

Section GG: Functional Abilities and Goals, Scoring Independence with or without Assistive Devices

Comment Summary

Some commenters noted that the current OASIS ADL/IADL items include separate response options for independent without use of an assistive device, and, independent with use of an assistive device, while there is one response for independent (with or without use of an assistive device) in the new Section GG mobility and self-care items. They note that this difference means improvement in function from SOC/ROC to DC will not be registered with the Section GG self-care and mobility items for those home health patients who start care independent with use of an assistive device, and end care independent without use of an assistive device.

Response

The new functional assessment items, entitled Section GG functional abilities and goals are based on the approach of the World Health Organization's (WHO) International Classification of Functioning, Disability, and Health (ICF) that recognizes functional independence and ability regardless of the use of assistive devices. The Section GG items measure a person's ability to perform functional activities with or without an assistive device. Coding of a functional item with or without an assistive device allows for the evaluation of the need for assistance when performing a self-care or mobility activity. CMS expects providers to consider the use of device(s) when assessing functional status and functional improvement. It should be noted that functional activities for Section GG may be completed with or without assistive devices, and the patient's use of an assistive device should not affect the coding of the activity. Use of assistive devices remains an important part of the patient's functional assessment.

Item Removals

In Favor

Comment Summary

Many commenters supported our proposal to remove data elements from OASIS and concurred that information that can be captured elsewhere or is not used for the purposes of determining patient outcomes should be removed.

Response

We appreciate the support from commenters for a more streamlined assessment set.

Against

Comment Summary

While supporting efforts to reduce burden, many commenters opposed removals of specific items, citing these as important indicators of safety at home, important for risk adjustment, or of clinical importance. Several commenters were concerned about the removal of items used for quality measure risk adjustment. Additionally, several commenters asked about the logic of removing some items and not others. For example, some noted that items regarding the healing status of stasis and surgical wounds

are still on OASIS-D, yet the items on healing status of pressure ulcers was removed. Similarly, a few commenters questioned the removal of M2250 while M2401 was retained. Several commenters were concerned that some items were important to track certain issues, for example, tracking the progress of wounds other than surgical, stasis or pressure ulcer. One pointed out that HHAs will continue to need to assess these conditions, and therefore, the removal from OASIS will have no effect on reducing burden. A few commenters requested that some items be retained for quality improvement purposes.

Response

With respect to the logic of removing some items and not others, we wish to clarify that in our decision-making, we have considered the multiple uses of OASIS data elements and we are coordinating with the other users of these data, for purposes of payment and provider survey. Consequently, some items are retained because they are used for purposes other than quality measurement. We wish to also note that other post-acute care settings covered by the IMPACT Act requirements also use assessment item sets that serve multiple purposes, and we are additionally coordinating with those stakeholders.

We wish to further clarify that the data for the measures no longer included in the Home Health Quality Initiative (HHQI) or removed from the Home Health Quality Reporting Program (HH QRP) may still appear on OASIS for previously established purposes that are not related to the HH QRP, and if still collected will be available to home health agencies, via the CASPER on-demand reports, for the purpose of monitoring and improving quality efforts. We also wish to clarify that we are developing and testing revised risk models that are limited to items included in OASIS-D. Model specifications will be released prior to January 2019.

Item Specific Comments

M0300

Comment

CMS references M0300---what is that and where is it?

Response

Thank you, this is an error. We have noted this typographical error and will correct.

M1021 Primary Diagnoses and -M1023 Other Diagnoses

Two commenters mentioned that items M1021 Primary Diagnoses and M1023 Other Diagnoses need more space on the form for entering diagnoses.

Response

CMS appreciates the recommendation to increase the space for these two items for clinicians to report diagnoses. CMS notes that ICD-10-CM codes vary in length, from 3 to 7 characters long, such that the space may be reasonable for most responses in column 2 of these items. Further, if more space is desired for entry of a response, agencies can add this to their forms, or have their vendors expand the space.

M1060 (Height and Weight)

Comment Summary

A few commenters raised concerns about M1060 (Height and Weight) and the challenges of securing accurate measurements in the home setting. Specifically they noted concerns about the process for obtaining most recent height or weight. One commenter asked about the process for identifying a patient weight in the event that the home health clinician was unable to obtain a weight on the SOC/ROC visit. Another suggested that most recent height and weight needs to allow height/weight obtained by either the patient or other health provider in order to get accurate results and minimize provider burden.

Response

CMS appreciates the commenters' concerns about collecting information on patient height and weight using item M1060. Height and weight are used to calculate the patient's body mass index (BMI), an important risk factor for developing pressure ulcers. This information will only be collected at start and resumption of care, not on an ongoing basis. The item is standardized across PAC patient assessment instruments. A patient's BMI at the beginning of the care episode is used to risk adjust the "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)" and the "Changes in Skin Integrity - Post Acute Care" quality measures for public reporting and thus allow a fairer comparison across agencies that serve different kinds of patients. We appreciate the commenters' concerns surrounding potential challenges related to obtaining a patient's height and weight but also believe that ensuring accurate information is a standard practice when providing patient care. For this item, as well as for many others in the item sets, CMS has provided guidance on the responses clinicians may enter in various circumstances such as when assessment is not attempted due to medical or safety concerns. The benefit of providing accurate height and weight data for this item is to support accurate, comprehensive risk adjustment for the quality measure. Further guidance will be available in the OASIS-D Guidance Manual and in future Q&As.

M1311 Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage

Comment Summary

Commenters remarked that CMS used the terms injury and ulcer (or injuries/ulcers) inconsistently across the pressure ulcer items M1306 Unhealed Pressure Ulcer/Injury at Stage 2 or Higher, M1311 Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage and M1322 Current Number of Stage 1 Pressure Injuries. . Specifically, M1311A Stage 2, M1311B Stage 3 and M1311C Stage 4 use the term "pressure ulcers," whereas M1311D Unstageable: Non-removable dressing/device and M1311E Unstageable: Slough and/or eschar use "pressure ulcers/injuries" and M1311F Unstageable: Deep tissue injury and M1322 Current Number of Stage 1 Pressure Injuries, use "pressure injuries."

Response

CMS has adapted the National Pressure Ulcer Advisory Panel terminology and guidelines for home health and other post-acute care settings' purposes. A Stage 1 is termed an "injury" while Stage 2, Stage 3 and Stage 4 are termed "ulcers". A deep tissue injury continues to be termed an injury. Classification of unstageable due to slough and/or eschar, or unstageable due to non-removable dressing/device as

ulcer or injury is not possible, until that point at which these become stageable. Thus, these are referred to as ulcers/injuries. The OASIS-D items and forthcoming Guidance Manual use phrasing consistent with this adapted terminology.

Comment Summary

Two commenters noted that M1311 at Discharge is missing a box in the right column at A2.

Response

Thank you, this is an error. This formatting error has been corrected.

Comment Summary

A commenter asked that item M1311 Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage, at Discharge, be clarified regarding ulcers/injuries that were present at the most recent SOC/ROC, or FU assessment.

Response

Thank you for the suggestion. The forthcoming Guidance Manual for OASIS-D includes revised and expanded guidance on this item, with a section devoted to identification of “present on admission.” Examples are included in this version of the Guidance Manual to offer additional reference for users.

M1845 Toileting Hygiene

One commenter stated that item M1845 Toileting Hygiene should specifically mention skills related to ostomy, including the ability to empty and change the pouching application system. The commenter additionally requested this information be clearly documented in the 2019 OASIS Guidance Manual for HHAs.

Similarly, the same commenter suggested that since daily care of an ostomy is not captured elsewhere and affects patient’s ability to remain independent in society, under the new proposed M1410 addition of Section O Special Treatments, Procedures and Programs to add item K - Ostomy Care.

Response

Item M1845, Toileting Hygiene, currently states “If managing ostomy, includes cleaning area around stoma, but not managing equipment.”

Thank you for the suggestions to revise M1845, Toileting Hygiene, or add Section O: Special Treatments, Procedures and Programs, Item K: Ostomy Care, to capture daily care of an ostomy. CMS will consider the requested revision to M1845, but notes that the items included under Section O are not currently proposed for OASIS-D.

J1800 Any Falls Since SOC/ROC and J1900 Number of Falls Since SOC/ROC

Comment Summary

Two commenters had specific comments about items J1800 Any Falls Since SOC/ROC and J1900 Number of Falls Since SOC/ROC. One commenter asked at what time point these items are addressed. Another

asked if responses are risk-adjusted for contributing diagnoses, comorbid conditions and medications that potentiate a fall; or for person living alone. The commenter questioned whether CMS has a standardized definition of a 'fall' for community dwelling elders that will be utilized for this question; or whether agencies will utilize their own definitions. The commenter noted that unwitnessed falls occur when the HHA staff is not in the home and suggested that the timeframe for this question needs to be more discrete and should only include those falls when staff are present.

Response

We wish to clarify that items J1800 and J1900 are assessed at Transfer to an Inpatient Facility, Discharge from Agency — not to an Inpatient Facility, and Death at Home. With respect to the item definitions, CMS has a standardized definition of a “fall” that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>) as an “unintentional change in position coming to rest on the ground, floor, or onto the next lower surface (such as a bed or chair). 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.” With respect to risk adjustment, CMS appreciates the commenter’s concern 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. CMS appreciates the feedback and is committed to providing appropriate guidance to address the definition of falls and the timeframe to which the items apply.

Dash vs Not Applicable vs Not Assessed

Comment Summary

One commenter requested clarification describing the difference between a dash and response options for “not applicable” or “not assessed.” Specifically the commenter asked if a dash is intended to serve as a “not assessed” response for situations that fell outside the scope of current “not assessed” or “not applicable” options in a given OASIS question.

Response

We intend to provide guidance and training pertaining to the assessment and scoring of the OASIS-D. A dash (-) indicates “No information.” CMS expects dash use to be a rare occurrence. Further guidance on the “dash” and Not Applicable or Not Assessed will be provided in the OASIS-D Guidance Manual and future Q&As. CMS has standardized guidance for the section GG items that can be reviewed in the other

PAC settings manuals

(https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>)

Home Health Setting/Standardization

Comment Summary

While supporting the overall concept of standardization across PAC settings, several commenters expressed that the home health setting is different than institutional settings and urged CMS to consider the implications of standardization for home health. Most of these commenters highlighted the differences between the uncontrolled environment a home versus the controlled environment of a facility, specifically physical features of the care setting are not under the control of the agency or the nurse/therapist conducting the assessment. Several highlighted specific limitations of the home environments typical of their clients. One commenter mentioned that standardizing across settings would negatively impact risk adjustment for home health.

Response

We appreciate the support for standardization to enable comparisons across post-acute care providers. We also thank commenters who have raised concerns about the home health setting. We acknowledge that the four PAC provider types have unique challenges and provide unique services and appreciate the commenters' concerns specific to the home health setting and the potential variation in populations. Because of this, we conducted a thorough process of phased testing and stakeholder consensus to ensure we considered items that are aligned across PAC settings and are relevant to and feasible in each setting. We specifically sought to identify standardized patient assessment data elements that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA patient assessment instruments and that have the following attributes: (1) being supported by current science; (2) testing well in terms of their reliability and validity (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We appreciate the commenter's concern for appropriate risk adjustment as we continue to adopt new and refined standardized measures. We will continue to assess and account for the unique characteristics of home health patients including the use of risk-adjustment models. However, we interpret the commenter's suggestion that we risk adjust for the non-standardized patient care settings to mean that we must risk adjust for care services rendered in non-institutional settings, such as with home health services. While we take such considerations into account we are also mindful that regardless of where services are rendered risk adjustment is generally applied to characteristics of the individual rather than the provider setting.

Guidance

Comment Summary

Several comments were received requesting timely guidance for the OASIS D item set. A few commenters said that guidance would be helpful to fully understand the items. Commenters also emphasized providers would need guidance to appropriately complete the new Section GG Functional Abilities and Goals assessment items, similar to the guidance for the existing OASIS functional items. For example, several expressed confusion over how the elements in Item GG0130 Self-Care would be assessed. Several commenters requested additional clarity and guidance on the meaning and significance of reason codes 07 (“Patient refused”), 09 (“Not applicable”), 10 (“Not attempted due to environmental limitations”) and 88 (“Not attempted due to medical conditions or safety concerns”). For example, a commenter stated that a task may be both medically contraindicated/unsafe for the patient and not feasible due to environmental limitations, and suggested clinicians will require guidance on which code to use in these instances. One commenter appreciated CMS's decision to allow a variety of responses in order to accommodate the needs of a particular patient or in a particular home, and requested additional guidance to help HHAs and their clinicians understand when to use which response and how different codes will be reflected in their data.

Response

We intend to provide guidance and training pertaining to the assessment and scoring of the OASIS-D, including scoring and assessment of new items such as GG0130 Self-Care. The OASIS-D Guidance Manual is scheduled for publication in early July, 2018. Additionally, educational and training opportunities will be offered as part of our ongoing strategy to ensure successful implementation of the HH QRP, and ultimately quality improvement. The Guidance Manual includes detailed guidance and examples for each item. Training will be provided in order to decrease any confusion and ensure the accuracy of the data reported. We invite HHAs to submit specific inquiries related to the OASIS through our help desk, HHQualityQuestions@cms.hhs.gov. Additionally, a Frequently Asked Questions document is provided quarterly for the HH QRP, in the Downloads section of the HH Quality Reporting FAQs Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html>. These FAQ documents are updated to reflect current decisions related to the HH QRP. CMS has guidance for standardized items that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>)

Request for Additional Support

Comment Summary

One commenter noted that with all of the changes with OASIS D, a centralized process for answering OASIS questions is needed. The commenter noted the process of contacting the state's central OASIS Coordinator to submit questions posed challenges in getting consistent responses. The commenter appreciated the April 2018 release of the OASIS Q&As and suggested quarterly updates are also necessary due to the high number of changes to ensure consistency and accuracy.

Response

We are currently engaged in efforts to provide educational activities related to the HH QRP, including training events and responses to questions submitted to the Help Desk. We invite HHAs to submit specific inquiries related to the OASIS through our help desk, HHQualityQuestions@cms.hhs.gov. Additionally, a Frequently Asked Questions document is provided quarterly for the HH QRP, in the Downloads section of the HH Quality Reporting FAQs Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html>. These FAQ documents are updated quarterly to reflect current guidance related to the HH QRP, including data submission deadlines and training materials. With regard to the concern about consistent information, included that provided by the State OECs, we appreciate this concern and will take this into account as we engage in training and provide resource information.

Section GG

GG0100C Prior Functioning: Everyday Activities - Stairs

Comment Summary

Clarification will be required if stairs will also include uneven surfaces and transitions.

Response

Thank you for the comment, indicating that clarification is needed regarding whether the item GG0100C - Prior Functioning: Everyday Activities - Stairs, includes walking up and down stairs with uneven surfaces and/or transitions. We interpret this comment to refer to uneven surface(s) on stairs, whether internal or external, distinct from the item GG0170L - Mobility - Walking 10 feet on uneven surfaces. We further interpret that "transitions" in the comment refers to the movement from one type of surface (such as carpet) to another (such as wood).

Guidance for standardized items, including GG0100, is consistent across the four PAC settings. Standardized guidance for this item that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>)

We acknowledge that clarification of items and response options is a necessary part of education and training for the HH QRP. We are currently engaged in efforts to provide educational activities and materials related to the HH QRP, including training events and the OASIS-D Guidance Manual. Such educational and training information is part of our ongoing strategy to ensure successful implementation of the HH QRP, and ultimately quality improvement. We will continue to make recordings of trainings available on the CMS YouTube Web site at <https://www.youtube.com/user/CMSHHSgov/featured>. We invite HHAs to submit specific inquiries related to the coding of the OASIS through our help desk, HHQualityQuestions@cms.hhs.gov.

GG0110 Prior Device Use

Comment Summary

Two commenters requested clarification on prior device use. One asked about whether GG0110 Prior Device Use A - Manual wheelchair, B - Motorized wheelchair and/or scooter, C - Mechanical lift, D - Walker, E - Orthotics/Prosthetics, Z - None of the above, includes any use vs safe use vs present in home but not really used. One mentioned that response E (Orthotics/Prosthetics) needs to be clearly defined in the 2019 OASIS Guidance Manual for HHAs to ensure this is checked for every patient with an ostomy. According to this commenter, ostomy supplies are not typically thought of as a prosthetic and therefore needs clarification for clinicians to answer the question accurately.

Response

Thank you for the comments. With regard to the clarification requested, we intend to provide guidance and training pertaining to the assessment and scoring of the OASIS-D, including scoring and assessment of new items such as GG0110 Prior Device Use. The OASIS-D Guidance Manual is scheduled for publication in early July, 2018.

Guidance for the standardized items is consistent across all four PAC settings. Standardized guidance for this item that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>).

One Clinician Rule

Comment Summary

Several commenters requested that CMS “lift the One Clinician Rule on OASIS” and allow agency nursing and therapy staff to collaborate on GG0170 Mobility items

Response

In August 2017, CMS posted notification (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html>) that the current home care guidance related to the one clinician convention would be modified. As required by the Conditions of Participation, the Comprehensive Assessment continues to be the responsibility of one clinician. However, effective January 1, 2018, the assessing clinician is allowed to elicit feedback from other agency staff, in order to complete any or all OASIS items integrated within the Comprehensive

Assessment. For OASIS items requiring a patient assessment, including the GG0170 Mobility items referenced in comments, the assessing clinician may collaborate with other agency clinical staff, including physical or occupational therapists that have assessed the patient.

When collaboration is utilized, the assessing clinician is responsible for considering available input from these other sources and selecting the appropriate OASIS item response(s), within the appropriate timeframe and consistent with data collection guidance.

Comment Summary

A commenter suggested that while registered nurses (RNs) are capable of assessing gross mobility, the level of detail required by tasks in the GG0170 – Mobility items are more appropriately assessed by a physical or occupational therapist. Another commenter suggested that many RNs may not have the training and experience to conduct such an in-depth functional assessment.

Response

Since the introduction of the OASIS to home health in 1999, the assessment items (including the functional items related to walking, bathing, transferring, etc.) have been considered discipline-neutral and able to be completed by Registered Nurses, Physical Therapists, Occupational Therapists, and Speech-Language Pathologists. When desired, the assessing clinician responsible for completing the comprehensive assessment may work collaboratively with other agency staff to assess a patient in items/domains where the scope of practice for the clinician may be limited by educational preparation, state, agency, or other policies/restrictions. This is consistent with the long-standing approach of allowing assessing clinician therapists to collaborate with nursing staff to complete components of the drug regimen review.

Comment Summary

Commenters suggested that in cases where therapy has not been ordered, the RN would not have the benefit of the therapy clinician to contribute to the functional assessment using the GG items. Another commenter suggested that for a patient who is particularly frail, an RN may correctly believe that his or her training does not allow the patient to perform an activity such as walking a distance or attempting stairs in a manner that is acceptably safe.

Response

In situations where the assessing clinician determines that a particular Section GG self-care or mobility activity could not be performed, specific guidance and response options may be utilized. For instance, if based on the RN's assessment, it was determined that walking a distance of 50 feet with two turns would be medically contraindicated for the patient, even if assistance was provided, then one of the "activity not performed" codes, such as 09 "Not applicable", or 88 "Not attempted due to medical conditions or safety concerns" could be considered. Additionally, assessment by the RN identifying concerns with safe mobility may be appropriate triggers for requesting therapy orders to assist with assessment and patient care planning.

Comment Summary

A commenter suggested that the tasks in GG0170 – Mobility would take a significant amount of time to complete, if all needed to be assessed during the SOC assessment

Response

HHAs have up to 5 calendar days after the Start of Care (SOC) date to complete the SOC assessment, with the option of utilizing information collected by multiple collaborating agency staff during visits conducted within the assessment time frame.

Duplication

Comment Summary

Many commenters expressed concerns with the addition of the Section GG items. Specifically, commenters expressed concern that some GG 0130 Self Care and GG0170 Mobility items are duplicative of the existing OASIS activities of daily living (ADL) and instrumental activities of daily living (IADL) items (e.g. M1810, M1820, M1830, M1840, M1845, M1850, M1860, M1870). Commenters expressed that the following functional activities are documented twice using different scoring methodologies: eating, toileting, showering, upper body dressing, lower body dressing, bed to chair transfers, toilet transfers and walking. Several commenters suggested that the OASIS items that would be duplicative with section GG items should be removed from the OASIS assessment to limit the additional burden to providers and patients.

Response

Data collection for the new *Section GG: Functional Abilities and Goals* items does not substitute for the data collection under the current OASIS ADL and IADL items as we do not believe that these data elements are duplicative. The current OASIS function items evaluate current ability, whereas the Section GG functional items evaluate an individual's usual performance at the time of start/resumption of care, and at the time of discharge assessment for goal setting purposes. We note that there are several key differences between the existing OASIS and new Section GG function items that may result in variation in the patient assessment results including: (1) the data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures.html> .

Further, we note that these new items are required to fulfill standardization of a functional status process measure across post-acute settings as outlined in the IMPACT Act. CMS is exploring options that would streamline the data collection of functional status data items such that providers can have the best opportunity for success in establishing functional status goals. Further, to reduce potential burden associated with collecting the proposed measure, we have included several mechanisms to reduce the number of items that apply to any one patient. For example, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the patient does not walk or does not use a wheelchair, respectively.

Differing Scope/Response Options between items that assess similar constructs.

Comment Summary

Several commenters mentioned concerns about conflicting documentation due to different scales on similar items. Several mentioned concerns about data accuracy due to clinician confusion between item scoring approaches. One respondent highlighted a formatting issue, noting home health clinicians are very used to how the current formatting and numbering schema for OASIS items. According to the commenter the structure of the "GG" and "J" questions, including the answer choices, are not consistent with the sequencing of the answer choices for the traditional "M" questions. They specifically noted that the response scales for the section GG items and the current OASIS functional items are reversed, which could affect the reliability and validity of the items. For example, GG130, lists "independent" as answer choice number 6, whereas the M1800 questions list "independent" as number 0. One commenter highlighted that the items have a different scope, with the (M18XX series) being global in nature and GG0130 and GG1070 allow the clinician to document progression or regression in patient status.

Response

We acknowledge that the numbers of the scale for the section GG items vary from the scales that are used in current OASIS-C2 items. We note the ordering of the scales is consistent in that 'independent' is the first listed, and 'dependent' or unable, the last. The scales are used to assess independence in functional activities (a higher score indicates greater independence). We believe that the 6-level scale will allow us to better distinguish change at the highest and lowest levels of patient functioning by documenting minimal change from no change at the low end of the scale. The items in section GG were developed with input from clinicians and stakeholders to better measure the change in function, regardless of the severity of the individual's impairment. The section GG items were rigorously tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD) (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html). The PAC PRD supported the use of the scale in HHAs with both the alpha testing and beta testing reinforcing the clinical logic and consistency of language for the section GG items. The section GG items were compared to other functional assessment instrument data (including OASIS functional assessment items), as part of the PAC-PRD analyses with positive results. The interrater reliability of the functional activity items has been tested and the results have been favorable with items' kappa scores between .59 and .80.

Feasibility in Home Health

Comment Summary

Three commenters specified a concern that the Section GG items are not appropriate for the home health setting and meaningful data couldn't be collected. Two mentioned the differences in between the uncontrolled environment a home versus the controlled environment of a facility.

Response

We thank commenters who have raised concerns about appropriateness of items for the home health setting. The items were recently tested in a comprehensive field test of existing and potential OASIS items and found to be feasible, as described at <https://www.cms.gov/Medicare/Quality-Initiatives->

[Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html](https://www.cms.gov/Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html). CMS is committed to providing guidance for specific scenarios in which an item cannot be feasibly assessed, including guidance that outlines how to appropriately use the “activity not attempted” codes “07”, “09”, “88” and “10” with respect to the new Section GG items. Finally, as CMS engages in ongoing monitoring and testing of the psychometric properties of OASIS items, we will test and retest the Section GG items to ensure they remain applicable to a home health patient population.

GG Burden

Estimates to time to complete assessment

Comment Summary

Several commenters stated that the OASIS-D, including new section GG data elements, will impose significant burden on providers. They raised the following concerns; 1) the minutes per data element used to calculate burden were underestimated, 2) the minutes per assessment across all time points were underestimates, and 3) estimates of burden did not include the amount of time it will take to assess the items in the data set. A few noted that implementing a new OASIS version would also add to HHAs’ administrative costs, and recommended incorporating this additional time into the OASIS-D burden estimate. Three commenters provided their own estimates of burden. One commenter mentioned the cost of outside consultants, reviewers, remote specialists, training and retraining that home health agencies have to incur as part of their OASIS documentation. One mentioned that CMS time estimations for clinician assessment does not include time variations based on patient condition and frailty.

Response

CMS thanks the commenters for their comments. We wish to clarify that the 0.3 minutes per item factor accounts for coding the items based on an assessment that takes place in the course of care. Our burden estimates are intended to reflect only the time needed to complete OASIS items and is independent of clinical time spent assessing the patient. Commenters provided examples of additional burden by having to observe the activity, which is an activity describing the patient assessment, not documentation. We believe that burden estimates should not account for the time spend conducting a comprehensive assessment of the patient. Burden estimates are also not intended to reflect costs of training and operational processes; these are considered part of the operating costs for a HHA. We wish to also point out that the PRA guide states, “Generally, estimates should not include burden hours for customary and usual business practices.”

Comment Summary

One commenter strongly suggested CMS field test new OASIS items with HH clinicians before implementing them in the home health setting, as well as incorporate home health field clinicians proactively to contribute to the development of OASIS modifications.

Response

We wish to note that reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration (PAC-PRD), and we concluded that the functional status items have acceptable reliability and validity in PAC settings, including Home Health. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. A description of the testing methodology and results are available in several reports, including the report entitled "The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3" and the report entitled "The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3." These reports are available on our Post-Acute Care Quality Initiatives webpage at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>. Additional testing of these functional assessment items was conducted in a small field test occurring in 2016-2017, capturing data from 12 HHAs. Data results showed moderate to substantial reliability for the self-care and mobility data items. More information about testing design and results can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>. Finally, as CMS engages in ongoing monitoring and testing of the psychometric properties of OASIS items, we will test and retest the Section GG items to ensure they remain applicable to a home health patient population.

Comment Summary

One commenter noted that the Section GG items are challenging to answer. The commenter expressed concerns that the accuracy of the data may be compromised given the complex nature of the questions.

Response

We intend to provide training pertaining to the assessment and scoring of the new items, including scoring and assessment pertaining to patient performance. In addition, detailed guidance and examples will be included in the OASIS-D Guidance Manual to assist clinicians in scoring the items. Training will be provided in order to decrease any confusion and ensure the accuracy of the data reported.

Burden of Items Added

Comment Summary

Several commenters stated that the items removed from the OASIS did not offset the burden of the added items. Commenters noted that the addition of new items would add time to each assessment and increase the burden of the OASIS data collection process. Commenters also noted that HHAs will likely assess for issues (i.e. pain and pressure ulcer risk) even if the items are removed from OASIS.

Response

CMS thanks the commenters for their feedback. We disagree that we are adding documentation requirements and believe that we are reducing burden with the removal of items from the instrument. The burden estimate provided is separate from the need to perform a comprehensive assessment of the patient. The burden estimate for the OASIS represents the reduced burden in the reporting of items

required when completing the form. We consider the assessment activities described as clinical time spent assessing the patient.

Comment Summary

CMS received the following comment from the National Association of Home Care (NAHC). NAHC expressed concerns that the per-item time estimates assume equal weight to all the data elements within the OASIS assessment, and thus does not yield an accurate estimate of the amount of time it would take a clinician to complete the OASIS-D data set.

Response

CMS appreciates the comment. We disagree that there is a difference in coding responses among coding data elements. The PRA/Collection of Information burden is an estimate of how long it takes to code and enter the responses. We believe the commenter may be taking into consideration assessment activities, which are not included in our burden calculation.

Increase length of time for Start of Care visits

Comment Summary

One commenter stated that the overall changes to the OASIS item set will increase the length of time to complete the Start of Care (SOC) assessment, potentially resulting in patients' frustration, impatience and unwillingness to cooperate with staff. The commenter suggested that CMS offer an updated communication handout for CMS home care patient population to facilitate patient understanding and cooperation with the lengthy and detailed SOC visits.

Response

CMS appreciates the suggestion, however, we disagree with the commenter's assessment that the implementation of OASIS-D will result in a lengthier and detailed SOC. Testing conducted to evaluate new and revised items for OASIS-D suggest this will not be the case. We anticipate the burden of new items will be offset by item removals.

GG: Item Specific Comments

GG0130

Comment Summary

Several comments were received about item GG0130 H (putting on/taking off footwear). Commenters asked how the patient would access shoes and socks safely in an uncontrolled environment that may include unsafe storage of both.

Response

CMS appreciates the commenters' emphasis on patient safety when considering assessment for functional status items. CMS assumes that patient safety is paramount when evaluating a patient's functional capabilities.

With regard to the guidance requested, we intend to publish the OASIS-D manual in the near future, and to provide training on how to complete OASIS-D, including clarification of assessment scenarios where safety is a concern. Guidance for this item will emphasize that appropriate assessment of patient functional capability will be grounded in the concern for patient safety. We anticipate that guidance for

these data elements will remain consistent with the standardized guidance for this item that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>)

Comment Summary

Several comments were received asking how items in GG1030 were selected. Commenters also wanted to know if these would be risk adjusted, and how responses to the items would affect reimbursement.

Response

CMS thanks the commenters for their feedback. The GG0130 Self-Care activities were selected to support the process measure Percent of Home Health Episodes with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. We wish to note that reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration (PAC-PRD), and we concluded that the functional status items have acceptable reliability and validity in PAC settings, including Home Health. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. At this time, this process measure is not risk adjusted. The measure satisfies the IMPACT Act domain of "function status, cognitive function, and changes in function and cognitive function", and was finalized in the CY 2018 HH PPS final rule for the HH QRP beginning with the CY 2020 program year. We refer the reader to 82 FR 51722-51727 for more details on this measure. The Section GG items are currently used in the context of quality for quality measures and standardized patient assessment data elements.

Comment Summary

One commenter had questions regarding instances when a client does not meet a functional goal at discharge.

Response

While CMS expects that clinicians and patients will work together to periodically update or revise goals, CMS does not intend any consequence for goals that are not met. CMS expects that goals established will serve as the basis for providing quality care to patients and as a component of ongoing assessment of the patient's capabilities and needs. We wish to note that the finalized process measure Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) only requires at least one goal be documented, not met.

Comment Summary

One commenter asked for CMS to add modifications reflecting proper ostomy toileting hygiene in item GG0130C. The same commenter suggested this should also be clearly documented in the 2019 OASIS Guidance Manual for HHAs.

Response

CMS thanks the commenter for their input on additional items for consideration with respect to functional assessment, and will take the comments into consideration.

GG0170

Expected to Observe

Comment Summary

Two commenters questioned whether clinicians would be expected to observe all of the activities in the GG0170 items in order to perform the OASIS assessments.

Response

CMS appreciates the comment. Licensed clinicians may assess the patient's performance based on direct observation (preferred) as well as reports from patient, clinicians, care staff, and/or family.

We intend to provide guidance and training pertaining to the assessment and scoring of the OASIS-D, including scoring and assessment of new items such as GG0170 Mobility. The OASIS-D Guidance Manual is scheduled for publication in early July, 2018. Guidance for the standardized items is consistent across all four PAC settings.

Standardized guidance for this item that can be reviewed in the other PAC settings manuals (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip and <https://downloads.cms.gov/files/1-MDS-30-RAI-Manual-v115R-October-1-2017-R.pdf>)

Intensity

Comment Summary

Several commenters had concerns regarding the intensity of the section GG0170 Mobility items. Specifically, commenters noted the number of items added and the level of patient effort involved in the ambulation items (e.g. ability/safety for patients ambulating 10 feet, 50 feet, 150 feet, one step, 4 steps and 12 steps). One commenter asked for evidence that supports rationale for the GG0170 items in the home health setting, and noted it was unique relative to other PAC settings.

Response

CMS appreciates the commenters' emphasis on the patient's experience during the home health visit. The data elements were recently tested in a comprehensive field test of existing and potential OASIS data elements and found to be feasible, as described at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>. However, CMS is aware that the assessment of some functional status items from Section GG items may not be practicable in some home health settings. CMS is investigating the best process for addressing scenarios in which an item cannot be feasibly assessed. Please note that there will be guidance that outlines how to use appropriately the "activity not attempted" codes "07", "09", "88" with respect to the new Section GG items.

Safety

Comment Summary

We received several comments about the safety of the GG0170 items for home health patients. Most commenters highlighted the differences in the home versus the controlled environment of a facility, such as lack of space, lack of stairs, unsafe living conditions such as hoarding, uneven surfaces. One commented that a clinician may deem some of the tasks in GG0170 unsafe for the patient in general, or unsafe given the clinician's training and equipment. Another commented that these activities often cannot be safely accomplished in the home setting because stairs are not available, may be unsafe, or the patient may be unsafe during the activity. This commenter requested removal of assessment GG0170N and GG0170O and mentioned that as is, there will be frequent responses of "not attempted" due to any/all of the reasons cited in responses 07, 09, 10, or 88. One commenter mentioned that patients can be injured attempting these activities.

Response

CMS is aware that the assessment of some functional status items from Section GG items may not be practicable in some home health settings. CMS appreciates the commenters' emphasis on patient safety when considering assessments for functional status items. CMS assumes that patient safety is paramount when evaluating a patient's functional capabilities. Guidance for this item will emphasize that appropriate assessment of patient functional capability will be grounded in the concern for patient safety. Please note that there will be guidance that outlines how to use appropriately the "activity not attempted" codes "07", "09", "88" with respect to the new Section GG items.