CMS Response to Public Comments Received for CMS-10545

The Centers for Medicare and Medicaid Services (CMS) received comments from Home Health stakeholders, clinicians, and industry organizations related to CMS-10545. This is the reconciliation of the comments.

Comment:

Several commenters expressed concern that the Burden Estimate for the OASIS C2 does not accurately reflect the additional time that would be required to administer and implement the new version. While commenters recognized the importance of identifying and establishing cross-setting measures as mandated in the IMPACT Act, they had concerns about the number of the items that have been added or proposed for revision to facilitate this effort.

The commenters highlighted three main issues with the Burden Estimate. First, 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 provided their own estimates of burden that ranged between 60 to 150 minutes to complete documentation of the entire assessment. Another commenter estimated the revisions to the OASIS would add 10 minutes to the time required to complete an assessment at the start or resumption of care.

Second, commenters said that OASIS C2 burden estimates for training did not fully capture the added burden to agencies. They noted that even seemingly minor changes to the OASIS will require additional training and could affect accuracy; one commenter estimated over 8 hours of continuous training per year. One commenter suggested that the estimates should include staff time and costs to develop and/or revise training materials for initial and ongoing trainings. One commenter questioned the estimated average–size of a home health agency (HHA) as having 18 staff members requiring OASIS-C2 training (13 clinicians and 5 administrative staff) and asked if this estimate of 18 staff reflected individual staff members or full time equivalents (FTEs) only. This commenter added that failure to count the total number of individuals would lead to an underestimate of training costs, given that a significant number of clinical staff providing care to home health patients are employed or contracted on a part time or as needed basis. The commenter recommended the Burden Estimate include the total number of individuals requiring training. Another commenter suggested that CMS include in the Burden Estimate the costs agencies incur when clinical staff is required to be away from the field in order to participate in training, for example, when agencies need to employ the services of additional staff or pay current staff for additional hours to make the home visits required by patients during the training period.

Finally, commenters recommended that CMS ensure adequate education and outreach to the home health community prior to implementing OASIC-C2.

A few commenters also noted that each change to OASIS requires additional quality assurance/quality control costs to address potential errors. Specifically they cited needing

quality checks to verify accuracy, given changes in formatting (e.g. converting multiple check boxes to a single box for data entry) and changes in look-back periods, which add to the complexity of the OASIS-C2 item set. They noted this would also add to the administrative costs; commenters estimated that comprehensive quality assurance reviews could add 15- 20 minutes to the average, time spent on each OASIS collection and submission, and recommended incorporating this additional time into the OASIS-C2 burden estimate.

Response:

CMS recognizes and appreciates the commenters' concerns related to potential increases in burden with the implementation of OASIS-C2. OASIS-C2 includes 3 new items that support risk-adjustment for application of the cross-setting measure "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)"." These items would only be collected at the start and resumption of care and are important to assuring published measure results account for underlying difference in patient characteristics that affect risk for developing pressure ulcers. In addition, five existing items we remodified so that they are standardized across post-acute care settings, in support of the IMPACT Act. The lookback period has additionally been changed in five items to create internal consistency, and to allow providers to capture and report best practices provided throughout the entire quality episode. Documentation estimates are based on previous item testing across multiple agencies. Our training estimates are based on the number of HHA employees, not FTEs, using data published previously by the National Association of Home Care. CMS intends to offer training for all HHAs on the revised OASIS-C2 in late 2016, and will develop a variety of training materials for HHA use.

Comment:

Two commenters expressed concerns about CMS's approach to implementing changes as required by the IMPACT Act. One commenter asked CMS to consider that the OASIS data items have multiple applications (such as payment, value-based purchasing, star ratings, and quality measure reporting). In addition, one commenter recommended that as CMS is developing its approach to calculating and reporting cross-setting measures, the differences between the home setting and the institutional settings of the three other post-acute provider types should be recognized. Both suggested that CMS carefully consider any alterations made to the OASIS instrument in terms of how the changes will impact HHAs.

Response:

CMS appreciates the comment about considering the effect on HHAs of implementing changes as required by the IMPACT Act. CMS has used multiple processes to gather feedback regarding IMPACT Act requirements. These include several technical expert panels (TEPs), the public comment process through rulemaking, Open Door Forums (ODFs), contractor input/recommendations, and a designated mailbox, PACQualityInitiative@cms.hhs.gov. In addition, we consult internally with payment policy and value-based payment staff, as well as other

federal and internal stakeholders. All changes to OASIS data items are vetted and approved by payment policy, value based purchasing, star ratings and quality measure reporting leads. 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. 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 also believe that ongoing stakeholder input is important to the success of the IMPACT Act and look forward to continued and regular input from the provider communities as we continue to implement the IMPACT Act. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure and assessment instrument development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to CMS to continue to engage stakeholders, including patients and their families, throughout the measure and assessment instrument development lifecycle through our measure development public comment periods, the pre-rulemaking activities, participation in the Technical Expert Panels (TEPs) convened by our measure development contractors, as well as open door forums, and other opportunities.

Comment:
One commenter noted that the introduction of competitive bidding has slowed the availability of many pieces of durable medical equipment to patients in their homes that could affect risk for developing pressure ulcers, such as specialty mattresses, unrelated to HHA performance.

Response:
CMS appreciates the comment regarding the impact of competitive bidding for durable medical equipment and we have shared the concern raised regarding competitive budding and the delay experienced by patients since its adoption.

Comment:
One commenter stated that there is no provision for client choice when a home health admissions assessment is done beyond 48 hours of discharge. The commenter stated that while early visits are important to prevent rehospitalizations, many times clients do not want a visit until Monday if they go home on a Friday or are having follow up care appointments and don't want to start home health until afterwards, noting that agencies should not be held accountable for patient choice.

Response:
CMS appreciates the comment regarding admissions assessments completed after 48 hours. We wish to note that the Medicare Conditions of Participation do allow the time frame for the start of care date to extend beyond 48 hours from inpatient discharge if approved by the physician.

Comment:

CMS received multiple comments on the impact of formatting and item wording changes from OASIS-C1/ICD-10 to OASIS-C2. Specifically, three commenters noted that for several items (M1500, M1510, M2015, M2300, and M2400) the lookback period and the item number had changed. Commenters noted that this will be confusing for staff and will require more education. One commenter was concerned that changing the 'look-back' period to most recent SOC/ROC for Heart Failure Follow-Up and Emergent Care will change how the outcomes are tabulated on Home Health Compare, resulting in negative ratings for many agencies. Currently, these measures do not include Follow-Up OASIS reporting, often done to report these significant changes or as a recertification. One commenter applauded the changes to the look-back period as enabling HHAs to better align assessment and documentation to the time period defined for quality measurement.

Several commenters noted that the change to a single check box, in which the clinician must enter a response code, would be more time consuming for clinicians and cause data entry errors that could impact quality measure results. One commenter noted that formatting changes such as removal of check boxes and number formatting changes (e.g. Roman to Arabic numerals) are not consistent throughout the entire document and will cause confusion, adding that some items include check boxes while others require a number to be entered. Two commenters identified potential end user issues. Specifically, one commenter noted that numbers can be difficult to use on a laptop and even more problematic if there is no keyboard - noting that most laptops have the function keys directly above the numbers, and if a clinician inadvertently taps the wrong function key(s), it may erase data. Another added that the check boxes used in OASIS-C1 versions allow clinicians to efficiently use an electronic stylus to check off a box next to the selected response, whereas the proposed change would require two clicks to pick a response, one for curser placement and another to type in a number corresponding to a selection.

Response:

CMS appreciates the commenters' concerns about the change in lookback period and the transition to a single box for data entry. We additionally appreciate the commenter's support for aligning the look-back periods.

Formatting changes, including the move to a single box for data entry, were made to the OASIS to enhance alignment with other post-acute assessment item sets, as part of the overall efforts of standardization required by the IMPACT Act, and to improve data accuracy. Look-back periods were modified for five items to create internal consistency within the OASIS, and to allow providers to capture and report best practices provided throughout the entire quality episode. CMS intends to provide training on the OASIS-C2 in late 2016 to address these and other changes.

Comment:

One commenter recommended adding guidance to M1000 defining whether a swing bed falls under nursing facility or hospital.

Response:
Thank you for your suggestion regarding guidance for M1000. We wish to note that item M1000 has not been modified in OASIS-C2; guidance related to swing-beds is available in the OASIS Guidance manual under "Response –Specific Instructions" for Item M1000. The manual can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.
For additional questions related to CMS data collection guidance, you may submit your inquiry to the CMS OASIS help desk at CMSOASISquestions@oasisanswers.com**.**

Comment:
One commenter recommended that the word "SAFELY" in all caps be added to each response option for functional assessment items, to reinforce for clinicians that the correct response describes the patient's safe performance.

Response:
CMS appreciates the recommendation to add "SAFELY" to function items. Additional guidance on scoring the OASIS functional items, including the expected emphasis on safety in OASIS response selection, is available in the guidance manual. CMS will also consider item revisions in efforts to create standardized assessment items required by the IMPACT Act.

Comment:
One commenter recommended CMS consider adding language from the Chapter 3 item-specific guidance for (M1710) When Confused and (M1720) When Anxious into the NA responses. The commenter noted that if these responses stated "NA – Patient nonresponsive (OR) responds in such a way that a clinical judgment cannot be made…" the full meaning of the NA response would be contained within the item itself.

Response:
CMS appreciates the suggestion to modify the response options for M1710 and M1720 and will take this recommendation into consideration for future changes to the instrument. CMS will continue to refine guidance materials as we continue the development of the items and associated measures. We use an iterative process to updated guidance, based on questions received, clinical guideline updates and other feedback. We note that these items have not been modified in OASIS-C2; detailed guidance on completing this item is available in the OASIS Guidance manual. The manual can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html .

Comment:
One commenter recommended CMS reconsider the wording of response options for Item M1620 (Bowel Incontinence Frequency), noting that "Response 4 – On a daily basis;"

could be interpreted as meaning that bowel incontinence occurs only once daily. The commenter added that, in common vernacular, the interpretation of the phrase "on a daily basis" is "every day" – but not necessarily only one time every day. Changing this response language to "4 – Once daily" would make it more consistent with the language found in Response 5 and reduce the potential for inaccurate selection of Response 4.

Response:
CMS appreciates the recommendation to modify the response options for M1620 and will take this recommendation into consideration for future changes to the instrument. CMS will continue to refine guidance materials as we continue the development of the items and associated measures. We use an iterative process to updated guidance, based on questions received, clinical guideline updates and other feedback. This item has not been modified in OASIS-C2; detailed guidance on completing this item is available in the OASIS Guidance manual. The manual can be accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html For questions related to CMS data collection guidance, you may submit your inquiry to the CMS OASIS help desk at CMShomehealthqualityquestions@cms.hhs.gov.

Comment:
One commenter expressed concerns about the continued inclusion of M1025 (Optional Diagnoses) on the OASIS, and asked about the potential value of this item for risk adjustment of quality measures. The commenter requested that the guidance for this item provide more information about its use in risk adjustment. Specifically, the commenter suggested the guidance include a listing of specific resolved conditions that have been shown to be significant factors for risk adjustments using the ICD-10-CM diagnosis codes.

Response:
CMS appreciates the recommendation to include a list of ICD-10 codes used for risk-adjustment, and is committed to continual refinement of guidance materials. We wish to note that ICD-10 codes from M1025 are included in the risk adjustment process to allow HHAs the opportunity to include information about as many patient conditions as is both reasonable and feasible that may affect outcomes. For questions related to the calculation of home health quality measures, including risk-adjustment, you may submit your inquiry to the Quality Measures help desk at CMShomehealthqualityquestions@cms.hhs.gov In addition, detailed information about the risk models and covariates for OASIS-based measures can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html in the "Downloads" section.

Comment:
Several commenters had questions or comments about item M1028 (Active Diagnoses).

Commenters noted that M1028 seemed duplicative of existing items, noting that diagnostic information should be available in items M1021 and M1023. Two commenters asked for the rationale for singling out Diabetes and Peripheral Vascular Disease when other conditions also cause co-morbidity. This commenter recommended that CMS either clarify the use of proposed M1028, or eliminate it.

Another commenter asked that CMS define "active" diagnosis, highlighting that the conditions included in M1028 could be considered stable, and may not be a part of the Plan of Care. The commenter asked if one or more of these conditions are marked "active", would a corresponding ICD-10 code be required on M1021/M1023 and/or on the affiliated claim, and further asked about the future availability of guidance on "active" diagnoses. Another commenter asked for clarification regarding the allowable use of a "dash" in M1028 (Active Diagnoses), and the lack of a "N/A", "None of the above" or other alternate answer. This commenter also noted that in M1028, the instruction is to 'Check all that apply' compared to other items that instruct the clinician to 'Mark all that apply.'

Response:

CMS appreciates the comments regarding the need for and use of item M1028. We wish to clarify that this item will be collected at start and resumption of care only. The separate collection of data for these two specific diagnoses is deliberate, in order to accurately and consistently capture information on these important diagnoses that are known risks for pressure ulcers. To be able to fully account for these risks in calculating the rate of new and worsened pressure ulcers and to compare providers(?) fairly, CMS added these standardized items to the OASIS. This further supports the goals of our quality reporting and quality improvement efforts. The ICD-10 codes in items M1021 and M1023 are used for payment; these items have a limited number of spaces to enter codes and therefore may not capture all co-morbidities that affect pressure ulcer risk. Item M1028 is being added as a standardized item across PAC settings for use in risk adjustment; therefore, the response options, including the dash, are aligned with other PAC assessment item sets, to meet the requirements of the IMPACT Act. Further guidance on the "dash" and accurate responses when no active diagnoses are present will be provided in the OASIS-C2 guidance manual and future Q&As. CMS intends to offer training on standardized OASIS assessment items in late 2016. In addition, the OASIS-C2 manual will include detailed guidance on this item, including the meaning of "active."

The guidance for M1021 and M1023 are defined within our guidance manual. CMS has not yet provided any guidance for M1028 requiring any alignment with M1021 or M1023, and is committed to further refining guidance based on comments and questions received. "Mark all that apply" items and "check all that apply" items are different from each other in that "mark all that apply" refers to a numerical response and "check all that apply" requires selection of the appropriate item from a list of items. In addition, requirements for coding claims have not changed with the addition of this item.

Comment:
Several commenters raised a concern about M1060 (Height and Weight) and the challenges of securing accurate measurements in the home setting. Specifically they noted that scales are often not immediately available in patients' homes and difficult for clinicians to provide. In addition, home health clinicians have variable schedules and may not be there at the optimal time to measure weight (upon awakening, after voiding). Further, patients may be bed-bound or unable to stand or walk, making securing accurate and consistent data collection as described in the item difficult to achieve. Several commenters asked CMS for clarification on how the clinician should document if height and weight could not be measured (e.g., patient is bed bound, refuses to be weighed, and has kyphosis). One commenter noted that the height of a patient would not change so the practicality of additional assessments of patient height was questionable. A different commenter recommended that CMS add a response to M1060 items that allows clinicians to indicate that securing the measurements was not possible because of environmental limitations or as a result of the patient's inability to participate.

Another commenter asked for clarification on CMS's intent in adding M1060 and whether this item was added in order to estimate body mass index (BMI) and/or to be used for risk adjustment. Finally, a commenter asked CMS for clarification about whether this item refers to the weight measured by HH clinicians, or a patient's self-reported weight.

Response:
CMS appreciates the commenters' concerns about collecting information on patient height and weight using item (M1060).

Height and weight will be 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, and is standardized across post-acute care assessment item sets. A patient's BMI at the beginning of the care episode is used to risk adjust the application of the "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)"quality measure 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 of care when providing patient services and with respect to that, such patient assessment activities would not be compromised by staffing schedules. In the event that a height and weight cannot be obtained due to impossibilities, CMS has provided guidance that the information can be identified as not assessed. However, we note that in not providing such data the agency is unable to account for a potential risk factor associated with pressure ulcers. Further guidance will be available in the OASIS-C2 manual, in future Q&As, and in training to be provided to HH clinicians in late 2016.

Comment:

One commenter noted that improvement will be more difficult to measure and show for Medicare Advantage patients, compared to those in traditional Medicare, and that this could result in some HHAs being unfairly penalized due to the number of Medicare Advantage patients they serve.

Response:
CMS appreciates the comment regarding the effect of measuring improvement among Medicare Advantage patients, which the agency interprets as referring to financial penalties within the HH QRP. We wish to clarify that there are no financial penalties in relation to the HH QRP, outside of the APU, which includes a penalty if the agency does not meet the performance requirement for submitting quality assessments that can used to construct quality measures. Furthermore, all outcome measures, including those assessing improvement in function, are risk-adjusted to account for differences in patient characteristics, such as payer type, including whether a patient is Medicare Advantage. The purpose of the risk adjustment is to account for differences in clinical severity, functional severity, and services used in each HHA's patient population that may affect outcomes, so that comparisons across agencies reflect differences in quality not differences in patient characteristics

Comment:
One commenter raised concerns about the use of an NA versus none of the above (option 7) for M1017 and M1018, noting that an OASIS submission may be rejected when the clinician has NA for M1017 but checked option (7) "none of the above" for M1018. The commenter additionally suggested that if M1000 is marked NA, respondents should skip M1017 and M1018.

Response:
CMS appreciates the feedback on response NA for M1017 and M1018, but notes that these items have not been altered in OASIS-C2 from their current wording and response options in OASIS-C1/ICD-10. All previous data collection and submission guidance still applies to these items. Further, we wish to confirm that any changes to OASIS items will be communicated through the appropriate regulatory processes. For questions related to CMS data collection guidance, you may submit your inquiry to the CMS OASIS help desk at CMSOASISquestions@oasisanswers.com. For questions related to OASIS data submission, rejection or edits, you may submit your inquiry to the QTSO help desk at help@qtso.com and/or to your electronic health record vendor.

Comment:
CMS received comments from multiple stakeholders recommending that CMS consider adopting changes in staging and terminology from the recent National Pressure Ulcer Advisory Panel (NPUAP) press release and incorporate them into the OASIS-C2 and the accompanying guidance manual. Specifically, they recommended terminology changes to "pressure injury" in place of "pressure ulcer" should be implemented to coincide with other language changes already being implemented and removing "suspected" from

references to deep tissue injuries. One commenter additionally noted that the NPUAP had refined their staging from Stage 1 to unstageable. One commenter raised concerns about the confusion that could arise as a result of changes to the integumentary section of the OASIS, noting that clinicians must be retrained and will be expected to adapt quickly to these modifications. This commenter added that agencies do not have comparable data across time to evaluate their performance when data definitions change, further noting that there are differences between the structure of pressure ulcer items in OASIS and in the MDS used by skilled nursing facilities. This commenter recommended that CMS identify the best pressure ulcer data collection items, definitions and terminology, and apply them across the continuum of providers, while allowing for minor differences when needed.

Another commenter noted that item M1311 (Current Number of Unhealed Pressure Ulcers at Each Stage – for the Follow-up and Discharge time points) has 8 subcomponents, which will make completing the item more complicated. However, another commenter said that the format of the revised item M1311 with the addition of rows A2, B2, C2, D2, E2, and F2,is much easier to understand than former, two-column version of M1308.

Response:

CMS appreciated the commenters' request to align with revised NPUAP guidance. We are committed to grounding the OASIS items in the strongest science possible. We wish to note that NPUAP published its new guidelines after the release of OASIS-C2 and that we are working to analyze the impact of the NPUAP guideline revisions for potential future adoption. The changes to the integumentary section of the OASIS, including item M1311, were made to standardize data collection across post-acute settings, to meet the requirements of the IMPACT Act and support calculation of a standardized, cross-setting measure of new and worsened pressure ulcers. We appreciate the need for additional guidance on the revised items, which will be provided in the forthcoming OASIS-C2 guidance manual, future Q&As, and via training, to be offered to HH clinicians in late 2016.

In addition, we appreciate the commenter's support for the revised, standardized structure of M1311, as well as the concern regarding changes to standardize this item.

Comment:

CMS received several comments about item GG0170C (Bed Mobility) and how this item would be understood by clinicians. Commenters noted that the current scoring and scale for this item are different from extant ADL and IADL items in OASIS. Specifically, in the GG0170C response "06" represents most independent and "01" indicates most dependent, which commenters stated may confuse staff collecting the information and result in inaccurate data. They also cited increased burden of training for the new item, and recommended altering the order of the answers to this question to be more consistent with the other items on the OASIS. They additionally requested clarification for

responses 03 and 02 and how less than or more than “half the effort” could be reliably standardized for assessment purposes.

Two commenters requested adding definitions of "set up" and "clean up" in the guidance and both, asked about how this related to a patient’s ability to transfer from the bed. One added that the description for some response options related to mobility or transfers indicates trunk or limb support and asked for clarification on which functional task the question relates to: ambulation, transfer, or bathing. An additional commenter asked for clarification in the guidance on how the clinician should score a discharge goal for a bedfast patient or a patient who currently uses a lift system.

Response:

CMS appreciates the recommendations and comments regarding the addition of GG0170C to the OASIS-C2. We wish to clarify that this item will only be collected at the start and resumption of care. The purpose of this standardized item is to support risk adjustment of a publicly-reported rate for new or worsened pressure ulcers. We do not feel, this will add significant burden for providers. Adjustment for the higher risk of a developing or worsening ulcer among patients with limited bed mobility is important to allow valid comparisons across providers. GG0170C is standardized across all four post-acute settings to help meet the intent of the IMPACT Act. We wish to note that the scoring of the function items and the associated scales reflect the consensus development process. Clinicians and clinical experts recommended to the Post-Acute Payment Reform Demonstration (PAC PRD) item development research team that a higher level of ability should be represented with a higher numerical score on the associated scale. We subsequently tested these items and found strong inter-rater reliability. Of note, this item was also successfully tested in home health settings as part of the PAC-PRD demonstration. 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-C2 manual to assist clinicians in scoring the item. Training will be provided in order to decrease any confusion and ensure the accuracy of the data reported.

Comment:

Two commenters noted that GG0170C (Bed Mobility) did not address sitting to standing as a component of mobility, adding that the transition from sitting to standing is associated with increased falls risk. They recommended that the sitting to standing transition would be a more valuable addition to the OASIS, given the range of items already available in OASIS-C1/ICD-10.

Two stakeholders commented that the new item is to be completed at SOC/ROC and measures core strength as well as balance. They added that, in addition to the item being redundant with existing functional items, they were concerns about any comparisons that may be made based on GG0170C between home health patients and those patients admitted to a skilled nursing facility. One additionally noted that clinical goals had

previously been separate from OASIS scoring and asked why CMS did not instead add a "Discharge Column" to existing functional measures to capture the discharge goals.

Additionally, one commenter recommended that if CMS plans to convert all of the post-acute setting assessment tools to the GG format; it should do so all at once, noting that an incremental approach would require ongoing retraining of staff and result in a lack of comparable data over time. Another stakeholder noted that the standardized section GG items could duplicate ADL performance already captured in other M items such as M1800 (grooming), M1845 (toilet hygiene), M1870 (feeding/eating). An additional commenter asked for clarification in the OASIS guidance of the interrelationship between GG item and the other functional assessment items in the M1800 section.

Response:

CMS appreciates the comments about functional items in OASIS-C2 and the support for including a standardized item assessing the ability to transition from sitting to standing to the OASIS. We are continuing to assess opportunities to further standardize collection of functional assessment information across post-acute care settings. CMS is developing quality measures and items that standardized in a phased approach, and will modify the assessment instruments, if needed, in an incremental manner as suggested by our cross-setting TEPs.

We wish to clarify that GG0170C will only be collected at start and resumption of care, as a potential risk-adjustor for the standardized, cross-setting "Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)" measure. Bed mobility has been shown to be related to the risk of developing ulcers and is a standardized item, which will allow all PAC settings to account for differences in patient characteristics when reporting outcomes. In accordance with the requirements of the IMPACT Act, CMS will continue to review options for standardized assessment items, in line with legislative timelines. We wish to note that we have convened several technical expert panels and conducted additional stakeholder outreach to inform development and application of standardized functional assessment items in all post-acute care settings.

Comment:

Several stakeholders commented that identifying a discharge goal for GG0170C (Bed Mobility) would be challenging for nurses in a home health setting, noting that, according to OASIS guidelines, if the patient is getting skilled nursing and therapy services, a Registered Nurse must complete the comprehensive assessment. They added that a nurse's assessment of functional potential for GG0170C may differ substantially from a therapist's assessment of the same. Commenters said that, although OASIS is designed to have a certain level of inter-rater reliability, the skill and expertise of a therapist in establishing a discharge goal is well within their scope of training and practice, in contrast to the current scope and practice of registered nurses.

One stakeholder additionally questioned how this item will be used, especially across various providers, adding that a discharge goal for mobility in a nursing facility may be

different than in the home setting. Similarly, another commenter asked CMS for clarification on how the 'discharge goal' will be utilized.

Response:
CMS appreciates the comments and suggestions about specifying discharge goals for GG0170C. We wish to clarify that a comprehensive clinical assessment is the basis for care planning, which should include the establishment of goals or outcomes expected as a result of the provision of clinical care. This is a best clinical practice and goal coding by the clinician should be coordinated with patients, family members and caregivers. As noted above, this standardized item is being added to the OASIS-C2 to support risk adjustment. The collection of the discharge goal item is also aligned in response to the IMPACT Act. We wish to note that the item used for this risk adjustment factor, GG0170C (Bed Mobility) was developed through consensus by clinicians and clinical experts, including all levels of skills associated with staff—with strong reliability and validity.

Comment:
CMS received several comments on items M2001, M2003, M2005.

Two commenters identified the reliance on the term "potentially clinically significant" in the items as challenging. One added that because of the wide array of medications and modes of administration, in addition to the rate of change and addition of new agents to the market, maintaining a knowledge base of "potentially clinically significant" across all staff, all agencies and all facility types is unreasonable. The second commenter noted that PAC settings begin patient care prior to the availability of full patient histories. If patients are transferred from acute settings, typically, discharge summaries arrive first and full records follow. Patients who are directly **a**dmitted to home care will start care with a summary from the physician with records to follow. The ability to identify "potentially clinically significant" medication issues is limited and care needs to be taken when evaluating results and interpreting responses against patient outcomes.

Three commenters on these items expressed concern about the requirement that the clinician contact the physician within the specified time frame and "complete prescribed/recommended actions in response to the identified potential clinically significant medication issues." While commenters agreed that prompt action in response to clinically significant medication issues is important, they stated that the item as written is open to widely varying interpretation and requested clarification of "complete prescribed/recommended action."

Commenters expressed concerns that the requirements for "complete prescribed/recommended actions" are not always feasible in the home health setting. One commenter noted that "prescribed/recommended actions" may include interventions that are ordered to be done on a date outside of the next day timeframe (e.g. laboratory results need to be obtained before changes). This commenter suggested either changing the phrase to 'complete prescribed/recommended actions ordered to be completed by midnight of the next calendar day' or removing this phrase.

Several commenters highlighted the need for physician response in order to complete the item. M2003 does not capture when a physician does not return the telephone call from the clinician, which is critical information for home health agencies as they attempt to develop performance improvement strategies. One commenter added that the need to document not only attempts to reach the provider but also the completion of actions by midnight of the next calendar day places responsibility on only the HHA when the responsibility should be shared with the physician or physician-designee, whose attentiveness and response is required for completion of the process. Commenters recommended that CMS revise proposed M2003 by replacing the word "complete" with language that requires that the agency "initiate" the prescribed/recommended actions in a manner that mitigates the potential threat represented by the identified clinically significant medication issues, and additionally capture when a physician or physician-designee does not respond.

One commenter noted that CMS eliminated the examples of the types of clinically significant medication issues in M2001 and M2003, noting that the examples serve as important reminders/cues for clinicians conducting a comprehensive assessment of patients with complex needs in the home environment. This commenter recommended that CMS restore the parenthetical examples that were eliminated from M2000 in the M2001 revision. Finally, one commenter felt that three items for medications review made the OASIS more complicated than necessary.

One commenter appreciated that the wording changes in the item stem of the Medication items (M2001, M2003, M2005, and M2016) are helpful to define the intent of these items.

Response:

CMS appreciates all the comments and recommendations regarding the revised medication items M2001, M2003, M2005 and M2016, including the commenter's support for the wording changes. A potential clinically significant medication issue is an issue that in the care provider's clinical judgment requires physician/physician-designee notification by midnight of the next calendar day. Examples of potential clinically significant medication issues will be included in the OASIS-C2 guidance manual; however, we wish to clarify that identification of such issues should ultimately be based on professional clinical judgment of the assessing clinician. Further, a complete drug regimen review, as defined in the OASIS-C2 manual, makes use of all information that the clinician is able to access at the time of assessment. With respect to M2003, obtaining and acting upon physician or physician-designee guidance is an everyday clinical best practice for issues that meet the definition of "potential clinically-significant medication issues." Forthcoming guidance and training will address prescribed actions that require additional time to complete. We also note that our efforts to meet the requirements of the IMPACT Act will entail continued review and refinement of standardized data elements.