act, is "as determined appropriate by the Secretary" under section 1899B(c) (3) (B) of the Act. While we acknowledge that patient characteristics that elevate risk for falls, such as cognitive impairment, vary across the HHA population, falls with major injury are considered to be "never events" and as such are not to be risk adjusted. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. The need for risk assessment, based on varying risk factors among residents, does not remove the obligation of providers to minimize that risk**

The numerator, denominator, and exclusions definitions provided to the TEP in 2015 are virtually identical to the specifications we proposed to adopt for this measure, and did not include risk adjustment. The majority of TEP members were supportive of not risk-adjusting the measure. For more information on the 2015 TEP, please visit <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf> .

## Measure Testing

Four commenters expressed concern that the final measure hasn't undergone testing and validation in the home health setting.

**Response: CMS appreciates this feedback. CMS is in the midst of comprehensive field testing of OASIS items to include all new and modified items, to further assess the reliability, feasibility, and validity of several items, including the items used in this measure. This field test will further inform guidance to home health clinicians on completing the Falls items.**

## Measure Specifications

### 1. Numerator

One commenter recommended that the specific HHA Medicare patient population be clarified in the final measure information.

### 2. Denominator

The same commenter also noted that the approach to configuring the denominator differed from the NQF #0674 measure exclusions for LTCHs, IRFs, and SNFs in that it excludes patients for whom the occurrence of falls was not assessed.

**Response: CMS acknowledges the reviewers' comments and notes that the foundation and intent of the quality measure is harmonized across PAC provider settings. The HH Falls measure will be an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).**

### 3. Item assessment timing

One commenter recommended, that the new J1800 Item asked at discharge regarding having any falls with major injury be asked at the Start of Care (SOC) with a time frame of 6 months. The commenter recommended that the question could read, 'Has the patient had any falls within the past 6 months?' If the response was yes, the clinician would proceed to the question, 'Number of falls in the past 6 months' (same coding of 0 – none; 1-one; 2-two or more) and A, B, C as listed on J1800.

**Response: CMS appreciates the feedback on item assessment timing. The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since start or resumption of care (prior assessment). Because the home health measure is based on patient-level data reported at discharge, the item (J1800) for the OASIS data set asks whether the patient has experienced any falls since admission/resumption (prior assessment).**

### 4. Alternative measure constructs

One commenter recommended that the falls with major injury proposal be a bundled composite measure that includes structure and process components. They noted that the structure measure specific to a fall-related injury should include assessment of fall injury risk and fall injury history upon enrollment in home health care services, and evidence of an injury prevention plan of care developed by the HHA. Multiple commenters suggested including the cost and/or level of care impact by requiring such information as emergency medical response, exact types of major injuries to include diagnoses and ICD-10 codes. Another commenter suggested it may be more important to combine a process measure of developing a falls prevention plan of care and an outcome measure of improving, staying the same or worsening the incidence of falls with major injury.

**Response: CMS appreciates the suggestions for alternative measure constructs. Currently the only NQF-endorsed HH Falls measure is in reserve status due to its limited variability. This HH Falls measure will be an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). CMS notes that the foundation and intent of the quality measure is harmonized across PAC provider settings.**

## 5. Changes in measure specifications

Multiple commenters raised the concern about non-adherent HH patients. One provided the example of when recommendations include removing loose rugs, the patient has the right to refuse to remove loose rugs, or if they are removed, the patient may return the rugs after the home health staff leave the home. Other examples include situations of hoarding or lack of proper lighting, especially at night when a patient needs to use the bathroom. One commenter suggested including additional factors to the measure to address non-adherence, lack of able informal caregivers, and patient refusal to accept the fall prevention plan and the associated potential consequences. They also noted that coding for J1900 could be modified to add additional codes, such as Injury (except major, with patient adherence) and Injury (except major, with patient non-adherence or refusal), and likewise for Major Injury. This would address the concerns on non-adherence or patient refusal and would provide data agency-specific and nationwide on issues that require additional education for home health patients. Another commenter suggested expanding the “no injury” definition to include, “no change to the patient’s mental or cognitive status in addition to behavior change. Noting behavior change does not necessarily address mental status, consciousness, or alertness, all of which can be impacted by a fall and should be considered in whether the fall has caused injury.”

**Response: CMS appreciates the suggestions for alternative measure constructs. As this measure will be an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), satisfying the domain in section 1899B(c)(1)(D) of the Act, the Incidence of Major Falls, the intent of the quality measure is standardization across PAC provider settings.**

### **Not just “major” but all injuries**

Three commenters offered that that all types of falls should be collected by HHAs not just “major” falls as defined by the Falls measure. One additionally noted that the presence and severity of a fall-related injury is not always immediately diagnosed at the time of the fall, but may be discoverable days or months after the fall, such as with hip fractures and delayed onset subdural hematoma.

**Response: CMS appreciates the feedback about types of injury for data collection. This measure assesses falls with major injuries, satisfying the domain in section 1899B(c)(1)(D) of the Act, the Incidence of Major Falls. We believe this domain mandates a quality measure related to falls with major injury.**

### **Definition of a fall**

One commenter noted that CMS should reevaluate the definition of a fall.

**Response: CMS appreciates the feedback and is committed to providing appropriate guidance in the clinician assessment manuals.**

### **Not National Quality Forum (NQF) endorsed**

Two commenters offered that the Falls measure is used in other Post Acute Care (PAC) settings and NQF endorsed in these settings, but not for home health.

**Response: CMS has defined that the quality measure addressing the incidence of major falls is an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). This measure is a cross-setting measure that we believe**

satisfies the measure required under section 1899B(c)(1)(D) of the Act domain, Incidence of Major Falls. CMS plan to seek NQF endorsement of this cross-setting measure in the home health setting in the future.

#### **Measure Focus on prevention instead of injury**

Four commenters stressed the importance of a falls prevention measure that focuses on prevention of falls not just falls once they've happened.

**Response: CMS appreciates the feedback on the importance of falls prevention measurement. This measure is a cross setting outcome measure that we believe satisfies the measure required under section 1899B(c)(1)(D) of the Act domain, Incidence of Major Falls. Currently, there is no measure that specifies the number of falls with major injury, and this gap would be addressed by the application of the cross-setting standardized measure.**

#### **Shared accountability to prevent falls**

One commenter noted the need for shared accountability in falls prevention, citing the example of the need for a physician or nurse practitioner to modify medication orders that may increase falls risk. Similarly, they noted that medication treatment of osteoporosis to prevent injuries associated with falls could not be done by home health agencies alone.

**Response: CMS appreciates the feedback on shared accountability. We will take this consideration under advisement as we evaluate all comments. As with other healthcare settings, home health agencies evaluate patient safety (including risk of falls) on admission and throughout an episode through patient assessment and care planning. Our environmental scan found evidence of successful interventions to reduce falls among community-dwelling older adults, including risk assessment and mitigation.**

#### **It's a "patient" not a "resident"**

Three commenters noted that this measure currently calls out "resident" in its title though it is a "patient" in the HH setting.

**Response: CMS appreciates the feedback about appropriate terminology defining the setting. As this an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), resident is listed in the measure title. However, since we are applying the measure in the home health setting, patient is used in our measure specifications and language.**

#### **Unintended Consequences**

One commenter reported concern about an unintended consequence of the measure would be that HHAs become less willing to take on high falls risk patients for care and/or not keeping these patients on for services if they became prone to falling. They noted that non-adherence to care plan interventions is a significant factor in falls prevention and that the measure as currently outlined may result in some providers selectively choosing which patients to serve in order to avoid high fall risk patients, leaving those patients without care options at home.

**Response: CMS appreciates the feedback on potential unintended consequences. In the 2015 National Impact Assessment of CMS Quality Measures Report, there was insufficient evidence**



**regarding teaching-to-the-test, cherry-picking, and gaming in the nursing home and ambulatory setting.<sup>2</sup> However, we will continue to monitor trends to identify potential unintended consequences, and would do so as well if this measure is adopted in CMS programs.**

### **Preliminary Recommendations**

We do not plan on making further changes to the measures' methodology in the immediate future, with the exception of changes to item wording. However, we will take under consideration suggestions for further testing. To the extent possible, we will also incorporate suggestions received during public comment on the implementation of these measures. Specifically, we will plan to:

- Continue measure testing and development
- Submit measures to the MAP for inclusion in the rulemaking cycle;
- Submit measures to NQF for review and endorsement; and
- Conducting pilot testing to assess feasibility, reliability, and validity of assessment data.

### **Overall Analysis of the Comments and Recommendations**

The comments and feedback received provided useful input for the development and implementation of the falls measure.

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<sup>2</sup> CMS. 2015 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report. March 2015. (136-151)

## Verbatim Comments

\* The comments included here are verbatim and the content was not changed or edited excepting out of scope comments

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization	Recommendations/ Actions Taken
1	9/16/2016	This commenter is looking for assistance with a medical insurance plan.	Jama Phillips	phillipsjama68@gmail.com		Out of scope
2	9/22/2016	This commenter offered some causes for falls in the elderly and concerns with MDS 2.0 RAP section.	DELORES L. GALIAS, RN RHIT	delores234@att.net		Out of scope
3	9/23/2016	<p>Please consider the following:</p> <ol style="list-style-type: none"> <li>1. Not all falls (with our without major injury) are witnessed by home health staff. A patient may fall during a time when no home health visit occurs. How will this be captured in the new measures? Should it be?</li> <li>2. Agencies vary with regard to their policies on completing occurrence reports for falls. Some complete reports for all witnessed, found and reported falls. Some complete reports for witnessed or found on floor or flat surface only.</li> <li>3. While we all agree that the incidence of falls should be as low as possible, it is not reasonable to hold agencies accountable for what happens when they are not present.</li> <li>4. Please consider taking away some items that are currently reported and not just add more items to the already complex OASIS data set. For example, very little is done with IADLs. Consider eliminating those from the data set.</li> </ol>	<p>Donna Goodwin            Operating Officer            (Contract)            Sunshine Health            Facilities, INC            509-991-1001</p>	DonnaG@shhc-llc.com	Nursing Home	
4	9/23/2016	This commenter is looking for assistance with a medical insurance plan.	Karen Mckee	ksquaredmckee@gmail.com		Out of scope

ID	Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization	Recommendations/ Actions Taken
5	9/24/2016	<p>Thank you for the opportunity to submit public comment on this measure. I am a Nurse Scientist and Patient Safety Expert with expertise in fall and fall injury prevention across the continuum of care, having lead national fall and fall injury prevention initiatives throughout the Department of Veterans Affairs and beyond.</p> <p>This Quality Measure is important. However, I would recommend that the data elements be expanded to include: Any fall with injury - not just major injury, as minor injuries due a fall in older adults can be grave. So, I think the measure should report all falls with injury.</p> <p>OASIS should also capture if the injury resulted in an ER visit and or hospitalization.</p> <p>The scenario being a patient who falls and hits his/her hip - no evidence of injury other than pain; goes to the ER, the initial X-ray is negative; the patient returns, home, continues to have pain upon standing, and a repeat X-ray in 2 months reveals the hip fracture. Or, a subdural one month later...</p> <p>OASIS should capture the extend of injuries: such as on a lateral fall: sprained wrist, abrasion to the elbow, head strike on the floor, and hip strike on the floor: the point is that patients' trauma and injury upon a fall is extensive, and should be captured, and not reduced to simply "major fall" that does not profile the extent of injury and trauma.</p> <p>The impact is to profile the burden of injurious falls to the vulnerable population in home health to the patient, family, home care and post fall management, along with morbidity and mortality.</p>	<p>Pat Quigley, PhD, ARNP, CRRN, FAAN, FAANP            Patricia A. Quigley, Nurse Consultant, LLC</p>	<p>pquigley1@tampabay.rr.com</p>	<p>Nurse Consultant</p>	

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6	10/7/2016	<p>Falls with Major Injury (OASIS) -1 Percent of Residents or Patients Experiencing One or More Falls with Major Injury.</p> <p>This measure reports the percentage of patients who experience one or more falls with major injury (defined as bone fractures, joint dislocations, and closed-head injuries with altered consciousness, or subdural hematoma) during a home health stay.</p> <p>The “No Injury” designation from a fall during a health home stay includes within its definition “no change in patient’s behavior is noted after the fall.” We recommend that this definition be expanded to include no change to the patient’s mental or cognitive status in addition to behavior change. Noting behavior change does not necessarily address mental status, consciousness, or alertness, all of which can be impacted by a fall and should be considered in whether the fall has caused injury.</p>	<p>Samantha O’Leary   Director, Medicaid Policy UnitedHealthcare Community &amp; State (cell) 732-371-9600   (office) 703-824-1796</p>	<p>sam.oleary@uhc.com</p>	<p>Health insurance company</p>	
7	10/7/2016	<p>In this measure, Falls with Major Injury is defined as: The percentage of patients who experience one or more falls with major injury (defined as bone fractures, joint dislocations, and closed-head injuries with altered consciousness, or subdural hematoma) during the home health stay. The quality measure addressing the incidence of major falls is an Application of the NQF endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). The data for the measure will be submitted via the OASIS Data Set for home health patients. New OASIS items will need to be added. This quality measure will be based on data reported for two items The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since admission/ resumption of care (prior assessment). Because the home health measure is based on patient-level data reported at discharge, the item (J1800) for the OASIS Data Set asks whether the patient has experienced any falls since admission/resumption (prior assessment). If the answer to J1800 is no, the next item (J1900) is skipped. If the answer to J1800 is yes, the next item</p>	<p>Peter Notarstefano   Director, Home &amp; Community-Based Services   LeadingAge   P 202.508.9406   LeadingAge.org</p>	<p>pnotarstefano@LeadingAge.org</p>	<p>Stakeholder</p>	

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		<p>(J1900) asks for the number of falls with a) no injury, b) injury (except major), and c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury).</p> <p>Of these, only Multifactor Fall Risk Assessment conducted for All Patients who Can Ambulate is NQF endorsed, and this measure has been placed in reserve status due to limited variability. Some literature suggests there may be variability in the effectiveness of a fall prevention intervention depending on the type of provider delivering it, specifically in environmental assessment and home modification fall prevention interventions. Also, this measure is not risk-adjusted or stratified.</p> <p>LeadingAge comments to Project Objectives:</p> <p>Introduce falls with major injury data elements for capturing data for a falls with major injury measure in the incidence of major falls domain for home health patients.</p> <p>Current Home Health Quality Improvement measures that address falls include the following:</p> <ul style="list-style-type: none"> <li>• Multifactor Fall Risk Assessment Conducted for All Patients who Can Ambulate</li> <li>• Falls Prevention Steps in Plan of Care</li> <li>• Falls Prevention Steps Implemented for All Episodes of Care</li> <li>• Emergent Care for Injury Caused by Fall</li> </ul> <p>We all know that if you can't measure it, you can't improve it. It is not difficult to collect data on rates of falls with injury. The problem is to determine what falls with injury were preventable within the scope of the services provided under the Medicare home health benefit. In a capitated type of program, such as a Program of All Inclusive Care for the Elderly (PACE) the provider could pay for and implement environmental changes that were determined to be one of the causes of a fall resulting in major injury in a home setting. Medicare home health is a skilled intermittent care service</p>				

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		<p>that has limited resources to address some of the potential causes of a fall. We agree the nurse and occupational/physical therapist should be working on fall prevention practices with the patient and caregiver, and the fall prevention strategies may include some environmental changes. Implementing those environmental changes may be beyond the scope of services provided by the home health agency. It may be more important to combine a process measure of developing a falls prevention plan of care and an outcome measure of improving, staying the same or worsening the incidence of falls with major injury. Another barrier is that the average amount of time that a home health agency is in the home is only 30 days depending on the clinical, functional and service needs of the patient. This short period of time also limits the scope of falls prevention strategies that could be implemented. The Medicare Improvement standard which states that an individual does not need to show improvement to receive the home health services is another challenge when implementing a falls with major injury measure. An individual with Parkinson's disease who is at a point where medication is no longer improving gait may benefit from PT in order to prevent further deterioration in range of motion, but the individual may still have a propensity to fall.</p> <p>Refine measure specifications.</p> <p>Falls in the elderly rarely have a single isolated cause, but typically occur because of the interaction of multiple intrinsic and extrinsic contributing factors. For example, a medication may cause an individual to have blurred vision to fall on a throw rug in a hallway. There are multiple possible causes of the fall- the medication, the loose throw rug, possibly the lighting in the hallway. The time of day or night may also be a factor. Let's say it is 2:00am, and the individual rushes to the bathroom from her bedroom and falls possibly because of the diuretic that she is taking or possibly because of a condition resulting in urge incontinence. The environmental issues of a loose throw rug and a poorly lit hallway could also</p>				

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		<p>be a factor.</p> <p>Identify setting-specific needs/concerns/barriers for capturing falls with major injury information using the data elements.</p> <p>Measuring falls with major injury in a nursing home versus falls with major injury in a home setting have two different sets of needs/concerns and barriers due to the amount of staff time allocated to the patient during the 24-hour period, and the physical environment within the nursing home and the individual's home. The home health agency is addressing the incidence of major falls domain in the framework of the home where the person resides and will continue to reside after the episode of care ends. The nursing home under the Medicare benefit is addressing the incidence of major falls domain in the framework of both preventing a fall with major injury in the nursing home setting, as well as considering what is needed for the patient to safely live in their own home after the episode of care ends.</p> <p>Gather feedback on importance, feasibility, usability and potential impact of adding falls with major injury data elements for quality measurement as new items to the OASIS item set.</p> <p>OASIS C-1 ICD10 already includes (M1033) Risk for Hospitalization- History of falls. There are other sections of OASIS C-1 ICD10 that tie into the Cause of Falls etiology, such as (M1400) When is the patient dyspneic or noticeably Short of Breath?; (M1810) Current Ability to Dress Upper Body safely (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps; (M1820) Current Ability to Dress Lower Body safely (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes; (M1830) Bathing: Current ability to wash entire body safely. Excludes grooming (washing face, washing hands, and shampooing hair); (M1840) Toilet Transferring: Current ability to get to and from the toilet or bedside commode safely and</p>				

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		transfer on and off toilet/commode; and (M1850) Transferring: Current ability to move safely from bed to chair, or ability to turn and position self in bed if patient is bedfast.				
8	10/11/2016	<p>McKesson appreciates the inclusive nature of the measure, which allows for the Outcome and Assessment Information Set (OASIS) items and related measures to be potentially used for other adult patients and populations that receive services in a community setting. We believe this inclusiveness will help to decrease the potential burden of additional measures for non-Medicare populations.</p> <p>With regards to the ICD10-CM codes that would meet the intent of “Major Injury” (defined as a bone fracture, joint dislocation, closed-head injury with altered consciousness, or subdural hematoma), McKesson recommends that CMS clarify whether the expectation for ICD-10 codes that support “Major Injury” be documented in a specific area and provide the list of codes relevant to post acute (home health) care.</p>	<p>Matt Shiraki Director, Public Policy Corporate Public Affairs (415) 983-7109 office (415) 866-8654 mobile</p>	matt.shiraki@mckesson.com	Vendor	
9	10/12/2016	<p>The AGS supports the definition of one or more “Falls with Major Injury” and the numerator for this quality measure. Since many interventions that reduce the number of falls may also compromise mobility, we agree that it is important to focus only on the most serious injuries that affect function.</p> <p>We are concerned that home health agencies are held accountable for this quality measure yet the implementation of some components of multifactorial interventions proven to successfully reduce the number of falls are often outside the purview of home health providers and/or require additional action. For example, while home health agencies may review medications associated with fall-related injuries, modification would require a physician or nurse practitioner. Similarly, medication treatment of osteoporosis to prevent injuries associated with falls could not be done by home health agencies alone. Therefore, we believe that there needs to be shared responsibility.</p> <p>Lastly, we urge CMS and Abt Associates to reference “Long-Stay Nursing Home Care: Percent of Residents Experiencing</p>	<p>Anna Mikhailovich Fax: (605) 361-5175</p>	amikhailovich@americangeriatrics	Stakeholder	



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		One or More Falls with Major Injury,” a similar quality measure designed for long-term care facilities (accessed here), to determine how closely the measures align.				
10	10/13/2016	<p>SDAHO and our home health members across the state of South Dakota, we agree that prevention of falls for patients is an important issue for preventing major injuries in the home. We also believe that home health providers play a valuable role in the assessment of risk and implementation of interventions to prevent falls. We also agree that the use of occupational therapists can be an effective influence to delivering fall prevention interventions. We do, however, have concerns regarding the proposed measure.</p> <p>Many home health patients reside in less than ideal settings, such as cluttered homes with unsafe floors. Some homes do not have universal design incorporated to address handicapped accessibility needs, such as narrow doorways to hallways and bathrooms. While the home health providers are able to teach and advise, patients are free to accept or reject provider recommendations. For example, if recommendations include removing loose rugs, the patient has the right to refuse to remove loose rugs, or if they are removed, the patient may return the rugs after the home health staff leaves the home. Other examples include situations of hoarding or lack of proper lighting, especially at night when a patient needs to use the bathroom.</p> <p>Non-adherence to care plan interventions is a significant factor in falls prevention. Our concern is the data measure as currently outlined may result in some providers selectively choosing which patients to serve in order to avoid high fall risk patients, leaving those patients without care options at home. Home health service is not a 24/7 service, thus relying on the patient and the informal caregiver support system to assist in implementing a safe environment to prevent falls and injuries. Medicare home health is a skilled intermittent care service that has limited resources to address some of the potential causes of a fall. Implementing certain</p>	<p>Jen Porter, Ed.D., M.B.A.  Vice President, Post-Acute Care  South Dakota Association of Healthcare Organizations (SDAHO)  3708 W Brooks Place  Sioux Falls, SD 57106  Direct: (605) 789-7530  Office: (605) 361-2281  Cell: (605) 261-8004</p>	jen.porter@sdaho.org	State trade association	

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		<p>environmental changes, such as wider doors/hallways and updated lighting are beyond the scope of services provided by the home health agency.</p> <p>In the measure descriptive information, 2.4 details that the data for the measure will be collected using the OASIS Data Set and that new OASIS items will need to be added. Since additional OASIS items will need to be added for this measure, we recommend including additional factors to the measure to address non-adherence, lack of able informal caregivers, and patient refusal to accept the fall prevention plan and the associated potential consequences. Coding for J1900 could be modified to add additional codes, such as Injury (except major, with patient adherence) and Injury (except major, with patient non-adherence or refusal), and likewise for Major Injury. This would address the concerns on non-adherence or patient refusal and would provide data agency-specific and nationwide on issues that require additional education for home health patients.</p>				
11	10/14/2016	<p>As noted in the draft specifications, this measure is required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act. A similar measure has already been applied to three other post-acute care (PAC) settings. Our primary concern with the direction of this—and similar measures implemented under the auspices of the IMPACT Act—is that it is not clear how reporting on the number of falls with major injury will improve quality. Instead, it seems prevention of falls, through the use of clinicians (e.g., audiologists), will lead to improved quality and efficiency of the care Medicare beneficiaries receive in post-acute settings.</p> <p>Audiologists play a critical role in identifying patients at risk for falls due to balance and other similar issues in a variety of health care settings, including those covered by the IMPACT Act. We believe it is critically important that—in addition to identifying patients who have experienced a fall with major injury—the Centers for Medicare &amp; Medicaid Services (CMS) and its contractors (e.g., Abt Associates) should identify a</p>	<p>Sarah Warren, MA            Director, Health Care            Regulatory Advocacy            American Speech-            Language-Hearing            Association (ASHA)            2200 Research            Boulevard            Rockville, MD 20850            301-296-5696</p>	swarren@asha.org	Stakeholder	

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		<p>mechanism to recognize those at risk for falls in order to develop a plan of care to reduce the patient’s ongoing risk of a fall. As a result, our comments will be focused on both the role of audiologists in identifying patients at risk for falls and also the importance and value of prevention of falls for patients, health care facilities, and payers, such as Medicare.</p> <p><b>Role of Audiologists in Identifying Patients at Risk for Falls</b></p> <p>Audiologists perform the screening, assessment, diagnosis, and management of persons with balance system disorders, often as part of an interdisciplinary team. Professional roles and activities in audiology include clinical/educational services (diagnosis, assessment, planning, and management); prevention and advocacy; and education, administration, and research. See ASHA's Scope of Practice in Audiology (ASHA, 2004).</p> <p><b>Falls Prevention Critical to Improving Quality of Care</b></p> <p>As noted in the draft measure specifications, prevention of falls is critical as approximately one-third of people over the age of 65 will experience at least one fall annually. Prevention of falls reduces health care spending and utilization, trips to emergency rooms, and readmissions to hospitals among other benefits. More importantly it maintains a patient’s quality of life and helps them remain as independent as possible. Measuring the incidence of falls is inadequate as opposed to measuring efforts taken to prevent falls for which audiologists have specialized training.</p> <p>We recommend that CMS transition to an approach of assessing efforts made to prevent falls rather than assessing the number of falls that a patient has experienced. Currently, there are two measures reported by audiologists under the Physician Quality Reporting System (PQRS), which may ultimately be used under the Merit-Based Incentive Payment System (MIPS). These measures are Measure #154: (Falls) Risk Assessment and Measure #155: (Falls) Plan of Care. Quantifying falls may be one method of evaluating the efficacy of fall-risk assessment and risk reduction, but other</p>				

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		measures to drive quality care—such as those referenced above—are critically important.				
12	10/14/2015	<p>I am sending in comment on the Quality Measure Falls with Major Injury as the Public Policy and Advocacy Coordinator of the Wound Ostomy Continence Nursing Society. I am also employed as a Clinical Specialist in home care.</p> <p>The issue of falls at home is an important concern, we know by the literature that many falls at home are related to urinary continence issues. The concern with this measure as written is that there is no risk adjustment language included in the measurement description. Home care services are intermittent and episodic in nature. Some of the major obstructions in being able to control falls at home are co-morbidities and the environmental, social, psychological and patient directed choices which contribute to fall at home. If the measurement is to be true to the reality of what can be changed and unchanged in the home for fall prevention, risk adjustment would be more valuable in measuring true outcome.</p>	<p>Kate Lawrence, MSN RN CWOCN ET/WOC NURSE Rutland Area VNA &amp; Hospice 802.770.1682</p>	katel@ravnah.org	HHA	
13	10/14/2016	<p>ARN affirms that patient outcome quality measures must be measured and monitored to evaluate, advance, and compare patient safety programs in health care. The impact and burden of falls and fall related injuries among vulnerable home-bound patients enrolled in home health settings contribute to increased hospitalization, morbidity, and mortality. Therefore, ARN asserts that the CMS impact measure “Major Falls” is insufficient to evaluate, compare, and contrast the burden of falls experienced by this patient population.</p> <p>ARN believes the following:</p> <ol style="list-style-type: none"> <li>1). Falls of all severity levels of injury should be reported, as is required in hospitals and long-term care settings. Among frail, geriatric, and /or disabled populations, minor injuries can result in grave consequences such as loss of function and loss of life.</li> <li>2). We recommend the falls with major injury proposal be a</li> </ol>	<p>Kara R. Gainer Senior Research &amp; Policy Analyst District Policy Group (202) 230-5649 phone (202) 842-8465 fax</p>	Kara.Gainer@dbr.com	Stakeholder	

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		<p>bundled composite measure that includes structure and process components. The structure measure specific to a fall-related injury should include assessment of fall injury risk and fall injury history upon enrollment in home health care services, and evidence of an injury prevention plan of care developed by the HHA.</p> <p>3). CMS should include the level of health care and cost burden of the fall by requiring the reporting of emergency medical response to the home, emergency room admission and/or hospital admission. Such process of care measures would increase validity and reliability of the fall and fall injury impact measure.</p> <p>ARN believes it is important to monitor and track falls which occur during the home health episode in an effort to improve patient outcomes. Nurses play a critical role in ensuring the safety of our patients as well as the quality of care that is delivered. However, ARN has concerns with the accuracy of the proposed quality measure, Falls with Major Injury in the home health setting, given that it is based on patient-level data reported to home health staff at the time of discharge. For the quality measure to properly serve its purpose, the accuracy of patient data is critical, and while patients' recollection may be reasonably accurate, it is likely subject to distortion.</p> <p>Moreover, we have concerns that documentation of falls with major injury may be prone to inaccuracies, which has previously been observed in the nursing home setting. As noted in the February 13, 2015 CMS Survey and Certification Memorandum (S&amp;C 15-25-NH), CMS conducted a voluntary pilot that was focused on coding practices and their relationship to resident care in nursing homes. During the pilot study, CMS found that nursing home staff, in an effort to capture falls and the level of injury sustained, often failed to accurately denote the level of injury following a fall. The presence and severity of a fall-related injury is not always immediately diagnosed at the time of the fall, but may be</p>				

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		<p>discoverable days or months after the fall, such as with hip fractures and delayed onset subdural hematoma. The inclusion of structure, process, and outcome measures aligns with the National Quality Forum’s Patient Safety Measures for hospital, long-term care, and primary care settings.</p> <p>4). Risk-adjust falls and falls with injury by age, comorbidity, and disability. It is well known that falls frequently occur in the home health setting. ARN has stated in previous comments the many confounding factors that contribute to a fall, repeat falls, and resulting injuries. A quality measure that merely tracks falls with major injury fails to provide an adequate comparison under a pay-for-performance model. One HHA may admit more patients who are prone to falling due to various risk factors, such as difficulty walking, use of certain medicines, or home hazards or dangers, than another HHA. Because the falls with major injury measure is not risk-adjusted by population, we have concerns that the measure will be better at identifying the HHAs that have the highest and lowest rates of falls resulting in major injury, which may inaccurately portray the quality of care being furnished.</p> <p>To properly measure and compare patient safety in the home health setting, ARN strongly believes that any measurement of falls and injury should be expanded, as previously discussed. We encourage CMS and Abt Associates to consider the development of a falls measure in the home health setting that is “with or without injury” and “assisted or non-assisted.” This should be tracked by preventable falls (patient-related or environment- and other-related) and non-preventable (patient condition like fainting).</p>				
14	10/14/2016	<p>VNAA supports the use of a measure that addresses major falls, consistent with the IMPACT Act, but has several concerns about the falls measure as described in the public comment document.</p> <p>The measure on which the proposed home health falls measure is based is currently endorsed by the National Quality Forum (NQF) for use in long-stay nursing homes. It is</p>	<p>Joy M. Cameron Vice President, Policy and Innovation Visiting Nurse Associations of America 2121 Crystal Drive,</p>	jcameron@vnaa.org	Stakeholder	

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		<p>not endorsed by NQF for use in home health agencies, nor is it endorsed for skilled nursing facilities (short stay), inpatient rehabilitation facilities and long-term care hospitals. Although there is a measure related to falls that is reported to individual home health providers, it is a different measure and it is not endorsed by NQF (and it is not publicly reported). Moreover, home health care is community-based, not facility based care. The measure described by Abt refers to “residents” (see the title of the public comment document), but in home health there are no “residents” because the patients are in their own homes, rather than in an institution. Understanding the unique nature of home health’s setting in the community is critical. If a home health patient falls, more often than not that fall is not witnessed by a home health care professional. A fall with major injury could occur when the patient is home alone, or even in the physician’s office, but it would still be considered a fall with major injury for purposes of this measure if it occurred during a home health episode. Care in the community is different from institutional care because the patient is in his or her own environment, with accompanying risks. Although the community and the home pose unique challenges for patient care, those risks are also important to navigate if the patient is to achieve self-management and transition back to the community.</p> <p>The question is whether it is possible for this measure to be comparable across post-acute care settings when in home health care there usually is nobody present to witness and document the fall and the consequent injury at the time of the incident. VNAA is therefore concerned about the reliability of the data collection for this measure as it applies to home health care. If a goal is for this measure to be meaningful across settings, standardization is key. At the very least, appropriate adjustment should take into consideration the very different nature of home health in comparison to the facility-based settings.</p> <p>Furthermore, VNAA is concerned about the impact of this</p>	<p>Suite 750, Arlington, VA 22202  P: 571-527-1536    F: 571-527-1521</p>			

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		<p>falls measure because it is neither risk adjusted nor risk stratified. Higher risk patients will certainly be at greater risk of having a fall with major injury. Although measuring the number of falls without risk adjustment would enable clear understanding of the incidence of falls, it is critical to bear in mind that provider incentives will be affected because CMS plans to begin public reporting of this measure in January 2021. In addition, if payment is eventually tied to this measure, provider incentives will change still more. In the absence of risk adjustment, providers will be punished for accepting patients at higher risk of falls and adverse selection of patients is likely to become an issue. It is therefore critical for this measure to be risk adjusted. VNAA recommends that any falls measure that is publicly reported be risk adjusted.</p> <p>Notwithstanding, VNAA recognizes the need to have transparent information on falls so that home health agencies can engage in quality assurance and performance improvement initiatives. Ideally, agencies should treat any fall with major injury as a sentinel event, focusing their efforts on understanding the root cause of such incidents so that they can prevent similar falls in the future. In order to provide agencies meaningful information for quality improvement efforts,</p> <p>VNAA recommends that home health agencies receive confidential feedback reports that contain the falls measure data that is not risk adjusted. Risk stratification, however, could prove useful for agencies in their quality improvement efforts. For example, it would be helpful to understand the percentages of low, medium and high risk patients, respectively, that had a fall with major injury. This information could enable home health agencies to better target their quality improvement efforts.</p>				
15	10/14/2016	<p>NAHC appreciates the importance of preventing falls among the community-dwelling elderly population and understands that the Improving Medicare Post-Acute Care Transformation (IMPACT) Act requires a measure for incidence of major falls</p>	<p>Mary K. Carr Vice President, Regulatory Affairs National Association</p>	<p>mkc@nahc.org</p>	<p>Stakeholder</p>	



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		<p>to be implemented across post-acute care (PAC) providers. However, NAHC has concerns with the measure construct as proposed and its intended purpose.</p> <p>Our main concern with the measure is that it is not risk adjusted. Although an unadjusted falls measure could provide valuable information regarding the overall rates of falls occurring within the agency, it has limited value when comparisons are made to other home health agencies.</p> <p>Home health agencies provide intermittent care to patients with varying care needs, living environments and caregiver support. Agencies have limited control over a patient/caregiver's ability or willingness to comply with fall prevention strategies. For example, the agency cannot require a patient to restrict living on a single level of the home in order to avoid stairs. Additionally, home health patients are permitted to leave the home infrequently or for short duration, and are allowed unlimited absences for medical reasons. Therefore, a home health patient could encounter fall risks for which the agency could not be expected to mitigate.</p> <p>Without risk adjustment, the measure could present a distorted correlation between the rate of major injuries related to falls and the quality of care provided by the agency, and as previously mentioned, has limitations when making comparisons among home health agencies. Consequently, concerns with the potential inclusion of the measure into a home health value-based purchasing program and/or CMS' public reporting systems, will likely result in agencies avoiding caring for patients perceived as high risk for falls.</p> <p>Of equal concern, is that the IMPACT Act requires the falls with major injury measure to be applied across other PAC settings; all of which are facility based with 24/7 supervision and the ability to affect fall prevention through direct interventions by the facility staff. The standard for fall risks and prevention that is applied to facility based care cannot be applied to community care settings.</p>	<p>for Home Care &amp; Hospice [NAHC]</p>			

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		<p>Further, this measure overlaps with the current Outcome and Assessment Information Set (OASIS) Potentially Avoidable Event Measure, Emergent Care for Injury Caused by Fall, and adds two new OASIS assessment items. NAHC has concerns that the requirements of the IMPACT Act are causing overlapping home health care quality measures and that items will continue to be added to the OASIS data set instrument resulting in an assessment tool that will become very burdensome for agencies to administer with increasing the number of OASIS assessment data set items</p> <p>Recommendations:</p> <ol style="list-style-type: none"> <li>1) NAHC urges the measure developers to risk adjust the measure for public reporting and any payment application. The following variables, at minimum, should be included in the risk adjustment model. <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Functional ability</li> <li>• Cognition</li> <li>• Vision and hearing</li> <li>• Caregiver support</li> <li>• Number of therapy visits</li> </ul> </li> <li>2) Report the unadjusted and the risk adjusted rate for the measure through agency confidential feedback reports</li> <li>3) Testing and validation of the measure in the home health setting should be conducted prior to implementation.</li> <li>4) CMS must consider the duplication of home health quality measures and the administrative burden for agencies associated with increasing the number of OASIS assessment data set items in implementing the IMPACT Act.</li> </ol>				
16	10/14/2016	<p>For older Americans, falls are the leading cause of fatal and non-fatal injuries. These incidents threaten seniors' safety and independence and generate enormous economic and personal costs. In 2013, the total cost of fall injuries was \$34 billion.(1 )As one of the largest home health providers in the state of Illinois and one of the largest Accountable Care</p>	<p>Shauna McCarthy Manager, Government Relations Advocate Health Care</p>	<p>Shauna.Mccarthy@advocatehealth.com</p>	<p>HHA</p>	

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		<p>Organizations in the country, Advocate greatly appreciates the importance of preventing falls among the elderly. We especially appreciate your efforts to propose thoughtful measures under the IMPACT Act for incidence of major falls to be implemented across post- acute care (PAC) providers. However, Advocate has concerns with the measure as currently proposed. We appreciate your consideration of our recommendations and comments below.</p> <p>Risk-Adjustment</p> <p>Home health agencies provide intermittent care to patients with varying levels of care needs and caregiver support and diverse living environments. Agencies have limited control over a patient/caregiver’s ability or willingness to comply with fall prevention strategies. For example, patients may choose not to install grab bars for bathroom safety, make necessary home repairs, or use prescribed ambulatory aids. Advocate has concerns that because the measure is not risk-adjusted, the measure fails to give home health agencies meaningful feedback in the category of major injury from the falls expected rate versus the actual fall rate. With major injury, it is critical for home health providers to understand performance improvement opportunities in order to assess how to address and decrease the rate of falls. We recommend Abt Associates include risk-adjustment in the proposed measure.</p> <p>Recommendations</p> <p>1). The Falls with Major Injury measure should be risk-adjusted at minimum for the following variables:</p> <ul style="list-style-type: none"> <li>• Diagnosis;</li> <li>• Functional ability;</li> <li>• Cognition;</li> <li>• Vision and hearing;</li> <li>• Caregiver support;</li> <li>• Living environment; and</li> <li>• Number of therapy visits.</li> </ul>	<p>3075 Highland Parkway, Suite 600 Downers Grove, IL 60515</p>			

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		<p>2). Prior to implementation, testing and validation of the measure in the home health setting should be conducted.</p> <p>3). As the Centers for Medicare and Medicaid Services (CMS) continues to implement the IMPACT Act, we encourage CMS to control for duplication of home health quality measures and account for the administrative burden on home health agencies associated with increasing the number of Outcome and Assessment Information Set (OASIS) data set items.</p> <p>Fall Reporting Categories</p> <p>Advocate has concerns regarding the accuracy of reporting the number of falls in three categories: no injury, minor injury, and major injury. Currently, home health documentation systems do not differentiate falls into these categories. Clinical documentation systems will need to be modified in order to collect fall information for no injury, minor, and major injury. This could lead to inaccurate data collection if the entire record must be reviewed to obtain this data on discharge or transfer. As major injury is the easiest to detect, we suggest initiating the measure with only this category.</p> <p>Fall Risks and Prevention Standard</p> <p>We also have concerns that the IMPACT Act requires the falls with major injury measure to be applied across all PAC settings, including community care settings; not all of which are facility-based with 24/7 staff supervision. Due to intermittent patient contact, home care workers have limited ability to affect fall prevention. Most falls that occur at home are not witnessed by home care staff; as such, staff members are unable to directly prevent falls in unsafe or high-risk situations.</p> <p>(1) National Council on Aging - <a href="https://www.ncoa.org/news/resources-for-reporters/get-the-facts/falls-prevention-facts/">https://www.ncoa.org/news/resources-for-reporters/get-the-facts/falls-prevention-facts/</a></p>				

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16	10/14/2016	<p>APTA supports the goal of improving the quality of health care. Physical therapists are committed to providing high quality, timely care and to the promotion of evidence-based and patient-centered practice. Furthermore, APTA feels it is essential to move toward standardized data elements and a common set of quality measures across the continuum of care.</p> <p>APTA supports the inclusion of a standardized cross-setting quality measure related to falls with major injury. APTA believes that the screening of falls risk and prevention of falls in patients is an important part of the care process. We do have several concerns regarding the implementation of this falls with major injury measure in the home health care setting, which we outline below.</p> <p>To date, the falls with major injury measure has been implemented in facility-based settings only (inpatient rehabilitation facilities, long-term care hospitals, and skilled nursing facilities). APTA is concerned about the accuracy of the data when applied to the home health setting. Unlike facility-based settings, falls are unlikely to be directly observed by health care professionals and will require patients to accurately self-report. In other post-acute care settings, patients who are identified as having a falls risk can receive more aggressive interventions for falls prevention and can receive increased monitoring to prevent falls with injuries. This is not the case in the home health setting. In the home health setting, patients receive interventions for falls risk, but adherence to certain interventions relies solely on the patient. As a result, we believe that comorbidities, such as cognitive disorders and chronic conditions that affect patient function, may have a greater impact on this measure outside of facility-based settings.</p> <p>For these reasons, we believe this measure will require a lengthy testing period to better understand falls with major injury data in the home health care setting. While APTA supports the inclusion of this standardized cross-cutting</p>	<p>Heather Smith, PT, MPH Director of Quality American Physical Therapy Association</p>	<p>heathersmith@apta.org</p>	<p>Trade Association</p>	

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		<p>measure as required under the implementation of the provisions of the IMPACT Act, we believe that testing should occur prior to using this measure as part of a value-based quality program; otherwise, home health settings may be at a disadvantage compared with other post-acute care settings under value-based payment. APTA encourages CMS and Abt Associates to perform data analysis and consider risk stratification or risk adjustment of this measure in the home health setting, as this may be necessary to adjust for the differences between facility-based and home health-based settings.</p>				
17	10/14/2016	<p>SHS supports the CMS' efforts to look at OASIS data elements for the Quality Measure Development and Maintenance Project, and we applaud the effort to show standardization between other post-acute entities, such as long term care. SHS approves that a similar format is being required for data elements as shown for falls with major injury. However, SHS urges consideration be taken in changing the descriptor of "resident" to either "patient" or "client," as the patient is receiving services in their home environment and is not a resident of an entity.</p> <p>It is important to note that the OASIS does not contain elements for this measure. SHS supports the inclusion of a measure that is endorsed by the National Quality Forum (NQF). However, SHS recommends risk adjustment for this measure in the home care environment due to the following factors:</p> <ul style="list-style-type: none"> <li>• Agency size: The numerator being a fall with major injury to the denominator of all patients with one or more eligible assessments could easily exaggerate the findings, and further misconstrue comparisons between smaller and larger home health agencies.</li> <li>• Agencies with a high percentage of therapy: This should be taken into consideration as typically therapy patients are being seen for balance or gait issues, which leads to a higher risk of falls.</li> </ul>	<p>Kathy Michael RN BSN Accreditation and Regulatory Specialist Spectrum Health Continuing Care Spectrum Health @ Home</p>	<p>kathy.michael@spectrumhealth.org</p>	<p>HHA</p>	

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		<ul style="list-style-type: none"> <li>The environment of care: Home care agencies are limited to the control of the patient environment in the home setting. Education occurs, but the patient may not have the means or desire to comply with recommendations made for a safer environment to prevent falls.</li> <li>Variations of risk factors: This measure should be risk adjusted based on primary diagnosis and co-morbidities, which have statistically demonstrated an increased fall risk. This data could be obtained from the OASIS or the UB-04 claim. Therefore, SHS recommends utilizing this measure only if risk adjustment can be made to improve the validity of the measure.</li> </ul>				
18	10/14/2016	<p>Response to Chapter 3. Measure Justification.</p> <p>The tool most commonly adopted as the standardized, validated assessment tool used to screen for fall risk in the home health practice setting is the Missouri Alliance for Home Care Fall Risk Assessment Tool (MAHC-10). This tool was widely adopted by CHHA's in 2012 when a validation article was e-published by Calys, et al. that met the standardized, multi-factorial and now validated requirement for M1910 Falls Risk Assessment criteria. (1 )The reason it was so widely adopted was that being a non-performance based assessment, non-ambulatory patients were able to be screened. This allowed CHHA's to reach 100% on the M1910 OASIS process measure assessing for fall risk.</p> <p>The Abt report, "Development of the Percent of Residents Experiencing One or More Falls with Major Injury During a Home Health Episode Measure" states in chapter 3.1 that patients were found to have falls risk 93% of the time and I contend that this number is not an accurate representation of the true risk based on the sensitivity and sensitivity. Using a cut off score of 4 on the MAHC-10 results in a very high sensitivity of 96.9% which is very impressive, but, the</p>	Kenneth L Miller, PT, DPT, GCS, CEEAA	kenmpt@aol.com	Individual response	

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		<p>specificity is a very poor value of 13.3% meaning that there will be an over-identification of people at risk for falling that are not actually at risk.</p> <p>I recommend that the IMPACT item review committee look further into the current OASIS Fall Risk Assessment tool for its usefulness to actually identify true fallers vs. non-fallers. Tracking 100% on a process measure for a flawed measure does not achieve the true intent of the item M1910.</p> <p>I recommend that the new J1800 Item asked at discharge regarding having any falls with major injury be asked at the SOC with a time frame of 6 months. The question could read, "Has the patient had any falls within the past 6 months?" If yes, then proceed to the question, "Number of falls in the past 6 months (same coding of 0 – none; 1-one; 2-two or more) and A, B, C as listed on J1800.</p> <p>Capturing the fall history across the care continuum will provide CMS with more relevant data than has the patient fallen while on a home health episode. Having a fall increases the risk for future fall.</p> <p>(1) Calys M, Gagnon K, Jernigan S. A Validation Study of the Missouri Alliance for Home Care Fall Risk Assessment Tool. Home Health Care Management &amp; Practice. 2013; 25(2):39-44.</p>				
19	10/14/2016	<p>The Alliance supports the use of a measure that addresses major falls, consistent with the IMPACT Act, but has several concerns about the falls measure as described in the public comment document. (1)</p> <p>The measure on which the proposed home health falls measure is based is currently only endorsed by the National Quality Forum (NQF) for use in long-stay nursing homes. It is not endorsed by NQF for use in home health agencies, nor is it endorsed</p> <p>for skilled nursing facilities (short stay), inpatient rehabilitation facilities, and long term care hospitals.</p> <p>Although there is a measure related to falls that is reported to</p>	Teresa Lee, JD, MPH Executive Director Alliance for Home Health Quality and Innovation Office: (571) 527-1530	tlee@ahhq.org	Stakeholder	



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		<p>individual home health providers, it is a different measure and it is not endorsed by NQF (and it is not publicly reported). Moreover, home health care is community-based, not facility-based care. The measure described by Abt refers to “residents” (see the title of the public comment document), but in home health there are no “residents” because the patients are in their own homes, rather than in an institution. Understanding the unique nature of home health’s setting in the community is critical. If a home health patient falls, more often than not that fall is not witnessed by a home health care professional. A fall with major injury could occur when the patient is home alone, or even in the physician’s office, but it would still be considered a fall with major injury for purposes of this measure if it occurred during a home health episode. Care in the community is different from institutional care because the patient is in his or her own environment, with accompanying risks. Although the community and the home pose unique challenges for patient care, those risks are also important to navigate if the patient is to achieve self-management and transition back to the community.</p> <p>The question is whether it is possible for this measure to be comparable across post-acute care settings, as in home health care there usually is nobody present to witness and document the fall and the consequent injury at the time of the incident. The Alliance is therefore concerned about the reliability of the data collection for this measure as it applies to home health care. If a goal is for this measure to be meaningful across settings, standardization is key. At the very least, appropriate adjustment should take into consideration the very different nature of home health in comparison to the facility-based settings.</p> <p>Furthermore, the Alliance is concerned about the impact of this falls measure because it is neither risk adjusted nor risk stratified. Higher risk patients will certainly be at greater risk of having a fall with major injury. Although measuring the number of falls without risk adjustment would enable clear</p>				

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		<p>understanding of the incidence of falls, it is critical to bear in mind that provider incentives will be affected because CMS plans to begin public reporting of this measure in January 2021.</p> <p>In addition, if payment is eventually tied to this measure, provider incentives will change still more. In the absence of risk adjustment, providers will be punished for accepting patients at higher risk of falls and adverse selection of patients is likely to become an issue. It is therefore critical for this measure to be risk adjusted. The Alliance recommends that any falls measure that is publicly reported be risk adjusted.</p> <p>Notwithstanding, the Alliance recognizes the need to have transparent information on falls so that home health agencies can engage in quality assurance and performance improvement initiatives. Ideally, agencies should treat any fall with major injury as a sentinel event, focusing their efforts on understanding the root cause of such incidents so that they can prevent similar falls in the future. In order to provide agencies meaningful information for quality improvement efforts, the Alliance recommends that home health agencies receive confidential feedback reports that contain the falls measure data that is not risk adjusted. Risk stratification, however, could prove useful for agencies in their quality improvement efforts. For example, it would be helpful to understand the percentages of low-, medium-, and high-risk patients, respectively that had a fall with major injury. This information could enable home health agencies to better target their quality improvement efforts.</p> <p>(1) Abt; “Development of the Percent of Residents Experiencing One or More Falls with Major Injury During a Home Health Episode” (HHS-500-2013-130011, Task Order HHS-500T0002) (herein after “public comment document”) <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</a></p>				

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		Instruments/MMS/Downloads/IMPACT_-Falls-with-Major-Injury-Measure_Public-Comment.pdf				
20	10/14/2016	<p>IRFs have been reporting assessment data on the incidence of falls and associated injuries on the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF PAI) since October 1, 2016. CMS conducted two in-person training sessions earlier this year in preparation for this change. We believe that since the proposed data items and the measure they feed into are intended to be a cross-setting measure for post-acute care (PAC), they should be developed in a way that PAC stakeholders believe is clinically accurate.</p> <p>CMS proposes to add items to the OASIS assessment instrument that would be completed at discharge, J1800: Any Falls Since Admission, and J1900: Number of Falls Since Admission. The collected data would feed into a proposed HHA quality measure, Percent of Residents Experiencing One or More Falls with Major Injury During a Home Health Episode. This measure would be an application of the measure Percent of Residents/Patients Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), currently required for IRFs, LTCHs, and SNFs. The proposed home health measure would report the percentage of patients/residents who experience one or more falls with major injury (defined as bone fractures, joint dislocations and closed head injuries with altered consciousness or subdural hematoma) during the home health episode of care. To accomplish this objective, the measure will be based on data reported for proposed item J1900C: Number of Falls with Major Injury.</p> <p>We have reviewed the report prepared by Abt Associates, "Development of the Percent of Residents Experiencing One or More Falls with Major Injury During a Home Health Episode," and offer the following comments. AMRPA shares Abt Associates' and CMS' concerns about the risk of falls in the home as well as in all other PAC settings, particularly in IRFs.</p>	<p>Mimi Zhang Government Relations and Policy Associate American Medical Rehabilitation Providers Association (AMRPA) 1710 N Street NW Washington, D.C. 20036 o: 202-223-1920   f: 202-223-1925</p>	mzhang@amrpa.org	Trade Association	

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		<p>I. Measure Specifications</p> <p><i>A. Numerator</i></p> <p>In reviewing the numerator, there was not a clear statement of the Medicare patient population included in the numerator. The draft specification states the numerator is the “number of patients who experienced one or more falls that resulted in major injury during the episode of care.” With respect to NQF #0674 as applied to IRFs, the numerator patient population is as the number of Medicare (Part A or Part C) patients stays during the selected time window who experienced one or more falls that resulted in major injury.(1)</p> <p>AMRPA recommends that the specific HHA Medicare patient population be clarified in the final measure information. Pursuant to the mandate in the IMPACT Act, the various quality measures are to be comparable across PAC settings. If each measure has a different patient population base, they cannot be considered comparable and hence defeat one of the Act’s primary objectives.</p> <p><i>B. Denominator</i></p> <p>The denominator is proposed to be all patients with one or more assessments that are eligible except those patients for whom:</p> <ul style="list-style-type: none"> <li>• The occurrence of falls was not assessed; or</li> <li>• The assessment indicates that a fall occurred and the number of falls with major injury was not assessed.</li> </ul> <p>We note that this approach again varies from NQF #0674 measure exclusions for LTCHs, IRFs, and SNFs in that it excludes patients for whom the occurrence of falls was not assessed. We reiterate our recommendation that CMS and its contractors prioritize cross-setting comparability across PAC settings as they develop IMPACT Act measures.</p> <p>II. Definition of Falls</p> <p>When Percent of Residents/Patients Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) was proposed in the IRF PPS FY 2016 rule, CMS laid out only the</p>				

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		<p>technical measure specifications (numerator, denominator, exclusions, etc.). (2)</p> <p>This measure was a SNF measure adapted for IRF and LTCH use. The rule and corresponding specification documents did not include guidance or descriptive examples of what should or should not be considered a fall. Following issuance of the IRF PPS FY 2016 final rule, however, CMS revised the IRF PAI Training Manual and conducted two training sessions in which it has revised the definition of falls. Specifically, the manual and the training sessions injected “intercepted falls” as a concept and that they are to be considered falls. Hence, the IRF PAI Training Manual effective October 1, 2016 for Section JJ defines falls as:</p> <p>“Falls - Unintentional change in position coming to rest on the ground, floor, or onto the next lower surface (e.g., onto a bed, chair, or bedside mat). The fall may be witnessed, reported by the patient or an observer, or identified when a patient is found on the floor or ground. Falls are not a result of an overwhelming external force (e.g., a patient pushes another patient). An intercepted fall occurs when the patient would have fallen if he or she had not caught him/herself or had not been intercepted by another person—this is still considered a fall.” (Emphasis added)</p> <p>Prior to October 1, 2016, the IRF PAI Training Manual defined a fall as “Unintentionally coming to rest on the ground, floor, or other surface.”</p> <p>We have several concerns. First, applying a SNF falls measure in other PAC contexts raises issues regarding inter-rater reliability. We do not see that point addressed in the report.</p> <p>Second, while CMS has now defined intercepted falls as falls, it has not provided detailed guidance on what clinical incidents constitute an intercepted fall. There appear to be various approaches in the IRF industry and possibly other PAC settings, and there does not appear to be an industry consensus. Due to these varying approaches, the data reported will be widely variable and not reliable for</p>				

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		<p>comparison between individual providers (e.g., from one IRF to another IRF), much less different among care settings (e.g., from an IRF to an HHA to a SNF). We fear that the lack of transparent dialogue between CMS and PAC providers regarding intercepted fall definition, particularly for mandatory quality reporting purposes, will result in data that is neither statistically valid nor reliable.</p> <p>Third, patients and caregivers do not perceive an intercepted fall as a fall incident. As an example, a patient may frequently use the furniture in their home as a way to steady themselves to use the bathroom touching on a chair, table or the wall on the walk from their recliner chair to the bathroom. Without such use of the furniture, the patient could fall on some trips to the bathroom, but not every trip. The patient would not describe this walk as a series of intercepted falls, but rather a normal trip to the bathroom. This perception issue is especially relevant as this measure is applied to HHAs because relying on patients and caregivers to report falls will be operationally challenging in the home health setting and cause the data to be even more inaccurate.</p> <p>One alternative is for CMS to abandon the concept of intercepted falls as amorphous as it appears to be and apply instead the standard of “assisted” and unassisted” falls. (3) We recommend CMS delete the term “intercepted falls” in each assessment instrument where it is used and change it to “assisted falls.”</p> <p>III. Utilizing an Outcome Orientation</p> <p>AMRPA thinks that a primary goals of quality measurement beyond straight reporting is the ability to act upon and to use the observed data act in order to enhance and improve quality outcomes for patients. As an example, the cross-setting drug regimen review measure slated to be collected starting in 2017-2018 takes a step in this direction. Not only does it ask to see if patient medications are reconciled, but it also asks if the provider then assessed the patient for any adverse side effects. To translate this concept into the falls</p>				

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		<p>arena, AMRPA suggests that CMS consider working with stakeholders to implement an education program. For example, once high-risk fall patients are identified, one recommendation would be ensuring they receive a lower bed and bed alarms, as well as equipping the room with a camera, etc., that would provide interventions to prevent future falls with major injury.</p> <p>IV. Summary</p> <p>AMRPA appreciates the opportunity to comment on this draft Percent of Residents Experiencing One or More Falls with Major Injury During a Home Health Episode measure specifications. In summary:</p> <p>A. We recommend CMS clarify the Medicare population included in the measure numerator.</p> <p>B. We recommend that CMS reexamine the denominator exclusions and parallel them with the denominator exclusions utilized for the other PAC settings. While we realize the home health setting has some unique challenges with respect to reporting and assessments, without paralleling the measures, the data will not be comparable and fail to meet a key objective of the IMPACT Act.</p> <p>C. We also recommend that CMS reexamine the definition of falls. The Agency’s inclusion of intercepted falls as a fall specifically is problematic in that it would lead to great variability in the data as reported by PAC settings. CMS needs to provide clear guidance on what is considered an intercepted fall and provide a range of examples. Alternatively, we recommend deleting the term “intercepted falls” in each assessment instrument where it is used and change it to “assisted falls.”</p> <p>D. We recommend that, as CMS moves forward with measure development for all PAC settings, it include taking the important step of seeking to require providers to develop interventions for outcome assessments.</p>				

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		<p>(1) RTI International, Inpatient Rehabilitation Facility Quality Reporting Program: Specifications for the Quality Measures Adopted through Fiscal Year 2016 Final Rule. Prepared for CMS August 2015.</p> <p>(2) RTI International, Inpatient Rehabilitation Facility Quality Reporting Program: Specifications for the Quality Measures Proposed Through the Fiscal Year 2016 Notice of Proposed Rulemaking. Prepared for CMS April 2015.</p> <p>(3 )The NQF-endorsed measure Falls with Injury (NQF #0202), defines assisted falls as “a fall in which any staff member...was with the patient and attempted to minimize the impact of the fall by easing the patient’s descent to the floor or in some manner attempting to break the patient’s fall, e.g., when a patient who is ambulating becomes weak and the staff lowers the patient to the floor. In this scenario, the staff was using professional judgment to prevent injury to the patient. A fall that is reported to have been assisted by a family member or a visitor counts as a fall, but does not count as an assisted fall. ‘Assisting’ the patient back into a bed or chair after a fall is not an assisted fall. Any fall that is not documented as an assisted fall counts as an ‘unassisted fall.’” National Quality Forum, endorsed December 10, 2015</p>				
21	10/14/2016	<p>AOTA is very pleased to see the interest of the Centers of Medicare and Medicaid Services (CMS) in measuring and improving quality of care for Medicaid beneficiaries who receive Home Health services. AOTA thanks Abt Associates and CMS for the opportunity to provide comments in the measure development process. AOTA supports the inclusion of an outcome measure related to falls. Although falls with a major injury should be a never event, it is an important outcome to measure.</p> <p>In a report, the Summary of Feedback from the Technical Expert Panel (TEP) Regarding Cross-Setting Measures Aligned with the IMPACT Act of 2014 (April 2015), a CMS TEP recommended that a Falls measure (#0674) be risk adjusted for cognitive status. AOTA fully supports this</p>	Jeremy Furniss, OTD, OTR/L, BCG, CDP Director of Quality Division of Academic & Scientific Affairs American Occupational Therapy Association, Inc. 240-800-5986	jfurniss@aota.org	Trade Association	



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		<p>recommendation and believes that it should be tested with this falls measure proposed by Abt Associates. This must be done in a manner that will ensure patients with cognitive issues that may be able to be addressed, by occupational therapy or other services, to improve or compensate for such problems. This would level the playing field by adjusting for the effects of characteristics of patients with cognitive impairments. Falls with major injury are a never event. Facilities with patients that have cognitive impairments must be allowed to adjust for patients whose cognitive issues may not be able to be changed or accommodated for. But any risk adjustment should not promote neglect of treatment. AOTA would recommend a more thorough discussion of the denominator exclusion criteria.</p> <p>While the outcome measure proposed is important, AOTA would recommend further refinement of process measures related to this outcome. The Medicare proposed rule for calendar year 2017 included the recommendation that two established process measures related to falls plans of care be retired due to limited variability. We believe that process measures related to falls prevention and assessment are important to include in HH and other PAC settings. While we agree that measures which are topped out should be removed from quality reporting programs, AOTA would like to emphasize the importance of ensuring falls prevention through quality measurement. Prevention of falls is especially important in reducing hospitalizations and readmissions and increasing safety, which helps control Medicare spending on potentially costly adverse events. Occupational therapy practitioners work with patients and their caregivers to scan the home environment for hazards and evaluate the individual for limitations that contribute to falls. Recommendations often include a combination of interventions that target improving physical abilities to safely perform daily tasks, modifying the home, and changing activity patterns and behaviors. Such changes may help prevent falls as well as hospitalizations/readmissions due to falls.</p>				

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		<p>More refined process measures may be more appropriate to improve practice and reduce falls risk. Falls risk may be combined with a home safety risk domain tool. The CDC identifies seven evidence-based areas that providers should focus on first:</p> <ul style="list-style-type: none"> <li>• Lower body weakness</li> <li>• Poor vision</li> <li>• Difficulties with gait and balance</li> <li>• Problems with feet and/or shoes</li> <li>• Use of psychoactive medications</li> <li>• Home hazards</li> <li>• Postural dizziness</li> </ul> <p>In fall risk screening, these items should be included at some level for a more thorough understanding of referrals that can prevent future falls and reduce potential costs associated with fall related injuries. Occupational therapy has been found to be particularly effective in reducing falls in the home health setting. This is likely because an occupational therapy is multifactorial examining both intrinsic factors (e.g., weakness, balance, cognition, sensory impairments, fear of falling) and extrinsic factors (e.g., home safety hazards, routines, community safety hazards) related to falls risk.</p>				