# PUBLIC SUBMISSION

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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-2008-0141-0138
Public Comment

## Submitter Information

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## General Comment

Please see the attachments

## Attachments

**CMS-2008-0141-0138:** Public Comment

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January 8, 2009

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

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

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

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

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

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

***Concern:*** **M1032** Frailty Indicators
***Suggestion for Change:*** Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of high risk chronic diagnoses place a patient at risk for rehospitalization and speak to the fragility of their overall status. These include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. Eliminate this item from SOC

***Rationale:*** At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measureable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

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

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

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

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

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

***Concern:*** **M1312 - M1314** Pressure Ulcer Length & Width
***Suggestion for Change***: Eliminate both items
***Rationale:*** Requiring length and width of the wound does not meet the guidelines for measurement and assessment as established by the Wound, Ostomy and Continence Nurses Society (WOCN). This question does not ask for the components of a complete wound assessment; therefore clinicians will be required to complete redundant documentation

in order to accurately document the wound condition. Providing only a length and width of a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measured at 12 o'clock to 6 o'clock with 12 o'clock always being toward the patient's head. Width is measured side to side from 3 o'clock to 9 o' clock. Simply asking for length and width does not support the guidelines.

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

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

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

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

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

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

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

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

***Concern:*** **M1890** Change in Self-care Ability
***Suggestion for Change:*** Eliminate this item

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

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

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

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

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

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

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

***Concern:*** **M2020** Management of Oral Medications
***Suggestion for Change:*** Go back to the question asking only about <u>prescription</u> medications (not <u>all</u> medications) and eliminate previous instructions to mark the patient as independent if taking the majority of medications. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?

***Rationale:*** The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with and ability to take 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,

Karen Seifert
Administrator, CEO
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# PUBLIC SUBMISSION

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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-2008-0141-0139
Public Comment

## Submitter Information

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**Organization:** Good Samaritan Society Homecare

## General Comment

Please see the attachments

## Attachments

**CMS-2008-0141-0139:** Public Comment

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*January 8, 2009*

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

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

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

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

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

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

***Concern:*** **M1032** Frailty Indicators
***Suggestion for Change:*** Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of

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

***Rationale:*** At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measureable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

***Concern:*** **M1034** Stability Prognosis

***Suggestion for Change***: Eliminate # 3 - The patient has serious progressive conditions that could lead to death within a year.

***Rationale:*** This language is similar to M0280 except that the predicted death time has changed. **Providers should not have to guess at time of death.** It is not a question that reflects the actual and clinically substantiated status of the patient. Clinicians will have much difficulty differentiating between number 2 and number 3 in this item. Defining "serious complications" and "high health risks" by various clinicians will result in useless data.

***Concern:*** **M1038** Guidelines for Physician Notification

***Suggestion for Change***: Delete this item

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

***Concern:*** **M1040 through M1055** Vaccinations

***Suggestion for Change***: **Clarify through CMS instructions that providers will not be mandated to provide vaccinations without payment for such.** Eliminate "from your agency" verbiage and remove #1 and 2 in M1045.

***Rationale:*** It is important to verify vaccination. However, providers should not have to assume the financial and resource burden of vaccination administration. There are more efficient ways to ensure vaccinations.

***Concern:*** **M1242** Formal Pain Assessment

***Suggestion for Change***: **Make suggestions and list appropriate standardized assessment tools for pain.** Eliminate this question on SOC.

***Rationale:*** The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools will help decrease data variance that is collected by providers.

***Concern:*** **M1300 - M1306** - Pressure Ulcer Assessment

***Suggestion for Change***: **Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen.**

***Rationale:*** What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? It is unrealistic to get all of this done in the 5-day time frame. Consultation with staff outside the home care agency, for example a wound healing clinic, is often necessary to gather all pertinent clinical information.

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

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

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

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

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

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

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

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

***Concern:*** **M1880** Change in Mobility
***Suggestion for Change***: **Eliminate this item**

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

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

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

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

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

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

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

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

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

***Concern:*** **M2020** Management of Oral Medications
***Suggestion for Change*: Go back to the question asking only about prescription medications (not all medications) and eliminate previous instructions to mark the patient as independent if taking the majority of medications**. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?
***Rationale:*** The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with and ability to take prescription medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all prescribed medications (including oral) when assessing a change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.

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

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

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

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

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

Instead of asking if standardized assessment tools have been completed to assess pain and risks for skin breakdown, add a tool into the assessment that is approved by nationally recognized experts. This will prevent the need to duplicate documentation in more than one area of the clinical record since many agencies already have tools like the Braden scale and pain assessment scales as requirements in their documentation. This would also be beneficial for national benchmarking.

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

Sincerely,

*Vickie Lynch, RN, BSN, MSN*
*Home Care Director*

*Good Samaritan Home Care*
*200 St. Paul St*
*Preston, MN 55965*

# PUBLIC SUBMISSION

**As of:** January 23, 2009
**Received:** January 13, 2009
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**Category:** Hospice - HPA30
**Tracking No.** 8082c99c
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**Submission Type:** Unknown

**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-2008-0141-0140
Public Comment

## Submitter Information

**Name:** Lanyard Dial
**Address:**
Thousand Oaks, CA, 91360
**Organization:** Livingston Memorial Visiting Nurse Association & Hospice

## General Comment

Please see the attachments

## Attachments

**CMS-2008-0141-0140:** Public Comment

LivingstonMemorial
Visiting Nurse Association & Hospice
est. 1947
"Home is where the Heart is"

The Joint Commission
Medicare Certified Home Health & Hospice Agency

January 5, 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 21244-1840

Dear Sirs:

Thank you for the opportunity to comment on the proposed changes to the Outcome and Assessment Information Set (OASIS) as described in the November 14, 2008 Federal Register.

Our comments follow in M0 item order:

M0150- Please add Medicare Advantage PPO to #2

M01010, M1012- We like the proposed changes to the coding section.

M1014, M1016, M1018- Please clarify how these items will be used. These items seem redundant with M1010, M0190 and old M0230, M0240.

M1032-

1 – "Unstable VS" – please define unstable. Assessing a patient's VS requires several visits. Is it your expectation that several visits be made to complete the assessment?

2 – "Debilitating pain" – please define debilitating.

How will these data be used?

M1034- We appreciate having more options to define prognosis.

M1038- This is a process item and we request removal from the outcome data set.

M1040-1055 – We request these process items be deleted. If they remain, since many patients/caregivers are poor historians we request another option "UK – patient/caregiver unable to recall.

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M1100- Responses c/11, 15 are illogical since the patient is an assisted living situation.

M1210, M1220- The separation of hearing and understanding is an improvement.

M1240- This version is much clearer and should increase inter-rater reliability.

M1242-M1246- These are process questions and we request removal.

M1300- Please make multiple responses possible.

M1310- The grid is an improvement and we like the addition of d3.

M1322- Why is this not included in M1310? We request an opportunity to document healed Stage III, IV pressure ulcers and because of the high risk, request no adverse event if there is a breakdown.

M1326, M1328- These are process items and we request removal.

M1330, M1340 – Please remove "likely". The attending physician needs to confirm what exactly is under the non-removable dressing.

M1350- We like this addition if it will result in case mix points or supplies. If not, please remove.

M1360, M1365- These are process questions and we request removal.

M1730- This is a process issue and should be removed. This is burdensome for the clinician. It is highly likely the patient/caregiver will not know if they have been screened using a standardized depression screening tool.

M1732- What other symptoms does # 6 refer to? Specificity is needed for inter-rater reliability.

M1775- Please add the following clarifying language: "The behaviors include but are not limited to those identified in M1740. Consider any behavior of concern for the patient's safety or social environment."

M2000-M2015- These are process items, please remove. Since these items appear outside the scope of therapies practice, are you, by inclusion, requiring only RN assessments?

M2300- Excludes "Urgent Care Center". Please clarify.

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As you can see, we have both positive and negative comments. However, of grave concern is what appears to be a substantial underestimation of the time necessary to complete the fifty four (54) additional items. Overall, this 29% increase in items is conservatively estimated to require an additional hour of clinician time. Not only does this increase our cost, we believe it will contribute to the already growing exodus of skilled professionals from Home Health due to the "paperwork" burden.

We respectfully ask you to consider implementation without the process items and to further field test for an accurate assessment of the time necessary to complete.

Thank you for your consideration.

Sincerely,

Lanyard K. Dial, MD
President/CEO & Medical Director

LKD:jh

HealthPartners
*Ramsey Integrated Home Care*

Integrated Home Care
475 Etna St. Suite 3, St. Paul, MN 55106
Tel: 651-776-2112

January 7, 2009

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

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

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

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

***Concern:*** **M1010 & 1012** Inpatient Diagnosis and ICD Code
***Suggestion for Change*:** Eliminate this requirement. If CMS needs the data it is available from the hospitals.

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

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

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

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

***Concern:*** **M1038** Guidelines for Physician Notification

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

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

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

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

***Concern:*** **M1312 - M1314** Pressure Ulcer Length & Width
***Suggestion for Change***: Eliminate both items
***Rationale:*** Requiring length and width of the wound does not meet the guidelines for measurement and assessment as established by the Wound, Ostomy and Continence Nurses Society (WOCN). This question does not ask for the components of a complete wound assessment; therefore clinicians will be required to complete redundant documentation in order to accurately document the wound condition. Providing only a

length and width of a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measured at 12 o'clock to 6 o'clock with 12 o'clock always being toward the patient's head. Width is measured side to side from 3 o'clock to 9 o' clock. Simply asking for length and width does not support the guidelines.

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

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

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

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

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

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

***Concern:*** **M1734** Depression Intervention Plan

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

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

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

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

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

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

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

***Concern:*** **M2002** Medication Follow-up
***Suggestion for Change***: Eliminate the need to contact the physician within one day and clarify what is considered "contacted" – does that mean a message has been left via

phone, a fax has been sent, the home care clinician contacted the physician's nurse or other staff? Define clinically significant. Does "contacted within one calendar day to resolve clinically significant medication issues" imply that both contact *and* resolution is expected in one day, or is the intent of the question to show contact within one day?
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***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?
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Other general comments and concerns:
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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,

Denise Edgett, PHN
Manager, Integrated Home Care

# PUBLIC SUBMISSION

**As of:** January 23, 2009
**Received:** January 13, 2009
**Status:** Posted
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**Category:** Home Health Facility - HPA25
**Tracking No.** 8082c9b6
**Comments Due:** January 13, 2009
**Submission Type:** Paper

**Docket:** CMS-2008-0141
Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

**Comment On:** CMS-2008-0141-0001
Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations in 42 CFR, Sections 484.55, 484.205, 484.245, 484.250 (CMS-R-245)

**Document:** CMS-2008-0141-0141
Public Comment

## Submitter Information

**Name:** Denise Edgett
**Address:**
St. Paul, MN, 55106
**Organization:** Health Partners - Ramsey Integrated Home Care

## General Comment

Please see the attachments

## Attachments

**CMS-2008-0141-0141:** Public Comment

# PUBLIC SUBMISSION

**As of:** January 23, 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-2008-0141-0142
Public Comments

## Submitter Information

**Address:**
Sante Fe, NM, 87505
**Organization:** Presbyterian Medical Services

## General Comment

Please see the attachments

## Attachments

**CMS-2008-0141-0142:** Public Comments

December 17, 2008

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

Dear Sirs and Madams,

This letter is to offer 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.

As direct providers of home health services, we believe the OASIS-C proposal will greatly increase the paperwork burden for home health agencies and recipients of home health services for the following reasons.

1. The number of items in the OASIS data set has increased
   As shown in the table on page 10 of the Supporting Statement, the number of OASIS items at the Start of Care is increasing from 76 to 105 (38 percent) and at Resumption of Care from 61 to 90 (48 percent).

2. The number of new items exceeds the number of items dropped.
   The Supporting Statement claims OASIS-C will have "no net burden impact". However, the data presented do not support this statement. The Supporting Statement claims that 21 items plus 11 prior ADL/IADL items were dropped. However, because only half of the ADL/1ADL items were eliminated, it is not reasonable to count these items as completely dropped since half of the items remain. Thus, the items dropped is actually 26.5 not 32. In contrast, the number of items added is 45. Thus, it would appear that the number of items added, exceeds the number dropped by 45/26.5 or 70 percent. Note that this estimate does not include the additional responses that were added to several questions. See, for example, Items M1010, M1016, M2310, and M2430.

3. There is no convincing rationale for why process items should be added to an outcomes data set.
   According to the Supporting Statement, "The revision of the OASIS instrument is an opportunity to consider various components of quality care and how patients might be better served as they (and information about them and their care) move among health care settings." The OASIS data set was designed to be home health setting–specific and based on outcomes. Now, apparently CMS is moving toward a Post Acute Care data set which includes process items. The net effect of this change in direction and experimentation is to increase the burden of data collection on home health providers.

4. There is no valid evidence that the burden will not be increased.
   The Supporting Statement in a number of different areas asserts that the proposed changes do not create an additional burden. First, the new instrument was field tested in just eleven home health agencies in three states. This is an extremely small sample (about 0.1 percent) on which to test an instrument with a current burden estimated at some 15.6 million hours annually.

Second, the Supporting Statement presents no data from the field testing. On page 4, it states that focus groups were conducted to obtain feedback on usability, burden, and how the revised data set might impact care patterns. However, no data are presented from the focus groups. On page 11, it states that field testing reported that the time required for the OASIS-C was "not greater than required for OASIS-B at most time points." It is hard to know how to interpret such a subjective statement.

5. The additional data items will not be used for the Prospective Payment System or the Home Health Compare.
   The rationale for collecting and reporting OASIS data is for quality monitoring and to operate the Prospective Payment System (PPS). Of the 130 items in OASIS-C, only about twenty-six items are used for PPS and Home Health Compare. While the current OASIS B1 data set contains many items that are not used for either purpose, the proposed OASIS-C has exacerbated this problem by adding additional elements, most prominently, the process items. It would seem reasonable, that if CMS wants to add additional items, particularly items not used for either of the two core purposes, they should eliminate other items to compensate for the new items. In this way, the net burden would actually not increase.

6. The burden estimate is likely low but even so is very considerable.
   The Supporting Statement estimates the total burden for 2009 at 15,590,610 hours and the average salary at $29.47 per clinician. Thus, CMS estimates the annual burden at nearly $460 million. This estimate likely understates the actual burden considerably for the following reasons.

   a. The burden estimate is based on the assumption that OASIS-C will not increase the burden. As discussed above, this assumption is unsupported.

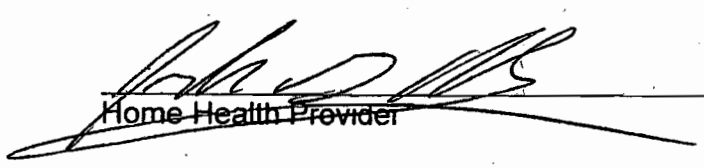
   b. The average salary does not reflect agency overhead. The true cost to the agency of a $29.47 hourly rate would be about $44 per hour.

   c. The training estimate does not account for annual turnover of new staff. Each time a new clinician is hired, they must be trained on OASIS. Assuming a turnover rate of 20 percent would add 146,448 hours to the burden estimate.

   d. The burden estimate does not reflect the fact that almost all agencies have clinical staff to over see the OASIS process and clerical staff to assist in the effort.

Given the above mentioned issues, we as direct home health providers recommend that CMS halt all "field testing" of the proposed OASIS–C. The additional burden of this proposed instrument will have severe, negative effects on the home health industry and beneficiary access to this vital Medicare benefit.

Thank you for your consideration.



Home Health Provider