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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-2008-0141-0071
MN

Submitter Information

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General Comment

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January 13, 2008

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,

Cindy Carruth
Registered Nurse
Swift County Benson Hospital Home Health Care

PUBLIC SUBMISSION

As of: January 16, 2009
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Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

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-2008-0141-0072
ME

Submitter Information

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ME, 04937
Organization: River Valley HomeCare

General Comment

Because the assessments and interventions are included in the OASIS, will it be mandatory for every agency to develop these? What level of detail will surveyors and intermediaries expect to see for these interventions?

Why must these interventions be on the physician-ordered plan of care? Many interventions, such as those to prevent falls or pressure ulcers, do not require physician orders and do not need to be on the plan of care. Because those interventions are preventive in nature, they would not be reasonable and necessary per Medicare's coverage criteria.

Why are these data elements included in the OASIS? There is little reason to debate that formal assessments and standardized interventions can be valuable. However, OASIS should not be the driving factor behind best practice initiatives—which will be the end result when a question asks whether something is planned and whether it was done. It is up to the agency to determine which best practices it will implement based on its patients and operations. Then OASIS can measure the results, the outcomes of care. Will CMS formulate standard best practices for use by all agencies? Given the population and culture diversity this seems unrealistic.

Will the clinician who updates the assessment know whether these interventions were implemented? Will an agency have to defend itself every time an assessment is not completed or interventions are not implemented?

Will CMS provide education and training for referral sources i.e. hospitals, physicians and Long Term Care Facilities as it relates to the data collection requirements at time of intake/referral/ROC?

Attachments

CMS-2008-0141-0072.1: ME

RIVER VALLEY HOMECARE
A part of the Eastern Maine HomeCare Family

#72

January 12, 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: 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 apatient'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 bench marking.

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

Sincerely,

Roxanne E. Smith RN, Staff Education/QI Assistant
Eastern Maine HomeCare
Representing; River Valley HomeCare

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PUBLIC SUBMISSION

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Submission Type: Web

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

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-2008-0141-0073
IA

Submitter Information

Name: Deanne Robbins
Address:
Dubuque, IA, 52001
Organization: The Finley Hospital Home Healthcare

General Comment

01/12/09

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Comments on OASIS C version. CMS -R- 245 OMB #0938-0760

Comments on the proposed changes for the OASIC-C document.

The numbering system: Clinicians are familiar with the M0's and would have less of a learning curve if the numbers were modified rather than totally changed. It would also be consistent with previous changes that have been made, such as M0825 to M0826 and M0245 to M0246.

M1038 Guidelines for physician notification: Additional burden of nurse and physician office time to get parameters. Also, what is the use for this in the outcome process? There is no comparative measure at DC.

M1045 Flu Vaccine: Data will not be captured for all patients on service ongoing as this information is not gathered on the Follow Up Oasis. It will be a burden to capture this information as the physician office will need to be contacted if patient does not have the information. For patients with extended episodes, it will be an added burden to capture this info at discharge (example: flu vaccine was given in October and patient discharged in February). Added documentation systems will need to be put in place to log this for ready capture of data. At this time software does not capture this data and it will be manual retrieval.

M1050 Pneumonia Vaccine: It would be a burden for both nursing and physician office staff to locate the information for a vaccine that is not given on an annual basis. A lot of patients are not eligible for the vaccine and it seems a burden to have to address it for all patients. Will need clear guidelines on the suggested frequency of receiving the pneumonia vaccine.

M1100 Pt living situations: Suggest separating the living situations and availability

of help into two questions instead of one. It is confusing having them combined.

M0440: Does the patient have a skin lesion or open wound? This question was dropped but does not appear as dropped in the comparison chart. Could the question be reintroduced and reworded to ask if any other wound is being treated that is not surgical, pressure or stasis? Many patients have wounds that are significant that should factor into the risk adjustment, such as cellulites, trauma etc. If that is included, clarify the definition to remove minor changes such as old scars, bruises, moles, etc.

M1310. Current number of unhealed pressure ulcers:
Add a descriptor for currently unstageable, but previous observed or documented Stage III or IV pressure ulcers. The rules already state: once a stage III or IV pressure ulcer, always a pressure ulcer. Adding this measure would allow the agency to get credit for treating this ulcer financially. When the wound is debrided later in the episode or the non removable dressing is removed the agency must still care for the ulcer, but the non routine supply reimbursement is not available if it is not stageable at the time of the OASIS.

M1342: Status of most problematic (observable) surgical wound:
Need clarification of time frame for surgery for answer 0 (re-epitheliazed or healed) in order to avoid marking all old surgical scars.

M1360 Diabetic foot care: Need to separate the question as it has 2 parts. There may be a plan for monitoring presence of skin lesions but not patient education. How is it answered if you have one but not the other? Either make 2 questions or take it off the Oasis.

M1365 Diabetic foot care plan follow up: Three issues:
This is a combined, 2 part question which would not give clear outcome data.
How would the question be answered if monitoring was done but patient education was not done or not indicated?
Locating this information in the record would cause an undue time burden in order to accurately answer the question.
One or both of these interventions may have been done at SOC and if patient is open multiple episodes, patient education may no longer be applicable. Patient education is basic skilled nursing and should be completed. Suggestion: Take the patient education out of the process question but leave the ongoing monitoring in.

M1500 Symptoms of Heart Failure: It would be very difficult and time consuming to research this information in the medical record in order to report accurately. It would involve going through every note. Also, these symptoms do not always mean an exacerbation of heart failure and there may be interpretation variations from clinicians. The complexity of this would require setting up a separate tracking sheet for each heart failure patient in advance – software does not have this option at this time.

M1510 Heart Failure follow up. See comments for M1500 for the burden for capturing this information. Could this just be an outcome measure captured in M2310 and M2430 for those who do seek emergent care/ hospitalization?

M1850. Transferring: Suggestion: Add a response between 1 and 2 that clarifies the need for both human assistance and an assistive device. There has been a need to clarify the OR statement in question 1 and it is confusing to clinicians. As it stands now, on question 1, if the patient needs human assistance and an assistive device, 2 should be marked. Please clarify this question further.

M1880: Change in Mobility:
• Need to define the information in the parentheses (i.e. before the onset of the accident or illness that initiated the episode of care) – What is the maximum time frame that this can go back ?
• Add exacerbation of illness / injury in addition to onset of illness or injury
• Need an NA option. Some patients under the Medicaid benefit have not had a recent onset or exacerbation.
• OASIS is required on these chronic patients as well. As this will be primarily based on patient opinion, perhaps this could be simplified to state "in patient's opinion is prior mobility better or worse?"

M1920: change in ability to perform routine household tasks:
• Need to define the information in the parentheses (i.e. before the onset

of the accident or illness that initiated the episode of care) – What is the maximum time frame that this can go back?
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• There are too many items combined here. As this will be primarily based on patient opinion, perhaps this could be simplified to state "in patient's opinion is Prior level of functioning better or worse?"

M2000 Medications: addresses potential adverse effects/ Reactions. There are too many items in this question for measure – 7 areas of medication issues. The outcome will show follow up, but not on what issue was of concern. This one should have an option box for measures to find out what problems the patient is having at home. I would like to know what the med issues are from an outcome standpoint. All these med questions will tell us is that there was some type of a medication problem and the clinician followed up and gave instruction. I want to know what the specific problems were.

M2004: Medication Intervention. If patient is open multiple episodes and medication issue was resolved in first episode, then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent Oasis. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information. Can gathering this data be limited to Early episodes that end in TSF or DC?

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Attachments

CMS-2008-0141-0073.1: IA

#73

01/12/09

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Department of Health and Human Services
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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-2008-0141-0074
MN

Submitter Information

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Duluth, MN, 55805
Organization: St. Lukes Home Health Care

General Comment

See attached letter.

Attachments

CMS-2008-0141-0074.1: MN

#74

St. Luke's
Home Health Services
220 North 6th Avenue East
Duluth, Minnesota 55805

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

Attention: Document Identifier: CMS–R–245 (OMB# 0938–0760)

I am 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).

I support the use of OASIS in home health as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, I have the following comments/concerns 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 homecare 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 homecare is not able to start care for an extended period of time; and sometimes patients make the request to 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, the information should be obtained from the inpatient facility.
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 coding often does not occur until the hospital generates their bill. It is not realistic for

homecare clinicians to have knowledge of the coding requirements for inpatient facilities; requiring them to enter this information with insufficient or incomplete data from referral sources will result in errors in a patient's medical record.

Concern: **M01014 Medical or Treatment Regiment 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 Quality Improvement Organizations (QIOs) as included on the Hospitalization Risk Assessment form at www.homehealthquality.org website. The presence of high risk chronic diagnoses place a patient at high risk for rehospitalization and speaks to the frailty of their overall status. These include the diagnoses of Congestive Heart Failure (CHF), Diabetes, Chronic Obstructive Pulmonary Disease (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 homecare population and are contributing factors to the frailty of the patients served. Eliminate this item from Start of Care assessment (SOC).
Rationale: At SOC, providers will not have historical data on vital 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 homecare 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 valueless 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. Benchmarking will be difficult and inconsistent if agencies use different standardized assessment tools that may vary on what indicates "severe 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, such as 0-10 scale and Wong-Baker Faces pain scale, 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. Please clarify how this question should be answered if I use a standardized tool and an evaluation of clinical factors to assess.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? Is it realistic to get all of this done in the 5-day time frame? Consultation with staff outside the homecare agency, for example a wound ostomy clinic, is often necessary to gather all pertinent clinical information.

***Concern:* M1312 - M1314 Pressure Ulcer Length & Width**
***Suggestion for Change*:** Eliminate both.
***Rationale*:** Requiring length and width of the ulcer 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 or a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include 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 WOCN guidelines.

***Concern:* M1320 Status of Most Problematic Pressure Ulcer**
***Suggestion for Change*:** Clarify that this pertains only to stages 3 and 4 pressure ulcers.
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 may be in the homecare 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.

***Concern:* M1350 Skin Lesion or Open Wound**
***Suggestion for Change*:** Clarify that Bowel ostomy is the only ostomy that is excluded when answering this question.
Rationale: Previous OASIS instructions were to exclude ALL ostomies, not just bowel ostomy.

M1328 Pressure Ulcer Intervention
***Suggestion for Change*:** Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is not the homecare 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 standardized 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 homecare 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 homecare 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, 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 ADLs. It is unlikely they will recover the abilities and show improvement during a Medicare episode. 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. 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 comments/concerns:
I am concerned that there were only 11 pilot agencies. This is not statistically significant. There are over 9,000 Medicare-certified providers. I suggest pilot studies on a much larger scale in order to 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 as is and will become increasingly exhausting for the patient as all of the other assessments are added. I know of instances where patients have decided that it just wasn't worth having homecare during the initial start of care visit due to the burdensome paperwork involved. 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 changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Several items on the proposed OASIS-C document would require the clinician to review the medical record documentation for the entire previous episode of care, which would be extremely time consuming. 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 expert bodies. This will prevent the need to duplicate documentation in more than one area of the medical 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.

PUBLIC SUBMISSION

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

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-2008-0141-0075
ME

Submitter Information

Name: Roxanne Smith
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ME, 04330
Organization: Bangor Area Visiting Nurses

General Comment

Because the assessments and interventions are included in the OASIS, will it be mandatory for every agency to develop these? What level of detail will surveyors and intermediaries expect to see for these interventions?

Why must these interventions be on the physician-ordered plan of care? Many interventions, such as those to prevent falls or pressure ulcers, do not require physician orders and do not need to be on the plan of care. Because those interventions are preventive in nature, they would not be reasonable and necessary per Medicare's coverage criteria.

Why are these data elements included in the OASIS? There is little reason to debate that formal assessments and standardized interventions can be valuable. However, OASIS should not be the driving factor behind best practice initiatives—which will be the end result when a question asks whether something is planned and whether it was done. It is up to the agency to determine which best practices it will implement based on its patients and operations. Then OASIS can measure the results, the outcomes of care. Will CMS formulate standard best practices for use by all agencies? Given the population and culture diversity this seems unrealistic.

Will the clinician who updates the assessment know whether these interventions were implemented? Will an agency have to defend itself every time an assessment is not completed or interventions are not implemented?

Will CMS provide education and training for referral sources i.e. hospitals, physicians and Long Term Care Facilities as it relates to the data collection requirements at time of intake/referral/ROC?
While the "Supporting Statement for Paperwork Reduction Act Submissions" states otherwise, we believe the OASIS-C proposal will increase the paperwork burden for home health agencies. Of particular concern are the following:

1. The number of items in the OASIS data set is increasing.

The number of OASIS items at the Start of Care is increasing from 76 to 105 (38 percent) and at Resumption of Care from 61 to 90 (48 percent).

2. The number of new items exceeds the number of items eliminated.
The Supporting Statement claims OASIS-C will have "no net burden impact" and yet the data shows otherwise. The 45 items that were added is more than half the number than eliminated.

3. Burden is additionally increased with the process items that were added to an outcomes data set.
The OASIS data set was designed to be home health setting–specific and based on outcomes. It now appears that CMS is moving toward a Post Acute Care data set, which includes process items. The impact is an increased burden of data collection on home health providers.

4. The additional data items will not be used for the Prospective Payment System or the Home Health Compare.
The rationale for collecting and reporting OASIS data is for quality monitoring and reimbursement under the Prospective Payment System (PPS). Of the 130 items in OASIS-C, only about twenty-six items are used for PPS and Home Health Compare. While the current OASIS B1 data set contains many items that are not used for either purpose, the proposed OASIS-C has exacerbated this problem by adding additional elements, most prominently, the process items. It seems unreasonable for CMS to add additional items, particularly items not used for either of the two core purposes.

Before proceeding with implementing OASIS-C, we respectfully request that CMS further field test the proposed instrument and collect accurate data on the burden of the proposed changes.

Attachments

CMS-2008-0141-0075.1: ME.

BANGOR AREA VISITING NURSES

A part of the Eastern Maine HomeCare Family

#75

January 12, 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: 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 apatient'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.

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Suggestion for Change: Do not require this at SOC

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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
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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
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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
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Sincerely,

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