CMS Response to Public Comments on the Testing of a Revised OASIS Instrument for Home Health Quality Measures & Data Analysis

The Centers for Medicare & Medicaid Services (CMS) was pleased to receive a number of comments from home care providers and organizations expressing their support for many of the proposed changes proposed for the OASIS-C instrument. These comments included the following:

- The changes address concerns submitted by home health agencies since the start of collection of OASIS data;
- Several of the items recommended for elimination by providers have been removed in the proposed instrument, including overall prognosis, skin lesions, intractable pain, most problematic wound, and the "prior" column for the activities of daily living (ADL) and instrumental activities of daily living (IADL) items;
- The tool includes process measures that will foster clinically appropriate case management;
- Risk assessments for pain, pressure ulcers, depression and falls are supportive of appropriate quality initiatives;
- For the most part, the changes and additions to the form are valuable, worthwhile and will foster improvement in the quality of home health care;
- Process measures will help raise the quality bar for agencies that have not adopted these procedures independently;
- The removal of the prior 14-day criterion for measuring ADLs is particularly appreciated;
- The new reporting format provided for diagnostic coding is excellent;
- Significant improvement in the Caregiver items and the addition of the grid in M0345 is most helpful;
- The revision of the transfer assessment will provide more specific data re: the patient's abilities;
- The revision of the toileting assessment will provide more accurate data on the toileting needs of the home health patient;
- The revision of the ambulation/locomotion item will finally acknowledge the true progression of patients in their use of ambulatory devices;
- The changes in these items will have a significant impact on outcome measurement for the data for each time-point will be more accurate;
- Revised items are clearer and will provide more reliable data for outcomes and adverse events;
- We welcome the opportunity to classify reasons for emergent care and rehospitalization that actually reflect planned and non-emergent situations such as chemotherapy or scheduled surgical procedures.

CMS also received many comments expressing concerns and suggesting changes to the proposed OASIS-C. Both general concerns and comments on specific OASIS items are addressed in the sections below. CMS appreciates greatly the efforts of individuals and organizations that contributed comments, and believe that the revisions made in response to comments have resulted in an improved instrument.

CMS Responses to General Comments on proposed OASIS-C testing

1. Time points for collecting items

Comments: Time points for collecting OASIS-C items are unclear. Some of the process requirements cannot and should not be determined as part of the first visit; too many requirements for the first visit result in incomplete data (too early to determine) and in exhaustion for the patient; patients often feel overwhelmed with the time the clinicians are spending with them on a first visit

Response:

- Many of the concerns expressed about OASIS-C appear to be a response to confusion about time points for collection of process items. For most process items, only an initial assessment item and/or a question about planned care processes are asked at SOC/ROC. Follow-up questions regarding the implementation of the process measures are completed at Follow-up, Transfer, and Discharge. For example, at SOC/ROC, the clinician is asked to assess whether the patient received an flu vaccination during this year's recommended time period, and can respond either “yes”, “no”, “does not apply” or “unknown”. At recertification, transfer and discharge, the clinician is asked to document whether the patient received the flu vaccine, and if not, why not.

- Agencies should refer to the box on page 2 of the OASIS “Items to be Used at Specific Time Points” for direction on when each item is to be collected. A number of changes and corrections have been made to the directions about collection times in response to comments. Note that when a range of items is specified (e.g., M0080-M0826) all OASIS items in that range are included. Individual SOC/ROC, Follow-up, Transfer and Discharge versions of the OASIS, consisting only of items relevant at each time point, will be used for testing the OASIS.

2. Appropriateness of including process measures in OASIS-C

Comments: Agencies should not be required to implement specific care practices or best practice initiatives; there is no regulatory requirement that agencies collect or document care process items proposed for testing; many of the new OASIS items go beyond what the home care episode is focusing on process measures are duplicative of documentation elsewhere in the clinical record.

Response:

- It is correct that there is currently no regulatory requirement for agencies to implement care processes, and the OASIS-C does not require agencies to implement care processes. However, quality health care for people with Medicare is a high priority for the Department of Health and Human Services, and CMS is trying to provide a balance of measures. Increasingly, CMS is aligning all of its quality improvement activities to achieve the vision of “the right care for every person every time.” To achieve this goal, CMS has adopted the six aims of the Institute of

Medicine (IOM) for healthcare services. Quality Improvement Organizations (QIOs) have been providing assistance to home health agencies seeking to improve performance on the quality measures.

- Many agencies may be already be collecting data for some of the proposed OASIS process items, but the data is not documented in such a way that CMS can access the information to measure both what data are actually being collected by agencies, or assess how the implementation of best practices impacts outcomes. Extensive guidance on many of these practices is available from the Quality Improvement Organizations along with user-friendly tips, tools and ideas.

3. Burden associated with collection of process items

Comments: The OASIS should allow agencies to "opt out" of a question; the requirement to record information in multiple areas and to determine whether or not an assessment was done is a burden to the clinician; proposed process items (e.g., depression screening, medication follow-up) will require specialized/additional visits or will require skills outside the scope of clinicians.

Response:

- In response to comments, additional skip patterns have been added to the OASIS items to allow clinicians to skip areas not relevant to a specific patient. For all process items, providers also have the option of responding to the questions by marking "No" or "Unknown".
- Upcoming testing is specifically designed to assess burden. It has been the long-standing CMS recommendation that if agencies are already collecting information, they should substitute the OASIS item in their assessment forms rather than add an additional item to avoid duplication and increased burden.
- Data collection for proposed process measures will not require any specialized skills and can be completed by all clinicians currently approved to collect OASIS data. One goal of upcoming testing will be to assess the usability and burden associated with all proposed items and any problems clinicians encounter while collecting the OASIS data.

4. Clarity and consistency of OASIS item wording and guidance

Comments: OASIS wording is inconsistent; OASIS items sometimes combine more than one question, which is can be confusing to clinicians; the potential use of process items in pay-for-performance initiatives heightens the need for clarity in guidance provided for their completion.

Response: The OASIS instrument attempts to balance the burden of answering a multi-prong assessment item with the burden associated with increasing the number of questions by further dividing items. CMS has made efforts to try to clarify and simplify OASIS items wherever possible. In response to comments, several items have been either split or placed into a grid format for greater clarity. Planned testing for reliability and user-friendliness provide feedback about reliability and user-friendliness of these revised items and will provide the

opportunity to further refine wording of items and response categories, and to revise the guidance to clinicians that will accompany the OASIS-C.

5. Number of items and associated burden

Comment: OASIS-C is a longer instrument and will add burden to the patient assessment process; it will exacerbate the problem of clinicians leaving home care due to burden of paperwork; CMS should examine whether other OASIS items, such as IADLs, could be removed to reduce burden.

Response:

- CMS is committed to minimizing burden while collecting accurate information to meet payment and quality objectives, which is why testing, is being done to evaluate both burden and reliability of the proposed OASIS-C items. In response to comments, the Transportation IADL has been deleted at all time points and a number of items were eliminated form the Discharge assessment because they are not currently being used for either payment or outcome. The remaining ADL and IADL items are used for outcome measurement or risk adjustment and have been retained.
- Commenters may have overestimated the number of items that are actually being tested in the OASIS-C due to confusion about time points for collection of items. In the revised OASIS-C submitted in response to comments, the base number of items asked of all patients at Start of Care is 91 (including the one-time collection of the 17 Home Health Patient Tracking Sheet items). In the "worst case scenario" of a patient that has all of the following – diabetes, heart failure, Stage 3 or 4 pressure ulcer, stasis ulcer, surgical wound, pain, ostomy, urinary incontinence, depression, falls risk, and has a potential medication adverse event/reaction identified – the number of OASIS items to be completed at Start of Care is 114, including the 17 tracking sheet items.

5. Coordination of OASIS and CARE post-acute instruments

Comments: OASIS changes need to be coordinated with CARE; implementing such a significant revision of the OASIS assessment followed by another major change in a short period of time will place a burden on both home health agencies and CMS and foster inaccuracy in the completion of assessment items; OASIS and CARE follow inconsistent conventions regarding the ordering and numbering of scaled responses.

Response:

- CMS is aware that maximizing the coordination of the OASIS and CARE instruments to the maximum extent feasible will benefit everyone - home health providers, patients, caregivers and CMS. Wherever possible, we have aligned OASIS language with CARE. Items assessing patient stability and caregiver support have been changed to mirror CARE items.
- The issue of consistency in the ordering and numbering of scaled responses (with OASIS assigning higher numbered choices to higher levels of impairment and CARE, in some cases, assigning higher number responses for higher levels of functioning) will be re-examined after initial testing of each of the instruments.

6. Impact of OASIS changes

Comments: The proposed changes to the OASIS instrument will be overwhelming for clinicians and agencies; the impact of the changes is significant from the perspective of computerized system changes and training of staff; there is concern about trying to incorporate changes within the proposed time frame. Based on the multiple interfaces of the OASIS assessment with other clinical data in an electronic record system; a 2-year window is needed to adequately accomplish the tool's implementation and integration after its release with final OMB approval.

Response: Home health providers have been requesting specific revisions to OASIS since data collection was first mandated. CMS's goal of having a revised OASIS instrument in use by January 2009 is based on the desire to implement those requested revisions as soon as possible. However, CMS understands the need to proceed with a schedule that is feasible for providers and the industry, including training and changes to software. Once the OASIS-C instrument is tested and finalized, we will work closely with the industry to develop a schedule that allows integration of the revised instrument within a reasonable timeframe.

7. Testing plan

Comments: The proposed plan for testing the OASIS-C is inadequate in terms of the number of OASIS assessments that will be conducted, the number and geographic distribution of agencies participating in testing, the time period proposed for testing and the lack of an electronic version of the instrument.

Response: CMS has worked with their contractors to develop a testing plan that will provide needed information about the reliability and burden of the proposed OASIS instrument in the most cost-efficient and least burdensome way. The testing period is scheduled to enable the collection of all proposed OASIS items, included those that are restricted by season. In order to include geographic and agency diversity, the original testing plan was increased from 1 to 3 areas of the country and from 5 to 11 agencies. Agencies recruited to participate will be selected to maximize diversity in terms of urban/suburban location, ownership type and size to obtain a representative cross-section of home care providers. It is not within CMS's budget to expand testing further, nor is it necessary to collection additional data for statistically accurate estimates of burden and reliability. Likewise, it is not possible to invest the considerable time and cost to develop an electronic version of the proposed OASIS-C instrument, which would be used only during the 3-month test period.

CMS Responses to Comments on Specific OASIS Items

M0102 Date of Referral

Comments: Questions were raised regarding the purpose of the item and the time points the item is collected; concerns were expressed that the item is duplicative of other documentation and could lead to deficiencies as part of the survey and certification process; and suggestions were made for a wording change.

Response:

- The purpose of the item is to allow CMS to collect data on length of time between referral and first visit as an indicator of quality of care. It is understood that the first visit may be delayed in some situations, and agencies may document the reason for that delay in the patient's record.
- As per suggestion, wording of the item has been changed to:"Indicate the date this referral for home health services was made."
- This item is collected at SOC/ROC only. Please refer to general comments above regarding collection time points.
- Please refer to general comments above regarding duplication of documentation elsewhere in the clinical record.

M0104 Date of Physician Ordered Start of Care

Comment: The item descriptor beginning with "If, when…" is confusing and may be a typographical error

Response: Wording has been changed to read: **"**If the physician indicated a specific start of care date when the patient was referred for home health services, record the date specified."

M0150 Current Payment Sources for Home Care

Comment: In light of the rapid growth in the number of Medicare beneficiaries enrolled in "private fee for service" plans - recommend that this be added as a selection.

Response: Medicare beneficiaries enrolled in "private fee for service", also known as Medicare Advantage plans, are included in M0150 response option #2. Wording of this option has been changed to specify the inclusion of Advantage plans.

M0175 Inpatient Facilities

Comment: Deletion recommended in light of the poor performance of home health agencies in accurately responding to this item.

Response: No changes have been proposed or tested for this item that continues to be statistically valuable as a component of the risk adjustment model.

M0230/240/246 Primary, Other and Payment Diagnoses

Comments: Concerns were raised about burden associated with the continuing coding requirements for V-codes when numerical codes are needed for payment, and a request was made for a change to the OASIS manual regarding nursing consultation with physicians on coding.

Response:

- No substantive change is being proposed or tested for this item as it appears in the OASIS B1 (1/2008). Coding requirements for V-codes are necessary when numerical codes for payment are needed until sufficient data have been collected to enable the payment system to transition to using V-codes for case mix adjustment.
- No change is being proposed or tested in the way that agencies code home health diagnoses. The OASIS manual directs agencies to verify patient diagnoses with the physician, but does not reference coding, which is the responsibility of the agency.
- Letters have been placed in front of ICD-9 items in column 2 to improve the usability of the grid; e.g.: **a**. (__ __ __ . _. __ __)

M0275 Frailty Indicators

Comments: Requests were made for a change in the wording of the title to "Hospitalization Risk Indicators", for inclusion of additional risk indicators, for clarification of time frame for history of falls and for parameters for unstable vital signs.

Response: The item is intended to collect data related to the patient's risk of both hospitalization and major decline. Wording has been added - "Which of the following signs or symptoms characterize this patient as at risk for major decline or hospitalization?" - to clarify this an option of "Other" has been added. Additional wording was added clarifying history of falls as 2 or more falls - or any fall with an injury - in the past year. Guidance clarifying time frame for and unstable vital signs will be tested in the draft guidance to clinicians (Chapter 8 of the OASIS Manual, Item-by-Item Tips).

M0285 Stability Prognosis

Comments: Questions were asked about the value of the item and the validity of data that will be collected.

Response:

- Although questions about life expectancy are challenging for clinicians, the current OASIS item continues to be statistically valuable as a component of the risk adjustment model. This item was designed to replace M0280 "Life Expectancy" in response to concerns expressed by agencies. It was also designed to coordinate with a proposed CARE tool item, which has since been modified.
- Item wording to be used in testing has been modified in response to comments. The item now uses a format and language common to the latest version of the CARE instrument.

M1020/1021/1025 Influenza Vaccine

Comments: Concerns were expressed that OASIS will require HH clinicians to administer immunizations and that the documentation of immunizations is duplicative and overly burdensome. There was confusion about time points when the items are administered; and a request to change wording on timeframes for flu season.

Response:

- CMS encourages the use of care processes that may improve clinical outcomes. Immunization is going to be a focus for improvement across many types of care providers and is included in the CARE instrument. However, OASIS does not create a requirement for agencies to administer immunizations. If a clinician cannot safely transport or administer a vaccine, there is an option of referring the patient to receive the vaccine from another source and responding to M1025 by indicating that the vaccine was received from another health care provider. Agencies can also respond that the patient was not eligible, vaccine was offered and declined, vaccine was not offered, there was an inability to obtain vaccine due to declared shortage, or none of the above. Based on comments received, response option 2 for M1025 has also been modified to allow the clinician to indicate that flu vaccine is not indicated for a patient.

- Some concerns about these items seem to stem from confusion about when they are collected. Items are asked at Follow-up, Transfer and Discharge, as indicated in the box on page 2 of the OASIS "**Items to be used at Specific Time Points".** At Start of Care or Recertification, the clinician is asked to document only whether the patient's Influenza Vaccination status is up to date (M1020). At Follow-up, Transfer and Discharge, the clinician is again asked to document whether the patient's status is up to date (M1021) and if not, to state the reason (M1025).

- Regarding duplication of documentation, currently immunization data are not documented in such a way that CMS can access the information or assess how the implementation of best practices impacts outcomes. If agencies are already collecting information, they should substitute the OASIS item for their existing item, to avoid duplication and increased burden.

- CMS agrees with comments suggesting that the time period identified for administration of vaccines should be modified. In consideration of the fact that recommended times for influenza vaccination may vary from year to year (refer to CDC guidelines), the following revisions have been made to proposed Influenza Vaccine items:

    - M1020 has been changed to read, "Has the patient received an influenza vaccination during this year's recommended time period?"

    - A response option has been added to M1020 allowing clinicians to select, "NA - Does not apply. SOC/ROC date is not within time period."

- M1021 has been revised to ask, “Did the patient receive the influenza vaccine from your agency during this year's recommended time period?”

- A response option has been added to M1021 allowing clinicians to select, "NA - Does not apply because entire care episode is outside this year's recommended time period. (Skip M1025)"

- Proposed guidance in Chapter 8 of the OASIS Manual, Item-by-Item Tips, will advise agencies to check with the CDC to determine appropriate timeframe for administering vaccines, which may change from season to season...

M1030/1031/1035 Pneumococcal Vaccine

Comments: Many of the concerns mirrored those expressed about influenza vaccination There was concern that OASIS will require HH clinicians to administer immunizations and that the documentation of immunizations is duplicative and burdensome. There was also confusion about time points when the items are administered; and a request to change wording on timeframes for flu season. Additionally, concern was expressed that patients will not be able to recall when they last received pneumonia vaccine.

Response:

- Some concerns about the Pneumococcal Vaccine (PPV) items seem to stem from confusion about when data are collected. At Start of Care or Resumption of Care, the clinician is asked to document only whether the patient’s PPV status is up to date. At Follow-up, Transfer and Discharge, the clinician is again asked to document whether the patient’s PPV status is up to date and if not, to state the reason. Item numbering and skip pattern advice have been modified to alleviate this confusion:

    - M1030 (Is the patient's PPV status up to date?) is to be asked only at SOC/ROC, and skip pattern advice has been deleted.

    - M1031 (Is the patient's PPV status up to date?) has been added. It will be asked only at Follow-up, Transfer and Discharge, with a notation indicating that M1035 is to be skipped if PPV status is up to date.

    - M1035 (If PPV is not up to date, state reason) is completed only at Follow-up, Transfer and Discharge and only if response to M1031 indicates PPV status is not up to date.

- As stated above, CMS encourages the use of care processes that may improve clinical outcomes, but OASIS does not create a requirement for agencies to administer immunizations. M1030 has a response category indicating the patient’s PPV status is unknown. If a clinician cannot safely administer a vaccine, there is an option of referring the patient to receive the vaccine from another source or of responding to M1035 by indicating that the patient’s PPV status is not up to date because the patient was not eligible, vaccine was offered and declined, or vaccine was not offered.

- Based on comments received, response option 2 for M1035 has also been modified to allow the clinician to indicate that pneumonia vaccine is not indicated for a patient. CMS agrees with comments suggesting that it may be difficult for patients to recall pneumococcal vaccine status. If an agency chooses not to offer the vaccine in that circumstance, the agency has the option of responding to M1035 by indicating that the patient's pneumococcal vaccination status is not up to date because vaccine was not offered, and documenting the reason in the medical record. A graphic designed to assist clinicians in determining patient need for pneumococcal vaccine will be tested as part of the draft OASIS Manual Item-by-Item Tips.

- Regarding duplication of documentation: Immunization data are not currently documented in such a way that CMS can access the information or assess how the implementation of best practices impacts outcomes. If agencies are already collecting information, they should substitute the OASIS item for their existing question to avoid duplication and increased burden.

M1040 Guidelines for Physician Notification

Comments: Suggestions were made to eliminate this item due to potential burden and the absence of a regulatory requirement. A wording change was also requested since this item may not be completed at the SOC/ROC visit.

Response:

- It is correct that there is no regulatory requirement to establish clinical parameters for when to contact the physician. The OASIS-C does not require that the plan of care include such parameters and care providers have the option of responding to the item by marking "0 - No". CMS does require that contact be made with the physician for initiating care and clarifications; this could be an appropriate time point for agencies to discuss with the physician if parameters are warranted for a patient, in order to improve communication and coordination. CMS has noted that many agencies have established their own similar policies for establishing clinical parameters for when to contact the physician. Care plans containing such parameters may be indicators of high quality care and have the potential to result in more consistency across care providers when responding to changes in the patient's clinical presentation. .
- When responding to M1040, the HHA indicates whether parameters *specific to the patient's health care problems* were established to guide clinicians on when to contact the physician. Therefore, for example, if a patient's health care problems are not related to diabetes mellitus or other metabolic conditions that affect blood glucose levels, and if blood glucose levels are not being measured for the patient, then parameters for blood glucose would not be indicated. Likewise, deviations from a baseline weight may be important for patients with heart failure, but not for patients with other conditions. Many agencies have policies for normal vital sign parameters, including temperature, pulse, respirations, and blood pressure. Clinical textbooks, clinical guidelines, or other references can also provide such parameters. If the agency is using clinical pathways or other clinical guidelines for patients with specific conditions, parameters for the pertinent clinical measurements may be present. Such pre-established parameters may be used with or without modifications specific to the patient or at the physician's request.

- While clinical parameters might not be established during the start or resumption of care visit, they would normally be included on the plan of care, which is typically completed following the first visit. M1040 can be completed at that time. The burden associated with this data item will be tested during OASIS-C burden and reliability testing.

M0345 Patient Living Situation

Comments: There was concern that this item is confusing because it mixes two different questions. In addition, there was concern that caregiver's effectiveness is not assessed. Recommendation was also made that the word "Assistance" be added to each of the Living Arrangement choices.

Response:

- This item was designed to replace multiple questions about living situation in the current OASIS and will be tested for user-friendliness and reliability.
- CMS does not think the addition of the word "Assistance" to each of the Living Arrangement choices is warranted, since it is clearly stated in the item, and additional text can make the table more difficult to read.
- Regarding documentation of caregiver's effectiveness, it is appropriate for clinicians to include this in their assessment of the patient's living situation and document it in the patient record. Additional information related to patient needs and caregiver assistance is now collected in Item M0822, an item that mirrors the CARE tool question.

M0382 Types of Assistance

Comments: Add response categories to indicate that the patient is not receiving assistance, to document additional types of assistance, and to allow documentation of care provided by a family member or friend.

Response: M0382 has been replaced with M0822/M0823, a CARE-based item. This new item is moved to new section entitled "Support Need" located just prior to "Therapy Need". It provides an opportunity for clinicians to document gaps in care and caregiver need for training or support.

M0384 How often does the patient receive ADL or IADL assistance

Comment: Add response categories to indicate that the patient is not receiving any assistance.

Response: M0384 has been replaced with M0824. This new item is moved to new section entitled "Support Need" located just prior to "Therapy Need".

M0420 Frequency of Pain

Comments: Item "0" should be separated into two distinct items: (1) "Patient has no pain," and (2) "Pain present but does not interfere with activity or movement." If no pain, then M1060 and M1065 could be skipped. If a patient has pain that does not interfere with activity, then pain interventions may be indicated.

Response: CMS implemented this suggestion allowing the clinician to skip items related to pain assessment and intervention if the patient is not experiencing any pain.

M1050 Pain Assessment

Comments: Items related to pain assessment should be reordered; CMS should add a tool into the assessment that is approved by nationally recognized expert bodies; time spent on the completion of assessment tools should be included in the study of the impact of the proposed OASIS revisions

Response:

- Changes to M0420 now allow improved skip patterns, with M1050 no longer being assessed for patients who are not experiencing any pain.
- CMS encourages the use of care processes, such as the use of a standardized pain assessment, which may improve clinical outcomes. CMS is also interested in collecting data that will enable them to identify agencies that are adopting these care processes and evaluate how they impact outcomes. The burden of data collection will be tested as part of the burden and reliability testing to be conducted in 2008. However, the decision about whether to incorporate a pain assessment into the agency's best practice processes, or which pain assessment tool to use, remains within the domain of the agency.

M1065 Pain Intervention

Comments: Confusion was expressed about time points for collection

Response: This item is to be collected at Transfer, Follow-Up and Discharge. The box on page 2 of the OASIS "**Items to be used at Specific Time Points"** has been corrected to reflect this.

M0446/M1070 Risk of Developing Pressure Ulcers

Comments: It may not be necessary to have a formal evaluation for pressure ulcer risk, because some patients can be evaluated without using a pressure ulcer risk tool (e.g., Braden scale). A specific tool should be specified in the data item and burden of administering the risk assessment should be estimated. CMS should include time spent on the completion of the assessment in the impact of the proposed revisions. The term "relieving device" should be replaced by "redistributing device."

Response:

- M0446 and M1070 have been revised so that clinicians can skip related items if the patient is not at risk of developing pressure ulcers. M0446 has been split into a "process" item (M1070) and an "assessment" item (M0446). Previously M0446 tried to measure both simultaneously, which may have contributed to the confusion about the originally proposed item.

- While CMS will not mandate the use of a single tool, the draft guidance for clinicians (i.e., OASIS Manual Chapter 8 Item-by-Item Tips) will note specific tools that HHAs may choose to use.
- The burden of data collection will be tested as part of the burden and reliability testing. However, the decision about whether to incorporate a formal evaluation for pressure ulcers into the agency's best practice processes remains within the domain of the agency.
- Wording has been added to allow the evaluation of pressure ulcer risk by clinical evaluation and to include the term "pressure-redistributing" device.

M0448 Pressure Ulcer

Comment: The term "unhealed" is confusing to clinicians.

Response: The item was reworded as follows: "Does this patient have at least one unhealed (non-epithelialized) pressure ulcer at Stage II or higher or designated as "non stageable."

M0452 Current Number of Unhealed Pressure Ulcers at Each Stage

Comment: It is not necessary to separate the Stage III and Stage IV with or without eschar and the language is not consistent with WOCN and NPUAP assessment guidelines. The item does not allow clinicians to represent the presence of healed Stage III and Stage IV ulcers.

Response:
- Based on comments, changes were made to eliminate "b.i. Stage III with eschar"; "b.ii State III without eschar", "c.i. Stage IV with eschar" and "Stage IV without eschar". The determination of the stage should be made according to WOCN and NPUAP guidelines.
- Wording was changed to include the term (non-epithelialized) as well as unhealed.
- M0452 is specific to unhealed pressure ulcers. While not required for OASIS reporting, CMS acknowledges that healed Stage III and IV ulcers are at risk for break-down and encourages care providers to document their presence in clinical notes and the plan of care.

M0454 and M0456 Wound Length and Width

Comment: Wound length and width are typically measured using the clock reference (with the patient head at 12 o'clock) and in centimeters. The item is a standard of care and requiring the information is duplicative.

Response:
- Currently there is inconsistency in the manner in which wounds are measured. Recent research (in press) has shown that the reliability of measurement improves when using the method described in the question. The measurement method described in the OASIS is consistent with the CARE item for pressure ulcer length and width measurement. The item has been changed to request the wound measurements in centimeters.

- Wording was also changed to include the term (non-epithelialized) as well as unhealed.
- Please refer to CMS's general comments on the issue of documentation of items that may be recorded elsewhere in the medical record, and on the inclusion of process items in the OASIS

M0461, M0478, M0487 Status of Most Problematic [Ulcer or Wound]

Comments: Why is the term re-epithelialized used versus healed?

Response: Response has been clarified to include the terms re-epithelialized or healed

M0465 Stage of Most Problematic (Observable) Pressure Ulcer

Comments: This item should be skipped if the patient has no pressure ulcers at all time points. It is not necessary to separate the Stage III and Stage IV with or without eschar, and the language is not consistent with WOCN and NPUAP assessment guidelines.

Response: OASIS skip patterns have been created to allow this item to be skipped if there is no pressure ulcer. The terms "with eschar" and "without eschar" have been removed and the responses will simply reflect the stage of the ulcer. The determination of the stage should be made according to WOCN and NPUAP guidelines.

M0488

Comments: Item is duplicative and should be removed.

Response: The OASIS-C does not contain an item identified as M0488.

M0489 Skin Lesion or Open Wound

Comments: Concern expressed that this item will need clear explanation. Question was asked about alignment with WOCN/NPUAP guidance and whether ostomies are included.

Response:

- The item simply requests information on skin lesions or open wounds other than pressure ulcers, stasis ulcers, or surgical wounds for which clinical interventions are occurring. This could include a variety of types of wounds, including burns, skin tears, abrasions, diabetic ulcers, etc.
- Current WOCN and NPUAP OASIS guidance is specific to pressure ulcers, stasis ulcers and surgical wounds which are not addressed in M0489.
- Ostomies *other than bowel* that are receiving clinical interventions should be included when responding to M0489. Bowel ostomies can be documented by ICD-9 in M0230/240/246 and are addressed by items M0540 and M0550. However, excoriated skin or granulation tissue around a bowel ostomy that requires clinical intervention (vs. a healthy ostomy) may be included when

responding to M0489. Draft clinical guidance (i.e., OASIS Manual Chapter 8 Item-by-item tips) will include these instructions.

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M1080 and M1085 Pressure Ulcer Intervention

Comments: The inclusion of specific types of dressing on the OASIS may lead to inaccurate assessment of data when the physician order is not provided for the use of a moisture retentive dressing. Unclear on why both items are included.

Response:

- Current research indicates moisture-retentive dressings produce a statistically significant improvement in the rate of healing for most open pressure ulcers. The wording of the item has been revised to indicate the item should be collected only if the wound is open. If a moisture-retentive dressing is not appropriate for a patient, the clinician can indicate that by selecting the "not indicated" response. If a moisture-retentive dressing is not contraindicated, but the physician has not ordered one, the clinician should select response "0 - No". If the clinician wishes to document additional rationale for not using moisture-retentive dressings, this can be done elsewhere in the clinical record, but is not required for OASIS-C reporting.
- Item M1080 refers to care planning and is answered at SOC/ROC. Item M1085 refers to clinical intervention and is answered at Follow-Up, Transfer and Discharge time points.

Diabetic Ulcers

Comment: Request for an additional item to address diabetic ulcers.

Response: While CMS acknowledges the importance of documenting diabetic ulcers in the clinical record, the prevalence of diabetic ulcers is not high enough to justify the addition of a new question in the OASIS instrument. Use of diagnosis codes for diabetic ulcers in M0230/240/246 will provide information needed by CMS to track prevalence and for case-mix reimbursement issues.

M1090 and M1095 Foot Care Education/Follow-up

Comments: Questions included whether the item includes PVD, how this item could be answered at SOC, and how the clinician should respond for noncompliant patients. Suggestions were made to add a tool that is approved by nationally recognized expert bodies.

Response: Item M1090 refers to care planning and is answered at SOC/ROC. Item 1095 refers to clinical intervention and is answered at Follow-Up, Transfer and Discharge time points. These items should only be answered for patients with the diagnosis of diabetes, and address one element of care for diabetic patients. OASIS items are not meant to represent all clinical documentation requirements and it is often necessary to supplement OASIS information with additional clinical notes. While other clinical interventions may be performed, they will not be

reported as part of OASIS-C. If a patient refuses foot care monitoring or education, the response to M1095 at Follow-Up, Transfer and Discharge would be, "0 - No." The care provider may document rationale (e.g., patient refusal) elsewhere in the clinical record.

M0490 Short of Breath

Comment: Change the first response option by removing the word “never” as it is unrealistic.

Response: Response changed to “0 – Patient is not short of breath”

M1100 and M1105 Symptoms of Volume Overload

Comments: Concerns were voiced about collection time points and that the enumeration of M1100 is confusing because it is too similar visually to M1110. There was also a comment that guidance on responding to these items must be made very clear.

Response: Item M1100 has been renumbered as M1102 to avoid confusion. Item M1102 refers to care planning and is answered at SOC/ROC. Items 1105 and M1110 refer to clinical intervention and are answered at Follow-Up, Transfer and Discharge time points. Clarity of guidance will be evaluated during OASIS-C burden and reliability testing.

M0590/1120/1130 Depressive Feelings/Depression Screening

Comments: Clinicians will need an option of no assessment indicated or needed. Assessment tools should be available as a choice for the best practice process of all agencies but not mandated as part of the Oasis Instrument. Screening for depression is out of the scope of practice for some clinicians collecting the OASIS. Time spent on the completion of these tools should be included in the study of the Impact of the proposed OASIS revisions.

Response:

- M0590 and M1120 have been reordered so that Depression Screening can be skipped if no signs or symptoms of depression are observed or reported.
- Clinicians are assessing depression as part of the OASIS tool currently in use; proposed screening with standardized screening tools does not require any specialized skills and can be completed by all clinicians currently approved to collect OASIS data. Several depression screening tools are identified in the draft guidance to clinicians (i.e., OASIS Manual Chapter 8 Item-by-item Tips). One goal of upcoming testing will be to assess the usability and burden associated with all proposed items.
- As stated previously, there is no requirement in the new OASIS-C for agencies to implement care processes such as depression screening. Care providers have the option of responding to the questions by marking "No." However, assessments and care plans containing such care processes may be indicators of high quality care. If a patient exhibits signs or symptoms of depression, CMS would expect some agency follow-up to be documented.

ADL General Comments

Comments: Elimination of “Unknown” from these data items may create dilemmas for clinicians who, for reasons out of their control, are unable to elicit the needed information to correctly respond. This could result in inappropriate selection of one of the other choices.

Response: OASIS-C eliminates the requirement to assess prior status for ADLs and IADLs, where "unknown" was previously an option. As is the case in the OASIS instrument currently in use, patient status on ADLs/IADLs at SOC/ROC must be assessed and cannot be “unknown”.

M0672 Bathing

Comment: There is an inability to show progress when patient achieves ability to bathe self in chair or commode

Response: A response category has been added to document a patient’s ability to bath self independently or with the use of devices in a chair or on the commode.

M0715/717/750/805 Change in Ability

Comments: There is a need to clearly define use of the term “prior to the current illness or injury". Prior should be defined as since home care started or change from baseline.

Response: Wording changed to “before the onset of the illness or injury that initiated this episode of care.”

IADL General Comments

Comments: IADLs seem a prime example in which items could either be removed or made optional depending on their relevance to the patient. Services to improve function in IADLs are not paid for by the Medicare benefit - it is inappropriate to require home health agencies to collect IADL data.

Response: Based on comments received, CMS has eliminated the IADL assessing Transportation (M0732). The remaining IADLs in the OASIS are used for outcome and risk adjustment and their removal would have a negative impact on home health outcomes assessment.

M1140/1150/1160 Falls Risk Assessment and Intervention

Comments: Confusion about time points for collection was expressed. A wording change was requested to allow “observation only assessment” such as “get up and go”. Commenters stated that decisions about implementing best practices/ assessment tools should be the agency choice and that the burden of OASIS should reflect time to conduct the falls assessment.

Response:

- Items M1140 and M1150 refer to care planning and are answered at SOC/ROC. Item M1160 refers to clinical intervention and is answered at Follow-Up, Transfer and Discharge time points.
- Wording has been changed to ask whether a multi-factorial assessment has been conducted "*such as* falls history, use of multiple medications, mental impairment, toileting frequency…." to clarify that not all the assessment of all the factors listed may be necessary for every patient. A balance test alone, although predictive, is not a comprehensive assessment of other risk factors.
- As stated previously, there is no requirement in the new OASIS-C for agencies to implement care processes such as falls assessment. Care providers have the option of responding to the questions by marking "No." However, assessments and care plans containing such care processes may be indicators of high quality care.

M0782/M0792 Management of Medications

Comments: Interest was expressed in adding the ability to document episodes of care where home health agencies successfully teach caregivers to safely administer medications when patients do not have the potential to do so themselves

Response: M0822, Support Need, has been added which will allow the documentation of progress in caregiver's ability to administer medication.

M0792 Management of Inhalant/ Mist Medications

Comments: Suggestions were made to include use of oxygen in the item stem since it would be clearer to state this inclusion in the question rather than have it as an instruction in the OASIS manual.

Response: Item wording has been modified to include the word "oxygen" in the question.

M1160 Potential Adverse Effects/Reaction

Comments: Request was made to include issues related to omissions and dose errors. Concern expressed that this is out of the scope of practice for physical therapists.

Response: Wording was changed to include omissions and dosage errors as part of the drug regimen review. Although some states have restrictions on taking medication orders, it is within the scope of the PT to notify the physician regarding concerns about the patient status and medication problems or non-compliance. Potential clinically significant adverse effects or drug reactions, including ineffective drug therapy, side effects, drug interactions, duplicate therapy, omissions, and dosage errors can be further assessed by the clinician who completes the drug regimen review at the agency.

M1170 Medication Follow-up

Comments: A wording change was requested to enable dealing with non-urgent medication issues. Concern was expressed that the title is confusing because it is inconsistent with JCAHO definition of Medication Reconciliation. Concerns were also raised about survey interpretation of "No" responses to this item.

Response: Item heading has been changed from "Medication Reconciliation" to"Medication Follow-up" to avoid confusion with JCAHO requirement. The wording of the item was changed to specify contact with physician for "clinically significant" medication issues per agency policy, although collection of this data may also be helpful in uncovering care coordination problems regarding medications. The item is being tested as a way to enable CMS to identify agencies using care processes that may be indicators of high quality care, not to alert surveyors to potential problems. Situations in which medication issues have been resolved without contacting the physician may be documented in the patient's record.

M0810 Patient Management of Equipment

Comments: Confusion about time points for collection.

Response: Added notation for skip pattern to be used at Discharge.

M0826 Therapy Need

Comments: A requirement to predict an exact number of therapy visits is very problematic. Should require only the level of detail that a clinician can reasonably be expected to predict at the Start of Care

Response: Number of therapy visits is collected at SOC in order to place the patient episode in the correct payment group so that CMS can make the most accurate estimated payment to the agency. As in the current OASIS, clinicians should review the plan to determine whether therapy services are ordered by the physician, and if so, how many total visits are indicated over the 60-day payment episode. This information should be obtained from the plan of care within the 5-day window for SOC completion. If the number of visits that will be needed is uncertain, clinicians should provide their best estimate.

M0831 Emergent Care

Comments: Confusion about time points for collection.

Response: M0831 is collected at Transfer and Discharge only

M0845 Reason for Emergent Care

Comments: Confusion was expressed over the reason for inclusion of chemotherapy and scheduled surgical procedure. Suggestion was made to include wound deterioration as well as infection.

Response: Response option wording was changed, so that chemotherapy and scheduled treatment or procedures were deleted, and wound deterioration was added as a reason.

M0896 Reason for Hospitalization

Comments: Confusion was expressed over the reason for inclusion of chemotherapy and scheduled surgical procedure. Suggestion was made to include wound deterioration as well as infection and other scheduled treatments

Response: Response option wording was changed, so that “scheduled treatment or procedure” was substituted for chemotherapy and scheduled surgical procedure, and wound deterioration was added. Some hospitalizations are scheduled and this will allow a measure beyond the existing reasons.