

**Response to Public Comments on the
Revised OASIS C Instrument
(Form# CMS–R–245/OMB# 0938–0760)
for Home Health Quality Measures & Data Analysis**

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CMS Response to Public Comments

The staff of the Centers for Medicare & Medicaid Services (CMS) and the OASIS C development team are pleased to have received so many comments from home care clinicians, agencies and organizations interested in the OASIS C. We received 142 responses, and each of them included comments on multiple topics and items. Many commenters expressed their support for proposed changes to the OASIS data set and others made numerous useful recommendations for modifications to improve the OASIS C. All of these suggestions were considered by CMS and in many cases they were implemented into the revised OASIS C.

Commenters also voiced specific questions about the content, format and purpose of some of the new and revised items, and expressed concerns about the impact of the OASIS C on their practice and agency functioning. In each instance we have attempted to address these comments, questions and concerns and hope that our responses provide clarity.

In the first part of this document, we summarize positive feedback and address the general comments that apply to issues such as OASIS burden and coordination with the CARE instrument being used in the Post-Acute Care (PAC- Payment) Reform Demonstrations Program. In the second half of the document, we respond to item-specific questions, comments and suggestions that were not addressed in the general comments section. Please note that in most cases the comments as they appear here are composites of comments received from multiple individuals and/or organizations.

Part 1 – Summary of General Public Comments

Positive Comments about OASIS C

1. **Improved relevance, usability, consistency and clarity**
 - We can see that CMS has put effort into improving many of the OASIS items and making them more practical for use with the home care patient to improve the delivery of home care.
 - The OASIS C should improve the data we collect; making it more specific with less room for inconsistencies.
 - Some questions are consolidated and the wording of other questions is improved.
 - There are many changes and additions that will improve patient outcome and monitoring statistics. Overall the assessment appears to be more comprehensive in nature and provide better detail for outcomes analysis.
 - While change will be challenging, the new questions have a clarity and patient-centered focus that will help to better serve patients in the home setting.

2. **OASIS C Deletions**
 - We appreciate CMS's response to industry input including the deletion of items not used for payment, quality, or risk adjustment.
 - We especially thank you for eliminating the prior status column on the ADL/IADL questions which was not helpful and prone to misinformation.

3. Improvements to emergency room and hospitalization items

- We are particularly supportive of the re-definition of emergent care as a visit to the ER only. The decision to exclude all but emergency room visits in the Emergent Care item will provide more realistic data on the true incidence of emergent care. This is a more helpful and reflective of health care cost than the current OASIS-B interpretation.
- We are very pleased with the proposed expansion on the list of reasons for emergent care and hospitalization. These are much more specific responses and will be helpful for chart review and aggregate data. The expansion of the in-patient diagnoses is welcome for many patients have multiple co-morbidities that should be considered in the risk adjustment.

4. Improvements to wound items

- In general the wound care questions are better phrased and the integumentary assessment has been greatly expanded and improved to include risk factors and measurements.
- Thanks for bringing the language up to date allow for a more descriptive portrayal of pressure ulcers.
- It is greatly appreciated by us that the question regarding the presence of a wound has been edited to specify wound that are receiving assessment and/or intervention.
- Being able to show that ulcers and surgical wounds have re-epithelialized is valuable.

5. Improvements to ADL items

- The increased specificity in the functional limitations assessments is welcome.
- The word “safely” added to many of the functional domain questions is felt by us to go a long way to improve data... so everyone understands it is the ability to perform safely, including getting in and out of the tub.
- Several items have modified wording or response categories to clarify and show progress. Change in response options for Ambulation/Locomotion should better reflect the more subtle changes that can occur during an episode of care. The new item better reflects the progress someone would make from a walker to a cane during an episode.
- Toileting: New answers make a lot more sense and the separation of toileting ability from hygiene ability is greatly supported.

6. Improvements to other items

- Urinary incontinence: the new answers are more appropriate.
- Frailty Indicators and Stability Prognosis (now Risk for Hospitalization and Overall Status): these are clearer and more comprehensive than previous questions. We appreciate having more options to define prognosis.
- The separation of hearing and understanding is an improvement.
- We like the proposed changes to the coding section.

7. Incorporation of best practices

- I believe that the new process questions are, for the most part, very appropriate quality indicators.

- The incorporated clinical process measures that support evidence-based practice are vital as the industry treats a sicker, more complex patient population with numerous comorbidities.
- We are pleased to see the inclusion of process measures that will highlight the critical role home health plays in areas such as diabetes care, congestive heart failure, falls risk assessment and other areas of critical concern to the Medicare and Medicaid programs and our nation's seniors.
- We strongly support the added emphasis on depression in the Medicare home health patient population.
- Risk of Developing Pressure Ulcers is a good addition to the assessment tool.

Concerns about OASIS C Burden

1. **The OASIS C data set represents a significant increase in burden for home health agencies (HHAs).** The number of items to be collected at Start of Care (SOC) and the process items at Transfer and Discharge asking whether interventions were implemented will be especially time-consuming and difficult to obtain. This increase in data collection will result in: extended SOC visit time for the assessing clinician which will be burdensome for both clinicians and home care clients; an increase in time spent contacting the physician regarding patient history, plan of care, and change in patient status; and an increase in time spent on chart review to determine interventions implemented during the 60-day episode. This increased burden has a potential for negative impact on staffing retention and recruitment and increased costs for HHAs during already challenging financial times.

Response:

CMS has placed a high priority on revising the OASIS data set in a way that is responsive to industry concerns while minimizing burden. Therefore, testing of new and revised items with actual users in a home health environment and obtaining their feedback prior to implementation was considered critical. In 2008, CMS contractors Abt Associates and subcontractors University of Colorado Health Sciences Center and Case Western Reserve University conducted field testing including analysis of time required for collection of OASIS C. A total of 68 clinicians at 11 HHAs in Colorado, Massachusetts, and Ohio participated. These included agencies that were for-profit and not-for-profit, large and small, hospital-based and freestanding, serving urban and rural populations, and using both paper-based OASIS assessments and electronic data collection.

Between May and September 2008, 370 OASIS C assessments were conducted on 183 patients (163 in Ohio, 108 in Massachusetts and 99 in Colorado). Of these, 202 were the full OASIS C assessment to be used for time analysis and 177 were determined to have sufficient information to be used in the time analysis.

- SOC/ROC ranged from 20 to 125 minutes, with a mean completion time of 49.6 minutes (Table 1). The considerable variation that existed in completion times is reflected in the 44.7 minute standard deviation in completion times. The 95% confidence interval of mean completion times was 38.5 to 60.7 minutes.

- Recertification ranged from 10 to 75 minutes, with a mean completion time was 33.4 minutes with a 95% confidence interval of 20.4 to 46.5 minutes.
- Transfer ranged from 2 to 40 minutes, with a mean completion time of 17.4 minutes. The standard deviation was 56.4 minutes, meaning that our estimates of completion times for these types of assessments are not precise.
- The average completion time for discharge assessments ranged from 8 to 80 minutes, with a mean of 26.3 minutes. The 95% confidence interval of the mean was 11 to 41.6 minutes.

Table 1
OASIS C Time Estimates: Minutes Required to Complete Assessments, by Assessment Type

	Sample Size	Mean	Std. Deviation	Std. Error of Mean	95% confidence interval	
					Lower	Upper
SOC/ROC	62	49.61	44.72	5.68	38.48	60.74
Recertification	49	33.45	46.74	6.68	20.36	46.54
Transfer	18	17.44	56.41	13.30	-8.62	43.50
Discharge	48	26.31	54.2	7.82	10.98	41.64

Completion times reported by PTs at each timepoint tended to be less than reported by RNs, but the sample size at each timepoint is too small for separate analysis.

These data reflect time to collect the information required to respond to the OASIS C items, including time spent in the home conducting the assessment and time spent outside the home collecting additional needed data. Time spent on assessment and data collection to complete items for agency-specific comprehensive assessments, which can vary widely between agencies, was not included. The field testing did not collect any quantitative information on the incremental time associated with completing OASIS C relative to the OASIS B-1 instrument. However, in comparison to previous studies for time required for collection of OASIS B-1, the data collected during the field test indicated minimal additional time burden related to collection of OASIS C data items.

Group interviews were also conducted with the clinicians who collected the OASIS C data to obtain feedback on issues such as usability, burden, and how the revised data set might impact care patterns. Overall OASIS C burden was described as being similar to OASIS B-1 for Start of Care and Resumption of Care. In many agencies, the new OASIS C items asked for data that clinicians were already collecting as part of their agency's comprehensive assessment, so the OASIS C item would just capture information from the agency's previously unreported item. Many clinicians expressed satisfaction that their agencies would now be credited for this care. Process items that asked if an assessment or care process was done were not perceived as burdensome, since clinicians simply

responded “no” to the item if it was not their agency’s practice or not appropriate for that patient.

In contrast, items at Recertification, Transfer, and Discharge that asked if an agency had implemented processes (such as diabetic foot care) were considered to add burden due to the need to review the record for the entire home health stay (sometimes many months or years). In response, CMS deleted these items at Recertification and limited the look-back period to the date of the most recent OASIS assessment at Transfer and Discharge. Clinicians said they thought that if these items were incorporated into the OASIS, their agency would develop tracking systems to facilitate accessing this information at the time of transfer or discharge, or their software vendor would include it in their programming.

Since the field testing concluded, CMS has continued to push toward the goal of eliminating unnecessarily burdensome or inefficient data collection requirements. Table 1, below shows how the item count has changed from OASIS B-1, through field testing and revision, to the current dataset. In response to comments received, we have deleted or consolidated several items that were included in the version of the OASIS C used for field testing. For example, items related to immunizations have been eliminated from the SOC/ROC timepoints, and all items related to Plan of Care have been consolidated into a grid near the end of the SOC/ROC timepoint version. The Follow-up dataset was reduced by 13 items when compared to the version used in the field testing (from 45 to 32 items) by eliminating items not used for payment or risk adjustment. A comparison of OASIS B-1 to OASIS C shows that deleted items include those related to intractable pain, symptoms of depression, number of surgical wounds, transportation, laundry, housekeeping, shopping, management of inhalant medications, equipment management, discharge disposition at transfer, and services after discharge. In comparison to the OASIS B-1 currently in use, the number of items in OASIS C has not increased significantly at any timepoint except Transfer, when items needed to calculate quality measures have been added to calculate measures which are considered critical to CMS’s efforts to examine the reasons for, and reduce the rate of, acute care hospitalization. Attachment A shows all item deletions, consolidations and additions that have occurred as part of the OASIS C revision in response to public and internal comments.

Table 2
Item count OASIS B-1 to C

Timepoint	OASIS B-1	OASIS C Field Test	OASIS C Nov 2008 (Version 10)	OASIS C Feb 2009 (Version 12.2)
SOC	94	112	104	95
ROC	78	97	89	80
FU	30	45	32	32
TRF	11	27	26	19
DC	72	84	73	66
Death at Home	4	4	4	5

When using item counts to assess the impact of the current version of OASIS C on burden, it must be remembered that some of the items added to OASIS C are condition-specific, so skip patterns will reduce the number of items collected on some patients. For example, a number of questions related to pressure ulcers have been added, but these apply only to the estimated 5 per cent or less of home health patients that have pressure ulcers. Item counts also cannot convey the complexity of a data element, which may be used to report one easily obtained piece of clinical information or several pieces of information that require additional assessment. For this reason, the field testing results are still considered to be the most useful estimate of burden associated with collection of the OASIS C. The exception might be the Follow-up data set, which has 13 fewer items than the field test version.

2. **It's going to require significant time and effort to collect information about past history that is asked for at SOC in the OASIS C.** Office staff or clinicians will need to contact referral sources such as hospitals, physicians and long term care facilities for home health data collection requirements at time of referral/intake regarding patient history.

Response: CMS suggests that agencies consider revising their referral forms to capture information useful in the OASIS C such as status of immunizations, previous diagnosis and procedure codes and history of pressure ulcers to reduce agency burden and enable agencies to respond to those items. Agencies should remember that all items that ask for documentation of this information only require agencies to respond to the best of their ability.

3. **OASIS C will require changes to standard care processes, office operations and clinical documentation systems including reprinting OASIS-related forms, modifications to software systems, development of tracking/communication tools, obtaining or updating assessment and screening tools, and integration of the OASIS C into the agency's comprehensive assessment.**

Response:

The last significant revision of the OASIS dataset occurred in 2002, and since then CMS has received numerous requests for refinements and enhancements from HHAs, industry associations, quality organizations, consumer representatives, researchers and other stakeholders. The OASIS C is the culmination of CMS's efforts to respond to those requests.

The new dataset eliminates items not used for payment, quality measurement or risk-adjustment purposes, it improves existing items by clarifying wording and improving ability to show progress, and it updates language to conform to current practice standards. The OASIS C includes process items that will support the public reporting of evidence-based practices and it advances the standardization of many OASIS assessment items with the Minimum Data Set (MDS) and the CARE instrument being developed for use across all post-acute care settings. These changes are considered to be high priority by CMS and necessary to ensure that OASIS reflects current practice standards, is

responsive to requests from the industry, and meets CMS's and the public's needs for reporting on home health quality. Delaying these needed changes will not be in the best interest of home health agencies or the patients they serve.

Any time a mandated data set undergoes modifications, there will be attendant costs related to forms, software and modifications in the way HHAs collect data; these are part of the cost of doing business as a Medicare-certified agency. However, CMS is committed to assisting HHAs with the transition and will be providing agencies with electronic versions of revised data sets for each collection timepoint. Updated HAVEN software for transmitting the OASIS data to state repositories can be downloaded at no charge to the HHA. In addition, data specifications, data dictionaries, the HAVEN manual, and the HHA data submission manual will be made available to agencies and to software developers and vendors.

CMS will also be providing optional tools that agencies can choose to incorporate into their agency communication and documentation processes to assist with the collection and tracking of new data elements, such as those items that collect information on care provided during the patient care episode. No new assessment or screening tools are mandated, although a 2-question depression screening (the PHQ-2[®] from Pfizer) has been incorporated into the OASIS C for agencies that **choose** to use it. The new OASIS C Guidance Manual will contain information to assist agencies with work flow along with guidance and web-links for assessment tools related to evidence-based practices that agencies may choose to adopt.

4. **Current time frames are burdensome for both patient and clinician and will become more so under OASIS C.** CMS should consider:
 - Expanding the time frame for OASIS SOC assessment completion to 7 days.
 - Expanding the time frame for OASIS recertification assessment completion to the last 2 weeks of the certification period.
 - Allowing the process items to be collected over the entire episode, not just at SOC.

Response: The requirements for the timing of OASIS data collection are part of the Conditions of Participation (CoPs) and changes to the CoPs are not being considered at this time. Field testing of the OASIS C did not indicate that changes to data collection timing were necessary. CMS will provide guidance in the new OASIS C Guidance Manual to assist agencies with adopting changes to work flow to assist with the timely collection of data needed for appropriate care planning and for timely completion of OASIS C data.

5. **Training costs will be higher than what has been estimated since OASIS C represents a significant change including a new numbering system, new definitions and new items that require teaching of uniform assessment or screening tools. At the very least, a full day seminar will be needed.**

Response: CMS acknowledges that clinicians will require training to prepare for transition to the OASIS C and is taking steps to ensure educational materials are available to everyone affected by these changes. In conjunction with the Medicare Learning Network, CMS will host open door forums to provide information and answer questions about OASIS C. We will also create a 4-hour Train-the-Trainer package (eligible for CEUs) available to HHA providers and to the OASIS Education Coordinators (OEC). Instructional materials available on the MEDQIC site will also be updated. In addition, a revised and newly formatted OASIS Guidance Manual is being created with the input of industry and provider groups and professional organizations, which will have web links to resources and current clinical practice guidelines. These steps should help offset agency costs for training, particularly for those who do not have the resources to send staff to industry conferences.

CMS also believes the half-day training previously estimated will be sufficient. As part of the field testing conducted for the OASIS C, participating clinicians were provided with one half day (4 hours) of training which was judged by participants to be adequate preparation for collecting the OASIS C items, even though an hour of training was devoted to training on the field test protocol.

Regarding the question of costs associated with training on new assessment tools, CMS wants to re-emphasize that the OASIS C does not mandate the use of any screening tools. The OASIS C allows agencies to report on certain screening tools (for pain, pressure ulcers, depression, and falls risk) they have chosen to incorporate into their clinical practice. In all instances, agencies have the opportunity to opt-out of these screening items on OASIS C by responding that the screening was not done.

- 6. Calculations of cost to agencies does not reflect agency overhead and do not include costs associated with clinical staff to oversee the OASIS process and clerical staff to assist with data entry and QI.** The average salary used to calculate burden does not reflect agency overhead. With fringe, the true cost to the agency of a \$29.47 hourly rate would be about \$44 per hour. Also, the burden estimate does not reflect the fact that almost all agencies have clinical staff to over see the OASIS process and clerical staff to assist in the effort. It will increase the amount of time needed for data entry and QI audit time.

Response: CMS acknowledges that the hourly wage rate used for estimating the cost burden of OASIS data collection (based on figures from the Bureau of Labor Statistics) does not include all fringe and/or overhead costs that could potentially be attributed to each hour of labor required for OASIS data collection and training. However, given the wide variation in agency fringe and overhead cost structures, and the fact that the current approach is consistent with previous estimation (and not inconsistent with OMB standards) CMS has chosen not to change the methodology at this time. The estimates of the time related to OASIS data collection based on the field testing, as well as subsequent modifications to the data set which have further reduced the number of items collected, suggest that the burden of data collection for OASIS C will be similar to the current estimates for version OASIS B-1. We believe that a adopting a modified methodology

that includes additional factors which were not included previously, and showed greatly increased cost burden relative to previous versions, would be misleading.

Appropriateness of Including Process Items in OASIS

1. **Documenting processes in the OASIS goes beyond the scope of the OASIS assessment tool.** OASIS was meant to be an assessment tool done to assess the patient in the home. OASIS C exceeds the scope of patient assessment. It mixes plan of treatment, physician orders, Best Practice Protocols and Standards of Care into an already cumbersome evaluation tool.

Response: OASIS was initially developed as a dataset for measuring and reporting quality. There are 3 different kinds of quality measures: structure, outcome and process. In the past, the OASIS dataset was used to calculate outcome measures such as improvement in ambulation and wound healing. For many years, home health clinicians have voiced the opinion that CMS should recognize the care that is provided to patients instead of basing all quality reporting on patient outcomes that are sometimes not under the control of the agency.

CMS is committed to developing and publicly reporting process measures that support evidence-based practices and give credit to the agencies that adopt them. CMS has added process measures and CAHPS to outcome measures to be as fair as possible and to give a well-rounded picture of overall agency quality. The new OASIS C has been designed to also be able to measure improvement in processes such as the percent of patient that are screened for falls risk or receive immunizations. Panels of technical experts, stakeholders, industry associations, professional organizations, MedPAC, and the National Quality Forum (NQF) have offered insights and suggestions on what processes of care reflect best practices for patients receiving care in their homes. Emphasis on incorporating NQF recommendations and promoting use of evidence-based strategies that improve health were integral to OASIS instrument revisions.

CMS determined that integrating the process items needed to support these new measures into the OASIS data set is the least burdensome method of collecting the data from home health agencies. Information collected in the OASIS C data set on patient assessment, plan of treatment, and evidence-based practices will be used in the calculation of: 1) publicly-reported measures that recognize agencies that have incorporated evidence-based practices into their agency processes; 2) OBQI/OBQM quality reports that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events; and 3) a Pay-for-Performance system that would link home health reimbursement to improvements in patient outcomes and/or adoption of evidence-based care processes and is under consideration for future implementation.

Please note that the NQF process for endorsement of publicly-reported measures is ongoing. The comments in this document represent our current understanding of which measures will be endorsed based on NQF Steering Committee recommendations.

2. **Documenting processes in the OASIS is duplicative.** Information on what interventions were ordered is available in the POC on the 485. Interventions that are implemented are documented in the visit notes. Including them on the OASIS increases the documentation burden and creates duplicate documenting. CMS should reference the POC and the visit notes if they are concerned with practice rather than requiring double documentation.

Response: Information about patient assessment, plan of treatment, and evidence-based practices is not currently recorded by HHAs or reported to CMS in a consistent way that would support the development of reportable measures. As stated above, incorporating those data elements into the OASIS is believed to be the least cumbersome and most cost-effective way of collecting the data needed for creating and reporting process measures and developing the Pay-for-Performance system which is under consideration. Agencies should also note that OASIS is considered to be part of the medical record and items that it proposes to collect related to patient assessment will not have to be duplicated elsewhere.

3. **Process items belong in the Medicare Conditions of Participation (CoPs).** The "best practices" have proven their worth, but the OASIS assessment is not the effective place to try to enforce these standards. They belong in the CoPs. CMS should remove process questions related to the Plan of Care and interventions from the OASIS and use them to establish clear, measurable and objective performance expectations that are used during the survey process. HHC Agencies would then be required to incorporate them in their policies and procedures, and State Surveyors can monitor their compliance and the outcomes recorded in the Medical Record.

Response: It would be inappropriate to incorporate evidence-based practices into the CoPs for several reasons. First, we agree with commenters who have said that it is up to each agency to determine which practices it will implement based on its patients and operations. Secondly, the body of clinical evidence that supports specific practices is updated more frequently than CMS could realistically update the CoPs. Lastly, incorporating evidence-based practices into the CoPs and then collecting information about adoption of these practices through the survey process is not a workable solution. Since surveys generally occur only once every three years and do not capture an adequate sample size, this approach would be insufficient to accomplish CMS's goals of developing and publicly-reported process measures, providing agencies with OBQI/OBQM process reports for internal quality improvement efforts, and supporting a potential Pay-for-Performance system.

4. **CMS should not be dictating what best practices are appropriate for specific agencies.** OASIS should not be the driving factor behind best practice initiatives. Given the population and cultural diversity it seems unrealistic for CMS to formulate standard best practices for use by all agencies. It is the responsibility of the agency and educational institutions to guide and direct appropriate care. It is up to the agency to determine which best practices it will implement based on its patients and operations – OASIS is not the appropriate mechanism for education.

Response: One of the goals of the inclusion of process items in the OASIS C is to acknowledge agencies that are incorporating evidence-based practices into their care processes. Evidence-based practice is an approach to health care in which the best available scientific evidence from research and quality improvement activities is integrated into clinical practice in order to inform decision-making and improve outcomes. CMS agrees that it is up to each agency to determine which evidence-based practices it will implement based on its patients and operations. In selecting the care processes targeted by the OASIS C, we extensively reviewed the literature on evidence-based practices and solicited input from technical experts, stakeholders, industry associations, professional organizations, MedPAC, and the National Quality Forum (NQF) on which processes of care are within the control of the agency and reflect best practices for patients receiving care in their homes. In fact, many of the process items in the OASIS C have been revised based on input from these sources, particularly NQF, which is currently reviewing the OASIS quality measures for endorsement.

Based on input from these resources, we included items in the OASIS that collect data on practices that have been shown to improve patient outcomes in some of the most high volume and high cost conditions. Agencies that incorporate these evidence-based practices into their agency processes will have those efforts acknowledged in publicly-reported measures and will receive reports designed to assist them in assessing how those practices impact patient outcomes. Agencies that choose not to adopt these evidence-based practices because they feel they are inappropriate for their agencies or their patient population or for other reasons are provided a response option to indicate that these processes were not conducted. There is no requirement for agencies to change their care processes to match the evidence-based practices measured in the OASIS C.

CMS did not design the OASIS C to be an educational tool, although having evidence-based practices integrated into the OASIS data set may serve as a reminder to clinicians of their importance. Since 2002, the Quality Improvement Organizations (QIOs) have served as an important resource for home health agencies, providing guidance and practical tools for agencies to improve their care of patients with conditions targeted by the new OASIS process items, such as diabetes, pain, heart failure, falls risk and pressure ulcers. It is CMS's plan to identify and acknowledge the agencies that have learned from these resources, responded to the challenges of improving the care they provide, and incorporated these care processes into their agency practices.

5. **CMS should not be dictating what interventions are appropriate for specific patients.** Specifying what assessments may need to be addressed discredits nursing judgment for what is appropriate for that client. Clinicians incorporate assessments and interventions when we believe them to be needed based on patient assessment. Nurses want to feel there is room for clinical judgment and doctors want nurses to use this judgment.

Response: CMS agrees it is up to the agency and individual clinicians, under the direction of the patient's physician, to determine whether a screening or intervention is

appropriate for a patient, based on patient assessment and clinical judgment. In response to comments, CMS has taken care to ensure that each process item in the latest version of the OASIS C provides an opportunity for clinicians to indicate that a process was not conducted. In some cases, a response has been added that reflects the reason why a practice might not be appropriate for that patient. For example, M2010 – Patient/Caregiver Drug Education – asks if the patient or caregiver has received instruction on special precautions for high-risk medications at Start of Care. The new version of this item includes the response, “N/A – Patient not taking any high risk drugs OR patient/caregiver fully knowledgeable about special precautions associated with high-risk medications.” If the clinician chose not to provide instruction on special precautions for high-risk medications at the Start of Care for a different reason, they can still check the “No” box and provide an explanation in the patient record.

6. **OASIS should include the PHQ-2 as in the CARE instrument** Depression is a very serious problem in the elderly. We strongly recommend that screening for depression be included in the OASIS C assessment instrument. To achieve this objective we recommend that the questions relating to depression in the proposed OASIS C be replaced by the Patient Health Questionnaire (PHQ-2) i.e. Sections F2 and F3 of Part IV. Cognitive Status, Mood & Pain section of the proposed Home Health CARE Admission Tool.

Response: CMS has reviewed this issue in response to comments and has changed the OASIS C depression items to include the PHQ-2[®] from Pfizer in the dataset as an option for agencies. CMS is also incorporating the PHQ-2[®] into the CARE instrument and the PHQ-9[®] into the MDS instrument. The OASIS C Guidance Manual will contain information and links to resources to assist users with implementing the PHQ-2[®] or selecting another depression screening tool if that is their preference. As explained earlier, the decision to use the PHQ-2[®], another depression screen or not to incorporate a depression screen remains in the domain of the agency. A measure on depression screening will be reported on Home Health Compare.

7. **OASIS should include screening/assessment tool(s) for all the assessments in the OASIS C. This would reduce duplication in documentation and be beneficial for national benchmarking.** Instead of asking if standardized assessment tools have been completed to assess pain and risks for skin breakdown, add a tool into the assessment that is approved by nationally recognized experts. This will prevent the need to duplicate documentation in more than one area of the clinical record since many agencies already have tools like the Braden scale and pain assessment scales as requirements in their documentation. This would also leads to less variable data for benchmarking than if agencies are all using the tools of their choice

Response: CMS has chosen not to be prescriptive about which screening and assessment tools agencies select, other than incorporating the PHQ-2[®] (which remains optional). Agencies that are currently using tools such as the Braden or Norton scales, or a specific pain assessment scale, may continue to use them. If these tools are integrated into their comprehensive assessment with the OASIS items then no duplication of documentation

will be needed. It is up to each agency to determine which practices it will implement based on its patients and operations and which assessment tools are most appropriate. Examples, guidance and resources on standardized assessment tools appropriate for use in the home health setting will be included in the revised OASIS C Guidance Manual.

8. **Responding to process items at recertification, transfer and discharge will be difficult to operationalize.** The clinician conducting the assessment at recertification, transfer or discharge may not be the clinician who provided care throughout the episode nor the clinician who created the Plan of Care. The assumption that every field clinician knows whether or not the agency has addressed vaccines, foot care & all the other processes at the time of D/C is unreasonable. The clinician who completes the assessment will be required to conduct a patient chart review in order to be able to answer honestly if all interventions were appropriately implemented. This will add significant burden.

Response: Based on feedback from the clinicians who collected the OASIS C data in the field test who reported it was overly burdensome to review the entire chart at recertification, transfer or discharge, CMS deleted these questions at recertification and limited the look-back period to the period since the last OASIS assessment (a maximum of 60 days) at transfer and discharge. Clinicians at agencies that were using electronic records said they predicted that software would likely be developed to promote automatic reporting of these data; agencies using paper-based records said they would consider developing check lists or tracking forms to access this data at the time of transfer or discharge. CMS agrees that there are methods available to agencies to record and store the data that will prevent the need for a full audit of the home health episode. Currently, the CoPs require that a written summary report for each patient be sent to the attending physician at least every 60 days, and a discharge summary must be made available to the attending physician at discharge, so the need to collect data on patients at those times is already a requirement. Since these summaries would include information on patient status and interventions implemented, some of the information needed to respond to OASIS C items is already being collected. Information, guidance and links to resources on the evidence-based practices in the OASIS C will be provided in the revised OASIS C Guidance Manual, along with optional tools to assist agencies with meeting OASIS C reporting.

9. **Questions about the patient's previous status will be difficult to answer when completing the OASIS.** There are many OASIS C items that ask how current status compares to the status of the client at the time of the previous OASIS assessment. When the same nurse or therapist is completing the OASIS assessments for each time period, this is a logical question. However, when two different caregivers are completing the OASIS assessment, these questions would be difficult to answer. Agencies will have even more difficulty completing the new process items when they use contract therapists to complete the transfer or discharge OASIS, as these clinicians typically do not have access to the entire chart.

Response: In the latest version of the OASIS C, almost all the patient status questions reference the patient status *at the time of the assessment*. There are items that ask about

prior level of independence for ADL/IADLs and medication, but these are only asked at SOC/ROC and reference the patient's functioning prior to the home health admission, so they would not require any chart review or knowledge sharing between agency staff.

There are also questions that ask about evidence-based practices the agency implemented since the previous OASIS. As noted above, the CoPs require that a written summary report for each patient be sent to the attending physician at least every 60 days, and a discharge summary must be made available to the attending physician at discharge, so the need to collect data on patients at those times is already a requirement. Since these summaries would include information on patient status and interventions implemented, some of the information needed to respond to OASIS C items is already being collected. Also as stated above, there are methods available to agencies to record and store the data that will facilitate agency accessing the data they need to complete the OASIS and prevent the need for a full audit of the home health episode.

10. **Process items may not provide accurate data.** While these questions have merit, they are being asked in a way that will certainly obtain a majority positive response. With a simple yes/no answer, you are not going to obtain adequate measurement. Also, clinicians may become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to all of them in order to get the assessment completed and off their to-do list.

Response: It is always a challenge to create assessment items that balance the need for clarity and readability with the complexity of issues surrounding patient clinical status and care decisions, especially while attempting to minimize burden. CMS has attempted to do this in the new OASIS C items and expects that in addition to the simple yes/no responses that the clinician provides in the OASIS data set, any necessary additional explanation will be documented in the patient care record. However, for the purpose of reporting process measures, only a yes or no answer is required. Regarding the suggestion that clinicians may fail to conduct the assessment or review needed to answer the questions accurately, CMS acknowledges this is always possible, but it is auditable during the survey process. In addition, it is anticipated that new data accuracy and validity safeguards will be put in place as payment comes to depend on outcomes under a pay-for-performance system. Based on the field testing, we have confidence that the process of OASIS data collection will not be so burdensome that they cause clinicians to consider compromising their professional standards of conduct or commit fraud.

11. **Are the processes in the OASIS process items now mandatory?** In many instances the issues addressed using these questions may not pertain to every patient and we are concerned about the impact on the agency will be at time of survey if these questions are answered "No." Will we have to defend ourselves if an intervention will not be implemented and what will the repercussions be?

Response: As stated previously, the processes documented in the OASIS C are not mandatory. Clinicians have the option of responding that an assessment or intervention was not implemented and of documenting in the record any additional information they

deem appropriate. The OASIS C process items will be used for quality reporting, but it is understood 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. Agencies that choose not to adopt these evidence-based practices for their patients will see that decision reflected in their scores for processes measures on the Home Health Compare website. If CMS develops a Pay-for-Performance component to the home health reimbursement system, a decision not to incorporate evidence-based practice could impact payment.

12. **Some of the best practices discussed in the POC process and intervention items would not be covered under Medicare coverage guidelines.** Because many of those interventions are preventive in nature, they would not be reasonable and necessary per Medicare's coverage criteria.

Response: All of the evidence-based practices included in the OASIS C dataset would be considered to fall under the categories of assessment, management and evaluation of the patient's care plan, teaching and training, treatment of the patient's illness or injury, or restoration or maintenance of function affected by the patient's illness or injury. Influenza and pneumonia vaccines are covered by Medicare Part B.

Process Items Related to Physician-ordered Plan of Care

1. **Not all interventions require a physician order.** Why must these interventions be on the physician-ordered plan of care? Many interventions, such as those to prevent falls or pressure ulcers, do not require physician orders and do not need to be on the plan of care. Questions such as this limit the scope of the home care clinician to use their clinical judgment when assessing their patients and tend to lead the assessment in a direction that it does not necessarily have to go.

Response: CMS encourages home care clinicians to use their clinical judgment when assessing their patients in order to develop the plan of care in consultation with the physician. As part of the CoPs, 42 CFR 484.18, (a) *Standard: Plan of care*, the plan of care “covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.” CMS is seeking to measure and report on the types of interventions that would need to be stated in the physician-ordered plan of care per the CoPs in the OASIS C items which report evidence-based practices for pain, pressure ulcers, depression, heart failure and falls risk. When interventions such as diabetic foot care or falls prevention are stated clearly in the plan of care, they are available for reference by all staff who provide care for the patient, thereby ensuring that their efforts are coordinated effectively and support the objectives outlined in the plan of care. Further explanation and examples of interventions that should be written in the physician-ordered plan of care will be included in the revised OASIS C Guidance Manual.

2. **Some OASIS POC items assess interventions that are the responsibility of the physician, not the Home Health Agency** In several cases these items reference interventions that fall outside the home care provider's scope and more rightfully are a physician's responsibility. They put the burden of action on home health providers when it more accurately belongs in the physician's scope of responsibility.

Response: Assessing the patient's clinical status and needs, communicating that information to the physician, and ensuring that pertinent diagnoses are addressed all fall within the home care provider's scope of practice. The physician and the agency share responsibility for determining a patient's need for any of the evidence-based practices measured by the OASIS C. As stated previously, it is understood that the evidence-based practices may not be implemented for every patient, and a rate of 100 percent is not expected for any agency or for any of the process measures. Clinicians have the option of responding that an intervention was not implemented and of documenting in the record any additional information they deem appropriate as to why a care practice was not implemented.

3. **Many of these process items fall outside of the usual workflow that occurs in a typical home care agency.** The OASIS C requires the clinician to work outside of their usual clinical process and combine assessing, analyzing and planning in the same step. The initial OASIS assessment performed at Start of Care is a part of the comprehensive assessment used to determine a patient's needs and to help determine a plan of care developed in consultation with the physician. Since the plan of care is not determined at the time of the OASIS SOC, many of these questions would be not applicable or the clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (often by someone else) in order to be able to answer honestly if all appropriate interventions are on the Plan of Care. Therefore these items will be cumbersome for providers to document.

Response: In response to public comments received, CMS has reordered some of the items in the OASIS C to facilitate work flow. In the new version of the data set, questions about plan of care have been consolidated and placed toward the end of the dataset following the patient assessment items. The process of patient assessment naturally informs the care plan, and the care plan should evolve from the findings of the assessment. The expectation remains that clinicians will complete the plan of care item within the 5-day SOC (or 2-day ROC) window after consulting with the patient's physician, and other agency staff as needed. Additional guidance regarding work flow and the plan of care items will be included in the revised OASIS C Guidance Manual.

4. **The POC can change over the course of the home care stay, so the responses will not be accurate.** One problem is a lack of accurate information revealed or present on the initial assessment. It is not unusual for a client to receive support the first few days or week after returning home and doing well, and then start to encounter more problems as the family and support system are reduced. Thus the process measurement of these areas would not be accurate.

Response: It is understood that the patient's needs change throughout the home care episode. The process items that measure assessments conducted and evidence-based practices planned at SOC/ROC will accurately reflect the patient's condition and care plan instituted at the time of the start of care assessment. If the status changes in the first 5 days of SOC, the SOC OASIS dataset can be changed to reflect this.

Items reporting implementation of evidence-based practices will reflect care practices that were implemented since the prior OASIS assessment. The burden reduction initiative of 2002 limits CMS's ability to add data items to the OASIS at Follow-up, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. In response to concerns raised by commenters and members of the NQF that measures might not accurately reflect care for longer-stay patients, home care episodes that exceed 60 days (i.e. that require a recertification) will not be included in publicly-reported measures on implementation of evidence-based practices. This applies to the measures on Diabetic Foot Care and Education, Drug Education on All Medications, Heart Failure Follow-up, Pressure Ulcer Treatments Implemented and Pain Interventions Implemented.

5. **The POC is already part of the Conditions of Participation so POC items should not be included in the OASIS** Under the CoPs: Home Health Agencies, 42 CFR 484.18, Home Health Agencies are required to establish a written plan of care for every patient. This plan of care must be developed in collaboration with agency staff, address all the patients' problems as identified on the initial assessment and must be authorized in writing by a physician. Given this mandate we wonder why it is necessary to include such questions on the OASIS assessment instrument.

Response: As stated previously, information about evidence-based practices specified in the physician-ordered plan of care is not currently recorded by HHAs or reported to CMS in a way that would support the development of reportable measures. Incorporating these data elements into the OASIS is believed to be the least cumbersome and most cost-effective way of collecting the data needed for creating and reporting process measures and any Pay-for-Performance system which may be instituted.

Questions about Who Can Complete OASIS Items

1. **More than one clinician should be allowed to contribute to the OASIS** With all the added information we need to gather, we would like to see more than one clinician allowed to contribute to the OASIS. Some OASIS C items will require input from office/supervisory staff. It might be better for case managers or staff assigned to review patient records to respond to the new OASIS process questions as they have better access to the whole patient record and more time to review the record compared to a field clinician. The complexity of this document indicates the need for collaboration.

Response: Current regulations require that only one person complete the OASIS assessment. The clinician completing the OASIS can consult with other agency staff, but the OASIS must be based on the clinician's assessment, and by signing the OASIS, the

clinician is attesting that the data contained in the OASIS are accurate. For the upcoming CARE instrument, CMS is considering allowing more than one clinician to contribute to the assessment, but no change in the OASIS regulatory requirement is anticipated at this time.

2. **OASIS items on wounds and depression require specialty training** We would need an ET nurse to evaluate for wound information and one with psych experience for depression screening.

Response: The 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. As an example, CMS has incorporated the PHQ-2[®] in the depression assessment item (M1730) for agencies that choose to use it. It consists of 2 questions asking if the patient has had little interest or pleasure in doing things, or has felt down, depressed or hopeless over the previous 2 weeks. No further assessment is required. Further explanation and examples of assessment tools for wounds and OASIS process items will be included in the revised OASIS C Guidance Manual.

3. **Clarify if screenings or interventions must be done by the assessor completing the OASIS** Must the process measure tasks (including development of plan of care and implementing actual clinical interventions like diabetic foot teaching or fall prevention steps) be completed by the home health agency or can the agency use assessment information (depression screen or fall risk assessment) conducted by the physician or other professional external to the agency. Also clarify if care planning and clinical interventions can be provided by another clinician seeing the patient.

Response: The purpose of the OASIS process items is to collect information on assessments and evidence-based practices that the agency has implemented for this patient. When the item asks, “Has the patient been screened for depression, using a standardized depression tool?” it means has the patient been screened by a clinician from the home health agency. If the assessment (e.g. depression screen or fall risk assessment) or clinical interventions is conducted by the physician or another professional external to the agency, these would not be counted as being performed by the agency. Further explanation and guidance on this issue will be included in the revised OASIS C Guidance Manual.

4. **Some OASIS items cannot be completed by therapists**

- **Therapists will be uncomfortable answering some areas of the OASIS**
Medications, heart failure, depression etc are very challenging and uncomfortable for some therapists. In some cases, clinicians completing the OASIS (such as therapists) may not feel that they are qualified to accurately assess many of these new items at.
- **Therapists do not have the training to answer some areas addressed by OASIS C** Additional data elements proposed in Oasis C increase the difficulties

faced by therapists whose education is focused on functional issues, rather than medical/ clinical ones.

- **Since therapists can't answer all OASIS C items, nurses will have to do all OASIS assessments** It appears that the end result of these new MO items will be to require that RNs complete the Oasis C in therapy-only cases, thereby increasing our costs and the overall costs to the health care system, resulting in many non-billable but payable visits on Therapy only ordered clients.

Response: The OASIS C remains discipline neutral and Physical Therapists can respond to all existing, new and revised items in the OASIS C dataset. Comments from the American Physical Therapy Association (APTA) were received as part of the public response and specifically addressed the issue about whether physical therapists can respond to all areas of the OASIS C. According to APTA:

- Wound care items: Physical therapists are and should be permitted to perform all wound care interventions legally mandated by state licensure and defined by the education curriculum of the physical therapist. This would include the coverage of interventions such as: dressings, debridement, application of topical agents; physical agents and mechanical modalities; electro therapeutic modalities; orthotics, protective and supportive devices; and assistive and adaptive devices.
- Heart failure items: Physical therapists are more than competent to complete the information needed for the cardiac items. We strongly encourage CMS to provide guidance to home health agencies that physical therapists are well-trained in cardiovascular conditions and should be able to initiate care for these items and coordinate with other appropriate health care practitioners when needed.
- Depression screening: APTA suggest that CMS consider the use of the PHQ-9[®] Depression Scale Form in order to harmonize home health assessment information with data collected in other settings (i.e. MDS in the skilled nursing facility setting).
- Medication management and education: Physical therapists are more than capable of completing the drug regimen review item. It is within the scope of the physical therapist to perform a patient screen in which medication issues are assessed even if the physical therapist does not perform the specific care needed to address the medication issue. The physical therapist is competent and qualified to serve as a case manager and facilitate coordination of care with physicians and nurses APTA strongly urges CMS to duly note and recognize the role of the physical therapists in OASIS items as they relate to medication management (i.e. screening, evaluation, collection of information, identification of adverse events/reactions, and education). APTA has a position statement adopted by its House of Delegates which states:

“Physical therapist patient/client management integrates an understanding of a patient’s/client’s prescription and nonprescription medication regimen with consideration of its impact upon health, impairments, functional limitations, and disabilities. The administration and storage of medications used for physical therapy interventions is also a component of patient/client management and thus within the scope of physical therapist practice.”

Coordination with the CARE Instrument

1. **Replace Neuro/Emotional/Behavioral Section with CARE Part IV.** OASIS lacks an appropriate mental status/cognitive assessment that addresses the patients' memory, recall, attention, concentration, mood, and thinking amongst others is essential to this process. The Neuro/Emotional/Behavioral Status section (M1700-M1750) should be replaced by Part IV. Cognitive Status, Mood & Pain section of the proposed CARE Tool.

Response: CMS has attempted to harmonize the items in the OASIS C with the CARE instrument to the extent possible, and we considered substituting Part IV of the CARE for the OASIS neuro/emotional/behavioral status section. However, many of the items in the OASIS neuro/emotional/behavioral status section are used for risk assessment of OBQI/OBQM measures. Also, the questions in Part IV are significantly different from the ones in the OASIS and were not part of the OASIS C field testing, so we have not received feedback from home health clinicians to determine their appropriateness in the home health setting. CMS ultimately determined that incorporating the Part IV items into the OASIS C would not be appropriate at this time. The OASIS C Guidance Manual will provide links to the types of assessments used in the CARE and MDS, such as the Brief Interview of Mental Status (BIMS) and the Mini-Mental State Examination (MMSE) so that clinicians who wish to incorporate those tools into their comprehensive assessment and use the results to inform OASIS C responses can do so.

2. **The numbering of the responses in the ADL and IADL items remains inconsistent with the FIMS, MDS or the proposed CARE tool where the highest numbered response is the highest level of function.**

Response: CMS has not chosen to convert the existing OASIS item responses to a numbering system where the highest numbered response represents the highest level of function. We prefer to use a metric in which "0" always represents absence of an impairment or "independent." Changing scales would disrupt scoring of items used in the payment algorithm.

3. **Changes to OASIS should be done in a more comprehensive manner. CMS should compare the information in OASIS C with the current development of the CARE tool.**

Response: CMS is aware that maximizing the coordination of the OASIS C and CARE instruments to the extent feasible will benefit everyone – home health providers, patients, caregivers and CMS. Wherever possible, we have harmonized and aligned OASIS language with CARE. Items assessing patient stability and caregiver support have been changed to mirror CARE items, as has M1000 Inpatient Facilities and items collected on understanding of verbal content, pressure ulcers, depression assessment, caregiver status, and prior level of function. The OASIS instrument was under development and ready for testing prior to the CARE instrument which is still being refined. It has also been important to work within the restrictions of NQF recommendations for future measure development, the pressure ulcer framework, and maintaining the data elements

requirements for payment the home health payment algorithm, so harmonization with CARE has not been possible in all cases.

Clarification of Instructions

1. **The guidance manual should be as complete as possible** to minimize Q&As. Otherwise we will end up with a document whose questions lead to confusion about how to interpret items and added rules that apply to one specific question. CMS should also clarify which previous OASIS Rules or Conventions still apply.

Response: The revised OASIS C Guidance Manual will address the questions which were raised by commenters and provide guidance, examples and web links to external resources to assist clinicians in understanding the OASIS C items and responding to them accurately.

2. **Consistency between OASIS items must be maximized and subjectivity minimized** Change of status items are particularly subjective. How do we answer if there has been a change from the prior ability for ADL's when the question includes multiple tasks however one response is expected? As we move toward a system with greater weight on the outcomes of care for public reporting and reimbursement, it is imperative that every attempt be made to improve the clarity of the items themselves.

Response: CMS has made efforts to maximize consistency between items throughout the dataset and to minimize subjectivity. We have revised the questions about prior status so that the tasks of ambulation and transfer are now responded to separately and the responses are aligned with those in the CARE instrument. As stated above, guidance will be included in the revised OASIS C Guidance Manual to assist clinicians in understanding the OASIS C items and responding to them accurately.

Concerns about Implementing OASIS C Changes

1. **OASIS C represents a major revision which could be overwhelming for clinicians.** It seems that phasing in some of these changes would be more realistic than doing everything at once.

Response: Home health providers have been requesting specific revisions to OASIS since data collection since 1999 when OASIS was first implemented, and it is not in the best interest of providers or patients to delay those revisions.

2. **OASIS C will require major system changes and CMS needs to provide adequate transition time.** The magnitude of the changes proposed will require a major revision of record systems throughout the industry, such as point of service system that have integrated specified OASIS items with other modules in order to provide a comprehensive documentation system. We understand that the document released in April 2009 will be a working document. However, a window of 3-4 months from the

final rule to implementation is very brief. We are concerned that it will not be sufficient to re-program documentation systems and re-train the clinicians on the new assessment.

Response: CMS's goal of having a revised OASIS instrument in use by January 2010 is based on the desire to implement requested revisions as soon as possible. However, we understand the need to proceed with a schedule that is feasible for providers and the industry, including training and changes to software. We will work closely with the industry to develop a schedule that allows integration of the revised instrument within a reasonable timeframe. We expect only minor changes to the OASIS C (if any) to occur in the final rule process and specifications should be available in the summer of 2009.

- 3. CMS needs to provide adequate reimbursement for training and system changes required.** It will take considerable time and resources, initially and long-term, to implement these changes. If CMS is anticipating that agencies become paperless, will there be financial assistance to help accomplish this?

Response: As discussed previously, CMS is committed to assisting HHAs with the transition and will be providing agencies with electronic versions of revised data sets for each collection timepoint and updated HAVEN software for transmitting the OASIS data to state repositories can be downloaded at no charge to the HHA. In addition, data specifications, data dictionaries, the HAVEN manual, and the HHA data submission manual will be made available to agencies and to software developers and vendors. The Office of the National Coordinator has been tasked with overseeing health information technology projects and moving the industry toward greater utilization of electronic health records, which is beyond the scope of this project. Based on the results of the field study, we are confident that agencies that rely on paper-based records can collect the OASIS C without undue burden.

- 4. CMS will need to offer educational outreach to agencies for these significant revisions** Due to the significant nature of these revisions, we strongly encourage the continuation of such activities that aid providers in understanding the OASIS C revisions and how to accurately complete the assessment instrument.

Response: As described previously, CMS is taking steps to ensure educational materials are available to everyone affected by these changes. In conjunction with the Medicare Learning Network, CMS will host open door forums to provide information and answer questions about OASIS C. We will also create a Train-the-Trainer package (eligible for CEUs) available to HHA providers and to the OASIS Education Coordinators (OEC). In addition, a revised and newly formatted OASIS Guidance Manual is being created with the input of industry and provider groups, which will have web links to resources and current clinical practice guidelines.

Questions about Field Testing

1. **The OASIS C field test was too small** – The size of the agency sample in the OASIS C field test was too small to be statistically significant. Pilot studies on a much larger scale are needed to determine the feasibility and usefulness of the proposed OASIS changes prior to implementation.

Response: CMS worked with their contractors to develop a testing plan that provided needed information about the reliability and burden of the proposed OASIS instrument in the most cost-efficient and least burdensome way. 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 were 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 was not within CMS's budget to expand testing further, nor was it necessary to collect the data needed to obtain accurate information on the feasibility and usefulness of the proposed OASIS C changes.

2. **Field test results need to be made public** – Field testing results on feasibility, burden, validity and reliability should be available to the public.

Response: Field testing results will be made public as part of the Home Health Quality Measures & Data Analysis project final report.

General Comments on Other Issues

1. **Numbering** – Clinicians are familiar with the M0's and would have less of a learning curve if the numbers were modified rather than totally changed.

Response: We agree that the new numbering system will require some adjustment. However, because of the changes, deletions and additions to the OASIS C, most numbers would have been needed to be changed anyway, and attempting to align the items with the previous numbering system proved impossible for some sections. CMS decided that providing each section with a range of numbers (i.e. tracking and clinical record items are M0xxx, patient history and diagnosis are M1xxx, etc) is a better long-term solution and one that mirrors systems being used by the datasets in other settings and the new CARE instrument.

2. **Problem of data not being collected at recertification** – failure to collect data at recertification for many of the new questions is problematic since that is when many new diagnoses, changes to care plans, etc., are noted.

Response: The burden reduction initiative of 2002 limits CMS's ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. Publicly-reported quality measures will only report on home health stays that last 60 days or less (i.e., do not have a

recertification assessment). OBQI/OBQM measures will report on implementation of evidence-based practices that are implemented during the episode ending in Transfer or Discharge, so that the measures will include patients whose home care stay exceeds 60 days.

3. **Limit outcomes measured** – CMS should limit the number of clinical outcomes measured to 10 or 12 at any one time, to allow agencies to focus on one or two outcomes intensely rather than be overwhelmed by a large number of measurements.

Response: CMS is aiming to develop a balanced set of measures for home health quality that include patient outcomes, care processes and CAHPS. As it has always been, it's up to agencies to decide what quality improvement areas to focus on based on considering their agency's needs as indicated by factors such as statistically significant scores on their OBQI/OBQM measures.

4. **Need for validation prior to public reporting** – CMS should ensure that the quality measures used for public reporting have been fully validated prior to their public release.

Response: The publicly-reported measures that have been submitted to NQF will be given time limited endorsement. During the next two years, CMS will collect additional data and conduct more extensive analyses, which will be reviewed by NQF in 2011 as part of the review for unlimited endorsement.

5. **Clarify impact on Case Mix Adjuster** – CMS should clarify if information from the new items and new diagnosis codes will be added to the case-mix adjuster.

Response: OASIS C was not intended to impact payment policy and OASIS items used in the payment algorithm were assessed to make sure they were not changed in a way that would affect the payment algorithm. Once OASIS C data are collected it will be possible to assess whether they could be useful for refinements to the case mix adjuster. In terms of risk-adjustment for outcome measures, all the information collected in the OASIS C will be considered for use in the updated risk-adjustment models that will be applied to OASIS C-based outcome measures in Home Health Compare, OBQI and OBQM measures.

Part 2 – Item-specific Comments

Tracking Items

M0140 Race/Ethnicity

Comments: CMS should restore the “unknown” response to M0140

Response: Office of Management and Budget (OMB) regulations state that “unknown” is not a permissible response for this item. The OASIS C Guidance Manual will contain instructions for completing this item when the patient does not self-identify.

M0150 Current Payment Sources for Home Care

Comments: M0150 (current payment sources) was moved ahead of M0080 so now it is not in numerical order. If it must be moved, please renumber with a number less than M0080.

Response: Numbers for M0150 and lower, plus M0903 and M0906 were not changed per the request of IFMC for data integrity and linkage purposes. Since M0150 is a Tracking Sheet item, not a Clinical Record item, the numbering of item is consistent within the Tracking Sheet.

Clinical Record Items

M0080 Discipline of Person Completing Assessment

Comments: Completion of an OASIS data set often cannot and should not be accomplished by a single individual. CMS should revise M0080 to capture information on all of the individuals and disciplines who contribute to the collection of information found in each data set.

Response: Current regulations require that only one person complete the OASIS assessment. The clinician completing the OASIS can consult with other agency staff, but the OASIS must be based on the clinician’s assessment, and by signing the OASIS, the clinician is attesting that the data contained in the OASIS is accurate. For the upcoming CARE instrument, CMS is considering allowing more than one clinician to contribute to the assessment, but no change in the OASIS regulatory requirement is anticipated at this time.

M0090 Date Assessment Completed

Comments: Does this need to be delayed until after all assessment, care planning and relevant clinical interventions are implemented?

Response: This item has not changed. It should be reflect the date that the OASIS C items are completed.

M0102 Date of Physician-ordered Start of Care / Resumption of Care
[previously item M0104]

Comments:

- Starting the services is not always within the home care provider’s control. Also, it’s unclear why this item is needed.
- This item will actually make it easier to track the 48 hour rule, but need clarification about whether we need a date for each type of service or just the opening discipline.

Response:

- Wording for the item has been clarified and item numbers M0102 and M0104 have been reversed to enhance logic and reinforce the understanding that only one date is required.
- The item refers to the order to start home care services – the discipline is irrelevant.
- The OASIS C Guidance Manual will contain instructions for completing these items and examples for how to answer this question if the start of care is delayed.

M0104 Date of Referral
[previously item M0102]

Comments:

- Wording needs to be clarified and the date of referral defined to differentiate between an inquiry about services and an actual referral for services.
- Not all referrals come from a physician so eliminate the word physician.
- Field staff usually doesn’t know the date of referral. Also, it’s unclear why these items (date of referral and date of start of care) are needed.

Response:

- These items are needed for the new measure on timely care.
- Wording for this item has been clarified and “physician or physician-designee” has been added.
- Item numbers M0102 and M0104 have been reversed to enhance logic and reinforce the understanding that only one date is required.
- The OASIS C Guidance Manual will contain instructions for completing these items and examples for how to differentiate between an inquiry about services and an actual referral for services.

M0110 Episode Timing

Comments:

- Recommend adding instructions to skip if completing a RFA 5 or if completing an RFA 3.
- This item should be deleted. Dates and sequence of episodes can be used to determine whether an episode is early or late. The time required for clinician education and data collection is not justified when an alternative method of determination is possible.

Response:

- The version of the instrument displayed in the PRA package is an “all time point” version. Skip patterns are not needed as this item is only collected at SOC/ROC and Follow-up.

- This item has not changed since OASIS B-1. It is used by the HAVEN software to identify the appropriate payment group.
- “Unknown” can always be checked.

M0903 Date of Last (Most Recent) Home Visit

M0906 Discharge/Transfer/Death Date: Enter the date of the discharge, transfer, or death (at home) of the patient

Comments: The new placement of M0903 and M0906 is confusing. We would like to propose renumbering M0903 and M0906 so they are at the end of the assessment.

Response:

- The version of the instrument displayed in the PRA package is an “all time point” version – note that the item is on Transfer/Discharge only.
- IFMC specifically requested that M0903 and M0906 were to not be renumbered because of their data system constraints.
- In the current version of OASIS dataset, we have moved these items to the end, although they have not been renumbered. We recommend that the HHA incorporate this item into its formal comprehensive assessment in the location that works best for them.

Patient History and Diagnosis

M1000 From which of the following Inpatient Facilities was the patient discharged during the past 14 days

Comments: Why include the response option “Other Nursing home”? Please harmonize the OASIS C with the proposed CARE instrument as much as possible.

Response: Two CARE items from Section II Admission Information, A1 and A3 were identified as related to this item. We have changed the responses to the OASIS C item to harmonize (to the extent possible) with current proposed CARE item Section II A1.

M1005 Inpatient Discharge Date (most recent):

Comments: If patient was not discharged from inpatient facility by marking # 5 in M1000 then do we answer UK which really is not accurate as an answer? There should be a NA category.

Response: The described situation is prevented by the “Go To” instruction that is part of M1000.

M1010 List each Inpatient Diagnosis and ICD code for conditions treated during an inpatient stay within the last 14 days

Comments:

- Eliminate this requirement. If CMS needs the data it is available from the hospitals. Not all institutions make this information available in a timely manner. This is an undue burden and unrealistic expectation because final hospital coding often does not occur until the hospital generates the bill.
- The items allow 7 spaces and ICD-9 codes have a maximum of 5 digits.

Response:

- Inpatient diagnosis is an existing item in OASIS B-1 and it used for risk adjustment. Additional spaces have been provided to better reflect the patient's condition. The agency should make a good faith effort to gather this information from the patient, as in the past. The only change is to add more opportunities to record these diagnoses. There is no requirement to fill in all of the spaces.
- The 7 spaces for recording each diagnostic code were intended to prepare for ICD-10. The number of spaces has been returned to 5 as in the OASIS B-1 since ICD-10 is not currently in use.

M1012 List each Inpatient Procedure and the associated ICD procedure code**Comments:**

- Eliminate this requirement. If CMS needs the data it is available from the hospitals. Not all institutions make this information available in a timely manner. This is an undue burden and unrealistic expectation because final hospital coding often does not occur until the hospital generates the bill.
- Addition of inpatient procedures will give a clearer picture of the patient.
- The items allow 7 spaces and ICD-9 codes have a maximum of 5 digits.
- CMS should clarify whether surgical codes are to be included in M1012.
- We strongly urge that CMS actively encourage home health agencies to provide educational opportunities to nurses and therapists on how to accurately document such information.

Response:

- Inpatient procedure has been added to better reflect the patient's condition and for its potential in improving risk adjustment. An example would be if a patient was returning home after a surgical procedure that was relevant to the plan of care such as a total knee replacement or bypass surgery. The agency should make a good faith effort to gather this information from the patient. There is no requirement to fill in all of the spaces. Check boxes to indicate Unknown or Not Applicable have been added.
- The 7 spaces for recording each procedure code were intended to prepare for ICD-10. The number of spaces has been reduced to 4 since ICD-10 is not currently in use.
- Wording in the grid was changed to reflect that surgical codes are to be used in M1012.

M1014 Medical or Treatment Regimen Change Within Past 14 Days**[DELETED]****Comments:** Eliminate this item. This information is collected in other M0 items.**Response:** CMS has eliminated this item and incorporated the Not Applicable option into M1016.

M1016 List the patient's Medical Diagnoses and ICD codes at the level of highest specificity for those conditions requiring changed medical or treatment regimen

Comments: The items allow 7 spaces and ICD-9 codes have a maximum of 5 digits.

Response:

- The 7 spaces for recording each diagnostic code were intended to prepare for ICD-10. The number of spaces has been returned to 5 as in the OASIS B-1 since ICD-10 is not currently in use.
- CMS has incorporated the Not Applicable option from M1014 to reduce duplication.

M1018 Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days

Comments: The question is referring to conditions prior to any inpatient stay, not just Acute Hospital correct? Also isn't "None of the above" the same as "Unknown"?

Response: This item reports changes in medical or treatment regimen in the past 14 days in any environment. There is a difference between "None of the above" and "Unknown"; further explanation will be included in the OASIS C Guidance Manual.

M1020/M1022 Diagnoses, Severity Index, and Payment Diagnoses

Comments:

- The items allow 7 spaces and ICD-9 codes have a maximum of 5 digits.
- Consider moving M0230/240/246 (diagnoses) from its current position in the document to placement after M0826.
- Eliminate the severity index – this rating system is foreign to professional clinical practice and unique to home care and probably one of the most inaccurate items recorded.

Response:

- The 7 spaces for recording each diagnostic code were intended to prepare for ICD-10. The number of spaces has been returned to 5 as in the OASIS B-1 since ICD-10 is not currently in use.
- CMS has not received indicators that moving this item is desired by the majority of OASIS users. We recommend that HHAs incorporate this item into their formal comprehensive assessment in the location that works best for them.
- The severity index continues to be useful for risk adjustment. Wording in column 2 of the grid was changed to reflect that sequencing of the ratings may not match sequencing of the diagnoses. Guidance on severity index rating will be included in the OASIS C Guidance Manual.

M1030 Therapies the patient receives at home

Comment: This item should be renamed "Nutritional Therapies" as it is too confusing otherwise when simply looking at the title.

Response: The therapies reported by this item (including intravenous medications) are not restricted to nutritional therapies.

M1032 Risk for Hospitalization
[previously Frailty Indicators]

Comments:

- Guidance will need to be provided for many of the response options as they are prone to subjectivity, particularly unstable vital signs which is an ambiguous statement and open to large interpretation.
- Pain and functional decline are collected elsewhere in the OASIS.
- Many patient characteristics regarding frailty are not captured.
- This item should include risk factors identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form.

Response: Based on comments, CMS decided to focus this item more specifically on risk for hospitalization, of which frailty is one risk factor among others. The item was revised to ensure that information collected elsewhere in the OASIS, e.g., debilitating pain, are not duplicated. Definitions and instructions on selecting responses will be included in the OASIS C Guidance Manual.

M1034 Overall Status
[previously Stability Prognosis]

Comments: While some commenters felt this item provides responses that more clearly reflect the clinician's assessment of the patient's prognosis than the current items in OASIS B-1 (M0260 and M0280), many others expressed concern that the responses contain imprecise and subjective language.

Response: The item responses are consistent with proposed CARE item VII A2 and have been used in the OASIS C as part of the attempt to harmonize OASIS with the CARE instrument. The title was changed to "Overall Status" to be consistent with CARE. Definitions and instructions on selecting responses will be included in the OASIS C Guidance Manual.

M1036 Risk Factors characterizing this patient

Comments: Time period being assessed ("either past or present") needs clarification and response items such as obesity need further definition.

Response: This item has been reworded to remove confusion about time period being assessed. Definitions such as BMI for obesity and time parameters will be included in the OASIS C Guidance Manual.

M1038 Guidelines for Physician Notification
[moved to M2250 Plan of Care Synopsis]

Comments:

- Our staff believes that this question will lead to better outcomes as it can be a path to the physicians ordering parameters that can be treated in the home vs. just sending the patient to the emergency department. It will also lead to a more consistent teaching of the patient to be involved in their own healthcare.
- We recommend that this item be dropped from the OASIS C. Most MD's do not provide parameters or guidelines. With the exception of very specific situations that require protocols, when to notify the physician falls within the scope of nursing practice,

judgment, and agency standards and policies. Most agencies have policies/protocols or standing orders to support nursing practice.

- Plans of care do not arrive from the physician to the home health agency complete and ready to go, but rather are generated by the agency staff after the comprehensive assessment is completed of which the OASIS is an integral part. Further guidance is needed here.
- What is the use for this in the outcome process?

Response:

- This item is responsive to the issue of Care Coordination and the enhancement of nurse/physician communication. It will be used in an OBQI/OBQM process measure.
- The item been moved to a new Plan of Care Synopsis item in grid form (M2250) and now includes an option for agencies to indicate that they are using standardized clinical guidelines relevant to the patient's condition to determine when to contact the physician, and available for all care providers, if the physician has chosen not to establish specific parameters for this patient.
- The “current physician-ordered plan of care” means the patient condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the measure definition. CMS recognizes that this may not happen for all patients at all agencies. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.
- Additional clarification and guidance on clinical parameters, instructions for responding accurately to this item and weblinks for resources on clinical guidelines will be included in the OASIS C Guidance Manual, along with guidance on workflow to enable reporting Plan of Care items in the OASIS C.

M1040 Influenza Vaccine

M1045 Reason Influenza Vaccine not received

M1050 Pneumococcal Vaccine

M1055 Reason PPV not received

Comments:

- Patient self-report is not likely to be reliable. The primary physician (not the home health agency) should be responsible for tracking whether vaccines have been administered and if any contraindications to receiving it exist.
- It will be a burden to capture this information as the physician office will need to be contacted if patient does not have the information. Added documentation systems will need to be put in place to log this for ready capture of data. At this time software does not capture this data and it will be manual retrieval.
- Agencies may think that the intent of this question is for the agency to provide the vaccine medication and administer it. Needs clarification of wording.
- Reason PPV not given does not include that the agency does not administer PPV due to concerns (well documented) of efficacy and safety.
- Will need clear guidelines on the suggested frequency of receiving the influenza and pneumonia vaccines and on age/condition guidelines.

Response:

- The language and logic of the OASIS C immunization items have been adopted to “harmonize” across all health care delivery settings through the NQF process.
- These items are collected at Transfer and Discharge, so the agency should in most cases have ample opportunity to obtain this information from the physician.
- The HHA is not mandated to give the vaccines but to check to see if the vaccines have been received.
- There are methods available to agencies to record and store data on vaccines that can facilitate tracking of immunization status for agencies that have paper-based records, and that can be integrated into software for agencies that use electronic records. Currently, the CoPs require that a written summary report for each patient be sent to the attending physician at least every 60 days, and a discharge summary must be made available to the attending physician at discharge, so the need to collect data on patients at those times is already a requirement. Since these summaries would include information on patient status and interventions implemented, some of the information needed to respond to OASIS C items is already being collected.
- The OASIS C immunization items will be used for quality reporting, but it is understood that there may be reasons why making sure a patient has received appropriate vaccines may not be possible. A response of “None of the above” is provided.
- Regarding efficacy and safety of vaccines, we expect the HHA to follow CDC guidelines on efficacy and safety of vaccines.
- Regarding guidelines on the suggested frequency of receiving the pneumonia vaccine, the OASIS C item only asks the clinician to document whether the patient has ever received the pneumovax.
- Guidance on resources for current information on medical contraindication(s) and age/condition guidelines will be included in the OASIS C Guidance Manual.

Living Arrangements**M1100 Patient Living Situation**

Comments: We will need clear definitions and guidance on what is considered “available assistance” and what is defined as “congregate living.” The format has the potential for confusion and inaccuracy.

Response: Guidance and clarification about terms such as “majority of the time,” “congregate living,” and “availability of assistance” will be included in the OASIS C Guidance Manual.

Sensory Status**M1200 Vision (with corrective lenses if the patient usually wears them)**

Comments: Do we not care about vision for folks that do not have corrective lenses? The question is misleading when read. It seems to request information only about the patient’s visual acuity, when it is intended to assess the patient’s functional vision.

Response: This item has not been changed from OASIS B-1. It is intended to capture the functional vision of the patient. If the patient wears corrective lenses, functional vision should be tested while the patient is wearing those lenses. If the patient does not wear corrective lenses, functional vision should be tested without lenses. Parentheses have been put around the phrase “with corrective lenses if the patient usually wears them” to improve clarity. Guidance will be provided in the OASIS C Guidance Manual.

M1210 Ability to Hear (with hearing aid or hearing appliance if normally used)

M1220 Understanding of Verbal Content

Comments: The separation of hearing and understanding is an improvement and will provide more relevant data than the current item, particularly for the cognitively impaired patient. That is very helpful from a functional standpoint.

Response: Understanding of Verbal Content has been harmonized with the CARE item.

M1240 Has this patient had a formal Pain Assessment

[previously M1242]

Comments:

- The sequence of M1240 and 1242 should be reversed so that the presence of pain is established before the clinician is requested to document some of the content of their formal pain assessment.
- Eliminate this question on SOC since the physician-ordered plan of care is not yet established at the time of SOC OASIS assessment and it takes time to gather this information.
- The item is unnecessary – clinicians always assess pain using a standardized pain assessment tool that is appropriate for the patient’s ability to communicate.
- CMS should recommend or incorporate a standardized assessment tool to help decrease variance in data collected by providers.
- We will need a ‘standard’ definition for severe pain as this could be interpreted differently by clinicians.
- The question is vague as to what time frame this question investigates. Is it limited to the day in question or does it expand to the entire episode of care? If so, what happens to patients whose response to the question varies between visits and services?

Response:

- Order of pain assessment (new M1240) and frequency of pain (new M1242) were reversed in response to comments, so pain assessment comes before frequency of pain.
- A pain assessment at SOC/ROC will accurately reflect the patient’s condition at the time of the start of care assessment. If the status changes in the first 5 days of SOC, the SOC OASIS dataset can be changed to reflect this.
- Our field testing did not indicate that clinicians at all agencies are currently using a standardized pain assessment tool that is appropriate for the patient’s ability to communicate.
- Given the variety of standardized pain assessment instruments available, specifying one to be used by all agencies would be inappropriate. Furthermore, new tools are developed and adopted more frequently than the OASIS data set can be revised. Each agency should

determine which tool it will implement. Examples, guidance and resources with web links to standardized assessment tools appropriate for use in the home health setting will be included in the revised OASIS C Guidance Manual, along with guidance on time frames and definitions of terms such as “severe.” Because tools vary in their thresholds for severe, CMS will include guidance in the OASIS C Guidance Manual to assist in defining severity based on the scoring systems used by the available instruments.

**M1242 Frequency of Pain interfering with patient's activity or movement
[previously M1240]**

Comments: Commenters made several suggestions about potential improvements to skip patterns (response of no pain should skip plan of care item) and wording of item or responses to clarify that pain is being measured in relation to interference with activity.

Response:

- This is a payment item, so CMS is extremely limited in ability to change skip patterns and item wording. However, we did capitalize the word “interfering” to add clarity.
- A response of “no pain” option will still take the assessor to the plan of care question since pain may be controlled in a patient who is receiving adequate medications and will still need pain monitoring or intervention in the plan of care.

**M1244 Planned Pain Intervention
[moved to M2250 Plan of Care Synopsis]**

Comments:

- It would appear that the intent of these process measures is to determine whether the patient’s needs were being met with appropriate plan of care interventions. This is vital information in determining the quality of care and will promote improved outcomes.
- The plan of care may not be formulated until after the completion of the assessment, so assessment items that require reporting of details of the “current physician-ordered plan of care” are confusing. One interpretation is that the “current physician-ordered plan of care” means the POC that is created from the collaboration of home health staff and the MD. These orders would not be considered current at the time of OASIS data gathering because clinicians must call the MD with POC recommendations and get their verbal orders (or agreements to the POC). Please clarify.
- Another discipline such as nursing may be monitoring or addressing pain – exclude the reference to “physician -ordered” altogether to imply that all disciplines are involved. A negative response to any of these measures may also be due to the inability to obtain an order from the MD and not an oversight on the part of the home health agency.
- This question prompts the clinician to respond in a certain way which compromises the quality of data.

Response:

- The item been moved to a new Plan of Care Synopsis item in grid form (M2250).
- This item is responsive to the issue of care coordination and the enhancement of clinician/physician communication. Although all disciplines can contribute to monitoring and mitigating a patient’s pain, the purpose is to measure whether patients with pain have relevant physician-ordered interventions in their care plan. It will be used in an

OBQI/OBQM process measure that will assist agencies in assessing their own performance on incorporating physician-ordered pain intervention into the POC.

- The “current physician-ordered plan of care” means the patient condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the measure definition. We recognize that this may not happen for all patients at all agencies. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.
- Additional clarification and guidance on clinical parameters, instructions for responding accurately to this item and web links for resources on clinical guidelines will be included in the OASIS C Guidance Manual.
- Based on the field testing, we have confidence that the process of OASIS data collection will not cause clinicians to consider compromising their professional standards of conduct or commit fraud by indicating an intervention was incorporated into the plan of care or implemented when it was not. Also, this item is auditable by survey and certification and it is anticipated that new data accuracy and validity safeguards will be put in place as payment comes to depend on outcomes under a pay-for-performance system.

**M1246 Pain Intervention since the previous OASIS assessment
[moved to M2400 Intervention Synopsis]**

Comments:

- As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians. When multiple clinicians are responsible for the care of a patient, it may be difficult to ascertain whether or not the pain interventions were followed according to physician orders.
- What will these data be used for?
- Implementing pain interventions are only captured at transfer and discharge. If patient is open multiple episodes and pain resolves in first episode (interventions are done at that time), then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent OASIS. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information
- Is the simple inclusion of a pain med in the medication list with an order to teach medication regime sufficient to meet the definition of pain med management?

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- This item will be used to calculate the publicly-reported measure on pain intervention. The burden reduction initiative of 2002 limits CMS’s ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. In response to concerns raised by commenters and members of the NQF that measures might not accurately reflect care for longer-stay patients, home care episodes that exceed 60 days (i.e. that require a recertification) will not be included in publicly-reported measures on implementation of evidence-based

practices. The item has been revised to collect the data needed to calculate the publicly-reported measure on implementation of pain interventions.

- There are methods available to agencies to avoid time consuming research into the documentation by recording and storing data on pain interventions. These tools can facilitate tracking across time periods and different personnel for agencies that have paper-based records, and that can be integrated into software for agencies that use electronic records. Currently, the CoPs require that a written summary report for each patient be sent to the attending physician at least every 60 days, and a discharge summary must be made available to the attending physician at discharge, so the need to collect data on patients at those times is already a requirement. Since these summaries would include information on patient status and interventions implemented, some of the information needed to respond to OASIS C items is already being collected.
- Additional clarification and guidance on what constitutes pain monitoring and mitigation, and instructions for responding accurately to this item will be included in the OASIS C Guidance Manual.

Integumentary Status

Note: Recommended revisions to pressure ulcer items in the OASIS C are based on CMS consultation with the WOCN and NPUAP. This consultation is on-going on a quarterly basis. CMS is also working with the National Quality Forum (NQF) to develop a framework for measuring quality related to prevention and management of pressure ulcers at both the facility and practitioner levels across the continuum of healthcare.

M1300 Pressure Ulcer Assessment

Comments:

- Responses 1 and 2 are not mutually exclusive.
- A tool such as the Braden should be required or incorporated into the OASIS
- The OASIS already includes a standardized tool for assessing pressure ulcer risk so this addition is unnecessary.

Response:

- Responses 1 and 2 have been reordered and reworded to improve clarity
- As with the specification of a pain instrument, it would be inappropriate to specify or incorporate a specific pressure ulcer risk assessment tool into the OASIS C instrument at this time. In addition, new tools are developed and adopted more frequently than the OASIS data set can be revised. Each agency should determine which practices it will implement based on its patients and operations and which assessment tools are most appropriate. Examples, guidance and resources on standardized assessment tools appropriate for use in the home health setting will be included in the revised OASIS C Guidance Manual.
- The OASIS B-1 includes items on pressure ulcer number, stage and status but does not include a standardized tool or an item to report use of a standardized tool. This item will be used in an OBQI/OBQM process measure that will assist agencies in assessing their performance on incorporating pressure ulcer risk assessment into their care processes.

M1302 Does this patient have a Risk of Developing Pressure Ulcers?

Comment: This is a good addition to the assessment tool. Consider defining or providing objective threshold for “RISK.” Risk assessment tools typically assign varying levels of risk which may make application subjective and inconsistent.

Response: Because tools vary in their "thresholds" for risk, CMS will include guidance in the OASIS C Guidance Manual for using standardized tools that assist in defining risk based on the scoring systems used by the available instruments.

**M1304 Planned Pressure Ulcer Prevention
[moved to Plan of Care Synopsis – M2250]****Comments:**

- The plan of care may not be formulated until after the completion of the assessment, so assessment items that require reporting of details of the “current physician-ordered plan of care” are confusing.
- It’s unrealistic to ask clinicians to do a pressure ulcer assessment and have a plan for pressure ulcer prevention in place during the SOC/ROC period; the time should be extended.
- Another discipline such as nursing may be addressing pressure ulcer prevention – exclude the reference to "physician -ordered" altogether to recognize that all disciplines are involved. A negative response to any of these measures may also be due to the inability to obtain an order from the MD and not an oversight on the part of the home health agency.

Response:

- The item used at SOC/ROC has been moved to the new Plan of Care Synopsis (M2250) and includes an option for agencies to indicate that the patient has not been assessed to be at risk of pressure ulcers or that no interventions to prevent pressure ulcers were included in the physician ordered plan of care. POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to respond yes to this item. We recognize that this may not happen for all patients at all agencies. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.
- We recognize that all disciplines can contribute to the prevention of pressure ulcers; however, the purpose of this item is to measure whether patients at risk of pressure ulcers have relevant physician-ordered interventions in their care plan.

**M1306 Pressure Ulcer Prevention since the previous OASIS
[moved to M2400 Intervention Synopsis]****Comments:**

- An accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians. When multiple clinicians are responsible for the care of a patient, it may be difficult to ascertain whether or not the pain interventions were followed according to physician orders.
- This item is only captured at transfer and discharge. If patient is open multiple episodes and pressure ulcer is resolved in the first episode (interventions are done at that time), then answering this question at DC would not capture what happened in the initial

episode as the question only goes back to the most recent OASIS. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information.

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- There are methods available to agencies to avoid time consuming research into the documentation by recording and storing data on pressure ulcer interventions that can facilitate tracking across time periods and different personnel for agencies that have paper-based records, and that can be integrated into software for agencies that use electronic records. Currently, the CoPs require that a written summary report for each patient be sent to the attending physician at least every 60 days, and a discharge summary must be made available to the attending physician at discharge, so the need to collect data on patients at those times is already a requirement. Since these summaries would include information on patient status and interventions implemented, some of the information needed to respond to OASIS C items is already being collected.
- The burden reduction initiative of 2002 limits CMS's ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. The item has been revised to collect the data needed to calculate the OBQI/OBQM measure that will provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events. The item will report whether interventions were implemented during the episode which ends in transfer or discharge. If the patient is no longer considered at risk for pressure ulcers during that episode, the response of N/A can be selected. Reporting on all episodes, including those that exceed 60 days, will provide agencies with information to assess process measures as they pertain to long-term as well as short-term patients.

M1306 Does this patient have at least one unhealed (non-epithelialized) Pressure Ulcer at Stage II or higher or designated as "not stageable"?
[previously M1308]

Comments:

- The order of the pressure ulcer items is not logical.
- Need a definition of unhealed.

Response:

- CMS has re-ordered some of the Pressure Ulcer items to facilitate a logical flow, but the need for skip patterns to minimize burden sometimes determines item placement.
- Definitions for pressure ulcer terminology and assessment strategies will be included in the OASIS C Guidance Manual.

M1307 Date of Onset of Oldest Unhealed Stage II Pressure Ulcer:
[new item]

Comment: There was a request to add the date of onset of the oldest Stage II pressure ulcer to OASIS C.

Response: This item will be used to assess healing of Stage II ulcers within the construct of the NQF pressure ulcer framework.

**M1308 Current Number of Unhealed Pressure Ulcers at Each Stage:
[previously M1310]**

Comments:

- The clinician will have to go back to the SOC/ROC OASIS and enter previously submitted data. The likelihood of inaccuracy is high. CMS should link the data 'behind the scenes' if they feel the data is reflective of quality. Could we have our system default to the SOC values? Determining what was present on admission will be burdensome.
- Remove the terms “known or likely” since these are vague.
- Add wording to help define Suspected Deep Tissue Injury.
- Information on location of the pressure ulcer should also be included.
- The item does not deal with the fact that Stage III or IV ulcers that can re-epithelialize but can never truly heal and does not account for non-stageable ulcers that are later able to be staged.

Response:

- This item is used for payment and to collect information to identify “Present at Admission” – whether pressure ulcers that are present at follow-up and discharge were also present when the patient was admitted to home care. This will help CMS to collect data on whether pressure ulcers are healing or developing during the home care episode. This information cannot be obtained by CMS by simply comparing what was entered on SOC/ROC with number of ulcers at each stage at follow-up or discharge, since the patient could have a single Stage II pressure ulcer on admission that heals, then develop 2 more Stage II ulcers. By identifying the number of ulcers present at follow-up/discharge that were also present on admission, more accurate information can be obtained about agencies’ record of healing ulcers during their care.
- There are methods available to agencies to avoid time consuming record review and facilitate tracking of pressure ulcer status across time periods. These tools can be developed by agencies that have paper-based records, and we anticipate they will be integrated into software for agencies that use electronic records. Guidance and suggestions for tracking tools will be included in the OASIS C Guidance Manual.
- The term “since admission” in the last column has been deleted and replaced with “since most recent SOC/ROC.”
- Definitions of terms such as “known or likely” and Suspected Deep Tissue Injury will be included in the OASIS C Guidance Manual.
- We concur that location of the pressure ulcer is important, but CMS does not need that information for payment or quality, so it has not been included in the OASIS dataset.
- If the patient has non-stageable ulcers that are able to be staged later, the measure specifications looking at present at admission will take the presence of an unstageable ulcer into consideration.

M1310 Pressure Ulcer Length [previously M1312]

M1312 Pressure Ulcer Width [previously M1314]

M1314 Pressure Ulcer Depth [new item]

Comments:

- Use measurements that are approved by WOCN and define length as head to toe.

- Add an item measuring depth.
- Measurement should be of the largest ulcer not the longest.
- Measurement should include evidence of undermining and tunneling.

Response:

- CMS has adopted the standards set by national wound expert associations (NPUAP and WOCN) for reporting pressure ulcer length and width to harmonize with the methods used by the MDS and to report dimensions on the pressure ulcer with the largest surface dimension (length x width).
- CMS has change measurements to define length as “Longest length head-to-toe.”
- Definition of width has been changed to “Width of the same pressure ulcer; greatest width perpendicular to the length.”
- Measurement of the depth of the same ulcer has been added and is harmonized with the NQF Pressure Ulcer Framework.
- OASIS C will not include report of tunneling and undermining, however agencies can include this information in their clinical records.
- Information and instructions on measuring length, width and depth, along with links to resources, will be included in the OASIS C Guidance Manual.

M1320 Status of Most Problematic (Observable) Pressure Ulcer:

Comments:

- Provide guidance as to how to identify “most problematic.”
- Stage should be identified before status.
- Use of the terms healed or re-epithelialized is confusing as they can only apply to Stage III and IV ulcers. If an ulcer is healed, why would it be listed here?
- There should be a definition of “non-observable ulcers” in the item.

Response:

- CMS has worked and continues to work closely with the NPUAP, WOCN and the NQF on identification, staging, terminology and treatment for pressure ulcers.
- Guidelines for identifying most problematic ulcer, when to include healed ulcers, and definitions of terms unobservable, healed and re-epithelialized will be included in the OASIS C Guidance Manual based on recommendations from NPUAP, WOCN and NQF projects focused on pressure ulcers. The OASIS C Guidance Manual will contain references for resources on these topics for agencies to use in training their staff.
- Skip patterns require the order of stage and status items to remain as they are.

M1322 Current Number of Stage I Pressure Ulcers:

Comments: Item appears to be out of sequence.

Response: Skip patterns require the order of items to remain as they are.

M1324 Stage of Most Problematic (Observable) Pressure Ulcer

Comments:

- Provide guidance as to how to identify “most problematic” and non-observable.
- Why should non-observable pressure ulcers skip the pressure ulcer intervention process item?

- Recommend adding comment “per WOCN Guidance” in question or on responses.

Response:

- Guidelines for identifying most problematic and defining non-observable will be included in the OASIS C Guidance Manual along with web links to guidance from NPUAP and WOCN.
- The skip pattern has been changed so that non-observable pressure ulcers will go to the pressure ulcer intervention process item.

**M1326 Pressure Ulcer Intervention in Plan of Care
[moved to Plan of Care Synopsis M2250]**

Comments:

- It is not in the home care clinician’s scope to recommend wound care treatments, this is the physician’s area of responsibility.
- Who will decide if moist dressings are appropriate; when can this item be selected?
- Moisture retentive dressings need to be defined.

Response:

- The item has been moved to the new Plan of Care Synopsis (M2250) and includes an option for agencies to indicate that an order has been requested but not received from the physician or patient has no pressure ulcers with need for moist wound healing.
- Wording of the item has been changed to identify whether the plan of care contains interventions for pressure ulcer treatment based on principles of moist wound healing.
- The OASIS C Guidance Manual will contain information on definitions and examples of interventions based on the principles of moist wound healing and when moist wound healing is appropriate.

**M1328 Pressure Ulcer Intervention since the previous OASIS assessment
[moved to M2400 Intervention Synopsis]**

Comments:

- It is not in the home care clinician’s scope to recommend wound care treatments, this is the physician’s area of responsibility.
- Moisture retentive dressings need to be defined.
- An accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians. When multiple clinicians are responsible for the care of a patient, it may be difficult to ascertain whether or not the pressure ulcer interventions were followed according to physician orders.
- This item is only captured at transfer and discharge. If patient is in home care for multiple episodes and the pressure ulcer is resolved in the first episode (interventions are done at that time), then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent OASIS. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information.

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- Wording of the item has been changed to identify whether the interventions for pressure ulcer treatment were implemented that were based on the principles of moist wound healing. The OASIS C Guidance Manual will contain information on definitions and examples of interventions based on the principles of moist wound healing.
- It is understood that the agency does not have control over physician orders for dressing treatments, but many agencies have had success in working with physicians to ensure that their patients receive wound care treatments that meet evidence-based practice guidelines for moist wound healing. The measure that will report this item will recognize those agencies and allow all agencies to assess their own progress on incorporating this practice.
- The burden reduction initiative of 2002 limits CMS’s ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. The item has been revised to collect the data needed to calculate the OBQI/OBQM measure that will provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events. The item will report whether interventions were implemented during the episode which ends in transfer or discharge. If the patient is no longer considered at risk for pressure ulcers during that episode, the response of N/A can be selected. Reporting on all episodes, including those that exceed 60 days, will provide agencies with information to assess process measures as they pertain to long-term as well as short-term patients.
- There are methods available to agencies to avoid time consuming record review and facilitate tracking of interventions implemented across time periods. These tools can be developed by agencies that have paper-based records, and we anticipate they will be integrated into software for agencies that use electronic records. Guidance and suggestions for tracking tools will be included in the OASIS C Guidance Manual.

M1330 Does this patient have a Stasis Ulcer**Comments:**

- The term “likely” is too vague – the physician should be able to confirm.
- Should agencies now report healed stasis ulcers?

Response:

- The term “likely” has been removed.
- Option for reporting healed stasis ulcer was removed from M1334.

M1332 Current Number of (Observable) Stasis Ulcer(s)

Comments: none.

M1334 Status of Most Problematic (Observable) Stasis Ulcer**Comments:**

- Provide guidance as to how to identify “most problematic.”
- Should agencies now report healed stasis ulcers?
- Recommend adding comment “per WOCN Guidance” in question or on responses.

Response:

- Option for reporting healed stasis ulcer was removed.
- Guidelines and resources for identifying most problematic will be included in the OASIS C Guidance Manual along with web links to guidance from NPUAP and WOCN.

M1340 Does this patient have a Surgical Wound?**Comments:**

- The term “likely” is too vague – the physician should be able to confirm.
- Please clarify what is included in definition of surgical wound.
- Information on type of wound dressing and passive nutrition for wound healing should be added.
- Removing the number of surgical wounds is an improvement.

Response:

- The term “likely” has been removed.
- Definitions of what surgical wound will be included in the OASIS C Guidance Manual.
- Information on type of wound dressing and passive nutrition for wound healing can be recorded in the clinical record but is not needed by CMS for payment or quality at this time.

M1342 Status of Most Problematic (Observable) Surgical Wound**Comments:**

- Provide guidance as to how to identify “most problematic.”
- Recommend adding comment “per WOCN Guidance” in question or on responses.
- Will need guidance on defining healed and what should be reported.

Response:

- Guidelines and resources for identifying most problematic will be included in the OASIS C Guidance Manual along with web links to guidance from NPUAP and WOCN.
- The term “healed” has been removed since guidance indicates this is difficult to determine or define.

M1350 Does this patient have a Skin Lesion or Open Wound**Comments:**

- We appreciate that this item now specifies wounds that are receiving intervention.
- Please clarify what is meant by “assessment” and what is included in definition of skin lesion or open wound.

Response:

- The term “assessment” has been dropped from the item.
- Definitions of skin lesion or open wound will be included in the OASIS C Guidance Manual, as will instructions on what qualifies as “receiving intervention.”

M1360 Diabetic Foot Care Plan
[moved to Plan of Care Synopsis M2250]

Comments:

- We recommend the addition of the word “caregiver” following “patient.”
- The plan of care may not be formulated until after the completion of the assessment, so assessment items that require reporting of details of the “current physician-ordered plan of care” are confusing. Consider adding response option: “NA – order requested from MD but to date, not received.”
- Define “regular monitoring.”
- It should not require a physician order to do diabetic foot care or teaching.
- In therapy only services, a PT won’t have time or won’t want to spend the time on this.
- What is the correct response if there is a plan for monitoring but not patient education or education but not monitoring?
- This isn’t necessary for patients with well-controlled diabetes.
- There could be a tendency to just answer the question as a yes without verifying the info.
- What is the purpose of this question?

Response:

- The item has been moved to the new Plan of Care Synopsis (M2250).
- Wording has been changed to include education of patient or caregiver.
- The “current physician-ordered plan of care” means the patient has been assessed, the condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the item definition. We recognize that this may not happen for all patients at all agencies. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.
- We recognize that all disciplines can contribute to monitoring for the presence of skin lesions on the lower extremities and patient/caregiver education on proper foot care. However, the purpose of this item is to measure whether these interventions have been included in the physician-ordered care plan. Both monitoring and education need to be present to respond yes.
- This item will be used to calculate an OBQI/OBQM quality measure that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events.
- Based on the field testing, we have confidence that the process of OASIS data collection will not be so burdensome that it will cause clinicians to consider compromising their professional standards of conduct or commit fraud. Also, this item is auditable by survey and certification and it is anticipated that new data accuracy and validity safeguards will be put in place as payment comes to depend on outcomes under a pay-for-performance system.
- This item is discipline neutral – it is within the scope of physical therapists.
- Evidence-based guidelines indicate that even diabetics at low risk of foot ulcers (normal sensation and palpable pulses) benefit from teaching about diabetic foot care and monitoring of lower extremities. Definitions and instructions for responding accurately to

this item along with weblinks for resources on diabetic foot care and teaching will be included in the OASIS C Guidance Manual.

**M1365 Diabetic Foot Care Plan Follow-up since the previous OASIS assessment
[moved to M2400 Intervention Synopsis]**

Comments:

- We recommend the addition of the word “caregiver” following “patient.”
- What is the correct response if there is a plan for monitoring but not patient education or education but not monitoring?
- An accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians. When multiple clinicians are responsible for the care of a patient, it may be difficult to ascertain whether or not the monitoring and education were implemented according to physician orders.
- The type and quality of patient education needs to be defined.
- The measure should be applied to all patients, not just diabetics.
- How will this information be used? The item is only collected at Transfer and Discharge.

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- Wording has been changed to include education of patient or caregiver and to collect the data needed to calculate the publicly-reported measure.
- Both monitoring and education need to be implemented to respond yes.
- There are methods available to agencies to avoid time consuming record review and facilitate tracking of interventions implemented across time periods. These tools can be developed by agencies that have paper-based records, and we anticipate they will be integrated into software for agencies that use electronic records.
- Guidance and suggestions for tracking tools will be included in the OASIS C Guidance Manual along with definitions and instructions for responding accurately to this item and web links for resources on diabetic foot care and teaching.
- This item will be used to calculate the publicly-reported measure on diabetic foot care that recognizes agencies that have incorporated evidence-based practices into their agency processes. The focus is on foot care for patients with diabetes (rather than all patients) because diabetes is a high frequency/high risk condition.
- The burden reduction initiative of 2002 limits CMS’s ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. In response to concerns raised by commenters and members of the NQF that measures might not accurately reflect care for longer-stay patients, home care episodes that exceed 60 days (i.e. that require a recertification) will not be included in publicly-reported measures on implementation of evidence-based practices.

Respiratory Status

M1400 When is the patient dyspneic or noticeably Short of Breath?

Comments: Change item wording to include time period under consideration and clarify intent of item.

Response: Because this is an item used in the payment algorithm, CMS is very limited in its ability to revise wording. Guidance on assessing dyspnea will be included in the OASIS C Guidance Manual.

M1410 Respiratory Treatments utilized at home

Comments: Add Nebulizer and Bi-PAP as choices for answering this question or specify that they are not included.

Response: Continuous / Bi-level positive airway pressure has been specified in response 3; additional guidance on respiratory treatments that are to be reported in this item will be included in the OASIS C Guidance Manual.

Cardiac Status

M1500 Symptoms of Heart Failure since the previous OASIS assessment

Comments:

- Item wording and skip pattern are confusing.
- APTA applauds CMS on the addition of these items as cardiac is the largest diagnostic group in home health. We would like to emphasize that physical therapists are more than competent to complete the information needed for these items.
- Clarify what heart failure guidelines include, or incorporate them into the dataset.
- Clarify how the items should be answered for multiple episodes of heart failure.
- Consider incorporating evidence-based scales into item (e.g. dyspnea scale, orthopnea scale, goal weight met).
- An accurate response might be difficult to obtain without time consuming research.
- Patients may have symptoms of heart failure without a diagnosis.

Response:

- Item wording and skip pattern have been changed for clarification.
- There are methods available to agencies to avoid time consuming review of prior documentation by recording and storing data on patient symptoms and interventions that will facilitate tracking across time periods.
- We do not think it is appropriate to incorporate specific guidelines on assessing heart failure symptoms into the OASIS C instrument at this time. Links to resources and guidelines for assessing heart failure and guidance on responding to this question will be included in the OASIS C Guidance Manual.
- We agree that assessment and intervention for symptoms of heart failure is appropriate for patients without a diagnosis of heart failure, but this item seeks to document care for patients with a diagnosis of heart failure for a measure reporting on appropriate and timely response to symptoms in those patients.

M1510 Heart Failure Follow-up since the previous OASIS assessment

Comments:

- Item wording and skip pattern are confusing.
- Other actions can be taken for Heart Failure – this is not an all-inclusive list.

- Clarify how the items should be answered for multiple episodes of heart failure and define “physician contact.”
- An accurate response might be difficult to obtain without time consuming research.
- For patients with multiple episodes, the measures will not capture the interventions which occurred in the episode where the problem was identified (usually SOC). Measures can only be captured at the time of DC.

Response:

- Item wording and skip pattern have been changed for clarification.
- Item response changed to include “other clinical interventions.”
- There are methods available to agencies to avoid time consuming review of prior documentation by recording and storing data on patient symptoms and interventions that will facilitate tracking across time periods.
- Additional guidance on responding to this question in cases of multiple episodes of heart failure symptoms, defining “physician contact,” and links to resources on symptoms of heart failure will be included in the OASIS C Guidance Manual.
- We agree that assessment and intervention for symptoms of heart failure is appropriate for patients without a diagnosis of heart failure, but this item seeks to document care for patients with a diagnosis of heart failure for a publicly-reported measure identifying appropriate and timely response to symptoms in those patients.
- The burden reduction initiative of 2002 limits CMS’s ability to add data items to the OASIS at Recertification, as does our interest in minimizing impact on agencies with additional OASIS collection requirements. In response to concerns raised by commenters and members of the NQF that measures might not accurately reflect care for longer-stay patients, home care episodes that exceed 60 days (i.e. that require a recertification) will not be included in measures on implementation of evidence-based practices.

Elimination Status

M1600 Has this patient been treated for a Urinary Tract Infection in the past 14 days?

Comment: How do we address the situation when the patient was on prophylactic treatment but developed a UTI anyway?

Response: This item is unchanged from OASIS B-1; guidance will be included in the OASIS C Guidance Manual.

M1610 Urinary Incontinence or Urinary Catheter Presence:

Comments: This question is confusing as it references both incontinence and catheter; unclear whether it includes ureterostomy.

Response: This is a payment item, so CMS is extremely limited in its ability to change item wording. Additional guidance will be provided in the OASIS C Guidance Manual.

M1615 When does Urinary Incontinence occur?

Comments:

- Delete response 0-timed voiding and move to previous question.

- Revisions CMS has made to the responses to this item insure that the data collected is now meaningful and accurate.

Response: We cannot move timed voiding to the previous item since it is a payment item, and CMS is extremely limited in its ability to change item wording on payment items. Additional guidance will be provided in the OASIS C Guidance Manual.

M1620 Bowel Incontinence Frequency

Comments: Response 5, “on a daily basis” should read “once a day.”

Response: We cannot change the wording since this is a payment item. Additional guidance will be provided in the OASIS C Guidance Manual.

M1630 Ostomy for Bowel Elimination

Comments:

- A patient can have an ostomy and also have bowel incontinence.
- We believe it is important to include urinary ostomies as part of this item.

Response: We cannot change the wording since this is a payment item. Additional guidance will be provided in the OASIS C Guidance Manual.

Neuro/Emotional/Behavioral Status

M1700 Cognitive Functioning

M1710 When Confused (Reported or Observed)

M1720 When Anxious (Reported or Observed)

Comments:

- Time period for assessment needs to be clarified.
- This section should be completely eliminated from the OASIS C and be replaced by Part IV. Cognitive Status, Mood & Pain section of the proposed Home Health CARE Admission Tool.

Response:

- Time period for assessment has been clarified in items based on timeframes included in the existing guidance for the OASIS B-1 version of these items.
- Replacing cognitive status with items in the CARE assessment tool would negatively impact burden and would eliminate items that are currently used extensively for risk adjustment.
- Additional guidance and links to information on assessing cognition, confusion and anxiety will be added to the OASIS C Guidance Manual.

M1730 Depression Screening

Comments:

- We commend CMS for addressing depression screening in this population.
- CMS should recommend a depression screening tool.

- CMS should incorporate a depression screening tool into the OASIS C such as the PHQ-2[®] used in the CARE tool or PHQ-9[®] Depression Scale used in MDS to harmonize home health assessment information with data collected in other settings.
- We believe that this question would be difficult to answer at the admission time point due to the inability to obtain psychiatric information without the expressed consent of the patient. Also, the patient is often not able or reluctant to admit to depression.
- Assessing for depression may not be appropriate for all patients.
- Clarify in the instructions how the question is answered should the patient already be diagnosed with a depressive disorder and is being treated.
- This will require all agencies to utilize a universal depression screening tool and that would create more paperwork and cost.
- An alternative to this question would be to list specific symptoms of depression in the elderly and specify that symptoms reported are not related to medication side effects.
- This should be done by a mental health professional or certified psych nurse.
- Time frame needs to be clarified – day of the assessment or during the prior 14 days?
- What is the value of this tool? Just because you can administer the tool does not mean that you can interpret it.

Response:

- We believe most of the comments have been addressed by CMS’s decision to include the PHQ-2[®], a 2-item screening tool that has been widely validated and is being incorporated into the CARE instrument. This screening tool can be used successfully by many disciplines and does not require any special training.
- Clinicians will also have the option of responding that screening was conducted with a different standardized assessment or no standardized assessment was done. There is no mandate that clinicians conduct screening for depression for all patients.
- Burden is not increased as the previous item on symptoms of depression currently in the OASIS B-1 has been replaced by this question.
- This item will be used for risk adjustment and to calculate the publicly-reported measure on depression screening that recognizes agencies that have incorporated this evidence-based practice into their agency processes.

M1732 Depressive Symptoms Reported or Observed in Patient in past 14 days

[Deleted]

Comments: this list does not include all items in a standardized depression screening tool.

Response: Item has been deleted.

M1734 Depression Intervention Plan

[moved to Plan of Care Synopsis M2250]

Comments:

- Define interventions and referral.
- The plan of care may not be formulated until after the completion of the assessment, so assessment items that require reporting of details of the “current physician-ordered plan of care” are confusing.

- Most providers are untrained in behavioral health and it is inappropriate to expect them to develop a care plan upon initial assessment.
- This is a physician responsibility. We cannot make it happen.
- The danger is that depression will be over rated and under treated if “formal” tools are used without regard to illness or medications. We are concerned that inclusion of these process items will result in inappropriate treatment of many Medicare beneficiaries, particularly in those agencies that do not offer a psychiatric nursing program.

Response:

- This item has been moved to the new Plan of Care Synopsis (M2250).
- Definitions of interventions and referral will be provided in the OASIS C Guidance Manual.
- The “current physician-ordered plan of care” means the patient condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the measure definition. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.
- We encourage agencies to communicate and work with physicians to assist patients with symptoms of depression. This may in many cases mean obtaining an order for referral to another care provider or development of a monitoring plan.
- Adoption of this evidence-based practice is not mandated. This item will be used to calculate OBQI/OBQM quality reports that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events.

M1736 Depression Intervention Implementation since the previous OASIS assessment [moved to M2400 Intervention Synopsis]

Comments:

- This will require a complete chart review.
- What is the purpose of collecting this data?

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- The period of review is limited to the time since the previous OASIS assessment (not more than 60 days). There are methods available to agencies to avoid time consuming review of prior documentation by recording and storing data on interventions that will facilitate tracking across time periods.
- This item will be used to calculate OBQI/OBQM quality reports that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events. The item and response wording has been revised to collect the data needed to calculate the measure,

**M1740 Cognitive, behavioral, and psychiatric symptoms
[previously Behaviors Demonstrated at Least Once a Week]**

Comments:

- Different kinds of symptoms are included in this item – one option would be to rename the item to be something like, “Cognitive, behavioral, and psychiatric symptoms.” Another option would be to separate the sub-items into three separate items.
- Responses 3, 4, and 5 use wording that conveys very negative impressions about individuals with behavioral symptoms. CMS and its contractors and advisors have attempted to revise the wording of the “Behavioral Symptoms” item (E200) in MDS. Consider revising OASIS C to harmonize with the MDS.
- Self-neglect is a demonstrated behavior that can lead to serious or fatal consequences and should be added to this list.

Response:

- The item has been renamed to more accurately reflect its content and has added the directions that symptoms can be either reported or observed.
- Incorporating the questions in the Behavioral Symptoms section of the MDS into the OASIS C would add significant burden. We will instead provide links to resources and standardized tools for clinicians who wish to employ those tools.
- Self-neglect is included in behaviors reported in the next item.

M1745 Frequency of Behavior Problems

Comments: When answering this question, clinicians often misinterpret the behaviors that should be included for this question.

Response: Item has been reworded to specify any physical, verbal, or other disruptive/dangerous behaviors that are injurious to self or others or jeopardize personal safety. The OASIS C Guidance Manual will provide further specification on this item.

M1750 Is this patient receiving Psychiatric Nursing Services at home

Comments: This item should be deleted – it belongs in the Conditions of Participation.

Response: The item is used for risk adjustment.

ADLs/IADLs

M1800 Grooming: Current ability to tend safely to personal hygiene needs

Comments: We are pleased with CMS’ elimination of the “Prior” column from the ADL and IADL items and welcome the increased emphasis on safety.

Response:

- The term “safely” has been added to all ADL/IADL items.
- Remaining data on “prior status” of ADL/IADL items is now in M1900.

M1810 Current Ability to Dress Upper Body safely**M1820 Current Ability to Dress Lower Body safely****Comments:**

- If buttons snaps, or zippers are not to be considered when answering these questions, why are they not being removed from the question.
- Add an additional answer that patient can dress without assistance but not in a timely manner.
- Dressing aids should matter and should be part of the answer.
- Wording is not consistent in each answer. This can cause confusion regarding which box to score a patient.
- The question refers to the majority of upper/lower body clothing, which should be indicated in the question.

Response:

- This is a payment item so ability to change wording or meaning of responses is limited.
- Guidance about scoring items and patient use of dressing aids is included in the OASIS C Guidance Manual.
- For OASIS ADL/IADLs, time required to accomplish the task is not relative to the response which seeks only to report if the patient can safely accomplish the task.

M1830 Bathing: Current ability to wash entire body safely**Comments:**

- The addition of response 4 (bathes in sink) makes it much easier to gather a good functional picture of the patient.
- Response 4 now includes the patient who bathes at the sink. However, the same response includes the patient who must bathe at a chair or commode. How is the set-up for this patient to be considered? How do we categorize the patient who is bathed at the sink or at the bedside but requires intermittent assistance?
- “Shower or tub” should be changed to ‘tub/shower’ will make the item technically correct.
- The numbering of the responses remains inconsistent with the FIMS, MDS or the proposed CARE tool where the highest numbered response is the highest level of function.

Response:

- Transferring in and out of the shower or tub was moved to this item from the transferring item based on requests from clinicians and input from experts.
- Ability to bathe at sink was added based on requests from clinicians.
- Further changes to responses are not advisable since this is a payment item.
- OASIS C Guidance Manual will contain guidance for selecting the new responses.
- CMS has chosen to maintain the existing OASIS response numbering system where “0” consistently represents independence and the scoring used for the payment algorithm is not disrupted.

M1840 Toilet Transferring

Comments:

- We support the separation of toileting ability from hygiene ability and the addition of the word “safely.”
- Separate bedpan and urinal use into two separate questions.
- There needs to be additional guidance on defining the term “assistance” with the bedpan and how to respond if the patient’s ability to get to the toilet is different from their ability to transfer.
- The numbering of the responses remains inconsistent with the FIMS, MDS or the proposed CARE tool where the highest numbered response is the highest level of function.

Response:

- Ability to modify this item is minimal due to it’s use by the payment algorithm.
- The OASIS C Guidance Manual will address questions about responses and definitions.
- CMS has chosen to maintain the existing OASIS response numbering system where “0” consistently represents independence and the scoring used for the payment algorithm is not disrupted.

M1845 Toileting Hygiene

Comments:

- The wording in the question is awkward and needs clarification and some of the responses are inconsistent.
- Response 2 says a patient needs help with hygiene or clothing. What if the patient needs help with both hygiene and clothing?
- Add with or without assistive device.

Response:

- The wording in the item has been clarified.
- The phrase “and/or” has been added to response 2 (patient needs help with hygiene and/or clothing).
- Guidance about item definitions including use of assistive devices will be included in the OASIS C Guidance Manual.

M1850 Transferring

Comments:

- Addition of the word SAFELY to the question, and the omission of measurement of transferring on and off the commode/toilet and in/out of shower has improved this item significantly.
- Some of the wording is confusing. Please clarify how to respond when the patient needs both human assistance and a device (response 1) and examine the placement of “able to pivot” in response 2.
- Improvement in patient outcomes could be better captured and accuracy could be improved if a response option was added between 1 and 2.

- Transferring and bed mobility are two distinct functional skills and should be assessed separately.

Response:

- We appreciate the comments offered for possible improvements to the transfer item. However, ability to modify this item is minimal due to its use in the payment algorithm. Additional responses were added to ambulation and bathing because they were recommended early in the revision process. We incorporated them as part of the field testing and assessed whether they had any impact on response selection that would affect payment. It would not be prudent to make any significant changes to any payment item at this time since we would not have an opportunity for testing.
- We did respond to comments on response 2 by placing “Able to pivot” first in the response.
- The OASIS C Guidance Manual will include guidance on questions raised about responses 1 and 2.

M1860 Ambulation/Locomotion

Comments:

- Nice change in this item to reflect improvement in ambulation from walker to cane and we are happy with the deletion of the prior column.
- Provide more clarification of what is meant by the statement “climb stairs.” We believe that this statement should include the ability of the patient to ascend and descend. Recommend clarifying a minimum number of steps for stairs.
- We would recommend in response item #2 the elimination of the “and/or” option and only allow “and.”
- Reword #2 just like #1 except change 2-handed to 1-handed; Add independent in ambulation with assistive device but needs assistance on stairs or steps.
- Please clarify the correct response for the patient who is able to safely ambulate without any device on level surfaces, but require minimal human assistance on stairs, steps, uneven surfaces who does not require assistance of another person at all times.
- Add the following choice to this item, following choice number (1), “With the use of a one-handed device, able to walk alone on level surface and/or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.”
- Do not combine even and uneven surfaces with stairs: there is a big difference between ability on even/uneven surfaces and curbs/stairs.
- Typically someone who needs to use a hemi-walker is someone who has so much upper extremity involvement from a CVA that they are not capable of using a walker. It does not seem correct that they would be scored as more functional than someone using a walker.
- The numbering of the items remains inconsistent with the FIMS, MDS or the proposed CARE tool where the highest numbered response is the highest level of function.

Response:

- Response 0 and 1 were clarified by substituting “negotiate” for “climb” (negotiate stairs).

- We appreciate the numerous thoughtful comments on possible improvements to the ambulation item. However, ability to modify this item is minimal due to its use in the payment algorithm. We were able to add the new response option about one-handed versus two-handed assistive device because it was recommended early in the revision process. We incorporated it as part of the field testing and assessed whether it had any impact on response selection that would affect payment. It would not be prudent to make any additional changes to the payment item at this time since we would not have an opportunity for testing.
- Numerous experts consulted in the OASIS revision process concurred that a patient moving from a two-handed to a one-handed device is considered to be progress toward independent functioning.
- CMS has chosen to maintain the existing OASIS response numbering system where “0” consistently represents independence and the scoring used for the payment algorithm is not disrupted.
- The OASIS C Guidance Manual will include additional definitions and guidance.

M1870 Feeding or Eating

Comments:

- We appreciate the inclusion of word “safely” and elimination of the prior status column.
- We request clarification in the new manual in regard to response 5 re: Unable to take in nutrients orally or by tube feeding.

Response: We will provide clarification on response 5 in the OASIS C Guidance Manual.

M1880 Change in Mobility

M1890 Change in Self-care Ability

M1920 Change in Ability to Perform Routine Household Tasks

We have combined all “change in functioning” items into a single matrix item, M1920, which has been harmonized to the extent possible with similar items in the CARE instrument. Please see M1920 for comments and responses.

M1880 Ability to Plan and Prepare Light Meals

(previously M1900 Current Planning and Preparing Light Meals)

Comments: We appreciate the inclusion of word “safely” and elimination of the prior status column.

Response: We appreciate your comments. The title of this item has been revised to be consistent with other ADLs/IADLs.

M1890 Ability to Use Telephone

(previously M1910)

Comments: Eliminate this item since this is covered in the emergency plan and safety assessment.

Response: This item provides data used in risk adjustment of outcomes. Data collected in an agency’s emergency plan and safety assessment are not reported to CMS. Agencies can choose

to incorporate this OASIS C item into their emergency plan/safety assessment to avoid duplication.

M1900 Prior Functioning ADL/IADL (previously Change in Ability to Perform Routine Household Tasks)

Comments:

- The new change in ability questions better reflect the impact of illness on the patient's function than the previous prior and current columns used in the OASIS B-1.
- The new change in ability questions are just as burdensome as the "prior" column used in the OASIS B-1 and don't capture the information as well.
- What information are these items trying to capture? Are these to be completed only on SOC and ROC? Will they be used at recert and discharge?
- Need guidance in defining timeframe for "prior level of functioning/onset of illness injury."
- Add exacerbation of illness / injury in addition to onset of illness or injury.
- Need an NA option. Some patients under the Medicaid benefit have not had a recent onset or exacerbation. What if the patient has been in a SNF or rehab for a long time?
- Multiple variables are being captured in one response. Need to address how to respond when the patient's status varies between the tasks listed. Ambulation is very different from transferring and shopping is different from other household tasks.
- Consider adding a grid to better capture detail.
- As this will be primarily based on patient opinion, perhaps this could be simplified to state "in patient's opinion is prior level of functioning better or worse?"

Response:

- This new item replaces M1880, M1890, and the previous M1920 and asks the clinician to rate the patient's usual ability with everyday activities prior to this current illness, exacerbation, or injury.
- The purpose of this item is to aid in assessing the patient's baseline abilities and potential for improvement. It is collected only at SOC/ROC and will be used for risk adjustment of patient outcomes. For example, a patient who has been using a walker for several years may be expected to make less progress in ambulation than a patient who was ambulating independently until a hip fracture 2 weeks prior to home care.
- The response options are "Independent," "Needed Some Help," or "Dependent" and are based on text from the CARE instrument. The OASIS C Guidance Manual will provide an operational definition of each of the 3 response categories for these terms based on the CARE definitions.
- The functional areas are divided into Self-Care (e.g., grooming, dressing, and bathing), Ambulation, Transfer, and Household tasks (e.g., light meal preparation, laundry, shopping).
- Although the OASIS C still asks clinicians to report on prior functional ability in this item, this is reported for fewer ADLs/IADLs than in the OASIS B-1.
- In the new grid, the word exacerbation has been added to assist in clarifying the time frame, and ambulation is separated from transferring to enable more accurate responses.

- Guidance on responding to these questions when the patient’s status varies on activities that are grouped together and for patients who have a long-term disability will be provided in the OASIS C Guidance Manual.

M1910 Has this patient had a multi-factor Fall Risk Assessment (previously M1930)

Comments:

- A single standardized assessment should be recommended for use by all agencies for valid data collection and comparison.
- Define specifically the components of a Multifactor Falls Risk Assessment or provide an approved list of Fall Risk Assessments.
- Sensory impairment should be part of the risk assessment.
- This item requires all agencies to do a falls risk assessment which creates additional costs.
- Please clarify who can do the falls risk assessment and when it must be done, when answering this question at SOC/ROC and at Transfer/Discharge.
- There should be an item related to outcome asking whether the patient had a fall/falls.
- Practice guidelines and literature on falls risk assessment are based primarily in the 65 and older population, so the falls assessment measure should be specific to those patients.

Response:

- CMS is not incorporating a specific multi-factor falls-risk assessment tool into the OASIS C instrument at this time. It is up to each agency to determine which practices it will implement based on its patients and operations and which assessment tools are most appropriate. In addition, new tools are developed and adopted more frequently than the OASIS data set can be revised. Examples, guidance and resources on standardized multi-factor assessment tools appropriate for use in the home health setting will be included in the revised OASIS C Guidance Manual.
- CMS is not mandating the multi-factor falls risk assessment be conducted by any agency or on any patient. The OASIS C allows agencies to report on certain evidence-based practices such as multi-factor falls risk assessment they have chosen to incorporate into their clinical practice. In all instances, agencies have the opportunity to respond that the screening was not done. This item will be used to calculate the publicly-reported measure on falls risk screening for patients 65 and older that recognizes agencies that have incorporated this evidence-based practice into their agency processes.
- At SOC/ROC, the item asks the clinician to report whether a multi-factor falls risk assessment was conducted by an agency clinician (RN or PT) within the 5-day SOC or 2-day ROC window. This item is no longer collected at Transfer/Discharge.
- CMS has considered adding an outcome measure for falls, but is instead focusing on whether agencies are implementing evidence-based practices on falls risk assessment and prevention. New responses in the Reason for Hospitalization and Reasons for Emergent Care will enable measurement of falls requiring emergent treatment or hospitalization.
- The publicly-reported measure based on this item will report falls risk assessment only in the 65 and older population.

**M1945 Falls Risk Intervention since the previous OASIS assessment
[moved to M2400 Intervention Synopsis]**

Comments:

- A time-consuming record review will be required to respond accurately to this item.
- If the patient is assessed to not be at risk of falls at Transfer/Discharge, this item should be skipped.
- How will outcome measures be calculated if the patient receives fall prevention interventions during early episodes of service and then has multiple episodes? Is the expectation that the plan of care will repeatedly include interventions if the patient no longer has a need?

Response:

- The item been moved to a new Interventions Synopsis item in grid form (M2400).
- The item requests data regarding the most recent home health episode (since the most recent OASIS assessment – no more than 60 days prior). There are also methods available to agencies that will facilitate tracking of interventions and prevent the need for a full record audit.
- The item wording has been revised to collect the data needed to calculate the OBQI/OBQM measure that will provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events. The item will report whether interventions were implemented during the episode which ends in transfer or discharge. If the patient is no longer considered at risk for falls during that episode, the response of N/A can be selected. Reporting on all episodes, including those that exceed 60 days, will provide agencies with information to assess process measures as they pertain to long-term as well as short-term patients.

**M1940 Falls Risk Intervention in plan of care
[moved to Plan of Care Synopsis M2250]**

Comments:

- Define interventions and referral.
- The plan of care may not be formulated until after the completion of the assessment, so assessment items that require reporting of details of the “current physician-ordered plan of care” are confusing.
- Falls risk interventions do not all require a physician order.
- How should we respond if the patient is at their baseline or refuses interventions?

Response:

- This item has been moved to the new Plan of Care Synopsis (M2250).
- The “current physician-ordered plan of care” means the patient condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the measure definition. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual.

- We recognize that all disciplines can contribute to plans for reducing falls risk in the home. However, the purpose of this item is to measure whether patients who have been assessed to be at risk for falls have interventions designed to mitigate the risk of falls included in the physician-ordered care plan. This item will be used to calculate OBQI/OBQM quality reports that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events.
- Guidance on responding to this item regarding issues such as non-compliance will be provided in the OASIS C Guidance Manual.

Medications

Comments: Some commenters expressed concern that there are so many items related to medications in the OASIS C.

Response: It must be remembered that these items are not all asked at the same timepoints. CMS anticipates that these items will support two publicly-reported measures related to medications and 3 OBQI process measures which will be reported to agencies. The publicly-reported measures are:

- “Improvement in management of oral medications,” an outcome measure which is currently reported on Home Health Compare; and
- “Drug Education on All Medications Provided to Patient/Caregiver During Short-term Episodes,” a process measure based on data collected at Transfer/DC.

The OBQI measures which will be reported to agencies are:

- “Drug Education on High Risk Medications Provided to Patient/Caregiver at Start of Episode,” a process measure based on data collected at SOC/ROC;
- “Potential Medication Issues Identified and Timely Physician Contact at Start of Episode,” a process measure based on data collected at SOC/ROC; and
- “Potential Medication Issues Identified and Timely Physician Contact during Episode,” a process measure based on data collected at Transfer/DC.

Please note that the NQF process for endorsement of publicly-reported measures is ongoing. The comments in this document represent our current understanding of which measures will be endorsed based on NQF Steering Committee recommendations.

M2000 Potential Adverse Effects/Reaction

Comments:

- All clinicians assess this. It is part of the Conditions of Participation (CoPs) and our Scope of Practice compels a clinician to take immediate action for patient safety.
- This is not an objective question; the data gathered will not have enough objectivity to allow for a structured outcome value.
- The wording needs to be clarified – need to define terms such as potentially significant adverse reactions, clinically significant issues, and medication follow-up.
- There are too many questions on medications and the intensity and detail in these items is excessive.

- The questions only report if there were problems, not what the problems were.
- We are concerned about therapists' ability to answer these questions and question if it is in their scope of practice.
- The American Physical Therapy Association (APTA) would like to point out that the physical therapist is more than capable of completing this item. It is within the scope of the physical therapist to perform a patient screen in which medication issues are assessed even if the physical therapist does not perform the specific care needed to address the medication issue. The physical therapist is competent and qualified to serve as a case manager and facilitate coordination of care with physicians and nurses.
- Medication issues may be managed by someone other than the clinician completing the OASIS and may be items better answered by someone else. How should we handle this since only one clinician is to complete the OASIS according to current regulations?
- There are computer-based point of care systems with drug interaction databases/tools that allow clinicians to respond to this item in a standardized way, but all home health agencies do not have access to such technology.
- No choice exists for the patients that have no medications.

Response:

- This item asks clinicians to report the outcome of a process that is already required as part of the CoPs. As some commenters pointed out, Section 484.55 (c) *Standard: Drug Regimen Review* already requires agencies to complete a drug regimen review as part of the initial assessment. This must include “a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.” This requirement applies to all home health patients, including those that are receiving PT services only. CMS is not changing the existing requirements for drug regimen review. Response “0,” indicating the drug review was not done, is there for completeness and consistency, allowing agencies to respond accurately if for some reason a drug review was not done for a specific patient. In those cases, the circumstances for failure to meet CoPs for that patient should be documented in the patient record.
- The OASIS C Guidance Manual will provide recommendations on how to respond to this item if medication issues are managed by someone other than the clinician completing the OASIS. The manual will also contain links to resources for drug interaction databases/tools.
- Wording of the question was clarified to decrease subjectivity and improve accuracy, and a response was added for patients not taking any medications.
- Information identifying the problems that were identified and the actions taken in response are not needed for quality reporting or payment and so are not collected by CMS. Agencies can document this information in the patient record.
- This item is used in combination with M2002 Medication Follow-up for the OBQI/OBQM measure “Potential Medication Issues Identified and Physician Contacted,” reporting the percent of episodes in which the patient’s drug regimen was assessed to pose a risk of significant adverse effects or drug reactions and the physician was contacted within one calendar day.

M2002 Medication Follow-up

Comments:

- The one day time frame required in this item may not be realistic in the home health environment, especially on weekends and holidays.
- Clarify what is considered “contacted” and define clinically significant.
- Clarify whether contact and resolution must be completed in one day.
- Does the M0090 – Date assessment completed – need to be delayed until physician contact is made?
- We are concerned about how this is handled if a PT is conducting the assessment.
- Home health agencies are often hampered in their efforts to accomplish this due to the lack of availability of medical supervision.

Response:

- Contacting the physician regarding clinically significant medication issues within one day is a critical patient safety issue. Timely contact with the patient’s care provider when significant medication issues are identified is necessary to prevent medication-related problems and errors which can lead to an increased risk of hospitalization, morbidity and mortality. Interventions aimed at identifying and promptly dealing with medication issues in home health patients have been shown to result in discontinuation of potentially harmful medicines, decreased confusion and dizziness, better pain control, decreased risk of falls, and improved blood pressure control.
- We recognize that in some cases the patient’s physician may not be available and the wording in the question has been revised to say “a physician or physician designee.”
- Guidelines for clinically significant interactions are available from online sources, point-of-care systems and other sources including computerized risk assessment screening and alert processes that use the medication list and clinical indicators to identify potential medication problems. Guidance accompanying the OASIS dataset will contain web links to those resources and suggestions for agencies on how to implement these processes.
- A response of “1-Yes” indicates that contact has been made with the physician or his/her designee and discussion of the issue has occurred. We will provide further guidance on responding to this item in the OASIS C Guidance Manual as to what is considered “contacted,” how to define “clinically significant,” and how to respond to this item if medication issues are managed by someone other than the clinician completing the OASIS. The OASIS will not be considered complete until the clinician can respond to M2002 and indicate whether physician contact was made and issue resolved. If the medication issue was not resolved in the one-day time frame, the clinician can mark “no” and the item will be complete. It is the expectation that agencies will not always be able to achieve 100 per cent compliance with this item.

M2004 Medication Intervention since the previous OASIS assessment

Comments:

- Responding accurately to this question will require a lengthy review of the record, especially if the a clinician unfamiliar with the case does the transfer or discharge.
- The purpose of this question is unclear.

- For patients with multiple episodes, the measures will not capture the interventions which occurred in the episode where the problem was identified (usually SOC). Measures can only be captured at the time of DC.
- The time component of 1 calendar day may be restrictive given we are dependent on physician office to answer.

Response:

- The period under review is restricted to the time since the most recent OASIS assessment (a maximum of 60 days). As stated previously, there are methods available to agencies to record and store the data that will facilitate clinicians accessing the information they need to complete the OASIS and prevent the need for a full audit of the home health episode.
- This item will be used for the calculation of the OBQI measure “Potential Medication Issues Identified and Timely Physician Contact during Episode.” The burden reduction initiative of 2002 limits CMS’s ability to add data items to the OASIS at Recertification.. The item will report whether interventions were implemented during the episode which ends in transfer or discharge. If the patient did not have any clinically significant medication issues since the previous OASIS assessment, the response of N/A can be selected.
- A response of “1-Yes” indicates that contact has been made with the physician or his designee and discussion of the issue has occurred. We will provide further guidance on responding to this item in the OASIS C Guidance Manual and on what is considered “contacted,” how to “define clinically significant,” and how to respond to this item if medication issues are managed by someone other than the clinician completing the OASIS.
- Contacting the physician regarding clinically significant medication issues within one day is a critical patient safety issue. We recognize that in some cases the patient’s physician may not be available and the wording in the question has been revised to say “a physician or physician-designee” to indicate that an on-call physician, agency medical director or other care provider can be contacted.

M2010 Patient/Caregiver High Risk Drug Education

Comments:

- This item goes beyond the regulatory language outlined in the Comprehensive Assessment CoPs for the Drug Regimen Review and moves into the realm of medication teaching/management.
- Is the expectation that med teaching is necessary for every patient? Consider modifying the item to identify if patient/caregiver med education needs are present, and if so, has action been taken to resolve.
- This item will pose a barrier related the discipline neutrality of OASIS, and a therapist’s ability to complete the assessment without nursing involvement. Allow resolution actions to include having the nurse identify the need and provided the teaching, or that the therapist identified the need and requested nursing involvement (as the resolving action).
- “High risk” must be clearly defined or CMS should provide a comprehensive list of "high-risk" medications with clarification provided as to its application to OTC and herbal supplements.

- This question seems to be redundant of M2015 Patient/Caregiver Drug Education Intervention.
- The item does not ask if the patient has received instruction on all high risk medications upon admission. For instance, if a therapist or a clinician teaches on Coumadin but defers teaching on insulin until a future visit, has the intent of the question been met?
- This may not be the most appropriate thing to do on the first visit. Replace the words “Has the patient/caregiver received instruction...” with the words “Does the care plan include instruction on high-risk...” to acknowledge teaching takes place throughout the home care stay.

Response:

- The commenter is correct that this item measures provider behavior that is not mandated specifically by the CoPs. Measurement and reporting of this care process is considered a high priority by CMS, but CMS is not at this time requiring that patient/caregiver education on high risk drugs be conducted at SOC. The OASIS C allows agencies to report on certain evidence-based practices they have chosen to incorporate into their clinical practice. In all instances, agencies have the opportunity to opt-out of these items on OASIS C by responding that the intervention was not done.
- In response to comments, the question statement has been changed to read: Patient/Caregiver **High Risk** Drug Education: “Has the patient/caregiver received instruction on special precautions for all high-risk medications (such as hypoglycemics, anticoagulants, etc.) and how and when to report problems that may occur?”
- This measure was specifically targeted toward medications identified as high risk since it is acknowledged that; 1) it is unrealistic to expect patient education on all medications to occur at the time of admission; and 2) failure to provide patient education on high risk medications such as anticoagulants and insulin at start of care could have severe negative impacts on patient safety and health.
- An N/A response has been added to be used when the patient/caregiver is fully knowledgeable about special precautions associated with high-risk medications.
- It is the position of the American Physical Therapy Association (APTA) that physical therapists are capable of completing this item. It is within the scope of the physical therapist to perform a patient screen in which medication issues are assessed even if the physical therapist does not perform the specific care needed to address the medication issue. The physical therapist is competent and qualified to serve as a case manager and facilitate coordination of care with physicians and nurses.
- We will provide further guidance on responding to this item in the OASIS C Guidance Manual and on what are considered “high-risk” drugs, including links to resources such as well-established high risk medication lists such as JCAHO, the Beers Potentially Inappropriate Medications for the Elderly criteria and the Institute for Safe Medication Practices “High Alert Medication List.” We will also include guidance on how to respond to this item if medication issues are managed by someone other than the clinician completing the OASIS.

M2015 Patient/Caregiver Drug Education Intervention since the previous OASIS assessment

Comments:

- An accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.
- If patient is open multiple episodes and education regarding the medication issue occurs in first episode, then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent OASIS. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information. Can gathering this data be limited to Early episodes that end in TSF or DC? If not, this question should be removed.
- Need to add an option that the patient is “fully knowledgeable” to NA.
- The wording needs to be clarified – it’s not clear if this covers ALL medications.
- We are concerned about therapists’ ability to answer these questions and question if it is in their scope of practice.
- The American Physical Therapy Association (APTA) would like to point out that the physical therapist is more than capable of completing this item. The physical therapist is competent and qualified to serve as a case manager and facilitate coordination of care with physicians and nurses.
- Medication education may be managed by someone other than the clinician completing the OASIS and may be items better answered by someone else. How should we handle this since only one clinician is to complete the OASIS according to current regulations?

Response:

- The period of review is limited to the time since the previous OASIS assessment (not more than 60 days). There are methods available to agencies to avoid time consuming review of prior documentation by recording and storing data on interventions that will facilitate tracking across time periods. In addition, the OASIS C allows agencies to report on certain evidence-based practices they have chosen to incorporate into their clinical practice. In all instances, agencies have the opportunity to opt-out of these items on OASIS C by responding that the intervention was not done.
- In response to comments, we added “by agency staff or other health care provider” to question to provide flexibility in who delivers drug education. “Since the previous OASIS assessment, was the patient/caregiver instructed by agency staff or other health care provider to monitor the effectiveness of drug therapy, drug reactions, and side effects, and how and when to report problems that may occur?”
- It is the position of the American Physical Therapy Association (APTA) that physical therapists are capable of completing this item. The physical therapist is competent and qualified to serve as a case manager and facilitate coordination of care with physicians and nurses. The OASIS C Guidance Manual will provide recommendations on how to respond to this item if medication education is managed by someone other than the clinician completing the OASIS.
- This measure will be used to report “Drug Education on All Medications Provided to Patient/Caregiver During Short-term Episodes,” a publicly-reported process measure based on data collected at Transfer/DC. The burden reduction initiative of 2002 limits

CMS's ability to add data items to the OASIS at Recertification. In response to concerns raised by commenters and members of the NQF that measures might not accurately reflect care for longer-stay patients, home care episodes that exceed 60 days (i.e. that require a recertification) will not be included in publicly-reported measures on implementation of evidence-based practices.

M2020 Management of Oral Medications

Comments:

- Go back to the question asking only about prescription medications (not all medications) and eliminate previous instructions to mark the patient as independent if taking the majority of medications. Compliance with and ability to take prescription medications impacts the outcome far greater than over-the-counter medications.
- Recommend response 1 a and b be two different responses. This is significant improvement for a patient to go from (a) dosages are prepared in advance by another person to (b) another person develops a drug diary or chart. Please give us room to capture our improvement that we assist the clients in achieving.
- Clarify how to answer the item for a patient who requires both dose set up and reminders? (Response 1 and 2 would both apply) Consider adding an additional response option (between the current #2 and #3) that reads "Able to take medications at the correct times if med dosages are prepared in advance AND patient is given daily reminders".
- What if oral meds are not daily, but the patient needs reminders? Recommend using same language as in M2030. ("given reminders based on the frequency of the administration").
- This item is difficult to assess and show improvement for patients residing in an assisted living facility where facility policy requires medication administration.

Response:

- The item was changed from OASIS B-1 based on clinicians' request to allow agencies to demonstrate improvement when a patient no longer required daily reminders but could be independent in medication management if a drug diary or chart was developed by another person or individual dosages are prepared in advance by another person. We do not want to split these 2 options into separate responses because the hierarchy of dependence is not clear – both require another person to assist with medications in advance but do not require a person to be in the home with the patient in order for the patient to take medications correctly.
- In response to comments, changed "daily" to "at the appropriate times" to recognize differences in medication schedules. "Patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals."
- The OASIS C Guidance Manual will clarify that the OR in response 1 applies whether one or both of these conditions is true, i.e., whether a patient requires either dose set up or a drug diary and chart or both.
- If the patient requires daily reminders they are a 2, regardless of whether they also require dosages prepared in advance. The OASIS C Guidance Manual will provide additional instructions for responding to this item.
- There are no consistent standards that apply to Assisted Living Facilities (ALFs) and policies vary widely regarding many aspects of care provided in these settings. Patients in

ALFs may still be able to become more independent in taking their oral medications with assistance from the home health agency, potentially enough to no longer require that setting. Agencies should also be aware that it is understood that there are numerous circumstances in which independence in taking medications is not possible. A rate of 100 percent improvement is not expected on this outcome.

M2030 Management of Injectable Medications

Comments:

- Need to clarify how to respond if someone has to create the med chart or calendar in order for the patient to safely administer?
- This item is difficult to assess and show improvement for patients residing in an assisted living facility where facility policy requires medication administration.

Response:

- Item has been revised in response to comments. Matched item options to M2020 Management of Oral Medications and added response to indicate someone has to create the med chart or calendar in order for the patient to safely administer.
- The OASIS C Guidance Manual will clarify that the “OR” in response 1 applies whether one or both of these conditions is true, i.e., whether a patient requires either dose set up or a drug diary and chart or both.
- As stated above, there are no consistent standards that apply to Assisted Living Facilities (ALFs). Patients in ALFs may still be able to become more independent in taking their oral medications with assistance from the home health agency. A rate of 100 percent improvement is not expected on this outcome.

M2040 Prior Medication Management

[previously Change in Ability to Manage Oral, Inhalant, or Injectable Medications]

Comments:

- It is confusing that M2040 refers to all prescribed medications (including oral, inhalant and injectable) when assessing a change in the management of medications when we are not assessing inhalant med ability.
- Consider clarifying that oxygen is a medication, either directly in the item, or in the supporting guidance.
- Need guidance in defining timeframe for “prior level of functioning/onset of illness injury.”
- Add exacerbation of illness / injury in addition to onset of illness or injury.
- Need an NA option. Some patients under the Medicaid benefit have not had a recent onset or exacerbation. What if the patient has been in a SNF or rehab for a long time?
- Multiple variables are being captured in one response. Need to address how to respond when the patient’s status varies between the tasks listed.
- Consider adding a grid to better capture detail.

Response:

- This item has been revised in response to comments and now uses the same grid and terminology as M1920 Change in ADLs/IADLs. It asks the clinician to rate the patient’s

usual ability with oral and injectable medications prior to this current illness, exacerbation, or injury.

- In the new grid, the word exacerbation has been added to assist in clarifying the time frame and oral medications are separated from injectable medications to enable more accurate responses.
- The purpose of this item is to aid in assessing the patient's baseline abilities and potential for improvement. It is collected only at SOC/ROC and will be used for risk adjustment of patient outcomes.
- The response options "Independent," "Needed Some Help," or "Dependent" and is based on text from CARE instrument. The OASIS C Guidance Manual will provide an operational definition of each of the 3 response categories for these terms based on CARE definitions.
- Guidance on responding to this item for patients who have a long-term disability will be provided in the OASIS C Guidance Manual.

Care Management

M2100 Patient Management of Equipment [DELETED]

No comments received. This item was deleted as it is not used for quality, payment or risk adjustment.

M2100 Types and Sources of Assistance [previously 2110]

Comments:

- This approach to collecting information about the patient's assistance needs is comprehensive and the format is attractive. It provides a great model for assessing the patient's needs and available resources, and for planning what will be needed to maximize the patient's caregiving environment and helps to harmonize the home health assessment instrument with information collected utilizing the CARE tool.
- CMS should include this item in the OASIS data set for discharge assessments. Use of the grid by Medicare home health agencies will help to improve transition outcomes for Medicare home health beneficiaries by explicitly identifying the types of assistance they need and who, if anyone, is available to provide that assistance. Situations in which no one is available or capable of providing the needed assistance or the family or other informal caregiver needs training to provide the needed assistance will be identified, and it will be possible to at least try to develop options to address these situations.
- This item is very confusing and more time consuming than the previous OASIS items. Why was this included?
- It will be difficult to complete this item accurately and completely within the first one or two visits to the patient upon admission.
- The patient is going to be completely exhausted after finishing just this part of the assessment.

- Format is difficult to decipher. Would recommend that headings be placed in bold, i.e. ADL Assistance. Items should be renumbered and the items included under each category should be indicated as “i.e.,” not “e.g.” By using “e.g.” you are allowing the clinician to look outside of the categories listed and randomly include other activities, thus compromising the integrity of the information gathered.
- To assist clinicians with accuracy of responses, move this item to follow after M1100. Living arrangements and assistance provided in the home are like items and listing the questions together will flow in the practitioner’s assessment of the patient.
- CMS should clarify how to answer this question if the patient can do some of the tasks and not others. There are so many items included in any one category (e.g., ADLs) that it makes it difficult for the clinician to choose just one response. This item requires clear instruction to “score” the level of assistance based on the item requiring the most assistance to complete the activity safely.”
- CMS should clarify how to answer this question when there are multiple caregivers at different levels of ability.
- CMS should clarify what is the difference between caregiver not likely to provide and unclear if caregivers will provide; seems to be the same question.
- Add column for home health agency to provide.
- The scope and meaning of the headings of each column need to be clearly defined in the new OASIS C Guidance Manual to enhance the inter-rater-reliability in the responses.
- Would recommend removal of column 'caregiver not likely to provide assistance' as it is subjective and judgmental. Would recommend response that caregiver is unable to provide assistance for physical or emotional reasons.
- Will the assessment validation show warnings if these questions are inconsistent with the functional questions?
- Supervision and safety seem to be part of ADL and IADL management, thus somewhat redundant.
- What are the implications if assistance is needed but no caregiver is available? What if we state that a patient requires assistance to safely compete any of the tasks and the patient refuses to get assistance?

Response:

- This item is based on a similar item in the proposed CARE tool. It was moved to the section now entitled "Care Management" located just prior to "Therapy Need." It provides an opportunity for clinicians to document gaps in care and caregiver need for training or support at both SOC/ROC and Discharge.
- The location of the item within the OASIS C dataset was determined based on the need for the clinician to have completed an evaluation of ADLs/IADLs in order to respond to this item accurately. Agencies can place items in their comprehensive assessment tool wherever they feel it is most appropriate.
- An explanatory sentence has been added to the item to clarify instructions for completion based on language in the CARE instrument: “Determine the level of caregiver ability and willingness to provide assistance for the following activities, if assistance is needed.”
- Headings have been placed in bold and numbering in boxes eliminated to assist with readability, and items included under each category have been indicated as “i.e.,” not “e.g.” for clarity.

- The OASIS C Guidance Manual will include clarification on scope and meaning of the headings of each column (including Supervision and Safety), how to answer this question if the patient can do some of the tasks and not others, how to answer this question when there are multiple caregivers at different levels of ability, and the difference between caregiver not likely to provide and unclear if caregivers will provide.
- The response 'caregiver not likely to provide assistance' would include multiple reasons why the caregiver is unlikely to provide assistance, including situations when they are unable to provide assistance for physical or emotional reasons. Further clarification on the response choices in heading columns will be provided in the OASIS C Guidance Manual.
- The column heading “unclear if caregiver will provide assistance” has been provided because it is acknowledged that it may be difficult to complete this item accurately and completely within the first one or two visits to the patient upon admission, or even at discharge in some situations.
- A column for “home health agency to provide” is not appropriate for this item that is designed to assess types and sources of assistance available other than that received by the agency; agency provision of assistance and other responses listed are not mutually exclusive.
- Completion of this item should not lead to patient exhaustion as the information needed to complete it should be obtained through ADL/IADL assessment and discussion of available supports, rather than a straight interview approach.
- Guidance about how to respond to this item if assistance is needed but no caregiver is available or a patient requires assistance to safely complete any of the tasks and the patient refuses to get assistance will be included in the OASIS C Guidance Manual based on similar guidance developed for this item in the CARE instrument.

**M2110 How Often does the patient receive ADL or IADL assistance
[previously 2120]**

Comments:

- To assist clinicians with accuracy of responses, move this item to follow after M1100. Living arrangements and assistance provided in the home are like items and listing the questions together will flow in the practitioner’s assessment of the patient.
- What is the purpose of this question?

Response:

- The location of the item within the OASIS C dataset was determined based on the need for the clinician to have completed an evaluation of ADLs/IADLs in order to respond to this item accurately. Agencies can place items in their comprehensive assessment tool wherever they feel it is most appropriate.
- This item is used for risk adjustment of outcomes.

Therapy Need and Plan of Care

M2200 Therapy Need

Comment: There is no way to accurately assess the number of therapy visits. This number is a guess at best.

Response: This item has not changed since OASIS B-1. The number of therapy visits is collected at SOC/ROC 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 SOC or 2-day ROC window. The payment algorithm will recalculate payment at transfer or discharge based on the actual number of therapy visits received.

M2250 Plan of Care Synopsis
[new consolidated item]

- This item has replaced and consolidated items reporting whether the physician-ordered plan of care includes interventions for diabetic foot care, falls prevention, depression, pain, preventing and treating pressure ulcers and establishing patient-specific parameters for notifying the physician of changes in vital signs or other clinical findings.
- The “current physician-ordered plan of care” means the patient condition has been discussed and there is agreement as to the plan of care between the home health staff and the physician. These POC orders must be in place within the 5-day SOC window and 2-day ROC window in order to meet the measure definition. Guidance on workflow to enable reporting Plan of Care items in the OASIS C will be included in the OASIS C Guidance Manual. This item will be used to calculate OBQI/OBQM quality reports that can provide guidance to agencies on how to improve care received by individual patients, prevent exacerbation of serious conditions and avoid adverse events.
- Guidance on responding to this item will be provided in the OASIS C Guidance Manual.

Emergent Care

M2300 Emergent Care

Comments:

- We agree with and support the proposed change that defines emergent care as the patient utilization of a hospital emergency department and the removal of the physician office w/in 24 hours from definition of emergent care. The decision to exclude all but emergency room visits in this item will provide more realistic data re: the true incidence of emergent care. This is a more helpful and cost reflective of health care data piece than the current OASIS-B interpretation.
- Please define "Urgent Care Center."
- Clarify if the response to this item should also apply to the circumstances related to the Transfer or Discharge if they include an emergency department visit.
- This item requires the clinician to look back at previous assessment time points, which is in conflict with current guidance.
- The item should include a response to identify physician referrals to the emergency department. Agencies are increasingly receiving instructions from the physician to have patients go to the ED when the doctor's office is closed.

Response:

- The look back period for this item has not changed since the OASIS B-1.
- The item responses have been clarified by removing “with or without hospital admission” from the question and providing 2 “yes” responses: 1-Yes, used hospital emergency department WITHOUT hospital admission; and 2-Yes, used hospital emergency department WITH hospital admission.
- The OASIS C Guidance Manual will include a definition of "Urgent Care Center" and will clarify how to respond to this item if the Transfer or Discharge included an emergency department visit or if the visit to the ED is based on physician referral.

M2310 Reason for Emergent Care**Comments:**

- The expanded reasons for emergent care and hospitalization will assist the HHA to better identify reasons the patient sought emergency services. This will be more helpful to agencies that are working on improving their Emergent Care scores. We also agree with the reasons being the same for hospitalization.
- We recommend adding IV Catheter-related issues (i.e. occlusion, dislodgement, questionable placement etc.), complications from chemotherapy or radiation therapy.
- Injury caused by fall or accident at home should be separated to improve the ability to accurately identify falls. Having the total number of falls and accidents combined skews the true number of falls per agency. While accidents are a small percentage of the total, smaller agencies are penalized when accidents are incorporated in the falls category.
- CMS should include an optional opportunity for clinicians to identify the “other” condition that might have led to either emergent care or hospitalization.
- We are concerned that emergent care is still not adequately risk adjusted. It is critical that risk adjustment be sufficient so that providers are not penalized for treating patients who are more clinically complex with multiple co-morbidities and do not have incentives to avoid treating complex patients.

Response:

- The words “or complication” have been added to response 14 so it now reads, “IV catheter-related infection or complication.”
- Complications from chemotherapy or radiation therapy would be included in response 1, “Improper medication administration, medication side effects, toxicity, anaphylaxis” and the OASIS C Guidance Manual will clarify that.
- Response 2 now captures only falls to improve the ability to accurately identify falls.
- Response 19 allows the response of “other.” The reason can be noted in the patient chart, but CMS does not need the agency to report that information.
- The word “upper” has been removed from response 11. It now reads, “GI bleeding, obstruction, constipation, impaction” so that it now includes both upper and lower GI bleeding.
- CMS intends to risk adjust all outcome measures that will appear on the Home Health Compare web site. A revised risk adjustment model for emergent care is already in use on Home Health Compare since June 2008. Over the past months, the developers have conducted further research and developed robust risk adjustment models for the emergent care -related potentially avoidable events (such as emergent care for specific reasons).

Such models will be used to risk-adjust those measures before they are publicly reported on Home Health Compare.

Data Items Collected at Inpatient Facility Admission or Agency Discharge

M2400 Intervention Synopsis

[new consolidated item]

- This item has replaced and consolidated items reporting on implementation of physician-ordered interventions for diabetic foot care, falls prevention, depression, pain, and preventing and treating pressure ulcers.
- The item will collect data on whether interventions that were included in the physician-ordered plan of care were implemented since the previous OASIS assessment. The item includes options for clinicians to indicate if an intervention was not appropriate for the patient. Responses will be used to support both publicly reported measures and OBQI/OBQM measures on evidence-based practice implementation.
- Guidance on responding to this item will be provided in the OASIS C Guidance Manual.

M2410 To which Inpatient Facility has the patient been admitted

[previously 2400]

Comments: How should we respond if the patient was admitted to more than one facility (hospital and SNF)?

Response: If the patient was admitted to more than one facility, indicate the facility that the patient was admitted to first. This guidance will be added to the OASIS C Guidance Manual.

M2420 Discharge Disposition

[previously 2410]

Comment: There remains a problem with new M2410 (old M0870/M0880). We end data collection on those individuals who no longer qualify for skilled services, but continue to qualify for Waivered services (personal care or homemaking) or elect to pay privately for personal care. The OASIS data set appears to indicate they are discharged to the community still requiring care. We would prefer to see an option for "remained under the care of the home health agency for non-skilled services." That would clarify the actual status of the home care patient and avoid confused responses from clinicians completing the data collection.

Response: Item has been modified in response to comments. New response categories indicate either with or without formal assistive services.

M2420 Hospital Reason (emergent/urgent/elective)

[DELETED]

This item was deleted as it is not used for quality, payment or risk adjustment.

M2430 Reason for Hospitalization: For what reason(s) did the patient require hospitalization?

Comments:

- The expanded reasons for hospitalization will assist the HHA to better identify reasons the patient was hospitalized.
- We recommend adding IV Catheter-related issues (i.e. occlusion, dislodgement, questionable placement etc.), complications from chemotherapy or radiation therapy.
- Injury caused by fall or accident at home should be separated to improve the ability to accurately identify falls. Having the total number of falls and accidents combined skews the true number of falls per agency. While accidents are a small percentage of the total, smaller agencies are penalized when accidents are incorporated in the falls category.
- CMS should include an optional opportunity for clinicians to identify the “other” condition that might have led to hospitalization.
- We request that patients with a response of 19 (scheduled treatments or procedures) be exempt from inclusion in the HHA hospitalization rates. The rate for hospitalization is inflated when are included.
- We have some concerns about the accuracy of the reasons for hospitalization since it is often reported by the family.

Response:

- The words “or complication” have been added to response 14 so it now reads, “IV catheter-related infection or complication.”
- Complications from chemotherapy or radiation therapy would be included in response 1, “Improper medication administration, medication side effects, toxicity, anaphylaxis” and the OASIS C Guidance Manual will clarify that.
- Response 2 now captures only falls to improve the ability to accurately identify falls.
- Response 19 allows the response of “other.” The reason can be noted in the patient chart, but CMS does not need the agency to report that information.
- The word “upper” has been removed from response 11. It now reads, “GI bleeding, obstruction, constipation, impaction” so that it now includes both upper and lower GI bleeding.
- Until Home Health has a method of verifying reason for hospitalization through a claims based hospitalization measure, we ask that agencies attempt to confirm and as accurately as possible report the reasons. This will assist in the important process of root cause analysis to examine what is driving the agency hospitalization rate.

M2440 For what Reason(s) was the patient Admitted to a Nursing Home?

Comment: What if the patient is admitted to a rehab facility at discharge from Home Care?

Response: This item is used to collect information on admission to nursing home only. Guidance on this will be included in the OASIS C Guidance Manual.