

**Response to Public Comments on the  
OASIS-C1 Data Set for  
Home Health Quality Measures & Data Analysis  
(Form# CMS-R-245/OMB# 0938-0760)  
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Overview.....	1
Part 1 – General Comments.....	1
A. Comments on changes to the data set.....	1
B. Comments on burden.....	3
Part 2 – Item-specific Comments.....	4
M1000 Inpatient Facilities in Past 14 Days.....	4
M1011 Inpatient Diagnosis.....	5
M1025 Optional Diagnoses.....	5
M1033 Risk for Hospitalization.....	6
M1046 Influenza Vaccine received.....	7
M1100 Patient Living Situation.....	7
M1240 Pain Assessment.....	7
M1306 Unhealed Pressure Ulcer Stage II or Higher.....	8
M1307 Oldest Stage II Pressure Ulcer.....	9
M1308 Current Number of Unhealed Pressure Ulcers.....	9
M1309 Worsening in Pressure Ulcer Status.....	10
M1320 Status of Most Problematic Pressure Ulcer.....	10
M1324 Stage of Most Problematic Pressure Ulcer.....	11
M1334 Status of Most Problematic Stasis Ulcer.....	11
M1340 Presence of Surgical Wound.....	11
M1342 Status of Most Problematic Surgical Wound.....	12
M1500 Symptoms in Heart Failure Patients.....	12
M1600 Treatment of Urinary Tract Infection.....	12
M1610 Urinary Incontinence or Catheter.....	13
M1700 Cognitive Functioning.....	13

M1800 Grooming..... 14

M1850 Transferring..... 14

M1860 Ambulation/Locomotion..... 14

M1910 Falls Risk Assessment..... 15

M2102 Types and Sources of Assistance..... 16

M2250 Plan of Care Synopsis..... 18

M2300 Emergent Care..... 18

M2400 Intervention Synopsis..... 19

## **Overview**

The Centers for Medicare & Medicaid Services (CMS) received comments on the Draft OASIS-C1 from a total of 10 home care clinicians, agencies and organizations . Many commenters addressed multiple topics and items.

Most commenters expressed their support for proposed changes to the OASIS data set and offered a number of useful recommendations for modifications to improve the OASIS-C1. All of these suggestions were considered by CMS and in many cases they were incorporated into the proposed OASIS-C1 revisions. We also received several comments on OASIS burden, primarily focused on the positive impacts of reduction of burden in OASIS-C1.

Some commenters voiced concerns about the content and format of new, revised and existing items. In each instance we have attempted to address these comments and concerns in our responses..

In the first part of this document, we summarize positive feedback and address general comments. In the second half of the document, we respond to item-specific comments and suggestions that are not covered in Part 1 (positive comments about individual items are not repeated in Part 2). Please note that in some cases the comments as they appear here are composites of comments received from multiple individuals and/or organizations.

## **Part 1 - General Comments**

### **A. Comments on changes to the data set**

We received multiple comments expressing approval of wording changes to OASIS items. These focused primarily on improvements in clarity in terminology, timeframes, and items that clinicians have found challenging, such as those that collect data on immunization and pressure ulcers.

#### **1. Clarification of terminology and time frames**

- We appreciate the clarifications that CMS has made in OASIS-C1, including the improved wording and the effort to use language and terms that are consistent across home health data collection methods and across health care settings. We believe these clarifications make OASIS items more intuitive for users.

- I applaud CMS for the OASIS-C1 proposed changes. In my opinion, most are designed to increase OASIS accuracy and efficiency. Specifically, (1) accommodation of the 7-digit format required by ICD-10-CM, and (2) changes for clarity in terminology.
- We support the efforts to simplify certain phrases or expressions used throughout the data set. This includes replacing the word “during” to “within” in item M1000, and replacing abbreviations such as “e.g.” and “i.e.” with more straightforward language. These are now clearly identified and hopefully will reduce the internal and external debates over what is and what is not included in data collection.
- We support the addition of the word “validated” to the description of the assessment tools referenced in the best practice items including M1240, M1300 and M1730. Inclusion of this term will reinforce the need to use properly validated measurement tools in these important process measures.
- Expansion of the language in the “Not Applicable” columns of M2250 and M2400 should help to improve accuracy in collection of this data.
- We support the clarification of the time frame language in M1500, M2004, M2015, M2300, and M2400 within the item which will assist both agency trainers and field clinicians to understand and accurately collect the required information.

## **2. Simplification of immunization items**

- We specifically appreciate the simplification of the influenza vaccine on admission items as these items have been especially problematic for clinicians to understand and to complete appropriately.
- The revision of the items related to pneumonia and flu vaccination (M1040, M1045, M1050 and M1055) refocus data collection on whether the patients have been vaccinated, not whether the vaccination was provided by the agency. The proposed revisions should provide better data for CMS and minimize the training, quality control monitoring and correction of these items that is currently required because of the confusing language.

## **3. Simplification of pressure ulcer and stasis ulcer documentation**

- Breaking some of the more difficult OASIS items into two questions reduces confusion and will increase accuracy. In my experience as an OASIS trainer, M1308 has been the most difficult item for clinicians to grasp and answer correctly. The modified M1308 and new M1309 in OASIS-C1 are an excellent improvement to the item and are now self-explanatory and will hopefully reduce training time!
- Revision of M1308 and addition of M1309 should finally clarify what has always been a confusing and challenging but critical area of data collection. Training staff and insuring the collection of accurate data using the current and prior versions of M1308 has always

been challenging for agencies and field clinicians. We truly appreciate this simplification of the reporting mechanism.

#### **4. General Improvements**

- The proposed changes would make OASIS data items clearer and allow users to focus more time on patient care and spend less time on instruction and administrative requirements.
- We appreciate CMS efforts to improve OASIS, and we support continued efforts to refine a tool that helps focus providers' efforts on quality and ultimately improves outcomes for patients, as well as the value for those patients and the public.

**Response:** We wish to express our appreciation to all the home care clinicians, agencies and organizations that provided suggestions and feedback on wording and format changes during both the OASIS-C1 development phase and the comment period. We appreciate your input and thank you for recognizing the value of these proposed changes.

#### **B. Comments on burden**

We received 4 comments expressing approval on OASIS-C1 burden reduction, and 1 comment expressing concern about OASIS burden.

##### **1. Improvements in burden**

- We support the proposed changes to the OASIS assessment instrument [and] appreciate CMS's willingness to address stakeholders' concerns and to reduce some of the burden associated with the OASIS C collection.
- We appreciate and support elimination of M1310, M1312 and M1314. These items do little to enhance the OASIS data and their elimination will save field clinicians precious time in completing the OASIS.
- We appreciate CMS's commitment to streamlining the OASIS data collection and including only the items that are necessary for payment or quality measure purposes.
- We support the deletion of the items and certain time points as a way to reduce administrative burden while continuing to collect key data.

##### **2. Concerns about burden**

We continue to believe that CMS is significantly underestimating the amount of time agencies devote to OASIS data collection, quality review and correction. Responsible agencies conduct a quality review of every diagnosis code that is included on an initial OASIS data set as it has profound implications for clinical planning, billing and compliance. The addition of the process measures in OASIS-C have significantly increased the amount of time spent in the field and in

the office reviewing the plan of care and the visit notes in order to insure that the items are completed accurately. In addition, ongoing training is provided to insure that clinicians remember to apply the detailed definitions on which the items rely in order to insure that data collection is accurate and uniform. In addition, the amount of time that CMS has estimated for data submission is quite inaccurate, particularly for agencies that do not employ an electronic clinical record.

**Response:** CMS appreciates the recognition of our efforts to revise the OASIS data set in a way that is responsive to industry concerns while minimizing burden. We acknowledge that estimates for the time required to complete OASIS-related activities represent the average time needed to complete the OASIS. The time needed to complete and submit OASIS data will vary based on factors such as the level of experience of the clinical professional, complexity of the patient's conditions, and use of paper or electronic data collection practices. Agencies are also reminded not to conflate time required for OASIS-related activities with either: a) time spent for collection of non-OASIS items that have are included in the agency-specific comprehensive assessment; or b) time spent on other non-OASIS activities such as general care planning, billing, monitoring, and training that are part of agency functioning and quality maintenance and improvement, but are unrelated to OASIS items.

## Part 2 - Item-specific Comments

### M1000 Inpatient Facilities in Past 14 Days

**Comment:** Has any consideration been given to aligning (M1000) Inpatient Facilities with other care settings such as acute care by changing the look back timeframe to 30 days? With the change to claims-based quality outcomes in Emergent Department Use and Acute Care Hospitalization, I would be very interested in the OASIS capturing inpatient facility discharges for the same time period. It could be more meaningful for care planning. For example, when an OASIS clinician identifies a patient was discharged from the hospital 28 days ago, an analysis could be made of that patient's potential to return to the acute setting within 2-3 days. Aligning the 30-day timeframe for all provider types (and their respective claims data) would be beneficial in the environment of ACO's, etc., as we work together to optimize patient outcomes. Additionally, I would be interested whether risk adjustment significantly differs for patients who have been hospitalized in the recent 30 days compared to our historical information for those hospitalized in the recent 14 days.

**Response:** While we are generally in favor of harmonization of time frames between provider types and settings, we do not believe that changing the time frame of this item would be beneficial for two reasons: 1) the accuracy of a look-back of 30 days vs. 14 days will inherently be less reliable; 2) patients may have had multiple inpatient stays within the 30 days prior to this

assessment and asking the clinician to review and document all inpatient stays in the past 30 days could be potentially burdensome.

### **M1011 Inpatient Diagnosis**

**Comment:** Please consider revising the question to clarify that the 14 days refers to the date of discharge and not when the condition was treated.

**Response:** CMS agrees it will improve clarity to make a simple text addition based on language contained in the Guidance Manual. Therefore, based on public comments, we have revised M1011 to read, "List each Inpatient Diagnosis and ICD-10-C M code at the level of highest specificity for only those conditions actively treated during an inpatient stay having a discharge date within the last 14 days (no V, W, X, Y, or Z codes or surgical codes)".

### **M1025 Optional Diagnoses**

**Comment:** We received 2 comments expressing concern about the continued inclusion of M1025.

- We are concerned about the continued inclusion of M1025 Optional Diagnoses within OASIS-C1. In the past several years, CMS has actively prepared the home health industry, through the promulgation of the Home Health Prospective Payment System and other aspects of Medicare home health billing, for the implementation of ICD-10. In fact, in the HHPPS CY 2014 proposed rule, CMS stated that modifications that took effect on January 1, 2013, would favorably position CMS "to eventually retire the payment diagnosis field" once there was a complete transition to ICD-10. Furthermore, CMS wrote in the HHPPS CY 2013 proposed rule that  
"Finally, effective October 1, 2014, with the implementation of ICD-10-CM diagnosis code reporting, we anticipate that HHAs will be able to report all of the conditions included in the HH PPS Grouper as a primary or secondary diagnosis. There will no longer be a need for any conditions to be reported in the payment diagnosis field because all of the ICD-10-CM codes included in our HH PPS Grouper will be appropriate for reporting as a primary or secondary condition. As such, we are retiring Appendix D of OASIS, effective October 1, 2014...."  
Therefore, we contend that M1025 is obsolete, as it has no impact on Medicare home health payment. The inclusion of this measure will only cause confusion and administrative burden for home health agencies, as they will be required to train their staff on how to document this measure. We urge CMS to remove M1025 Optional Diagnoses from OASIS-C1."
- I have concerns about continued inclusion of (M1025) Optional Diagnoses. This item is not expected to have impact on payment calculation. Because it is a replacement for (M1024) Payment Diagnoses, I am curious whether it will have any true purpose. It has

been my experience that providers historically have had difficulty coding into M1024 appropriately; I anticipate continued difficulty with the proposed replacement item . Since the original purpose of M1024 was to capture case mix points only in specific situations, and the new M1025 item is not going to serve that purpose, I would like to see it eliminated entirely. CMS has indicated there is potential value in this item for risk adjustment of quality measures. I understand that risk regression models cannot be generated until the dataset has been implemented (with ICD-10-CM diagnosis codes). Nevertheless, I would suggest that there has been sufficient data collected on the role that resolved underlying conditions play in risk adjustment. If (M1025) Optional Diagnoses is retained in the database, then I would like to see a listing of the specific resolved conditions that might be appropriate (i.e., the ICD-10 equivalent for those diagnoses that have been found to be significant factors toward risk adjustment of quality measures).

**Response:** In the public comments received on the 2013 Home Health Proposed Rule, there was concern expressed that our plan to eliminate M1024 (now M1025 in OASIS-C1) would have an impact on risk adjustment of quality measures. For this reason, we intend to retain M1025 in OASIS-C1 in order to collect and analyze diagnosis information that HHAs may voluntarily choose to report. Instructions for responding to M1025 were revised to delete references to Appendix D and refer clinicians to the OASIS Guidance Manual.

### **M1033 Risk for Hospitalization**

**Comment:** We appreciate and support the proposed revision of M1033 to include evidence-based risks for hospitalization as well as the addition of time frames for each of the potential risk factors.

**Response:** We appreciate your input and thank you for recognizing the value of these proposed changes.

**Comment:** Response 7 was changed from 5 medications to 6 medications. Was that intentional?

**Response:** The research literature contains several different cut-points for the number of medications that increase the risk for hospitalization or other adverse outcomes in older community-dwelling adults. After reviewing this comment, we agree with the commenter that the original response option for M1033 “5 or more medications” reflects a conservative and evidence-based cut-point to identify patients at risk for hospitalization. Accordingly, M1033 response option #7, has been revised in the OASIS-C1 to read, “Currently taking 5 or more medications”.



**Comment:** Remove response 9 “other” or add a line next to it with the direction to “specify” (like M0150 Response 11) to make the selection of “other” more clinically useful in care planning.

**Response:** In order to improve clarity, we have changed response 9 to read, “Other risk(s) not listed in 1 –8”. We are not in favor of adding a write-in line, since this would require agencies to report information that would be difficult to analyze and would not be used for payment, quality measurement or risk adjustment. Agencies can choose to add a place to write in other risk factors that may be useful to document for care planning.

#### **M1046 Influenza Vaccine received**

**Comment:** Add “(SOC/ROC to Transfer/Discharge)” after “episode of care” in Responses 1 and 2. Although the time frame for episode of care is defined in the item description for M1041, clinicians read quickly and there is frequently little or no carry over to the response choices.

**Response:** In order to improve clarity, we have added explanatory language from the Guidance Manual to response 1 and 2 based on public comment. Response 1 now reads, “Yes; received from your agency during this episode of care (SOC/ROC to Transfer/Discharge).” Response 2 now reads, “Yes; received from your agency during a prior episode of care (SOC/ROC to Transfer/Discharge).”

#### **M1100 Patient Living Situation**

**Comment:** The formatting of this table is difficult for some clinicians. Please consider splitting this item into separate items that ask about where the patient lives and then the level of assistance available.

**Response:** The formatting of the table was introduced in OASIS-C as a way of reducing burden, as agencies need to enter only one response to identify both the living situation and the availability of assistance. We have not proposed any changes to this item in OASIS-C1, have not tested any potential reformatting of the item, and do not have any evidence regarding how a revision to the item format would impact data validity and reliability. Therefore we do not intend to make any significant revisions to the item at this time, but will reserve your comment for future consideration.

#### **M1240 Pain Assessment**

**Comment:** Provide examples of standardized, validated pain assessment tools that would be acceptable for the home health agency to use in the instructions for this item.

**Response:** CMS has chosen not to be prescriptive about which screening and assessment tools agencies select, other than incorporating the PHQ-2<sup>®</sup> (which remains optional). The Guidance Manual notes that a variety of standardized pain assessment approaches have been tested and are available for provider use in patient assessment. Examples of standardized, validated pain assessments (such as visual analog scales, the Wong-Baker FACES Pain Rating Scale, numerical

scales, and the Memorial Pain Assessment Card) are provided in the Guidance Manual. It is up to each agency to determine which assessment tools are most appropriate for their patients and operations.

**Comment:** Add an NA response for those patients who are cognitively intact and physically able to answer questions but unable to answer the specific questions required of a pain assessment tool (e.g. unable to identify a number to rate their pain on a scale of 0-10 or unable to identify with a face on the Wong Baker faces tool). This would improve consistency with the NA response in M1730, used for those patients who are cognitively able to understand and physically able to answer questions but are unable to answer the specific questions of the PHQ-2<sup>©</sup>.

**Response:** The quality measure that is derived from this item reports whether a pain assessment was conducted on all patients. In cases where a clinician is unable to complete a pain assessment on a patient, response 0 – No standardized, validated assessment conducted should be selected. The clinician has the option of documenting any additional information they deem appropriate in the patient record. The OASIS Guidance Manual notes that the evidence-based practices being measured do not pertain to every patient, and a rate of 100 percent is not expected for any agency or for any of the process measures. CMS is in favor of harmonizing item responses when possible, but notes that we are not proposing any changes to this item in OASIS-C1. We have not obtained clinician input of any potential changes to the item, and do not have any evidence regarding how a revision to the item would impact validity and reliability of the item or measure. Therefore we do not intend to make any revisions to the item at this time, but will reserve your comment for future consideration.

### **M1306 Unhealed Pressure Ulcer Stage II or Higher**

**Comment:** Though CMS has made significant progress in clarifying the integumentary status items over the several versions of OASIS, we believe there are a few more changes CMS can make in OASIS-C1 to reduce the potential for confusion and inaccurate data collection. We recommend that CMS reword M1306 as follows: Does this patient have at least one Unhealed Pressure Ulcer at Stage II or Higher (INCLUDES closed Stage III & IV) or designated as “unstageable”? Adding this would be in alignment with the published OASIS guidance. These recommendations are made to assist field clinicians in knowing how to record the presence of a Stage III or IV pressure ulcer that has closed without having to refer to the Item Specific Guidance. Anything that CMS can do to facilitate rapid collection of accurate OASIS data will be of benefit to both agencies and CMS. We believe that the addition of the language identified above will help to achieve this goal.

**Response:** M1306 refers to all pressure ulcers (including partial thickness, full thickness, and unstageable due to non-removable dressing or device, unstageable due to slough/eschar, and suspected DTI) other than Stage I and healed Stage II. Therefore CMS has concluded that it is

more appropriate for brevity and clarity to identify the pressure ulcers that are excluded rather than included in the actual item, with remaining guidance on identifying pressure ulcers in the Guidance Manual. Because the identification and assessment of pressure ulcers is clinically complex and relatively rare in home health, we expect that clinicians will need to reference instructions in the Guidance Manual until they are thoroughly familiar with the items. We have made one revision to the wording in M1306 to improve clarity and harmonize with changes recommended to other items, changing the phrase “healed Stage II ulcers to healed Stage II pressure ulcers”. The item stem now reads, “Does this patient have at least one Unhealed Pressure Ulcer at Stage II or Higher or designated as “unstageable”? (Excludes Stage I pressure ulcers and healed Stage II pressure ulcers)”

#### **M1307 Oldest Stage II Pressure Ulcer**

**Comment:** Please consider removing the wording “non-epithelialized” from the item stem and from the NA response. Per OASIS guidance and by definition, it’s no longer a Stage II if it’s epithelialized so having non-epithelialized in the wording is confusing and redundant.

**Response:** CMS consulted with wound care experts to determine the most appropriate and correct wording to convey the information that a Stage II pressure ulcer that was previously present and has now healed should not be included when responding to this item. Based on their feedback and on public comment, the item has been changed to read, “The Oldest Stage II Pressure Ulcer that is present at discharge: (Excludes healed Stage II Pressure Ulcers)”. The NA response now reads, “NA - No Stage II pressure ulcers are present at discharge”.

#### **M1308 Current Number of Unhealed Pressure Ulcers**

**Comment:** In the item description, restate the exclusion to identify that both Stage I and Stage II refer to pressure ulcers. Suggest: “excludes Stage I pressure ulcers and healed Stage II pressure ulcers” or “excludes Stage I and healed Stage II pressure ulcers.”

**Response:** The item wording has been revised per public comment to read, “Current Number of Unhealed Pressure Ulcers at Each Stage or Unstageable: (Enter “0” if none; Excludes Stage I pressure ulcers and healed Stage II pressure ulcers )

**Comment:** We recommend that CMS reword the title of M1308 to read: Current Number of Unhealed Pressure Ulcers at Each Stage (INCLUDES Closed Stage III and Stage IV) or Unstageable.

**Response:** As in M1306, M1308 refers to all pressure ulcers (including partial thickness, full thickness, and unstageable due to non-removable dressing or device, unstageable due to slough/eschar, and suspected DTI) other than Stage I and healed Stage II. As stated above, CMS has concluded that it is more appropriate for brevity and clarity to identify the pressure ulcers that are excluded rather than included in the actual item, with remaining guidance on identifying pressure ulcers in the Guidance Manual.

### **M1309 Worsening in Pressure Ulcer Status**

**Comment:** Consider including a selection in the responses for “unstageable”. The current wording does not take into consideration any pressure ulcers that at SOC/ROC were identified in M1308 rows d.1 (dressing/device), d.2 (slough/eschar), and/or d.3 (suspected DTI).

**Response:** CMS consulted wound care experts to determine the appropriateness of including unstageable pressure ulcers in M1309. Based on public comments and expert guidance, we have added a row to permit clinicians to record unstageable pressure ulcers that are new or that were previously Stage I or Stage II. Expert guidance indicated that: a) it is not possible to determine worsening status of pressure ulcers that are unstageable due to slough or eschar but were previously Stage III or IV; and b) it is not appropriate to include known or suspected DTI (deep tissue injuries) or pressure ulcers that are known or likely but unstageable due to non-removal dressing or device. Therefore the added response option is restricted to unstageable pressure ulcers that are new or that were previously Stage I or Stage II.

**Comment:** Additional clarification in the item and/or guidance is needed for proposed M1309. For example, if a suspected DTI was noted at SOC/ROC, but is a Stage IV at Discharge, has it worsened?

**Response:** As noted above, CMS consulted wound care experts to determine the appropriateness of including unstageable pressure ulcers in M1309. Expert guidance indicated that it is not appropriate to identify worsening of known or suspected DTI (deep tissue injuries). Further guidance on identifying new and worsened pressure ulcers will be provided in the Response-Specific Instructions in the OASIS-C1 Guidance Manual.

### **M1320 Status of Most Problematic Pressure Ulcer**

**Comment:** In M1320, M1324, M1334, M1342, should “(Observable)” precede “problematic” to help identify the priority of the characteristic? In M1320 and M1324, we recommend that CMS include language defining the term “observable”. Member agency trainers have found that field clinicians often confuse the notion of a pressure ulcer being unobservable with unstageable, and these are not the same concepts. CMS has defined unobservable in the stasis ulcer and surgical wound items, and could make a similar effort here.

**Response:** Based on the comments, the word order was revised and explanatory text from the Guidance Manual has been added to facilitate the identification of pressure ulcers that are excluded. The item now reads, “Status of Most Problematic Pressure Ulcer that is Observable: (Excludes pressure ulcer that cannot be staged due to non-removable dressing/device)”.

### **M1324 Stage of Most Problematic Pressure Ulcer**

**Comment:** In M1320, M1324, M1334, M1342, should “(Observable)” precede “problematic” to help identify the priority of the characteristic? In M1320 and M1324, we recommend that CMS include language defining the term “observable”. Member agency trainers have found that

field clinicians often confuse the notion of a pressure ulcer being unobservable with unstageable, and these are not the same concepts. CMS has defined unobservable in the stasis ulcer and surgical wound items, and could make a similar effort here.

**Response:** Based on the comments, the word order was revised and explanatory text from the Guidance Manual has been added to facilitate the identification of pressure ulcers that are excluded. The item now reads, “**Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable:** (Excludes pressure ulcer that cannot be staged due to a non-removable dressing/device, coverage of wound bed by slough and/or eschar, or suspected deep tissue injury).”

#### **M1334 Status of Most Problematic Stasis Ulcer**

**Comment:** In the item description for M1320, M1324, M1334, M1342, should “(Observable)” precede “problematic” to help identify the priority of the characteristic?

**Response:** Based on the comment, the word order was revised and the item now reads, “Status of Most Problematic Stasis Ulcer that is Observable”.

**Comment:** I was overjoyed to see the removal of Response 0-Newly epithelialized from (M1334) Status of Most Problematic Stasis Ulcer; this change will greatly improve accuracy for this stasis ulcer item.

**Response:** We appreciate your input and thank you for recognizing the value of this proposed change.

#### **M1340 Presence of Surgical Wound**

**Comment:** Please consider adding to the item stem for clarity: (Excludes surgical wounds that have been newly epithelialized for 30 days or greater).

**Response:** CMS does not agree that adding this phrase would add clarity because (as discussed in the OASIS Guidance Manual, Response-Specific Instructions for M1340 and M1342) a surgical wound that is epithelialized for 30 days or more should still be reported if it dehisces or presents with signs of infection, or represents an implanted venous access device or infusion device.

**Comment:** Consider excluding Tessiocaths for hemodialysis from the outcome measure for “Improvement in Surgical Wounds” Because these surgical wounds are being held open by a line their status must be reported as "non-healing". Their inclusion in the outcome measure artificially inflates the number of patients with wounds that do not heal and negatively impacts agencies who have a high portion of patients with these types of devices.

**Response:** As the commenter notes, the outcome measure related to surgical wounds identifies patients with unhealed surgical wounds regardless of the reason that the wound has not healed. We have not obtained expert or clinician input on potential changes to the

measure, and do not have any evidence regarding how a revision such as the one proposed would impact validity and reliability of the item or measure. Therefore we do not intend to add any exclusions to the item at this time, but will reserve your comment for future consideration of whether the measure and the Response-Specific Instructions in the OASIS Guidance Manual will be revised to exclude wounds that are being held open for a therapeutic reason.

#### **M1342 Status of Most Problematic Surgical Wound**

**Comment:** In the item description for M1320, M1324, M1334, M1342, should “(Observable)” precede “problematic” to help identify the priority of the characteristic?

**Response:** In response to comments, CMS has revised the word order. The stem now reads, “Status of Most Problematic Surgical Wound that is Observable”.

#### **M1500 Symptoms in Heart Failure Patients**

**Comment:** Please consider adding to response for clarity: Response 0- No, Patient has diagnosis of heart failure, but no symptoms present; and Response 1- Yes, Patient has diagnosis of heart failure with symptoms indicated by clinical heart failure guidelines and the doctor or doctor’s liaison was notified within one calendar day

**Response:** Currently, M1500 reports whether the patient was assessed for heart failure, and M1510 reports the action(s) taken by clinicians in response to heart failure. Many comments have been received indicating that having concepts separated into 2 questions (such as was done for immunizations and pressure ulcers) enhances an item’s clarity and improves accuracy of the response. In addition, several options for actions other than contacting the doctor are provided in M1510. For these reasons, CMS is not in favor of modifying these items as suggested by the commenter.

#### **M1600 Treatment of Urinary Tract Infection**

**Comment:** Please consider adding to the item stem for clarity: treated “with an antibiotic”.

**Response:** Since there are multiple possible treatments for urinary tract infections, specification of a particular treatment in the item would not be appropriate.

#### **M1610 Urinary Incontinence or Catheter**

**Comment:** In order to clearly capture the most accurate and meaningful information about the patient’s level of incontinence or use of a urinary catheter, we recommend that the item response options be reworded to allow clinicians to distinguish between those patients who are not incontinent or have anuria and those who require an ostomy for urinary drainage. The costs and clinical management of individuals who have no incontinence and those who require a catheter for urinary drainage are totally different, and these individuals should be distinguished from one another within OASIS.

**Response:** We have not proposed any changes to this item in OASIS-C1, which is used in the HHPPS payment algorithm. Therefore, we have not obtained clinician input of any potential

changes to the item, and do not have evidence regarding how the proposed revision to the item would change the validity and reliability of the item, or its impact on the payment case-mix adjustment. Therefore we do not intend to make any revisions to the item at this time, but will reserve your comment for future consideration.

### **M1700 Cognitive Functioning**

**Comment:** In order to distinguish between Responses 0, 1 and 2 and Response 3, we suggest that CMS begin each of the first three responses with the phrase “alert/oriented.”

**Response:** The responses in M1700 describe a continuum of cognitive status that is functionally oriented. Response 0 is used to report patients that are alert and oriented and able to carry out the cognitive tasks described in that response. Patients who would be appropriately reported in responses 1 – 3 may or may not be fully alert or oriented in all 3 spheres of person, place and time. Therefore the addition of the phrase “alert and oriented” would not be appropriate for these responses. Determination of the correct response should be based on the need for assistance to carry out cognitive tasks as described in each of the responses.

**Comment:** The Neuro/Emotional/Behavioral Status items refer to differing time periods for assessment from the day of assessment to the past 14 days to at least once a week. Please consider grouping these items so that the time period under consideration for the assessment would be easier to determine.

**Response:** The OASIS data set items are not meant to be “administered” in a fixed order, but are to be completed by the clinician based on the results of a comprehensive patient assessment. Evaluation of Neuro/Emotional/Behavioral conditions will vary due to the unique nature of each of these conditions. The current grouping of items by cognitive/neurological (M1700 and M1710), emotional (M1720 and M1730), and behavioral (M1740 - M1750) allows clinicians to focus on the clinical status of the patient, not the different periods of time when different behaviors or conditions are evidenced.

### **M1800 Grooming**

**Comment:** As the time frames for data collection vary by item, in the M1800 functional activity descriptions, add “on the day of assessment” to the item description. Clinicians frequently do not know and do not collect the data for the functional activity items with that time frame in mind.

**Response:** As described in Chapter 1 of the OASIS Guidance Manual, “Current” is defined as “on the day of assessment”. This is the default time frame for most items in the OASIS; items with a different time frame have that time frame specified in the item. We are not in favor of adding additional definition of “current” to the items, but will consider adding this clarification to the Response-Specific Instructions in the OASIS Guidance Manual for each item where the default “current” time frame is used.

### **M1850 Transferring**

**Comment:** In order to further clarify how CMS defines “minimal” and save field clinicians the time and effort to consult the OASIS Item Guidance, we recommend that Response 1 be revised to read “Able to transfer with minimal (less than 25%) human assistance OR with use of an assistive device”. Please consider adding to response 2 for clarity, “Able to bear weight and pivot during the transfer process but unable to transfer self “OR requires minimal human assistance AND assistive device during the transfer process”.

**Response:** As reviewed in the OASIS Guidance Manual, the definition of minimal human assistance is more complex than can be conveyed by the phrase “less than 25%”. CMS does not agree that the addition of the phrase in the response would add clarity in response 1. Regarding the addition of the phrase “OR requires minimal human assistance AND assistive device during the transfer process” to Response 2, we believe that level of detailed guidance belongs in the Response-Specific Instructions rather than in the item itself.

### **M1860 Ambulation/Locomotion**

**Comment:** We would like to offer some general comments on the OASIS-C1 to be considered for future changes. The wording in response 2 for this item should be changed to more closely match the wording in responses 0 and 1. Response 2 should begin with the phrase “With the use....” rather than “Requires use of .....” This would add consistency between these responses which would assist clinicians during their assessments.

**Response:** We will consider your comments for future versions of the OASIS. M1860 is a payment item. Therefore, any changes to wording would need to be carefully evaluated for potential impacts to HHPPS case-mix adjustment.

**Comment:** Please consider adding to response item 4 for clarity: to include power chairs

**Response:** Instructions on responding to this item when the patient uses a powered wheelchair are included in the OASIS Guidance Manual. The response could be either a 4 or 5 depending on whether the patient can use the powered wheelchair independently. CMS does not agree that the addition of the phrase in the response would add clarity in response 4.

### **M1910 Falls Risk Assessment**

**Comment:** Not all standardized, validated fall risk assessment tools indicate risk on a scale of that can be equated with the proposed language found in Responses 1 and 2 (e.g. no, low, or minimal risk for falls)low or minimal risk. Several fall risk assessment tools only indicate whether or not the patient is at risk for falls. We are getting a lot of questions about how this proposed revision will impact responses to M1910 when a fall risk assessment tool is used that only indicates a patient is at risk or not at risk for falls. Asking clinicians to identify a patient’s risk of falling as low or minimal or even more than minimal is quite subjective and cannot be based on a single measure.



**Response:** Based on comments received we have revised the language used in Response 1 and 2 to reflect the responses currently present in OASIS-C. Response 1 now reads: Yes, and it does not indicate a risk for falls. Response 2 now reads: Yes, and it does indicate a risk for falls. We will add guidance to the OASIS Guidance Manual on M1910 to assist responding to the item when a fall risk assessment tool with multiple thresholds is used.

**Comment:** Physical therapists can use a number of tests and measures to determine a patient's risk of falling. It is important to match the correct test and measure with the correct patient and environment to aptly measure falls risk. This may require using more than one test and measure to take into account the multiple factors that may contribute to the patient's falls risk. Within the examination, physical therapists include tests that focus on range of motion, muscle strength, and sensory integrity. Foot and ankle deficits in tactile sensitivity, ankle flexibility, and toe strength are important factors in balance and functional ability in older adults. Weakness around the knee and ankle relate to increased incidence of falls. Therefore, we strongly recommend that CMS, in its accompanying guidance to this assessment instrument, reflect the importance of the role of the physical therapist in falls risk assessment and the utilization of multiple standardized tools to accurately determine falls risk.

**Response:** We will consider your recommendation when we revise the OASIS Guidance Manual. The manual currently has instructions on the use of multiple tools in falls assessment. While we agree that the physical therapist can play an important role in falls risk assessment, it is up to each agency to determine which assessment tools and processes are most appropriate for their patients and operations. In addition, OASIS items that report assessment results are discipline-neutral, do not require special training, and are not beyond the scope of practice for Registered Nurses or Physical Therapists.

**Comment:** We are concerned that this measure does not address how often the patient should be assessed for falls. While it is appropriate to assess the patient at the start of care and the resumption of care, we believe it may also be appropriate to assess the patient's risk of falling at other intervals during the episode of care based on changes in the patient's condition and environment such as the addition of stairs, new furniture or family dynamics.

**Response:** We agree it may be appropriate to assess the patient's risk of falling at other intervals during the episode of care. When developing the quality measure on Falls Risk Assessment, we considered including assessment at timepoints other than SOC/ROC, but evidence does not support this practice for all patients and it was also determined to be too burdensome for clinicians. The agency and individual clinicians, under the direction of the patient's physician, should determine how often a screening or intervention is appropriate for a patient, based on patient status and clinical judgment, and the clinician can record any information deemed relevant in the patient's record, per agency procedures.

**Comment:** We urge CMS to delineate between treating the patient for overall falls risk and falls risk when walking. In some instances, it would not be medically necessary to assess the patient for falls risk. For example, when providing physical therapy to patients with double amputations or cervical spinal conditions, it may be irrelevant to assess them for their falls risk but not assessing for falls risk does not diminish the quality of care. Therefore, APTA recommends that CMS revise this measure accordingly and add an extra option that allows the home health clinician to indicate that there was no clinical need to assess for falls risk.

**Response:** CMS acknowledges that it may not be possible to conduct a standardized, validated multifactor falls risk assessment on every patient. The quality measure that is derived from this item reports whether a falls risk assessment has recently been revised to exclude non-ambulatory patients. In cases where a clinician is unable to complete an assessment on a patient, response 0 should be selected; the clinician has the option of documenting any additional information they deem appropriate in the patient record.

#### **M2102 Types and Sources of Assistance**

**Comment:** The combined “not likely and unclear” caregiver assistance response in M2102 helps to simplify the busy and overwhelming amount of data collection the clinicians must do for this item. However further improvement is needed. When this item is placed in number order on the agency assessment, by the time the clinicians get to this item, both the clinician and the patient are tired.

**Response:** As stated previously, the OASIS data set items are not meant to be “administered” in a fixed order; they are questions that are to be completed by the clinician based on the results of a comprehensive patient assessment. Agencies and clinicians are free to determine the order of information is elicited from the patients during the 5 day SOC or 2 day ROC window.

**Comment:** Clinicians are instructed that if a patient needs assistance with any aspect of a category of assistance (e.g., needs assistance with some IADLs but not others), consider the aspect that represents the most need and the availability and ability of the caregiver(s) to meet that need. With so many examples and possibilities within a grouping, and no opportunity within the item to specify which task requires the greatest assistance, there is no way for any reader of the document to determine accuracy or significance of the response as a stand alone or in relationship to other ADL responses or services utilized. It is very difficult to use this item for specific care planning. Greater specificity regarding which tasks the patient needs assistance with would provide more meaningful information.

**Response:** Requiring clinicians to report the level of needed assistance for each possible item within a category (for example, all possible ADLs) would increase the number of items as well as increase the complexity of the individual resulting items. Both of these would increase the burden to clinicians, which is not a desirable outcome. Agencies can determine the type and

amount of additional information they want clinicians to document on the patient record for the areas identified in M2102 as needing assistance.

**Comment:** It is very difficult to determine the adequacy of available caregivers when they may not be present at the time of the data collection, such as whether they need training or are likely to provide assistance. Therefore, the information is not always reliable.

**Response:** We understand that collecting this type of information, which is important for determining patient needs and care planning, can be challenging. This would be true regardless of the format of the OASIS item. We do remind agencies that they have 5 days to collect the SOC assessment so this does not all need to be completed in the first visit.

**Comment:** Please consider adding to response d. (for example: HEP) and c. (for example: walker, canes) for clarity.

**Response:** Based on the comment, we added “home exercise program” as an example of Medical procedures/ treatments in response “d.” We do not think it is appropriate to add walker and cane in response “e.” as there are a number of examples provided currently. CMS expects the clinician to determine what is considered medical equipment using the examples provided in the item, the OASIS Guidance Manual, and good clinical judgment.

**Comment:** The formatting of this table is difficult for some clinicians. Please consider alternatives to how this information is presented.

**Response:** We believe the reduced number of columns and clarification in item wording should simplify the process of responding to M2102.

## **M2250 Plan of Care Synopsis**

**Comment:** For more clarity, reword the response to read “Patient is not a diabetic or is a diabetic and is missing lower legs due to congenital or acquired condition (bilateral amputee).”

**Response:** We believe the proposed language in the Draft OASIS-C1 is more patient-centric and adequately and concisely identifies the population for which foot care is not appropriate.

**Comment:** Though the language CMS has added to the “Not Applicable” column will assist clinicians in accurately completing these items, one other addition would be helpful as well. We recommend that CMS include language in each item advising clinicians to begin their response to these items by considering whether the particular intervention is applicable or not. Once applicability is determined, the clinician can then determine whether the intervention has been included in the plan of care and whether it has been implemented.

**Response:** The focus of the item is for agencies to report whether the physician-ordered plan of care includes specific interventions, not whether interventions are appropriate for the patient. The last column provides an easy method of documenting appropriate reasons for why an intervention is not in the plan of care. In fact a plan of care may include an intervention even if there is a reason not to include it. For example, a physician may order interventions to monitor and mitigate pain even if the initial pain assessment indicates no pain. "In that case, the clinician could select response 1 - Yes, even if the assessment indicated the intervention was not applicable."

**Comment:** The formatting of the tables is difficult for some clinicians. Please consider alternatives to how this information is presented.

**Response:** Tables are used to reduce burden of multiple questions by limiting the number of responses clinicians need to make. The version of the table in the Draft OASIS-C1 includes changes to the table format based on clinician input during the OASIS-C1 development process.

#### **M2300 Emergent Care**

**Comment:** In order to eliminate potential confusion, we recommend that CMS delete the phrase "used hospital emergency department" from both Responses 1 and 2. The opening statement of the item already references a hospital emergency department. Including the phrase along with the other language in the response is redundant and potentially confusing.

**Response:** We agree that the phrase "used hospital emergency department" is somewhat redundant but it's there for added clarity and we do not believe the item would be improved by removing it.

#### **M2400 Intervention Synopsis**

**Comment:** For more clarity, reword the response to read "Patient is not a diabetic or is a diabetic and is missing lower legs due to congenital or acquired condition (bilateral amputee)."

**Response:** We believe the currently proposed language in the Draft OASIS-C1 is more patient-centric and adequately and concisely identifies the population for which foot care is not appropriate.

**Comment:** Though the language CMS has added to the "Not Applicable" column in M2400 will assist clinicians in accurately completing these items, one other addition would be helpful as well. We recommend that CMS include language in each item advising clinicians to begin their response to these items by considering whether the particular intervention is applicable or not. Once applicability is determined, the clinician can then determine whether the intervention has been implemented.

**Response:** The focus of the item is for agencies to report whether specific interventions have been implemented, not whether interventions are appropriate for the patient. The last column

provides an easy method of documenting appropriate reasons for why an intervention was not implemented. In fact an intervention may have been implemented even if one of the conditions listed in NA exists. In that case, the clinician could select response 1 - Yes, even if the assessment indicated the intervention was not applicable.

**Comment:** The formatting of the tables is difficult for some clinicians. Please consider alternatives to how this information is presented.

**Response:** Tables are used to reduce burden of multiple questions by limiting the number of responses clinicians need to make. The version of the table in the Draft OASIS-C1 includes changes to the way the table looks based on previous feedback.