PUBLIC SUBMISSION

As of: January 20, 2009 Received: January 13, 2009 Status: Posted

Posted: January 15, 2009

Category: Health Care Professional/Association - Nurse

Tracking No. 8081cfbf

Comments Due: January 13, 2009

Submission Type: Web

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-2008-0141-0096

Submitter Information

Name: Pamela Gibson

Address:

Norwood, MA, 02062

Organization: Caritas Home Care

General Comment

I do like the way the new OASIS C M 1010 and M 1016 has been upgraded to accept ICD 10 CM codes, but there is also an increased number of slots, to six, for inpatient procedure codes in M 1012. The information about Inpatient procedures will be difficult to obtain from the referring sources.

M1034 is a nice addition for frality factors but I am not sure what the time frame for measurement is. I get the idea that the time frame is "within the past year" by some of the answer choices. I would like the time frame worded into the question.

M 1312 - the measurement of pressure ulcers has not taken into account that the pressure ulcer being measured may be a differnet pressure ulcer from episode to episode. Also a standard means of measuring needs to be established.

PUBLIC SUBMISSION

As of: January 20, 2009 Received: January 13, 2009

Status: Posted

Posted: January 15, 2009

Category: Health Care Provider/Association - Home Health Facility

Tracking No. 8081cfce

Comments Due: January 13, 2009

Submission Type: Web

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-2008-0141-0097

MΑ

Submitter Information

Name: Andrea De Sosa

Address:

Shirley, MA, 01464

Organization: Nashoba Nursing Service & Hospice

General Comment

See attached additional comments. Thanks

PUBLIC SUBMISSION

As of: January 20, 2009 Received: January 13, 2009 Status: Posted

Posted: January 15, 2009

Category: Health Care Provider/Association - Home Health Facility

Tracking No. 8081d06e

Comments Due: January 13, 2009

Submission Type: Web

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-2008-0141-0098

MN

Submitter Information

Name: Darlene Tuma

Address:

LeCenter, MN, 56057

Organization: LeSueur County Public Health

General Comment

Please review the following concerns thank you Darlene Tuma

Attachments

CMS-2008-0141-0098.1: MN CMS-2008-0141-0098.2: MN



Le Sueur County Public Health

88 South Park Avenue, Le Center, Minnesota 56057

Phone 507-357-8246

Fax 507-357-4223



Le Sueur County

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 fraility 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 <u>prescription</u> medications (not <u>all</u> 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 <u>prescription</u> medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all <u>prescribed</u> 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 <u>frequency</u> 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, Darlene Tuma, RN, PHN



Le Sueur County Public Health

Le Sueur County

88 South Park Avenue, Le Center, Minnesota 56057
Phone 507-357-8246
• Fax 507-357-4223



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 fraility 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 <u>prescription</u> medications (not <u>all</u> 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 <u>prescription</u> medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all <u>prescribed</u> 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 <u>frequency</u> 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, Darlene Tuma, RN, PHN

PUBLIC SUBMISSION

As of: January 20, 2009 Received: January 13, 2009

Status: Posted

Posted: January 15, 2009 Category: Association - Other Tracking No. 8081d07b

Comments Due: January 13, 2009

Submission Type: Web

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-2008-0141-0099

Submitter Information

Name: Katie Maslow

Address:

Washington, DC, 20004

Organization: Alzheimer's Association

General Comment

The Alzheimer's Association recommends that CMS revise the wording in the "Behaviors" item (M1740) to correct errors and reduce negative implications about people with cognitive impairment.

The Alzheimer's Association also recommends that CMS include the "Types and Sources of Assistance" grid in the OASIS data set for discharge assessments.

Attachments

CMS-2008-0141-0099.1: DC

alzheimer's Po association

January 13, 2009

Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Quality Measurement and Health Assessment Group
7500 Security Blvd.,
Baltimore, MD

Re: Medicare and Medicaid Programs OASIS Collection Requirements

The Alzheimer's Association appreciates the opportunity to comment on the proposed modifications to the OASIS data set that home health agencies are required to collect in order to participate in the Medicare program. The Alzheimer's Association is the premier source of information and support for as many as 5.2 million Americans with Alzheimer's disease. Data provided to the Alzheimer's Association from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse show that in 2004, 24.9 percent of all Medicare home health care beneficiaries had Alzheimer's disease or other dementias. This large proportion explains our strong interest in the OASIS data set and the potential of modifications to the data set to impact the care received by large numbers of people with Alzheimer's disease and other dementias.

Behaviors Demonstrated at Least Once a Week (Reported or Observed): (M1740)

This item has not been proposed for modification, but CMS should take this opportunity to correct two problems with the item that convey erroneous and negative assumptions about people with cognitive impairments.

1. Although the title of the item refers to behaviors, the first sub-item is "memory deficit," and the second sub-item is "impaired decision-making." These are cognitive symptoms, not behaviors. Sub-items 3, 4, and 5 are behavioral symptoms that occur for some people with cognitive impairment, including some people with Alzheimer's disease and other dementias at some times in the course of their illness, and also occur for some people who do not have cognitive impairment. Sub-item 6 lists psychiatric symptoms that occur for some people with cognitive impairment, including some people with Alzheimer's disease and other dementias at some times in the course of their illness, and may also occur for people who do not have cognitive impairment. Listing these cognitive, behavioral, and psychiatric symptoms under the same item, titled "behaviors," conveys the assumption that these symptoms are all behaviors, that they are interrelated, and that it is reasonable to expect that individuals who have cognitive impairments will have the listed behavioral and psychiatric symptoms while those

who do not have cognitive impairment will not have behavioral and psychiatric symptoms.

2. Sub-items 3, 4, and 5 use wording that conveys very negative impressions about individuals with behavioral symptoms. The wording combines terms that describe actual behaviors objectively, e.g., "yelling" and "hits self," with terms that describe the intention of the individual who exhibits the behavior, e.g., "threatening" and "combative," and terms that describe the impact of the behavior on others, e.g., "disruptive." This combination of terms implies that behavioral symptoms are intended by the individual to have negative effects on others and that they do have such negative effects. Neither of these implications is correct. In all care settings, and certainly in the home, it is important to identify behaviors objectively, figure out why they are happening, and determine whether they are troublesome to others. In the home, it is primarily family members who might or might not be troubled by particular behaviors, and many studies have shown that when family members receive counseling about how to identify behaviors objectively, determine what causes the behaviors, and decide whether the behaviors bother them, they can frequently help to reduce the behaviors and are very often less bothered by the behaviors. The current wording of the sub-items is not consistent with this more constructive and effective approach to behavioral symptoms.

The Alzheimer's Association requests and recommends that CMS take this opportunity of modifications to the OASIS data set to correct these problems. One option to clarify that different kinds of symptoms are included in the item would be to rename the item to be something like, "Cognitive, behavioral, and psychiatric symptom." Another option would be to separate the sub-items into three separate items.

In developing the latest version of the Minimum Data Set (MDS 3.0), CMS and its contractors and advisors have attempted to revise the wording of the "Behavioral Symptoms" item (E200). This has been a difficult process, and CMS is to be commended for its support of the effort and attention to the concerns of advocates and others about the wording of the item. No wording is perfect, of course, but we recommend that CMS review the wording in the MDS 3.0 item when thinking about wording for OASIS. The MDS 3.0 wording separates the description of behavioral symptoms from the impact of the symptoms on the resident and others and eliminates terms that suggest that the behavioral symptoms express negative intentions of the individual who exhibits the behavior. We would be happy to work with CMS and others to achieve this result in the OASIS data set.

Inclusion of the Types and Sources of Assistance Grid in the OASIS Data Set

The Alzheimer's Association urges CMS to include this grid, which identifies specific types of assistance needed by the beneficiary and the available sources of that assistance, in the OASIS data set for <u>discharge</u> assessments. The grid is part of the agency's CARE

Tool and hopefully will eventually be required in discharges of Medicare beneficiaries from hospitals and four post-acute care settings, including Medicare home health care. Use of the grid by Medicare home health agencies will help to improve transition outcomes for Medicare home health beneficiaries by explicitly identifying the types of assistance they need and who, if anyone, is available to provide that assistance. Situations in which no one is available or capable of providing the needed assistance or the family or other informal caregiver needs training to provide the needed assistance will be identified, and it will be possible to at least try to develop options to address these situations.

Thank you for your consideration of these comments. Please feel free to contact me at (202) 638-8667 or katie.maslow@alz.org, to further discuss these matters.

Sincerely,

Katie Maslow Associate Director for Quality Care Advocacy Alzheimer's Association

PUBLIC SUBMISSION

As of: January 20, 2009 Received: January 13, 2009

Status: Posted

Posted: January 15, 2009

Category: Private Industry - Device

Tracking No. 8081d28c

Comments Due: January 13, 2009

Submission Type: Web

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-2008-0141-0100

N:

Submitter Information

Name: Joseph Rolley

Address:

Skillman, NJ, 08558

Organization: ConvaTec Inc.

General Comment

ConvaTec is a leading global manufacturer of ostomy supplies, advanced wound dressings, fecal containment systems and diabetic infusion supplies. We welcome the opportunity to provide the following comments on OASIS C.

Item M1630: Ostomy for Bowel Elimination.

Comment:

We believe it is important to include urinary ostomies as part of this item. Ostomies can be created from the intestines to form fecal stomas, but they can also be created from the urinary system to form urinary stomas. Urostomies account for about 25% of all ostomy types. As such, they will be encountered in home health settings. Since home care agencies are required to provide training and the required supplies for people with ostomies regardless of ostomy type, it is important to include urostomies in this item. We thus recommend adding the words "or urinary" wherever the word "bowei" appears in this item descriptor and subsequent check boxes.

ConvaTec also expresses its support for the following comments submitted under separate cover by the National Pressure Ulcer Advisory Panel (NPUAP).

(M1310) Current Number of Unhealed (non-epithelialized) Pressure Ulcers at Each Stage d.1 Unstageable: Suspected deep tissue injury in evolution

Comment:

We recommend the following additional wording be included to assist in defining Suspected Deep Tissue Injury:

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

(M1314) Pressure Ulcer Width: Width	of the	same	pressure	ulcer, grea	atest
width measured at right angles to ler	igth []	1_		(cm)	

Comment:

We recommend two additional questions for this section:

- 1. Is there evidence of undermining of the wound?
- 2. Is there evidence of wound tunneling?
- a. If yes, indicate tunneling length

(M1326) Pressure Ulcer Intervention: Are moisture retentive dressings specified on the physician-ordered plan of care?

Comment:

The term "moisture retentive dressings" needs to be further defined in order to differentiate from saline soaked gauze which is often incorrectly thought to be moisture retentive. Also, exudate management dressings such as foam and alginate dressings are often not thought to be moisture retentive as they wick excess moisture away from wounds. These dressing categories may be appropriate nonetheless for certain wound types as they maintain a moist wound environment.

We recommend the following wording:

Are dressings supportive of the principles of moist wound healing* on the physician-ordered plan of care? (*Dressings that retain enough moisture to stimulate healing yet not cause maceration or irritation.)

(M1350) Does this patient have a Skin Lesion or Open Wound, excluding bowel ostomy, other than those described above that is receiving assessment and/or intervention by the home health agency?

Comment:

We recommend the following wording for clarity:

Does this patient have a Skin Lesion or Open Wound, other than pressure ulcer (s), stasis ulcer(s) or surgical wound(s) that require assessment and/or intervention by the home health agency? (Excludes ostomy for bowel/bladder elimination.)

(M1360) Diabetic Foot Care Plan: Does the physician-ordered plan of care include regular monitoring for the presence of skin lesions on the lower extremities and patient education on proper foot care?

Comment:

We recommend the addition of the word "caregiver" following "patient". The new wording would be as follows:

Does the physician-ordered plan of care include regular monitoring for the presence of skin lesions on the lower extremities and patient/caregiver education on proper foot care?

(M1365) Diabetic Foot Care Plan Follow-up: Since the previous OASIS assessment, was the physician-ordered plan of care regarding regular monitoring for the presence of lesions on the lower extremities and patient education on proper foot care followed?

Comment:

We recommend the addition of the word "caregiver" following "patient". The new wording would be as follows:

Since the previous OASIS assessment, was the physician-ordered plan of care regarding regular monitoring for the presence of lesions on the lower extremities and patient/caregiver education on proper foot care followed?