PUBLIC SUBMISSION

As of: January 23, 2009
Received: January 13, 2009
Status: Posted
Posted: January 23, 2009
Category: Government - Local
Tracking No. 8082ca93
Comments Due: January 13, 2009
Submission Type: Paper

Docket: CMS-2008-0141
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)

Comment On: CMS-2008-0141-0001
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)

Document: CMS-2008-0141-0130
Public Comment

Submitter Information

Name: Lindi Fink
Address:
Fremont, OH, 43420
Organization: Sandusky County Health Department

General Comment

Please see the attachments

Attachments

CMS-2008-0141-0130: Public Comment

Sandusky County Department of Public Health

"Serving Fremont, Clyde and All of Rural Sandusky County"

David G. Pollick, MA and Ed
Health Commissioner

January 9, 2009

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

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: **MO102** 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 to 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?

General Offices and Clinics
2000 Countryside Drive
Fremont, Ohio 43420
(419) 334-6377
FAX (419) 334-6380

www.sandusky cohd.org

Home Care Programs
2000 Countryside Drive
Fremont, Ohio 43420
(419) 334-6191

***Concern*: M1014** Medical or Treatment Regimen Change
***Suggestion for Change*:** Eliminate this item
Rationale: This information is collected in other MO 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 places 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 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**
Suggestions 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 in 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 would 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 would 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 would 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 to 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. 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 "contact" – 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 stuff? 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 on 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,

Lindi Finke, RN
Home Health Supervisor
Sandusky County Health Department
2000 Countryside Drive
Fremont, Ohio 43420

PUBLIC SUBMISSION

As of: January 23, 2009
Received: January 13, 2009
Status: Posted
Posted: January 23, 2009
Tracking No. 8082cac6
Comments Due: January 13, 2009
Submission Type: Paper

Docket: CMS-2008-0141
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)

Comment On: CMS-2008-0141-0001
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)

Document: CMS-2008-0141-0131
Public Comment

Submitter Information

General Comment

Please see the attachments

Attachments

CMS-2008-0141-0131: Public Comment

01-13-09

The revised OASIS due to be implemented 01/2010 has been reviewed by both clinicians and management at our facility and these are our general impressions. On the whole, this new assessment tool appears to be a marriage between the care plan and OASIS: information more appropriate for the care plan is being duplicated here, and certain questions are aimed specifically at the accountability of the care plan, which seems inappropriate for an assessment tool. More information on plans and interventions are included that, although possibly helpful to a system like Home Health Compare, will be cumbersome for providers to document (again), and in several cases these "questions", (actually more like directives), are putting the burden of action on home health providers when it more accurately belongs in the physician's scope of responsibility. Specifics will be briefly addressed below.

Several positive clarifications have been added to this revised form and they deserve mention:

1) M1032, M1034: Frailty Indicators and Stability Prognosis are clearer and more comprehensive than previous questions,(MO260, 270, 280)
2) M1220: Understanding of Verbal Content, separates this question from the hearing question (MO400)
3) M1302: Risk of Developing Pressure Ulcers is a good addition to the assessment tool
4) M1308-1310: a clearer way of staging pressure ulcers
5) M1500:Symptoms of Heart Failure, good addition to assessment
6) M1615: Urinary Incontinence, addition of stress incontinence
7) M1350: Skin lesion, there are many such skin lesions requiring assessment and/or care that are not reported on the current assessment tool
8) M1880,1890,1920,- Changes in ability, a clearer way to present this than the "prior" box
9) M2110: a more comprehensive caregiver assessment, but perhaps too complex to be easily understood by clinicians

The portions of the OASIS 10 we take issue with mostly pertain to questions that touch more on Quality Assurance, (eg., checking whether items are on Care Plan) or checking on interventions that fall outside the home care provider's scope and more rightfully are a physician's responsibility. Here is a detailed list:

1) M0104: Physician referral date, not appropriate for OASIS, more QA
2) M1038,1040,1050,1055: Flu and Pneumovax, these are PCP issues, not Home Care providers, although education is often provided upon patient request
3) M1242,1244, 1246: once again, these are QA questions, the pain assessment is already provided in the current OASIS, so a question asking whether the assessment was done or not is redundant, and pain management plans belong in the care plan and the notes
4) M1304, M1306: same issue, QA questions concerning prevention and management of pressure ulcers do not belong in the SOC OASIS
5) M1360,1365: Diabetic foot care, also belongs in plan of care or ongoing notes

6) M1510: Heart Failure Follow-Up, another question for tracking care as opposed to assessing it
7) M1730,1734, 1736: Depression, the implementation of a depression screening tool could be a useful addition to an initial assessment, however, most providers are untrained in behavioral health and it is inappropriate to expect them to develop a care plan upon initial assessment, and again, it is more of a QA issue
8) M1930,1940,1945: Fall Risk, this assessment is already including in OASIS SOC, so 1930 is redundant and the other questions again are QA and inappropriate for an assessment
9) M2000, 2002,2004,2010,2015: Medications, only an RN is qualified to answer 2000, the other questions are again about tracking care, not assessing the pt.'s level of need

We thank you in advance for considering these opinions. We strongly believe that this new tool is not only unwieldy but also inappropriate in its emphasis on intervention

Sincerely,
Ellen Swicegood, Administrator, PMS HomeCare/Hospice
Deirdre Heightchew, RN Clinical Supervisor, PMS HomeCare/Hospice
Mark Matthiessen, RN, PMS HomeCare/Hospice
Patti Wood, RN, PMS HomeCare/Hospice

Mark Matthiessen, R.N., BSN, MA

PUBLIC SUBMISSION

As of: January 23, 2009
Received: January 13, 2009
Status: Posted
Posted: January 23, 2009
Category: Hospital - HPA35
Tracking No. 8082cad0
Comments Due: January 13, 2009
Submission Type: Paper

Docket: CMS-2008-0141
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)

Comment On: CMS-2008-0141-0001
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)

Document: CMS-2008-0141-0132
Public Comment

Submitter Information

Name: Rhonda DuVall
Address:
Atlantic, IA, 50022
Organization: Cass County Memorial Hospital

General Comment

Please see the attachments

Attachments

CMS-2008-0141-0132: Public Comment

Oasis C-1 Comments Burden of Collection concerns:

1. I do not even know how to estimate the time to collect the proposed Oasis C-1 data but it will be significantly increased because of the following:

A. Intake Process: MO 1010 & MO 1012 Obtaining the information on Inpatient diagnosis & Procedures then coding them will increase the intake process for us by a min of 20-30 min if we can the complete documentation from our discharge planners. I see much of that data will be duplication o MO 1016.

B. MO138 Guidelines for physician Notification. If these are to be client specific I have a hard time seeing how we will get our Physicians to give their input in a timely manor. I see doctors giving very broad ranges to lessen the burden of communication from us.

C. Process questions: Many of the questions read something like this. "Since the previous OASIS assessment was the patient's physician (or primary care practioner) contacted with in on calendar day to resolve clinically significant medication issues , including reconciliation." The amount of chart research needing to be done for the assessing clinician to give an accurate response will be a heavy burden. I estimate with out clinical documentation system it would take 1 hour prior to going out on a recert or discharge to know if these things were actually done or not. (There are 11 such questions if you include the pneumonia and flu shot questions)

D. Like wise M1500 and M1510 on Heart Failures will require chart research to answer.

E. M1830 Bathing question response 0 is CMS going to change their directive on this question. Currently we are told to disregard the second have of the response " including getting in and out of tub/shower" I believe it should be excluded or develop a separate tub/shower transfer question. As a patient could be completely independent with the shower but not be able to get in and out independently and thus we would not be able to capture the improvement that was made with the actual showering process.

F. Change in Mobility(M1880)/self care(M1890). These are subjective and do not measure anything. Improvement can be captured in the ADL questions.

G. Management of Oral medications M2020 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.

H. M2110 Question and agencies liability when we state that a patient requires assistance to safely compete any of the task listed in a-g and the patient refuses to get assistance.

Thanks for your attention to this very timely and potentially highly impactful concerns.

Rhonda DuVall RN
Rhonda DuVall
Clinical Manager
Cass County Memorial Hospital
Home Care/Hospice
1500 East Tenth St
Atlantic, IA 50022
phone (712) 243-8006 ext 3378
fax (712) 243-7439
duvrr@casshealth.org

PUBLIC SUBMISSION

As of: January 23, 2009
Received: January 13, 2009
Status: Posted
Posted: January 23, 2009
Category: Home Health Facility - HPA25
Tracking No. 8082cad6
Comments Due: January 13, 2009
Submission Type: Paper

Docket: CMS-2008-0141
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)

Comment On: CMS-2008-0141-0001
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)

Document: CMS-2008-0141-0133
Public Comment

Submitter Information

Name: Kim Lindy
Address:
Fergus Falls, MN, 56538
Organization: New Dimensions Home Health Care

General Comment

Please see the attachments

Attachments

CMS-2008-0141-0133: Public Comment

HOME HEALTH CARE, P.O. Box 415, Fergus Falls, MN 56538-0415, Phone (218) 739-5856

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

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,

Kim Hadley RN, DON