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-2008-0141-0002
PA

Submitter Information

Name: Terri Cullen
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Drexel hill, PA, 19064
Organization: CKHS HOME CARE AND HOSPICE

General Comment

The initial purpose of the OASIS data collection was to identify a patient's condition at a certain point in time during the continuum of care, evaluate their individual needs, develop an intervention plan and hopefully improve their outcome. I believe that we are now mixing Best Practice Protocols and Standards of Care into an already cumbersome evaluation tool. This OASIS data collection cannot stand alone. I think nurses as professionals need to refer to Best Practice Gidelines/Protocols to aid them in developing individual careplans, but I do not think these additional questions other than those related to preventive health(flu and pneumonia vaccine) questions belong in an initial assessment. Standards of Care is an established set of practices evident in both daily practice and documented in clinical findings.

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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-2008-0141-0003
TX

Submitter Information

Name: Jeanette Morris
Address:
Mt. Pleasant, TX, 75456
Organization: Cypress Home Care, Inc.

General Comment

If the OASIS is being updated and changed and new instruction being added, with M1810 and M1820 dressing of upper and lower body. If upper dressing pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps are not truly being considered to answer this question then they need to be removed. As I understand the instruction for this question now if the patient wears pullover clothes or clothes without buttons or snaps they are supposed to be scored as 0 or 1 that they are able to dress. I see this patient as being a 2 or 3 because if they are wearing pullover clothes or no buttons, snaps, or zippers they have trouble with these objects. If buttons, snaps, or zippers are not to be considered when answering these questions, why are they not being removed from the question. I have they same concerns with garments in lower body dressing.

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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-2008-0141-0004
KY

Submitter Information

Name: Karen Jackson
Address:
Murray, KY, 42071
Organization: Intrepid USA Healthcare Services - Murray

General Comment

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

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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-2008-0141-0005
LA

Submitter Information

Name: Ron Devillier
Address:
Baton Rouge, LA, 70809
Organization: Lewis, Inc.

General Comment

The new placement of M0903 and M0906 is confusing. Upon review of the proposed OASIS-C data set, we noticed that M0903 and M0906 have not been renumbered in the new question set. In certain instances, these questions are skipped in the beginning of the assessment only to be jumped back to when answering M2400 - M2440.

In prior data sets skip logic never jumped backwards in the assessment. We would like to propose renumbering M0903 and M0906 so they are at the end of the assessment (after M2300 – M2440) since all paths for transfer or discharge end with them.

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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-2008-0141-0006
SD

Submitter Information

Name: Charleen Weismantel
Address:
Watertown, SD, 57201
Organization: Prairie Lakes Health Care System

General Comment

) M01310: Please modify this question so the clinician does not have to enter previously submitted data. It currently appears that the clinician would have to go back to the SOC OASIS and 'discover' what had been entered on admission and then re-enter that data into the DC OASIS. This would require a mostly 'virtual employee' group to access previously submitted data...CMS should link the data 'behind the scenes' if they feel the data is reflective of quality. HOWEVER, some patients are on HH for months (and in rare cases years) and the admission data may not link to the discharge data at all.
2) The admission and discharge OASIS -C data would take more time. The discharge assessment, in particular, is more time consuming. The reimbursement should be modified to reflect the additional time requried.

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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-2008-0141-0007
MN

Submitter Information

Address:
MN, 56308

General Comment

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
Page 2 of 5
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
Page 3 of 5
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
Page 4 of 5
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?
Page 5 of 5
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,

PUBLIC SUBMISSION

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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-2008-0141-0008
MN

Submitter Information

Name: Deb Klein
Address:
Buffalo, MN, 55313
Organization: Guardian Angels Home Care

General Comment

See Attached

Attachments

CMS-2008-0141-0008.1: MN

#8

[Letterhead]

[Date]

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 <u>all</u> 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,

[Person's name, title]
[Organization Name, Address]

PUBLIC SUBMISSION

As of: January 15, 2009
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Posted: January 05, 2009
Category: Home Health Facility - HPA25
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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-2008-0141-0009
MN

Submitter Information

Name: Deborah Foster
Address:
Maplewood, MN, 55109
Organization: HealthStar Home Health

General Comment

Page 4: M1000 #4 why state: Other Nursing home"?
M1005 If patient was not discharged from inpatient facility by marking # 5 in M1000 then do we answer UK which really is not accurate as an answer? There should be a NA category simi;ar to M1018

Page 5: M1018: The intent of this INPATIENT FACILIYT question means any inpatient environment not just Acute Hospital correct?
Also isn't #7 the same as UK in this grouping?

Page6: M1020 Column # (optional) text needs to have the first "reported" removed for the sentence to make sense.

Page 7: M1030 Should specifiy in the title Nutritional therapies(too confusing otherwise when simply looking at the title) The other therapies is at the end.

M1032: What if the answer is #7 don't we want to know what "Other" means?

M1036: Do we want other Risk Factors such as Poor compliance with treatment plan and Multipharma?

Page 8: M1200: Do we not care about vision for folks that do not have corrective lenses?

M1210: Same with hearing appliances. Do we not care about the hearing of those without appliances.

M1220: If we answer UK, don't we want to know why their understanding can't be assessed?

Page 9: M1242: Is the intent only to address Severe Pain? That can be subjective by patient, tool used and assessor.
M1244 and M1246: Same issue as above

M1306: Under NA>>Change wording to "No pressure ulcer prevention 'necessary' in physician-ordered POC"

Page 10: M1308: Change the end of the sentence to read Stage 1, higher, or designated as "not stageable"

Page 11: M1330 and M1340 : BOLD "NOT OBSERVABLE" under #2 for clarity
M1350 What about a Ureterostomy?

M1360 and M1365: Uncapitalize Patient to read patient. and D in diabetic foot care

Page 12: M1610 #2 do we not want to reference ureterostomy here as well?

Page 13: M1620: Bowel incontince On a daily basis should read once a day if #5 is to make any sense.
M1730: Are there standardized Depression screenings tools we all should use to make this a valid apples to apples comparison?

Page 21: M2440: What if the patient is admitted to a rehab facility at discharge form Home Care?

PUBLIC SUBMISSION

As of: January 15, 2009
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Category: Health Care Professional/Association - Nurse
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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-2008-0141-0010
FL

Submitter Information

Name: Rhonda Will
Address:
Venice, FL, 34293
Organization: Fazzi Associates

General Comment

As you contemplate further changes to OASIS C, please consider moving M0230/240/246 (diagnoses) from its current position in the document to placement after M0826. I know that agencies can change the order of items when they integrate them in their comprehensive assessments, but many agencies, forms companies and software systems place the OASIS items in numerical order when setting up their forms. In the process of assessment, naming the primary and secondary diagnoses for a plan of care does not logically occur until after all the assessment data has been collected and documented. It's only at that point that a clinician can put it all together, discern the problems and begin to develop the 485/Plan of Care. As they think about they need to do for the patient, they can more clearly and accurately determine the condition and comorbidities of the patient that lead them to these decisions for services, interventions and goals for care.

In its current placement in the document, I find that clinicians are not thinking about the 485/POC when they complete this item, they are simply filling in a blank space for OASIS. When I work with clinicians I often recommend they leave M0230/240/246 until last. However, with paper and pencil, this practice can lead to forgetting to go back; and with an electronic system, sometimes it is too cumbersome to go back and complete it.

Since one of the goals of the OASIS revisions is to make the document easier to connect to care planning and to be more user friendly, I recommend you consider this placement change. I suspect that if M0230/240/246 is one of the last things completed in the assessment, we would have greater accuracy with the naming of the diagnoses, a better connection to the 485 and a reduction in the calls from the QI staff to the assessing clinician that query "Are you sure you want these diagnoses?"

PUBLIC SUBMISSION

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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-2008-0141-0011
FL

Submitter Information

Name: Rhonda Will
Address:
Venice, FL, 34293
Organization: Fazzi Associates

General Comment

I am resubmitting my comments with the tracking number of 8080fcc4. I'm not sure that the document attached correctly.

Attachments

CMS-2008-0141-0011.1: FL

#11

I generally support the use of OASIS data items as part of a comprehensive assessment tool provided the items are relevant to clinical practice and the home health industry's charge to keep patient's at home, managing their disease and/or injury to the best of their ability in the safest environment possible. OASIS items can accurately measure an agency's ability to provide effective quality care provided the items clearly define their intention, use consistent terminology and conventions and are easily and universally understood by home care clinicians. A document which requires frequent clarification and/or consultation of the source manual to make response selections diminishes the accuracy and relevance of the reports generated by the information. In this draft OASIS C document there is a notable effort to improve relevance, understanding and consistency. Based on my last 6 six years of experience concentrated on training clinicians from agencies across the country to use the tool correctly, I raise the following concerns and recommendations for your consideration.

Concern: 1020/1022/1024 Diagnosis, Severity Index and Payment Diagnosis
Suggestion for Change: Eliminate the index.
Rationale: This rating system is foreign to professional clinical practice and unique to home care and probably one of the most inaccurate items recorded. There is not an obvious or logical connection between severity rating and V-codes that describe clinical interventions and procedures. CMS guidance indicates that severity rating and sequencing are not directly related which has added to the confusion although the more "severe", unstable or symptomatic a condition is one would expect it to have a greater significance to the plan of care. In addition, the time period under consideration for application of the severity rating is not defined. Does history of rehospitalizations include the last year? Should it be different from the time period in a Falls Risk Assessment?

Concern: M1032 Frailty Indicators
Suggestion for Change: Define "unstable" vial signs and specify which vital signs are included (T, P, R, BP only?). Change response 3 to read "*recent decline in mental, emotional or behavioral status*"
Rationale: An objective description of "unstable will improve consistent selection and reduce subjective variables. Declining emotional and/or behavioral status generally carry the same risk for rehospitalizations or ability to effectively care for self safely at home.

Concern: M1036 Risk Factors
Suggestion for Change: Expand the item description. For example, "*Risk factors, either present or past, likely to affect current health status and ability to recover from this illness.*"
Rationale: When the time period under consideration for the data item is not the day of assessment, the item should contain the variable/exception for greatest accuracy and consideration for care planning and clinical interventions.

Concern M01240: Frequency of Pain

Suggestion for Change: Change item description to "*How often does* **Pain Interfere** *with the patient's activity or movement?"*
Rationale: Clinician's often report how often the patient experiences pain in this item. Clinicians admit that reading the item quickly and focusing on the bolded words **"Frequency of pain"** contributes to that incorrect response.

Concern: M1320/M1334/M1342 Status of the most problematic pressure/stasus ulcer/surgical wound
Suggestion for change: Provide an additional prompt to identify which wound is reflected in the response choice when there are multiple wounds of the same type. For example, *"If multiple pressure ulcers, provide location of the most problematic one _____."*
Rationale: As a third party reviewer, records of patients with multiple wounds of the same type rarely identify which wound is being described as the most problematic. This contributes to inaccurate outcome reporting for improvement in surgical wound status.

Concern: M01400 Short of Breath
Suggestion: Change item wording to include time period under consideration and clarify intent of item. For example "*In the last 24 hours, what level of activity has caused the patient to be* **short of breath**?"
Change "0" response to "*patient has not been short of breath with any activity or rest in the last 24 hours"*
Rationale: Clinician's often report the incorrect information in this item.
Alternate suggestion: Expand the time period under consideration for this item to include the recent past.
Rationale: For patient's with chronic respiratory or pulmonary disease, there is more clinical relevance in determining what the patient can endure and tolerate than what they are experiencing in this point in time. A patient with CHF who was rigorously diuresed in the hospital may be doing very well the day of admit, but that is not their usual level of activity tolerance. It would be more helpful in long term care planning.

Concern: M1700-1745 Neuro/emotional/behavioral status
Suggestion: Add a directive that the time period under consideration for these items includes the recent past.
Rationale: Improve correct reporting of these items.

Concern: M1850 Transferring
Suggestion: Change item wording for clarity. For example, "Current ability to move safely *from a seated position in bed to a seated position in a chair*, or…..
Rationale: Clinicians often ask where the transfer begins and ends. It would provide more consist and reliable responses for outcomes.
Suggestion: Change the word "self" to "safely alone" for response "2" and "3".
Rationale: By far, these response choices are the most difficult to understand and comprehend in my experience which I believe greatly contribute to inaccurate outcome reporting. These descriptions are unique to home care and not professionally useful in other care settings. In addition, clinicians rarely see the word "self" and find it difficult

to accept that a patient who requires both a device and human intervention to safely accomplish the transfer is described in Response 2 which begins with "unable to transfer". Clinicians admit to stop reading the rest of the response once they read "unable to transfer".

Suggestion: Add a N/A response.

Rationale: There are patients who do not have a chair in their immediate environment but are able to get out of bed and walk to the next room.

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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-2008-0141-0012
MN

Submitter Information

Name: Julie Pahlen
Address:
Roseau, MN, 56751
Organization: LifeCare Medical Center

General Comment

See attached document with comments.

Attachments

CMS-2008-0141-0012.1: MN

#12

LifeCare Medical Center
715 Delmore Drive
Roseau MN 56751

Jan. 6, 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

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 as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to clients served by our home care agency. However, I 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 major decline and clarify all the following terms: unstable vital signs; debilitating pain; recent decline in mental health status; 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.
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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
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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: **M2010** Patient *caregiver drug education*
Suggestion for Change: Define and more clarification is needed on high risk medications is the intent of this OASIS item hypoglycemic and anticoagulants only or other high risk medications. What reference source is being used for a list of high risk medications? For accuracy of OASIS data collections all home care agencies should be referring to the same high risk medications.

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:
I am greatly 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 client in its current form and will become increasingly exhausting for the clients 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 client 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.

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

Sincerely,

Julie Pahlen RN BS PHN COS-C
Director Home Care and Hospice
LifeCare Medical Center
715 Delmore Drive
Roseau, MN 56751

PUBLIC SUBMISSION

As of: January 15, 2009
Received: January 06, 2009
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Tracking No. 8081041f
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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-2008-0141-0013
IA

Submitter Information

Name: Nancy Farmer
Address:
Vinton, IA, 52349

General Comment

M1012 will place an additional burden on clinical staff to obtain information from a referring hospital. Obtaining accurate detailed information from a hospital is already a challenge. Hospital discharge summaries are not yet available at the time of a home health admission. Completion of the comprehensive assessment will be delayed when agency's are required to gather this information.

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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-2008-0141-0014
PA

Submitter Information

Name: Vicki Latta
Address:
Meadville, PA, 16335
Organization: VNA of Crawford County

General Comment

Please find attached a letter with comment on the proposed changes to OASIS-C.

Attachments

CMS-2008-0141-0014.1: PA

#14

January 6, 2009

Centers for Medicare and 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

Reference: Outcome and Assessment Information Set, OASIS-C, CMS-R-245 OMB# 0938-0760

I am writing to comment on the following proposed changes to OASIS-C.

M1010 and M1012 Inpatient diagnosis and ICD code
I suggest eliminating these items, as this information is not always readily available to the Home Health provider. Many hospitals do not provide complete information on referral or do not complete their final coding until after the hospital generates the bill. In any instance, this creates a time consuming burden on the Homecare provider to track down accurate information for the patient record.

M1038 Guidelines for Physician Notification
If the answer is "yes" there is no place to validate or list the parameters. If the answer is "no", does this trigger an edit or warning for the clinician?

M1240 Frequency of Pain interfering with patient's activity or movement
If the clinician answers "0" Patient has no pain, or "1" Patient has pain that does not interfere with activity or movement, it does not appear that a skip pattern is built in to allow questions M1244 and M1246 to be skipped.

M1350 Skin lesion or open wound
The question specifically excludes "bowel ostomy" but does not address other ostomies. Previous guidance excluded anything that ended in "ostomy" from consideration as a lesion.

M1930 Has this patient had a multi-factor fall risk assessment?
I am suggesting that a single standardized assessment be used by all agencies for valid data collection and comparison.

M2310 Reason for Emergent Care
I am glad the response selection has been expanded from 9 to 19 identified reasons. This will be more helpful to agencies that are working on improving their Emergent Care scores.

Thank you for the opportunity to comment on these proposed changes to the OASIS dataset.

Vicki Latta RN
Quality Improvement Coordinator
VNA of Crawford Co.
149 North Main Street
Meadville, Pa. 16335

PUBLIC SUBMISSION

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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-2008-0141-0015
MN

Submitter Information

Name: Anne Marie Nelson
Address:
Walker, MN, 56484
Organization: Cass County Public Health

General Comment

Please review comments/letter on oasis c.

Attachments

CMS-2008-0141-0015.1: MN

Cass County Health, Human & Veterans Services
Dorothy Opheim, Director

Human Services Division
P.O. Box 519, Walker, MN 56484
218-547-1340
Fax 218-547-1448

Public Health Division
P.O. Box 40, Walker, MN 56484
218-547-1340
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Veterans Services Division
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218-547-1340
Fax 218-547-7252

Date: 1/5/2009

#15

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulation Development
Attention: Document Identifier/OMB Control Number 09380760
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 re-hospitalization and speak to the fragility of their overall status. These

include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. Eliminate this item from SOC

Rationale: At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not 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 5day 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.

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Sincerely,

PUBLIC SUBMISSION

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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-2008-0141-0016
MN

Submitter Information

NO ATTACHMENT

Name: Dana Helton
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Caledonia, MN, 52101
Organization: Houston County Public Health

General Comment

Submission of OASIS C comment.

PUBLIC SUBMISSION

As of: January 15, 2009
Received: January 06, 2009
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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-2008-0141-0017
RI

Submitter Information

Name: Janice Muehlberg
Address:
Providence, RI, 02908
Organization: Roger Williams Home Care

General Comment

OASIS C adds an incredible burden of paperwork. SOC is now 105 items as opposed to 76 in OASIS B).
Positives are clarification of wound and ADL items, and elimination of "Prior"
Negatives:
The inclusion of "Process" items is inappropriate and insulting. Assessment includes all screeings, ie, pain, depression. After the assessment is done, then the plan is developed. This is documented in the clinical notes, and does not belong on the assessment. Also, who would check answer "No" for M1242? this would immediately imply negligence on the part of the clinician.
M2110 is very confusing and more time consuming than the previous OASIS items. And what are the implications if assistance is needed but no caregiver is available? Why was this included?
Regarding influenza and pneumovax, how can this be tracked? M1055:
Reason PPV not given does not include that the agency does not administer PPV due to concerns (well documented) of efficacy and safety. Not sure why these have been included, and what are the implications of an agency not administering?

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-2008-0141-0018
MN

Submitter Information

Name: Linda Miller
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Vadnais Heights, MN, 55127
Organization: Allina HomeCare, Hospice and Palliative Care

General Comment

Please review this attachment for comments regarding the proposed changes to OASIS-C

Attachments

CMS-2008-0141-0018.1: MN

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#18

ALLINA
HOME CARE, HOSPICE
& PALLIATIVE CARE
Allina Hospitals & Clinics

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*: *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 so clarification is necessary for consistent practice among agencies. *Rationale:* Keep in mind that 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. Provide direction for how agencies are to answer this question when the initial physician's order start of care is delayed for reasons such as patient choice or need for the patient to receive other outpatient follow up. 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, get the data 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 coding often does not occur until the hospital generates their 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 frailty 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. *Rationale:* If this is a SOC, providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. What makes the vitals signs unstable? Unclear instructions regarding pain, mental status and functional decline will result in unreliable data. The frailty indicators are not measureable. Additionally, "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. *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.

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.

Concern: **M1300 - M1306** -Pressure Ulcer Assessment *Suggestion for Change*: Extend the 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers and 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? Is it realistic 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. *Rationale:* It 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.

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?

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.

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 NP? 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. Ability to resolve is dependent upon willingness and availability of practitioners outside of home care 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 "lookback" on OASIS – are those instructions no longer valid?

Concern: **M2020** Management of Oral Medications

Suggestion for Change:

1 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.

2. Further clarify how to answer the item choices if both 1 and 2 pertain how should the question be answered? 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 as is 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 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. Also there will be a significant burden to the agencies due to the extended time the admission will take the staff therefore decreasing the staff productivity. Also many admissions are performed over the weekend esp. in hospital based home care agencies so this extensive oasis assessment would create an undue burden to these agencies. 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 record since many agencies already have tools like the Braden scale and pain assessment scales as requirements in their documentation. This would also be beneficial for national benchmarking.

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

Sincerely,
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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-2008-0141-0019
CO

Submitter Information

Name: Nancy Miller
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Grand Junction, CO, 81506
Organization: Rocky Mountain Health Plans Home Health

General Comment

Changes in the pressure ulcer OASIS items-thanks for bringing the language up to date.
Problem #1 is the process questions on Diabetic Foot Care. Routine diabetic teaching standards for home health patients routinely include foot checks and teaching reminders to patients to watch their feet. Home health nurses just do this. It is an unnecesasry burden for home health nurses to have to do these OASIS questions. It should not be necessary to have a physician order to teach diabetic foot care. On the other hand there may be home health patients with diabetes as a secondary diagnosis sho are receiving therapy only services. It is unlikely that a PT will want to spend adequate time on this OASIS item. If there was some nursing involved at the SOC and they did the foot care reminders to the patient then turned the pt over to the PT and now the PT is doing the D/C is ssupposed to somehow look back at the patient record at D/C to see how to mark this OASIS item and verify that nursing did this. I think the tendency to just answer the question as a yes without verifying the info is high.
Problem #2 The other issue with all the process questions happens if a nurse is D/C'ing the patient who is not familiar with the patient and having to answer all the process questions. I believe that CMS is making the assumption that every field clinician knows whether on not the agency has addressed vaccines, foot care & all the other processes at the time of D/C is unreasonable. It will take any field clinician added time to go back through the patient record to find all the information. This will add minimally 30 minutes to the D/C OASIS visit.

I believe that the new process questions are, for the most part, very appropriate quality indicators. Perhaps it would be better if the process questions did not have to be answered by the field clinician at D/C. A better choice would be for case managers or staff assigned to review patient records to accurately and consistenly respond to the new OASIS process questions as they have better access to the whole patient record and more time to review the record compared to a field clinician.

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Document: CMS-2008-0141-0020
KY

Submitter Information

Name: Ruth Wong
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Richmond, KY, 40476
Organization: MEPCO Home Health Agency

General Comment

Regarding the OASIS document, the questions that trigger the Adverse Outcome Results are a bit skewed. In particular, MO340 asks if a patient lives alone or with others. Prior to the current instruction, when the patient had 24 hour care, whether it was from shared family members and paid caregivers, as long as the care was over the 24 hour time period, the person was not officially "living alone." Current advice tells us that if the caregivers return to their own homes after taking their turns for care, then the patient IS living alone, even if he/she has 24 hour coverage.

These patients are thrown onto the Adverse Outcome Event Report (AOE) if they have behavior problems, wounds needing ongoing care, and need for medication assistance. This is an artifact and needs to be resolved, as it is affecting our agency outcomes incorrectly.

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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-2008-0141-0021
KY

Submitter Information

Name: Anthony Bush
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General Comment

I want to know if there is going to be more diagnosis codes added to the case-mix list that we currently have. For instance with the New (current) Payment system we get points and reimbursement for Vision (MO390) and a related vision diagnosis. Will the new Hearing M-questions (M1210 & M1220) be related to a new or existing case-mix diagnosis?

Also with the new oasis comes new issues in relation to Procedures performed during the inpatient stay. Will these procedures codes be ICD-9 Procedure codes or CPT (current procedural terminology) codes, which have noticeable differences? Will these Procedure codes be for surgeries and the like or will we need Procedure codes that relate to the reason for admission to Home Health? This section for procedure codes, in my opinion, is unnecessary for reimbursement and data collection in the current HHRG format. The data for procedure codes should already be collected in the Hospital Inpatient MS-DRG billing process, which in turn is usually billed with ICD-9 and Revenue codes. This will be adding more confusion to a field that currently lacks Certified Professional Coders (CPC) that have a more detailed understanding of various billing and coding formats used for reimbursement.

Anthony Bush, CPC, CCP, CCP-P

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Document: CMS-2008-0141-0022
OH

Submitter Information

Name: Kaye Smith
Address:
Columbus, OH, 43085
Organization: Homereach Homecare

General Comment

Regarding the proposed OASIS-C changes -
Two questions regarding measurements for wounds are not per WOCN guidelines for measuring wounds.
M1312 asks for "longest length in ANY direction
M1314 asks for "Greatest width measured at right angles to length.

WOCN says that the length of a wound is to be "clock orientation 12-6 at the longest measurement. The pt;s head is reference for 12 o'clock.

The width is the measurement at the right angle to the determined length measurement.

Hence, the length could potentially be shorter than the width.
Again, this is what WOCN directs for wound measurement - NOT JUST THE LONGEST POINT IN THE WOUND.

Thanks.
Kaye Smith RN

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Document: CMS-2008-0141-0023
SD

Submitter Information

Name: Jamie Joyce
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Sioux Falls, SD, 57103
Organization: Interim HealthCare

General Comment

• Thank you for listening to our expressed concerns over the past several years regarding many of these OASIS items. We can see that you have put effort into improving many of them and making them more practical for the home care patient.
• However, the number of questions in two data sets has increased dramatically:
B1 C
SOC/ROC ~81 102
Transfer ~11 27

This increase of the number of questions will cause extended visit time for the assessing clinician—at least an additional 30 to 45 minutes for the SOC visit, which is already 90 to 120 minutes long. Even if you do not consider the extra burden on the home health agency (i.e., the time of the clinician and the extra data entry time), the additional stress to the patient cannot be overlooked. Patients already make comments to the clinicians about the process and all of the question asking being too lengthy. Several clinicians have had clients state they can not finish, they are too tired and need to go lay down. Burden to the clients also needs to be considered.

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Document: CMS-2008-0141-0024
OH

Submitter Information

Name: Kaye Smith
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Columbus, OH, 43085
Organization: Homereach Homecare

General Comment

Regarding OASIS-C -
The questions regarding measurements for wounds, are NOT per WOCN guidelines for measruing wounds.
M1312 asks for "longest length in ANY direction.
WOCN says that the length of a wound is to be "clock orientation 12-6 (patient's head) or the longest point of the wound closest to the 12-6 orientation.
WOCN says the width is the measurement of the wound at the right angle to the length measurement.
Hence, the length measurement could potentially be shorter than the width measurement.
I know CMS goes by WOCN guidelines. Please continue this committment.
Thank you.
Kaye Smith

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Document: CMS-2008-0141-0025
MI

Submitter Information

Name: Marlene Hamme
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Canton, MI, 48187

General Comment

The OASIS-C does not support the intended simplification and reduced burden of paperwork. The OASIS has been known to support home care agency outcomes and reimbursement. The OASIS-C goes beyond that intent and now includes intervention and follow-up data elements which imply certain standards of practice for home health agencies. Please consider the following comments regarding specific data elements.

Attachments

CMS-2008-0141-0025.1: MI

Comments for CMS Regarding OASISC (11108 revision)
010809

#25

Data Element # & Page #	Comment
M1038- p. 7 Guidelines for Physician Notification	Many home health care agencies have established medical policies with parameters for vital signs and clinical findings such as blood glucose levels. This data element seems to be stating that every patient=s physician-ordered plan of care has to have specific parameters. This is not always necessary.
M1242- p. 9 Formal Pain Assessment	This is a valid concern but it should not be part of the OASIS assessment.
M1310- p. 10 Current number of Unhealed Pressure Ulcers at Each Stage	It is unnecessary to have two columns. The column titled "Number of these that were present on admission" is not necessary. It is repetitive information and should be eliminated.
M1360- p. 11 Diabetic Foot Care Plan M1365- p. 11 Diabetic Foot Care Plan Follow-up	These are valid questions but are not appropriate for outcome-based OASIS data elements.
Planned Intervention/Intervention Data Elements M1244- p. 9 M1246- p. 9 M1304- p. 9 M1306- p. 9 M1326- p. 11 M1328- p. 11 M1734- p. 14 M1736- p. 14 M1940- p. 17 M1945- p. 17 M2002- p. 17 M2004- p. 17 M2015- p. 17	The physician-ordered plan of care elements do not belong on OASIS. They are not outcome-based. The information is repetitive and will cause additional work for the clinician. Many preventive interventions do not require physician orders and do not need to be on the plan of care. It appears that CMS through OASIS is developing a plan of care for agencies to follow.
M2000- p. 17 Potential Adverse Events/Reaction	It is not logical to have a possible response of ANot assessed/reviewed.@
M2002- p. 17	Clinically significant medication issues will need to be clearly

Medication Follow-Up	defined. One calendar day is unrealistic. The physician may not respond within one calendar day, especially on the weekends.
Type and Sources of Assistance M2110 f.- p. 19 M2110 g.- p.19	 The words ASupervision and Safety@ are vague terms under this data element. It is not clear what is included under this category.