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Comment On: CMS-2008-0141-0001
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Document: CMS-2008-0141-0106
NY

Submitter Information

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General Comment

These comments are submitted on behalf of the agency and are the product of a collabortive effort of all levels of the agency's staff.

Attachments

CMS-2008-0141-0106.1: NY

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number 0938-0760
Room C4-25-06
7500 security Boulevard
Baltimore, Maryland 21244-1850

#106

Comments on Form NumberCMS-R-245
OASIS-C

We would like to first commend CMS for the work that has been done to respond to providers concerns regarding the current OASIS-B1 assessment. Since the implementation of OASIS in October 2000, we have relied upon frequent clarifications of various unclear items in order to be compliant with the intent of the regulation. This has led to inconsistency in responses between clinicians in home health agencies nation-wide. Explicit guidelines will still be required as a resource for this new assessment but the items should be clear enough for the clinician in the field to accurately respond to the items. 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. We would first like to provide our support for several items where we noted such improvements.

- **M1034 Stability Prognosis** provides responses that more clearly reflect the clinician's assessment of the patient's prognosis than the current items in OASIS-B1 (M0260 and M0 280).
- **M1210 Ability to Hear and M1220 Understanding of Verbal content** will provide more relevant data than the current single M0 item (M0400) particularly for the cognitively impaired patient.
- **M1240 Frequency of Pain**: The proposed assessment item is clearer. It differentiates between the patients who do not have any pain and the patients whose pain does not interfere with activity. In addition, the inclusion of the process measures M1242 Pain assessment, M1244 Planned Pain Intervention and M1246 Pain Intervention will provide valuable data re: the management of patient's pain. They are more relevant than the current item Intractable Pain (M0430) that is not included in OASIS-C.
- **Emergent care (M2300):** The decision to exclude all but emergency room visits in this item will provide more realistic data re: the true incidence of emergent care.

Upon review of the assessment we continued to note items where the intent was not totally clear. We will organize our comments below by either type of issue or the section of the assessment.

1. The definition of ***current physician-ordered plan of care*** needs to be clarified when responding to the following items:
   - M1244 Planned Pain Intervention
   - M1304 Planned Pressure Ulcer Prevention
   - M1326 Pressure Ulcer Intervention
   - M1360 Diabetic Foot Care Plan
   - M1734 Depression Intervention Plan
   - M1940 Falls Risk Intervention

   Does the term "current physician-ordered plan of care" only refer to the plan of care, as it exists at the time of the assessment visit? Does it include orders for interventions obtained as a result of the assessment?

The current guidance on OASIS-B1 includes the orders obtained as a result of the assessment in the response. 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. How will this be viewed for the purposes of outcomes and eventually Pay for Performance (P4P)?
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.

2. In some items multiple variables are included in one response.
   - **M1890 Change in Self Care Ability**: The level of ability may vary among the tasks listed (grooming, dressing **and** bathing). The concept of the majority of the tasks in the current OASIS guidance has been confusing to clinicians and does not accurately reflect patient status. The question should be phrased "and/or" and not "and".

   - **M2110 Types and Sources of Assistance**: This item will provide data as to the impact of caregiver availability for both outcomes and cost. The revised item provides greater specificity among categories of caregiver assistance and the level of support needed. The item **M1100 Living Arrangements** also seeks information re: the availability of assistance and may be more appropriately grouped with the proposed M2110.

3. **Integumentary Status Items**: We found many improvements in this section but continue to have concerns with certain items. We felt some of the improvements included the following:
   - OASIS-C enables the clinician to indicate a wound is healed not just fully granulated.
   - **M1350 Does this patient have a Skin Lesion or Open Wound...**
     The proposed item only includes lesions or wounds receiving assessment and/or treatment unlike the current M0440 in OASIS-B1.
   - The removal of the requirement to count the number of surgical wounds will also more clearly reflect the true outcomes of care. Clinicians have long complained that in certain circumstances the number of surgical wounds has increased in number as the wound develops islands of granulation as it heals.

However, we felt the following items required comment.
   - **M1310 Current Number of Unhealed (non-epitheliazed) Pressure Ulcers at Each Stage**

     a. This item does not appear to include the stage 3 and 4 ulcers that have re-epithialized. These ulcers may re-epitheliaze but they are never truly healed and should be accurately documented on the assessment. The patient with a re-epitheliazed stage 3 or 4 ulcer will always require interventions such as caregiver instruction, clinician oversight and support surfaces. The site of the ulcer is always at risk for breakdown.
     b. As the OASIS-C is currently written a patient with a stage 3 or 4 ulcer that was re-epitheliazed at admission will be viewed as a new pressure ulcer if it is not re-epitheliazed at resumption, recertification or discharge. The ulcer that has broken down during an in-patient stay is not clearly defined. We would suggest that the item should compare current ulcers to ulcers at start of care/ resumption of care.

   - **M1312 Pressure Ulcer Length and M1314 Pressure Ulcer Width** do not utilize anatomical markers to assist in the measurement of the ulcers. We feel the lack of such a standard will lead to discrepancies between clinicians. Many agencies, including our own, use the head to toe measurement as the length and the width is at

a 90-degree angle to the length. A process that utilizes uniform anatomical positions is needed in order to maintain consistency in wound measurement.

4. **Cardiac Status (M1500-1510)**:
   These items require that the clinician indicate on either transfer or discharge, if at any time during the episode, the patient developed symptoms of heart failure and whether f/u was provided. This type of item provides a challenge for tracking the report of these symptoms, particularly when nursing no longer follows the case.

5. The **functional assessment** includes some needed improvements but increased clarity is still required in the items listed below. 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.
   - **M1830 Bathing**
     - Option #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? The patient may be able to bathe independently once the basin of water and the bathing items are brought to them. They are certainly not independent as stated in the item.
     - Option #5 requires assistance throughout the bathing process. How do we categorize the patient who is bathed at the sink or at the bedside but requires intermittent assistance? Another selection is needed to more clearly define this patient's level of ability.

   - **M1840 Toilet Transfer**:
     - Option #1 of the item includes two activities: getting to the toilet and the transfer. The patient may need assistance with one but not the other. Combining the two activities will cause confusion. It would seem that the ambulation/locomotion item includes the ability to ambulate to the toilet. Is the item asking if the patient has access to the toilet or are environmental and medical restrictions preventing this activity? This needs to be clarified.
     - In option #3 a patient is using a bedpan or urinal. How is the emptying of the device to be considered? The term independently in option #3 does not appear to apply to any patient using a bedpan or urinal. The management of the equipment does not appear to be included in this item or in the Toilet Hygiene item (M1845). This is a personal care service that a patient using such a device requires.

   - **M1860 Ambulation/Locomotion**: This item has been improved to include the ability to show progress from a two-handed device to a one-handed device. However, the options provided continue to require increased clarity:
     - Option #1 includes patients ambulating with a one-handed device independently on a variety of surfaces.
     - Option #2 includes patients ambulating alone with a two-handed device on level surfaces and/or human supervision on uneven surfaces. Combining various levels of patient ability in one response reduces the accuracy of the item. We would suggest a separate response to define the patient who requires human supervision to safely negotiate stairs/steps and uneven surfaces without a device or using a one-handed device.

6. **Medications (M2000to M2040)**:
   - Medication reconciliation is critical when a patient is admitted to home care and needs to be maintained throughout the episode of care. Home health agencies are often hampered in their efforts to accomplish this due to the lack of availability of the

medical supervision. For the purposes of **M2002 Medication Follow-up** is an attempt (or in some cases repeated attempts) to contact the MD sufficient for an affirmative response? This will be significant issue for cases assessed on the weekends/holidays.

- Guidelines need to be clear as to what medications are high-risk medications so the clinician can accurately respond to **M2010 Patient/Caregiver Drug Education.** Will only hypoglycemics and anticoagulants be considered on this item?
- The management of inhalant medications was included in the OASIS B 1in item M0790. It is not included in OASIS-C. However, in order to respond to **M2040 Change in Ability to Manage Oral, Inhalant, or Injectable Medications** the clinician will need to assess the patient's management of inhalant medications. Why was the management of inhalants excluded if this data is needed to respond to M2040?

7. **Coding of Diagnoses and Procedures:**
   The expansion of the in-patient diagnoses is welcome for many patients have multiple co-morbidities that should be considered in the risk adjustment. The lack of coding data at hospital discharge is a potential issue. The hospital does not code a patient record until after discharge. When the start of care or resumption OASIS is completed the in-patient codes are not available. The lack of diagnostic and procedural coding at referral to home health will be more critical since there will be greater weight on these items. This is a particular issue for the procedural coding. Hospital based agencies will have an advantage over community based agencies for they have easier access to the in-patient medical record post discharge when the coding has been completed. In addition, the current coding system is scheduled to convert to ICD-10 CM/PCS in 2011 barring any changes in the proposed schedule. The procedural coding in ICD-10-PCS is much more specific than in the current ICD-9-CM system and will require more data than is currently available to home health agencies on a routine basis. As we move toward a standard post acute care assessment it will be more imperative that the patient's diagnostic and procedural coding data is universally available.

In addition to the specific items we wished to include an overall concern re: the timetable for the implementation of this major revision. Our clinical record system is a point of service system and has integrated specified OASIS items with other modules in order to provide a comprehensive documentation system. The magnitude of the changes proposed will require a major revision of record systems throughout the industry. 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.

In summary, we have found significant improvement in the proposed assessment over the current OASIS-B1. We hope these comments assist in the effort to provide a clear instrument to assess the home health patient and document the outcomes of care.

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Document: CMS-2008-0141-0107
CA

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General Comment

This comment is addressing the format of several new OASIS-C responses, for example M1242, M1244, M1246. We understand the type of information that CMS is looking for with these responses, however, are concerned with the way the information is being asked. While these questions have merit, they are being asked in a way that will certainly obtain a majority positive response. Similar to the current M0440, which asks if a patient has a skin lesion or wound at all, the phenomena that there-in occurs is that 98-100% of responses are "yes". What then is the point to the question - if nearly every patient is in one group, then there is no specificity, no strata from which to glean meaningful data. We fear that in fact these new questions, in the way they are proposed to appear, will do the exact same thing - create a meaningless group of yesses.

The objective is clear and good - to trigger agencies to think about their minimum standards of assessment (e.g., using a pain scale), promote teamwork/communication with the physician, and improve minimum standard careplanning. However, with a simple yes/no answer, you are not going to obtain adequate measurement where it matters.

Is it possible to stratify the answers to these questions? Perhaps the first in the triad (e.g., M1242) does not require change, but the second and third could have levels/choices? This is not an easy fix, however, the data would be richer.

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Document: CMS-2008-0141-0108
DC

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General Comment

Please see comments in attachment

Attachments

CMS-2008-0141-0108.1: DC

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January 13, 2009

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB
Control Number 0938-0760
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Filed Electronically

Re: CMS-R-245 (OMB Control Number 0938-0760) Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs

To Whom It May Concern:
The National Association for Home Care & Hospice (NAHC) is the largest trade association in the country representing home health agencies. NAHC has supported the OASIS development and refinement processes through participation in research and educational efforts since the early 1990s. NAHC is pleased to see that CMS has proposed revisions of OASIS to ensure that this standardized assessment tool reflects current clinical practice and accurately identifies patient's status for quality measurement and accurate payment.

NAHC is pleased to see that many of the recommendations made by the home health industry, including those made in response to the Office of Management and Budget (OMB) request for comments on the planned testing of the revised OASIS, have been incorporated into the 111108 version. We congratulate the Centers for Medicare & Medicaid Services (CMS) and its contractors on the significant improvements in the refined OASIS set. The general consensus of home health agencies about changes to OASIS is positive.

In response to the invitation to comment on OASIS revisions, NAHC proposes to offer comments on the burden estimates in the Information Collection package. In addition, we would like to take this opportunity to point out where further clarification might be needed to ensure accurate interpretation of certain OASIS items and to offer our suggestions for possible additional refinements.

Burden

In the Paperwork Reduction document for CMS refinements to OASIS collection requirements, CMS reported their estimate of the total burden for start up training, assessment data collection, and training new staff in 2009 to be 15, 590, 610 hours. CMS stated that there will be no net burden impact from the added OASIS items. NAHC believes that this is an underestimate of the training costs that home health agencies will encounter in implementation of OASIS-C.

In a survey of the industry, home health agencies reported that a minimum of 8 hours of training will be required to educate clinicians on how to properly code OASIS-C. This number is based on the significant changes to existing OASIS items and the number of new items. It is reasonable in light of the industry standard for training established by nationally recognized OASIS training programs. The cost estimates below do not begin to estimate the ongoing costs to agencies to ensure that their staff remains proficient and their knowledge base current with the large number of data item reinterpretations that are released by CMS in the form of questions and answers on a quarterly basis. Home health agencies estimate an average ongoing training of 2 hours per clinician per month as opposed to the 8 hours/agency per year. These cost projections do not include the estimated 8 hours of training for new employees that must be taken into consideration with staff turnover.

Staff Training Burden

Agencies	10,170
Clinicians/agency	18
Hours 1st year	8
Total hours 1st year	1,464,480
Hourly rate	$29.47
Total 1st year training costs	$43,158,225

Agencies	10,170
Clinicians/agency	18
Hours ongoing training	2
Hourly rate	$29.47
Total annual cost	$10,789,556
Total training cost	**$53,947,780**

Changes Burden

CMS presented the following chart which provides a comparison of the number of OASIS items in the current OASIS-B1 and those in the proposed OASIS-C. Home health agencies predict that clinician time spent on collection of OASIS data will be considerably greater in light of the net increase in OASIS data items that will be collected at start of care, resumption of care and transfer. Some of these OASIS questions could be answered in seconds, while others will require several minutes (especially in light of implied added burden of use of other tools for further refinement). Therefore, we estimate that the start of care and resumption of care assessments will take an additional 30 minutes per assessment.

	Start of Care	Resumption of Care	Follow up/recertification	Transfer	Discharge
OASIS B-1	76	61	30	11	75
OASIS-C	105	90	32	26	74

Based on an estimate of 7,000,000, at a minimum, start of care and resumption of care assessments the cost to home health agencies of the Changes would be:

Number of assessments	7,000,000
Hourly rate	$29.47
Added hours per assessment	.5
Total cost of added items	$103,180,000

This estimate does not account for the costs that home health agencies will incur to implement computerized or manual systems to harvest information needed for transfer and discharge assessments related to process interventions implemented during the course of care.

General Comments

Issue: During discussions with home health agencies, a question commonly posed was CMS' rationale for inclusion of process measures in individual patient assessments. Several agencies suggested that measurement of adoption of recommended processes, for example the use of standardized pain and fall assessment tools, be carried out during agency surveys, rather than through OASIS data collection on every patient.

Recommendation: CMS should provide its rationale for assessment of home health agency compliance with process measure adoption through individual patient assessments rather then by way of sampling during survey.

Issue: Another question posed by home health agencies was about CMS' goals in regard to "plan of care" questions for several of the processes. Since the OASIS questions about the presence of processes in the plan of care (M1244, M1304, M1326, M1360, M1734, M1940) are not gathered at transfer or discharge, it appears that these items are simply present to prod clinicians to include them, rather then to measure agency performance in this area.

Recommendation: CMS should revisit the intent of including "plan of care" questions in the OASIS data set. If it is considered to be appropriate to collect this information via individual patient assessments, rather than evaluation of an agency at the time of survey, CMS should provide agencies with its rationale.

Issue: Since the home health plan of care is established with the physician after completion of the comprehensive patient assessment, agencies expressed confusion about the fact that "plan of care" process items are written as "does the physician-ordered plan of care include..."

Recommendation: If these items are to remain in individual patient assessments, CMS should amend the wording to reflect action once the assessment is completed, such as "will the physician-ordered plan of care reflect…"

Issue: It is unclear why certain process measure responses (M1246, M1306, M1328, M1365, M1510, M2015) should be based on "since the previous OASIS assessment." This appears to eliminate "yes" responses for multiple episode patients who received the services prior to a recertification assessment.
Recommendation: CMS should either eliminate "since the previous OASIS assessment" or provide the rationale for limiting the delivery of these services since the previous assessment only.

Suggested Item Clarification
Issue: M0102 Date of Referral and M0104 Date of Physician-ordered Start of Care. Referral practices vary, with many referrals made by individuals other than the physician. Also, situations often arise where patients are not available for care on the physician order start of care date.
Recommendation: CMS should provide the rationale for this item and clear instructions on how to complete it. These instructions should explain the difference between referral versus physician orders and describe actions agencies should take in cases where patients are unavailable.

Issue: M1032 does not include certain clear indicators of frailty and the potential for complications/problems
Recommendation: CMS should develop detailed guidance for home health agencies that includes:

- Consideration of impact of polypharmacy
- Define "unstable" vital signs including timelines
- Define "debilitating" pain or use the same language found in other OASIS items "pain interfering with activity."
- Define the term "recent"

Issue: M0134 Stability Prognosis response "1" descriptor "temporarily" is vague.
Recommendation: CMS should define the term "temporarily" in guidance.

Issue: M1100 Patient Living Situation has certain terms that need clarification to ensure that clinicians respond appropriately
Recommendation: CMS should provide extensive guidance for this item:

- The term "Availability of Assistance" is clearly defined to mean "assistance from an able and willing caregiver."
- "Availability" should be defined as actually providing needed services, rather than "reachable"
- "Congregate living" guidance should be clearly defined to ensure that responses are not based on assumptions about services provided at such sites.

Issue: M1312 and M1314 Pressure ulcer length and width

Recommendation: CMS should determine whether this item is appropriate for quality since increase in size is not always indicative of wound deterioration. For example, wound measurements may increase with debridement

Issue: M1326 Pressure ulcer Intervention: Home health agencies have expressed confusion about the definition of "moisture retentive dressings."
Recommendation: CMS should clearly define "moisture retentive dressings."

Issue: M1350 Skin Lesion or Open Wound excludes bowel ostomy. However, it does not identify whether other ostomies should be excluded.
Recommendation: CMS should provide clear guidance on whether all ostomies should be excluded when responding to this item. In the determination, consideration should be given to skin care that might be required for other ostomies. Also, consider changing the word "described above" to "pressure ulcer, stasis ulcers, and surgical wounds" in order to clarify exclusions.

Issue: M1600 Urinary tract infection: could be problematic since a patient may have been treated for a urinary tract infection in the past 14 days but is now on prophylactic treatment
Recommendation: CMS should provide clear guidance for responding to this question should more than one response apply

Issue: M1870 Feeding does not provide sufficient descriptive language for response "5" and could result in failure of clinicians to interpret correctly.
Recommendation: CMS should provide guidance to establish the intent of this response. For example, it should be made clear whether this item applies to persons on TPN or persons who are NPO.

Suggested Amendments
Issue: M0138 implies that parameters are required in the plan of care for all changes in vital signs and clinical findings that a patient might experience. If this is the intent, the plan of care burden would be untenable and impossible for agencies to fulfill.
Recommendation: Eliminate or rephrase this item to limit the requirement to establish parameters to those situations where the patient has a disease process that necessitates establishment of abnormal finding parameters.

Issue: M1040 Influenza Vaccine and M1045 Influenza Vaccine not received imply that home health agencies are required to administer vaccine to all patients who do not receive it from other sources. Some State regulations prohibit "dispensing" of vaccines by home health agencies. In addition, transport of vaccine by home health clinicians cannot always be done safely at required temperatures. Therefore, such a quality measure is not appropriate for home health.
Recommendation: CMS should re-phrase M1040 to "Did the patient receive the vaccine from the agency or was assisted by the agency in arranging for vaccine from another source."

Issue: M1050 Pneumococcal Vaccine implies that home health agencies are required to provide this vaccine to their patients. Home health agencies are often unable to determine whether an individual has already received this vaccine. Also, some State regulations prohibit "dispensing" of vaccines by home health agencies. In addition, transport of vaccine by home health clinicians cannot always be done safely at required temperatures.
Recommendation: CMS should re-phrase M1045 to "Did the patient receive the vaccine from the agency or was assisted by the agency in arranging for vaccine from another source."

Issue: M1240 Frequency of Pain and M1242 Pain Assessment seem to be in reverse order since a pain assessment should be conducted and existence of pain confirmed prior to determination of the frequency of pain. Also, a skip pattern seems indicated for this item. Also, the word "severe" is subject to individual interpretation
Recommendation: Reverse the order of M0140 and M0142. Include a skip pattern if "patient has no pain." Either delete the word "severe" or provide a clear definition in guidance. Also, this item should include pain that interferes with sleep since its presence could have a negative impact.

Issue: M1732 Depression symptoms. It has been suggested by home health agencies that the CARE tool PHQ depression screening questions are more sensitive for identification of depression.
Recommendation: CMS should replace the OASIS M1732 with the CARE tool depression screening items.

Issue: M1860 Ambulation/locomotion does not differentiate between ascending and descending stairs, curbs versus multiple steps, and even and uneven surfaces.
Recommendation: CMS should reevaluate the responses and consider amending them as follows:

- "0" should apply to curbs and stairs of 3 steps or greater without assistance or a device
- "1" should include individuals who can walk independently on even and uneven surfaces with no human assistance or devices but require assistance or devices to manage curbs and/or steps
- "2" should include individuals who require use of a 1 hand device or assistance to manage curbs and/or steps

Thank you for consideration of our comments. If you wish to discuss these further, I can be reached at 202 547-7424.

Sincerely

Mary St. Pierre

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MN

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General Comment

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Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulation Development
Attention: Document Identifier/OMB Control Number 0938-0760
Room CA-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

We are writing to comment on the proposed changes to the Outcome and Assessment Information Set, referred to as OASIS-C, noticed in the November 14, 2008 Federal Register. Document Identifier: CMS–R–245 (OMB# 0938–0760)

We support the use of OASIS as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, we have the following comments regarding the OASIS-C changes.

Concern: M0102 Date of Referral
Suggestion for Change: Define the date of referral. Suggestions include altering item to read "Indicate the ordered date the agency is to initiate homecare." Differentiate between an inquiry about services and an actual referral for services. Not all referrals come from a physician so eliminate the word physician.
Rationale: .Clarification is necessary for consistent practice among agencies. Starting the services is not always within the home care provider's control. For example, providers may be waiting for authorization from Medicare Advantage programs which may delay the start of care; sometimes referrals are made while the patient is still hospitalized and home care is not able to start care for an extended period of time; and sometimes patients make the request not be seen

on a certain day, also delaying the start of services. Provide direction for how agencies are to answer this question when the initial physician's order start of care is delayed. Does the date an agency updates the physician on the patient's availability for start of care become the referral date?

Concern: M1010 & 1012 Inpatient Diagnosis and ICD Code
Suggestion for Change: Eliminate this requirement. If CMS needs the data, it is available from the hospitals.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final hospital coding often does not occur until the hospital generates the bill. It is not realistic for home care clinicians to have knowledge of the coding requirements for inpatient facilities; requiring them to enter this information with insufficient or completed data from referrals sources will result in errors in a patient's medical record.

Concern: M1014 Medical or Treatment Regimen Change
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

Concern: M1032 Frailty Indicators
Suggestion for Change: Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of high-risk chronic diagnoses place a patient at risk for re-hospitalization and speak to the fragility of their overall status. These include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. Eliminate this item from SOC
Rationale: At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes, and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measurable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

Concern: M1034 Stability Prognosis
Suggestion for Change: Eliminate # 3 - The patient has serious progressive conditions that could lead to death within a year.
Rationale: This language is similar to M0280 except that the predicted death time has changed. Providers should not have to guess at time of death. It is not a question that reflects the actual and clinically substantiated status of the patient. Clinicians will have much difficulty differentiating between number 2 and number 3 in this item. Defining "serious complications" and "high health risks" by various clinicians will result in useless data.

Concern: M1038 Guidelines for Physician Notification
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

Concern: M1040 through M1055 Vaccinations
Suggestion for Change: Clarify through CMS instructions that providers will not be mandated to provide vaccinations without payment for such. Eliminate "from your agency" verbiage and remove #1 and 2 in M1045.
Rationale: It is important to verify vaccination. However, providers should not have to assume the financial and resource burden of vaccination administration. There

are more efficient ways to ensure vaccinations.

Concern: M1242 Formal Pain Assessment
Suggestion for Change: Make suggestions and list appropriate standardized assessment tools for pain. Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools will help decrease data variance that is collected by providers.

Concern: M1300 - M1306 - Pressure Ulcer Assessment
Suggestion for Change: Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? It is unrealistic to get all of this done in the 5-day time frame. Consultation with staff outside the home care agency, for example a wound healing clinic, is often necessary to gather all pertinent clinical information.

Concern: M1312 - M1314 Pressure Ulcer Length & Width
Suggestion for Change: Eliminate both items
Rationale: Requiring length and width of the wound does not meet the guidelines for measurement and assessment as established by the Wound, Ostomy and Continence Nurses Society (WOCN). This question does not ask for the components of a complete wound assessment; therefore clinicians will be required to complete redundant documentation in order to accurately document the wound condition. Providing only a length and width of a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measured at 12 o'clock to 6 o'clock with 12 o'clock always being toward the patient's head. Width is measured side to side from 3 o'clock to 9 o' clock. Simply asking for length and width does not support the guidelines.

Concern: M1320 Status of Most Problematic Pressure Ulcer
Suggestion for Change: Clarify that this pertains only to stages 3 and 4
Rationale: A healed stage 1 or 2 would no longer be considered a pressure ulcer.

Concern: M1326 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item.
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings.

Concern: M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings. It is not the home care clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

Concern: M1360 Diabetic Foot Care Plan
Suggestion for Change: Do not collect this at start of care.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: M1500 Symptoms of Heart Failure
Suggestion for Change: Clarify what heart failure guidelines include, one symptom or combination of all symptoms referred to in question?
Rationale: Improve data collection by having all clinicians doing the same type of assessment.

Concern: M1730 Depression Screening
Suggestion for Change: Offer suggestions for specific screening tools
Rationale: Clinicians need to use a standardized screening tool in order to collect and report on standardize data. Comparison across patients will be less accurate

if individual providers are using a wide variety of screening tools.

Concern: M1734 Depression Intervention Plan
Suggestion for Change: Eliminate this from SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: M1880 Change in Mobility
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. What if they are worse as a result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

Concern: M1890 Change in Self-care Ability
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at dressing but not at bathing – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. Various aspects of this item are unclear and likely will result in confusion and inaccurate answers

Concern: M1910 Ability to use Telephone
Suggestion for Change: Eliminate this item
Rationale: This assessment is covered in an emergency plan and safety assessment.

Concern: M1920 Change in Ability to Perform Household Tasks
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at meal preparation but not at laundry – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. The question is too broad to achieve consistent and meaningful data.

Concern: M1930 Has patient had multi-factor Falls Risk Assessment
Suggestion for Change: Recommend a standardized falls risk assessment.
Rationale: In order to have consistent data collection and comparison across patients and agencies, it is important for clinicians to collect data in a consistent manner.

Concern: M1940 Falls Risk Assessment Intervention
Suggestion for Change: Do not require this at SOC
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: M2002 Medication Follow-up
Suggestion for Change: Eliminate the need to contact the physician within one day and clarify what is considered "contacted" – does that mean a message has been left via phone, a fax has been sent, the home care clinician contacted the physician's nurse or other staff? Define clinically significant. Does "contacted within one calendar day to resolve clinically significant medication issues" imply that both contact and resolution is expected in one day, or is the intent of the question to show contact within one day?
Rationale: What if the person completing the OASIS assessment isn't the same person doing the follow-up – does this result in 2 clinicians completing the OASIS assessment? What if the physician is contacted but nothing is resolved – what is the CMS expectation? Consider the discharge disposition for patients in assisted living facilities. The risk adjustment is inadequate. Patients move to assisted living BECAUSE they can't manage their medications and/or ADLs. It is unlikely they will recover the abilities and show improvement during a Medicare episode. This is especially problematic if the Assisted Living facility has a policy requiring the AL staff to administer all medications. This skews outcomes for this population. Is a pharmacist considered a primary care practitioner? What about weekend admissions – it is unlikely that the issue would be resolved in one day. Ability to "resolve" is dependent upon willingness and availability of practitioners outside of the home care provider's control. Providers should not be expected to resolve something that is outside of the scope of practice (ordering medications).

Concern: M2004 Medication Interventions
Suggestion for Change: Eliminate this item
Rationale: It is unrealistic to expect the discharging or transferring clinician to know all of this without reviewing the entire medical record including looking at

previous OASIS assessments. This is burdensome and time consuming to have to review an entire episode to make this determination. Additionally, previous instructions did not allow a "look-back" on OASIS – are those instructions no longer valid?

Concern: M2020 Management of Oral Medications
Suggestion for Change: 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. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?
Rationale: The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with and ability to take prescription medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all prescribed medications (including oral) when assessing a change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.

Concern: M2110 Types and Sources of Assistance Matrix
Suggestion for Change: Clarify how to answer this question. For example, in item a, what if the patient can do some of the tasks and not others? If they need help, does frequency impact the patient?
Rationale: Lack of direction will result in inconsistent and unreliable data.

Other general comments and concerns:
We are concerned that there were only 11 pilot agencies. This is not statistically significant. There are over 9,000 Medicare-certified providers. We suggest pilot studies on a much larger scale in order determine the feasibility and usefulness of the proposed OASIS changes.

Please also clarify what previous instructions still apply or no longer apply (i.e.: majority of the time, day of assessment etc.)

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient in its current form and will become increasingly exhausting for the patient as all of the other assessments are added. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other home care changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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 be beneficial for national benchmarking.

Please carefully consider our concerns before proceeding with the plan to change the OASIS as proposed.

Sincerely,

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PUBLIC SUBMISSION

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Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

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Document: CMS-2008-0141-0110
MN

Submitter Information

Address:
MN, 56220

General Comment

Please see attached letter.

Attachments

CMS-2008-0141-0110.1: MN

SANFORD HOME CARE CANBY

1/12/2009

We are writing to comment on the proposed changes to the Outcome and Assessment Information Set, referred to as OASIS-C, noticed in the November 14, 2008 Federal Register. Document Identifier: CMS–R–245 (OMB# 0938–0760)

We support the use of OASIS as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, we have the following comments regarding the OASIS-C changes.

Concern: **M0102** Date of Referral
Suggestion for Change: Define the date of referral. Suggestions include altering item to read "Indicate the ordered date the agency is to initiate homecare." Differentiate between an inquiry about services and an actual referral for services. Not all referrals come from a physician so eliminate the word physician.
Rationale: .Clarification is necessary for consistent practice among agencies. Starting the services is not always within the home care provider's control. For example, providers may be waiting for authorization from Medicare Advantage programs which may delay the start of care; sometimes referrals are made while the patient is still hospitalized and home care is not able to start care for an extended period of time; and sometimes patients make the request not be seen on a certain day, also delaying the start of services. Provide direction for how agencies are to answer this question when the initial physician's order start of care is delayed. Does the date an agency updates the physician on the patient's availability for start of care become the referral date?

Concern: **M1010 & 1012** Inpatient Diagnosis and ICD Code
Suggestion for Change: Eliminate this requirement. If CMS needs the data it is available from the hospitals.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final hospital coding often does not occur until the hospital generates the bill. It is not realistic for home care clinicians to have knowledge of the coding requirements for inpatient facilities; requiring them to enter this information with insufficient or completed data from referrals sources will result in errors in a patient's medical record.

Concern: **M1014** Medical or Treatment Regimen Change
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

Concern: **M1032** Frailty Indicators
Suggestion for Change: Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of high risk chronic diagnoses place a patient at risk for rehospitalization and speak to the fragility of their overall status. These include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. Eliminate this item from SOC
Rationale: At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measureable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

Concern: **M1034** Stability Prognosis
Suggestion for Change: Eliminate # 3 - The patient has serious progressive conditions that could lead to death within a year.
Rationale: This language is similar to M0280 except that the predicted death time has changed. Providers should not have to guess at time of death. It is not a question that reflects the actual and clinically substantiated status of the patient. Clinicians will have much difficulty differentiating between number 2 and number 3 in this item. Defining "serious complications" and "high health risks" by various clinicians will result in useless data.

Concern: **M1038** Guidelines for Physician Notification
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

Concern: **M1040 through M1055** Vaccinations
Suggestion for Change: Clarify through CMS instructions that providers will not be mandated to provide vaccinations without payment for such. Eliminate "from your agency" verbiage and remove #1 and 2 in M1045.
Rationale: It is important to verify vaccination. However, providers should not have to assume the financial and resource burden of vaccination administration. There are more efficient ways to ensure vaccinations.

Concern: **M1242** Formal Pain Assessment
Suggestion for Change: Make suggestions and list appropriate standardized assessment tools for pain. Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools will help decrease data variance that is collected by providers.

Concern: **M1300 - M1306** - Pressure Ulcer Assessment
Suggestion for Change: Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? It is unrealistic to get all of this done in the 5-day time frame. Consultation with staff outside the home care agency, for example a wound healing clinic, is often necessary to gather all pertinent clinical information.

Concern: **M1312** - **M1314** Pressure Ulcer Length & Width
Suggestion for Change: Eliminate both items
Rationale: Requiring length and width of the wound does not meet the guidelines for measurement and assessment as established by the Wound, Ostomy and Continence Nurses Society (WOCN). This question does not ask for the components of a complete wound assessment; therefore clinicians will be required to complete redundant documentation in order to accurately document the wound condition. Providing only a length and width of a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measured at 12 o'clock to 6 o'clock with 12 o'clock always being toward the patient's head. Width is measured side to side from 3 o'clock to 9 o' clock. Simply asking for length and width does not support the guidelines.

Concern: **M1320** Status of Most Problematic Pressure Ulcer
Suggestion for Change: Clarify that this pertains only to stages 3 and 4

Rationale: A healed stage 1 or 2 would no longer be considered a pressure ulcer.

Concern: **M1326** Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item.
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings.

Concern: **M1328** Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings. It is not the home care clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

Concern: **M1360** Diabetic Foot Care Plan
Suggestion for Change: Do not collect this at start of care.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: **M1500** Symptoms of Heart Failure
Suggestion for Change: Clarify what heart failure guidelines include, one symptom or combination of all symptoms referred to in question?
Rationale: Improve data collection by having all clinicians doing the same type of assessment.

Concern: **M1730** Depression Screening
Suggestion for Change: Offer suggestions for specific screening tools
Rationale: Clinicians need to use a standardized screening tool in order to collect and report on standardize data. Comparison across patients will be less accurate if individual providers are using a wide variety of screening tools.

Concern: **M1734** Depression Intervention Plan
Suggestion for Change: Eliminate this from SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: **M1880** Change in Mobility
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. What if they are worse as a result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

Concern: **M1890** Change in Self-care Ability
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at dressing but not at bathing – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. Various aspects of this item are unclear and likely will result in confusion and inaccurate answers

Concern: **M1910** Ability to use Telephone
Suggestion for Change: Eliminate this item
Rationale: This assessment is covered in an emergency plan and safety assessment.

Concern: **M1920** Change in Ability to Perform Household Tasks
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at meal preparation but not at laundry – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. The question is too broad to achieve consistent and meaningful data.

Concern: **M1930** Has patient had multi-factor Falls Risk Assessment
Suggestion for Change: Recommend a standardized falls risk assessment.
Rationale: In order to have consistent data collection and comparison across patients and agencies, it is important for clinicians to collect data in a consistent manner.

Concern: **M1940** Falls Risk Assessment Intervention
Suggestion for Change: Do not require this at SOC
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: **M2002** Medication Follow-up
Suggestion for Change: Eliminate the need to contact the physician within one day and clarify what is considered "contacted" – does that mean a message has been left via phone, a fax has been sent, the home care clinician contacted the physician's nurse or other staff? Define clinically significant. Does "contacted within one calendar day to resolve clinically significant medication issues" imply that both contact *and* resolution is expected in one day, or is the intent of the question to show contact within one day?
Rationale: What if the person completing the OASIS assessment isn't the same person doing the follow-up – does this result in 2 clinicians completing the OASIS assessment? What if the physician is contacted but nothing is resolved – what is the CMS expectation? Consider the discharge disposition for patients in assisted living facilities. The risk adjustment is inadequate. Patients move to assisted living BECAUSE they can't manage their medications and/or ADLs. It is unlikely they will recover the abilities and show improvement during a Medicare episode. This is especially problematic if the Assisted Living facility has a policy requiring the AL staff to administer all medications. This skews outcomes for this population. Is a pharmacist considered a primary care practitioner? What about weekend admissions – it is unlikely that the issue would be resolved in one day. Ability to "resolve" is dependent upon willingness and availability of practitioners outside of the home care provider's control. Providers should not be expected to resolve something that is outside of the scope of practice (ordering medications).

Concern: **M2004** Medication Interventions
Suggestion for Change: Eliminate this item
Rationale: It is unrealistic to expect the discharging or transferring clinician to know all of this without reviewing the entire medical record including looking at previous OASIS assessments. This is burdensome and time consuming to have to review an entire episode to make this determination. Additionally, previous instructions did not allow a "look-back" on OASIS – are those instructions no longer valid?

Concern: **M2020** Management of Oral Medications
Suggestion for Change: 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. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?
Rationale: The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with and ability to take prescription medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all prescribed medications (including oral) when assessing a change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.

Concern: **M2110** Types and Sources of Assistance Matrix

Suggestion for Change: Clarify how to answer this question. For example, in item a, what if the patient can do some of the tasks and not others? If they need help, does frequency impact the patient?
Rationale: Lack of direction will result in inconsistent and unreliable data.

Other general comments and concerns:
We are concerned that there were only 11 pilot agencies. This is not statistically significant. There are over 9,000 Medicare-certified providers. We suggest pilot studies on a much larger scale in order determine the feasibility and usefulness of the proposed OASIS changes.

Please also clarify what previous instructions still apply or no longer apply (i.e.: majority of the time, day of assessment etc.)

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient in its current form and will become increasingly exhausting for the patient as all of the other assessments are added. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other home care changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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 be beneficial for national benchmarking.

Please carefully consider our concerns before proceeding with the plan to change the OASIS as proposed.

Sincerely,

SANFORD HOME CARE CANBY
112 ST OLAF AVE
CANBY, MN 56220