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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-2008-0141-0026
MN

Submitter Information

Name: Dori Finch
Address:
New Prague, MN, 56071

General Comment

I am a nurse that works in Home Health Care and have concerns about the OASIS-C document. Please take a moment to read the comments attached and consider implementing these suggestions from the ones who actually work with the OASIS on a daily basis.
Thank you,
Dori Finch RN

Attachments

CMS-2008-0141-0026.1: MN

#26

Queen of Peace Home Health Care
301 2nd St NE
New Prague, MN 56071

010809

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 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. 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,

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

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Comment On: CMS-2008-0141-0001
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Document: CMS-2008-0141-0027
MS

Submitter Information

Name: Penny Lovitt
Address:
Hattiesburg, MS, 39402
Organization: Deaconess HomeCare

General Comment

See Attachment

Attachments

CMS-2008-0141-0027.1: MS

January 8, 2009

#27

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Numberllll
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

We believe for the most part the changes are an improvement and should improve the data we collect; making it more specific with less room for inconsistencies.

We recommend removing the "prior" column for scoring ADL's, it is difficult to determine status 14 days prior and is subjective, based solely on the patient/caregiver response.

M0845

recommend adding another item: IV Catheter-related issue (i.e. occlusion, dislodgement, questionable placement etc.)

M1032 Frailty Indicators - Risk for hospitalization

Frequently patients with CHF are hospitalized for fluid overload or respiratory distress. Would recommend that the also be listed as a factor.

M1034 Stability Prognosis

It is unclear what 'serious complications' means. Does this mean life threatening? If not, 'serious complications and/or death' may be better wording.

M1038 Vaccine received during episode of care

Would recommend that parenthetical note be included (SOC/ROC to Transfer/Discharge) similar to that on the pneumococcal vaccine question.

M1100 Living Arrangement and Availability of Assistance

We believe this is poorly formatted. This question is very likely to be answered incorrectly. From first glance, it appears that the question is looking for how often the patient is alone, with someone else, etc. rather than how often assistance is available. Would recommend this question be split into two, or that the response fields be re-formatted with a clear distinction of the information requested so that accurate data can be collected.

M1240 Pain interfering with movement

Response '1 - has pain that does not interfere with activity or movement'. Would recommend that this response be changed to 'NA - has pain that does not interfere with activity or movement', and that other responses be renumbered.

M1308 Pressure ulcers stage II or higher

We agree that stage I be removed, but would recommend that M1322 be placed before M1308.

M1320/M1324 Status/stage of most problematic pressure ulcer

Would recommend that these be reversed so that stage is identified before status

M1326 Pressure ulcer intervention / moisture retentive dressings

Would recommend that this be defined. Would this include a dressing like duoderm that prevents moisture from escaping?

M1360 Skin lesion or open wound

We like that it only asks for skin lesions that require assessment/intervention. Bowel ostomy is only exclusion. What about the other -ostomies (trach, urostomies, chest tubes)?

Would also recommend another question to elicit type of open wound, i.e. burn, trauma, surgical drain site, etc for the most common types of wounds encountered that require treatment

M1360/1365 Diabetic foot care plan/ follow-up

Would recommend question that asks 'does patient have diabetic ulcer on feet'.

M1400 Respiratory status

Item 1, would recommend that response include 'when performing physically demanding transfer activities if chairbound, when positioning and turning self in bed if bedbound'

M1500 Symptoms of heart failure

Not sure why we go to M1736 if no symptoms or not assessed

NA response, would recommend skip pattern to omit M1510

M1510 Heart failure follow up

Would recommend change in wording 'each instance of heart failure' to 'symptoms indicative of heart failure'.

M1610 Urinary incontinence or urinary catheter

Would recommend that this question be split in two; one to address incontinence, the other to address catheter or ostomy. Would include timed-voiding in question related to incontinence.

M1615 Timing of urinary incontinence

Would delete response 0-timed voiding, and place timed-voiding response in question regarding incontinence

M1830 Bathing

Has the ruling on this changed? From the first 3 responses, it would indicate that now getting in and out of the tub counts as assistance. If not, then recommend deleting response 2(b).

M1850 Transferring

Would recommend a response be included to indicate use of lift device (Hoyer) to transfer.

M1860 Ambulation

Would change wording to reflect that 'on a variety of surfaces' refers to walking and not to use of wheelchair

M1880/M1890/M1920 Change in mobility/self-care ability/household tasks

Wording not clear for definition of prior level of functioning. What information is this item trying to capture? Is this to be completed only on SOC and ROC? Will it be used at recert and discharge?

M2110 Types and sources of assistance

Needs a lead-in question, i.e. 'Determine the level of caregiver ability and willingness to provide assistance for the following activities, if assistance is needed.'

Format is poor, and difficult to decipher. Would recommend that headings be placed in bold, i.e. **ADL Assistance, IADL Assistance** etc.

Would also recommend that items a-g be renumbered to 1-6 with columns changed to a-f.

Would recommend removal of column 'caregiver not likely to provide assistance'. Judgmental.

Would recommend response that caregiver is unable to provide assistance for physical or emotional reasons.

M2400 Inpatient facility admit

What if patient admitted to two separate facilities, hospital and SNF, for example.

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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-2008-0141-0028
OR

Submitter Information

Name: Katherine Kahler
Address:
The Dalles, OR, 97058
Organization: Visiting Health Services

General Comment

Attached are the cooments of the staff regarding the new OASIS C data set.
Thank you

Attachments

CMS-2008-0141-0028.1: OR

#28

January 8, 2009

RE: Medicare and Medicaid Programs OASIS Collection requirements
Docket ID: CMS-2008-0141 Document ID: CMS-2008-0141-008.1

From: Katherine Kahler RN, MSN

In response the proposed changes to the home health OASIS data set; our small rural agency has reviewed the draft of the proposed OASIS C data set. With careful consideration we are including the comments and impact our staff believes that the changes will make. We are a rural agency serving approximant 7000 square miles with an average census of 165. We serve a population that lives in very remote outlying area which requires significant driving time and mileage. This increased driving impacts our finances. We believe that some of the changes being proposed will cause a burden on our finances which could lead to us having to forgo seeing the patients in outlying rural areas, thus depriving clients of a Medicare Service that can and has proven to decrease the cost of health care. We believe that there are new questions that point toward collecting data for a survey instead of collecting data that would show outcomes on patients. Our agency believes that many of questions will need revision to be able to support the gathering of data to show outcomes. We support some of the new questions, viewing them as a positive contribution, not only to home health but to the increasing need to involve the physician in consistent care in the home. Each comment will be addressed according to the new OASIS question.

M1012: List each inpatient procedure and the associated ICD-9-CM procedure code

We believe that this question will cause an undue burden on the staff doing the intake as well as the clinicians doing the admit. This will require staff to acquire information on a patient discharged from a facility, information that is not readily available. Currently it can take our home care coordinator up to 7-10 hours to merely obtain information from faculties due to the lack of electronic medical records, facility staff, and many other reasons. The increased burden of time is estimated to be up to 5 hours per referral, which is not reimbursed by Medicare. Average increase to cost to our agency per month is $9000 with a potential of over $100,000 over a 12 month time period. This figure comes from an average of 15 Medicare referrals per week, increased 5 hours of time needed to find this information at $31/hour. This is not a reimbursable part of an admit and there are many times that the referral then 'falls through' so our agency has to absorb the cost. Absorbing this cost would cause us have to decrease our service area. Currently we are the only home health agency to serve this are so the decrease would negatively impact patients in outlying areas.

M1032 and M1034 Frailty and Stability

Our staff believes that these are valid questions which can lead to a better use of resources and outcomes for our patients.

M1038: Guidelines for Physician Notification

Our staff believes that this question will lead to better outcomes as it can be a path to the physicians ordering parameters that can be treated in the home vs. just sending the patient to the emergency department. It will also lead to a more consistent teaching of the patient to be involved in their own healthcare.

M1040- M1055 Vaccination questions

Although these questions are very pertinent to the overall healthcare of a patient, we believe that to locate the information can be almost impossible. Most of our elderly patients do not remember nor have the paperwork to let us know if the vaccine were given. This can lead to multiple administration of the vaccine in one season. We did have a patient that had a vaccine by every agency involved in his care because he could not remember nor was there an easily retrievable record to make the information readily available. Before this becomes a standard question, we believe there needs to be an easy way to indentify if a vaccine has been given such as a label on their Medicare card or insurance card.

M1300 –M1340: Integumentary status

After careful consideration by the wound care staff, the concern was the use of the word "likely" in many of the new questions. Likely means with considerable certainty or without much doubt. This can lead to judgment call based on lack of knowledge especially with the therapy staff doing the OASIS assessment in a clinical area they have no expertise in. This posting of the uncertainty of an answer would lead to an inconsistent assessment and affect the recorded outcome of the patient. We believe that the questions should only contain the word "known" so there is no possibility of error of gathering information.

M1500: Symptoms of Heart Failure

We believe that this question is poorly worded. The questions asked if there were symptoms of heat failure. The answers include: 2 not assessed and NA patient does not have a diagnosis of heart failure. We believe that not assessing for symptoms is not really an option since a cardiac/ respiratory assessment is part of a comprehensive assessment done at each time point on a patient. Not having a diagnosis of heart failure does not exclude the need to assess for symptoms of heart failure.

M1730 Depression Screening

We believe that this question would be difficult to answer at the admit time point due the inability to obtain psychiatric information without the expressed consent of the patient. The patient is often not able or reluctant to admit to depression. This question could be misleading in planning the care of patient. This question could include the answer "unknown" on admit only and be used as a follow up question for other time points.

M1732-M1736 Depression

We believe these to be valid questions to be assessed. The answers will assist in planning the overall care of the patient and will show the need for depression screening and implementation of care to assist in the prevention and misuse of health care resources.

M1930- M1940 Fall Risk Intervention

Although these questions are vital in assessing the patients fall status, there is no OASIS question the specifically addresses the outcome of the intervention. The need for a question addressing, 'has a fall occurred in the last six months or since the previous OASIS assessment?' would point to a better and consistent approach to the fall intervention and if the fall interventions were effective in mitigating a fall.

M2000-M2015 Medications

We believe that these questions are geared towards a screening for the agency and not to improve or even show the outcome of a medication management program. They are worded to assist a surveyor in determining if an agency is doing a medication review. M2010 and M2015 would cause an undo burden on clinical staff not familiar with the patient's entire previous episode. The clinician would be required to review the entire previous episode charting as well as ask multiple question to determine if the instructions were given. This would cause an increase in the amount of time needed to do the OASIS assessment, time that would not have an increase in reimbursement.

We thank you for the opportunity for input. We look forward to reviewing the comments and responses from CMS as well as the final OASIS C data set. Our agency believes that CMS is on the right track as they push forward with the development and implementation of a standard home health assessment that can be utilized from agency to agency. Please feel free to contact me if you require further clarification and/ or questions about our comments.

Thank you,
Katherine Kahler, RN MSN
Director of Visiting Health Services
The Dalles, OR
541-296-7280

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Document: CMS-2008-0141-0029
OH

Submitter Information

Name: Sharon Starr
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Organization: Genesis HomeCare

General Comment

The proposed OASIS C will be a tremendous resource burden for home care agencies. The cost of training clinicians and clerical staff will be high. I would estimate that an additional 16 hrs of divided training will be needed prior to implementation. Also the time burden will be significant for collecting the additional data. Cost associated with integration of the OASIS C into the comprehensive assessment will be high for providers as well. I think that the financial consequences for the provider community for implementing this revised document have been greatly underestimated.

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-2008-0141-0030
IA

Submitter Information

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General Comment

See attachment

Attachments

CMS-2008-0141-0030.1: IA

#30

1/09/09

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

I am writing to comment on the proposed changes for the OASIC-C document.

The numbering system: I have concerns about changing the numbering system entirely on most of the items. I can appreciate the need to renumber items, however I am requesting selecting numbers that resemble prior numbers used. For example: M0175. The proposal is for M1000. Why not make it M0176? This suggestion would prevail through all the numbering. Clinicians are familiar with the M0's and would have less of a learning curve if the numbers were modified rather than totally changed. It would also be consistent with previous changes that have been made, such as M0825 to M0826 and M0245 to M0246.

Sequencing of OASIS questions: M0150 (current payment sources) was moved ahead of M0080 so now it is not in numerical order. If it must be moved, please renumber with a number less than M0080.

M0102: Date of referral: Suggest clarifying this statement from "the date the physician made the referral" to "the date the physician orders were received for the referral." Add a clarifier to explain the date should reflect the date that all the necessary information was obtained prior to the referral in order to safely accept the patient.

M0104: Date of physician ordered SOC / ROC: Please clarify the purpose and overall importance in knowing the answer to this question. This is non clinical information and an extra burden for the clinician to complete. This seems to be a question the state surveyors can evaluate so it should be eliminated.

M1034: Stability Prognosis: It would be difficult to accurately assess stability at the SOC timepoint. To be accurate, periods of stability are assessed over a period of time. CMS recognizes that for coverage purposes, allowing 3 weeks for determination. I also would suggest clarification of the use of the word stable. It could affect Medicare reimbursement coverage issues.

- Could the title be rephrased as only "prognosis," dropping the word "stability?"
- Suggest rephrase 0 to say: "the patient has no heightened risks"….leaving off the word stable.
- Change #3 to….. lead to death within **6** months rather than a year. Six months is a good indicator for hospice referrals. If you want to have the year on there, please add the 6 month option additionally.

M1038 Guidelines for physician notification: Additional burden of nurse and physician office time to get parameters. Also, what is the use for this in the outcome

process? There is no comparative measure at DC. This seems to be a question the state surveyors can evaluate, so it should be eliminated.

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

M1050 Pneumonia Vaccine: It would be a burden for both nursing and physician office staff to locate the information for a vaccine that is not given on an annual basis. A lot of patients are not eligible for the vaccine and it seems a burden to have to address it for all patients. Will need clear guidelines on the suggested frequency of receiving the pneumonia vaccine. If this question must remain on the OASIS C, could there be a leading question that says: Does patient meet criteria for pneumonia yes/ no, then ask a follow up question to find if it was received and the reasons why not. This question should be a skip if the patient cannot take the vaccine.

M1100 Pt living situations: Suggest separating the living situations and availability of help into two questions instead of one. It is confusing having them combined.

M1246 Pain Interventions: Implementing pain interventions are only captured at TRF and DC. If patient is open multiple episodes and pain resolves in first episode (interventions are done at that time), then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent Oasis. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information. Can gathering this data be limited to Early episodes that end in TSF or DC?

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

M1306: Pressure ulcer interventions: (Same issue with M1246). Interventions may have been done at SOC and if the patient is open a long time and interventions have been implemented long ago, but not since the most recent Oasis. Can gathering this data be limited to Early episodes that end in TSF or DC?

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

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

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

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

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

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

M1730: Depression screening tool: Assessing for depression may not be appropriate to use on all patients and may not appropriate to be done within 5 days. It would be helpful to allow other disciplines to do screening, for example MSW and contribute to the Oasis information, much like the hospice IDG planning and coordination.

M1732 Depressive symptoms. Answer 6:Other s/ sx is too vague. Suggest saying s/sx of depression not mentioned above.

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

M1880: Change in Mobility:

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

M1920 : change in ability to perform routine household tasks.

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

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

M2004: Medication Intervention. If patient is open multiple episodes and medication issue was resolved in first episode, then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent Oasis. This question would be valuable if there is only one episode of care. The lack of

the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information. Can gathering this data be limited to Early episodes that end in TSF or DC?

M2015: Pt / CG drug education interventions. If patient is open multiple episodes and education regarding the medication issue occurs in first episode, then answering this question at DC would not capture what happened in the initial episode as the question only goes back to the most recent Oasis. This question would be valuable if there is only one episode of care. The lack of the ability to capture outcome data at the time of Recert is a barrier for accurately getting this process information. Can gathering this data be limited to Early episodes that end in TSF or DC? If not, this question should be removed.

M2040. Change in ability to manage meds:

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

M2300: Glad to see removal of the physician office w/in 24 hours as emergent care.

M2310: Reason for Emergent Care: Add complications from chemotherapy or radiation therapy

M2430: Reason for Hospitalization: Add complications from chemotherapy or radiation therapy

With all the added information needed to gather, would like to see more than one clinician allowed to contribute to the Oasis. Our agency has an admission nurse do the SOC comprehensive assessment, but with these added elements it would be a burden to the clinician and patient to be able to complete this in one visit. The complexity of this document indicates the need for collaboration. I would like to recommend the allowance for multiple clinicians to contribute to the OASIS, much like the IDG for hospice. Also would like to see the time frame extended from 5 to 7 days for completion to allow for the research for flu vaccine history, getting parameters from the physician and care planning/ coordination based on all the new process measures.

Our nurse case managers who reviewed the tool felt it would add significant time. Average times were 1 – 2 hours per Oasis, especially the discharge Oasis. The biggest concern for them was the time involved in researching the discharge Oasis additional

components. Efforts to contact the physician office for chart specific data will add time and delay completion of the document. Waiting on hold for physician office personnel is only one of the barriers.

With a multidisciplinary approach the time to capture the other discipline's process interventions would be significant. For example, nursing opens the case but skilled care is completed. Therapy continues care and completes the DC Oasis that requires completion of all the process measures. The therapist does not have ready knowledge of the process measures the nurse initiated. Elaborate communication tools will need to be created and accessed in order to get the tool completed accurately.

From an office perspective, the new process measures will require the development of tracking tools for tracking process measures. This is additional paperwork requirement and does not fit into the intent of the Paperwork Reduction Act.

Lastly, the nurses are using laptops. They have limited amounts of visits that pull to the laptop in order to keep transfers from the server to the laptop running quickly. In order to answer these process questions, they will need to transfer up to 60 days' worth of visits, slowing the system and taking valuable clinician time to research these process questions.

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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-2008-0141-0031
VA

Submitter Information

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General Comment

I have reviewed the proposed changes for the OASIS and have several concerns.

1. The increase in the the amount of time to complete the assessment will be very tiring for those patients who have just been discharged from the hospital and do not feel well. With the present OASIS, it takes approximately 1.5 hour to complete an OASIS and a complete assessment upon admission. That does not include patient teaching, dressing changes, medication review, etc. You have increased the number of questions from from 77 to 102. Many of these patients will be exhausted by this process.

2. Some of these questions are subjective and more appropriately answered by physicians. (i.e. M1034 Stability Prognosis: this will be answered differently from one clinician to another and is more appropriately answered by a physician.)

3. Some questions are more for research and will add no value to planning care (i.e. M1045 & M1055 which asks reason patients have not received a flu and pneumococcal vacines) .

3. The depression screening will add more time to the admission process. I have found in the elderly, many will be offended by these questions because they think of depression as taboo and a failure in life. I have found that depression is usually picked up during episodes by noting behaviors and comments which indicate depression and addressed at that time.

4. M2002 asks if patients are compliant with their medications. This cannot be assessed upon admission.

5. M2120 Living Arrangement- choices are vague or do not make sense.

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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-2008-0141-0032
CA

Submitter Information

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General Comment

CAHSAH Comments

Attachments

CMS-2008-0141-0032.1: CA

CAHSAH
Shaping the Future of Home Care California Association for Health Services at Home

#32

January 9, 2009

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

Dear Sirs:

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.

Contrary to much of the information presented in the "Supporting Statement for Paperwork Reduction Act Submissions", we believe the OASIS-C proposal will increase the paperwork burden for home health agencies for the following reasons.

1. The number of items in the OASIS data set is increasing.
   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/IADL 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. Many of the new items are redundant, ambiguous, or unnecessarily burdensome. The following summarizes some of the concerns.

   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 to be seen on a certain day, also delaying the start of services. Provide direction for how agencies are to answer this question when the initial physician's order start of care is delayed. Does the date an agency updates the physician on the patient's availability for start of care become the referral date?

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 referral 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 places a patient at risk for rehospitalization and speaks 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: All providers will not have historical data on vital signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measurable and "other" data would be clinically significant to the patient's 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 the 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 home health 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 a standardized assessment tool 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:** 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 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 stage 3 and 4 pressure ulcers.
Rationale: A healed stage 1 or 2 would no longer be considered a pressure ulcer.

Concern: M1326 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item.
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It 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: Eliminate 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 standardized data. Comparison across patients will be less accurate if individual providers are using a wide variety of screening tools.

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

Concern: M1880 Change in Mobility
Suggestion for Change: Eliminate this item
Rationale: 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: M1890 Change in Self-care Ability
Suggestion for Change: Eliminate this item
Rationale: 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: 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 this patient had a 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: Eliminate 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.

5. <u>There is no valid evidence that the burden will not be increased.</u>
The Supporting Statement, in a number of different areas, asserts that the proposed changes do not create an additional burden. There is little or no evidence to support this. 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.

6. <u>The additional data items will not be used for the Prospective Payment System or the Home Health Compare.</u>
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, in fact, not increase.

7. <u>The burden estimate is likely low but even so is very considerable.</u>
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.

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

Thank you for your consideration.

Sincerely,

Joseph H. Hafkenschiel
President

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PUBLIC SUBMISSION

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Document: CMS-2008-0141-0033
MA

Submitter Information

Address:
MA, 01440
Organization: Gardner Visiting Nursing Association

General Comment

M1032: Frailty indicators will rely heavily on subjective report from the patient/caregiver and may not be accurate. Unless the patient is known to the Agency, how would we know that vital signs were unstable? If the patient were clinically unstable at the time of admission, we would likely send them to the ED and no OASIS would be generated.

M1034: How will stability prognosis impact adverse outcome reports related to unexpected death? The wording of this item appears open to misinterpretation. Choice zero seems to be in conflict with the admission criteria for skilled services. Why would one admit a patient who is stable with no heightened risk for serious complications and death?

M1040-1055: Why are home health agencies going to be responsible for tracking vaccine administration? Patient self-report is not likely to be reliable.

M1100: A patient living in congregate housing cannot have no available assistance therefore, option 15 should not exist.

M1246: As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M1365: As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M1500 & M1510: As a best practice, these items seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M 1630: A patient can have an Ostomy and have bowel incontinence.

M1830: Nice revisions to this item to reflect patient ability to bathe out of the shower or tub.

M 1845: Nice revisions to this item to reflect toileting hygiene and clothing management.

M1860: Nice change in this item to reflect improvement in ambulation from walker to cane.

M1880 & M1890 & M1920: These items better reflect the impact of illness on the patient's function than the previous prior and current columns.

M1945: As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M2002: Is the purpose of this item to determine whether the physician is contacted within one calendar or to resolve/reconcile medication issues within one calendar day? If the later is true, the timeframe is not realistic.

M2004: As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M2015: As a best practice, this item seems to be appropriate, but an accurate response might be difficult to obtain without time consuming research into the documentation which is an unrealistic expectation of clinicians.

M2020: The current choices for this item direct you to score a two for the patient who requires more than one component of option 1. The patient who requires reminding to take his/her medications likely requires dosage preparation in advance as well. How do I score them now?

M2110: This grid captures the patients' level of dependence well.

Overall, the training requirements seem grossly under-estimated. Training involves more than the clinicians. Supervisory and other clinical staff also requires this knowledge of OASIS. The process of completing the assessment, even for experienced clinicians will be longer, as they must now read each question and corresponding choices until they become intensely familiar.

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Document: CMS-2008-0141-0034
MN

Submitter Information

Name: Jennifer Stark
Address:
Duluth, MN, 55805

General Comment

Please refer to attached comment letter.

Thank you.

Attachments

CMS-2008-0141-0034.1: MN

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

#34

January 9, 2009

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

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

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

I support the use of OASIS in home health as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, I have the following comments/concerns regarding the OASIS-C changes.

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

***Concern:* M1010 & 1012 Inpatient Diagnosis and ICD Code**
Suggestion for Change: Eliminate this requirement. If CMS needs the data, the information should be obtained from the inpatient facility.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final coding often does not occur until the hospital generates their bill. It is not realistic for

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

***Concern:* M01014 Medical or Treatment Regiment Change**
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

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

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

***Concern:* M1038 Guidelines for Physician Notification**
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a

physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

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

***Concern:* M1242 Formal Pain Assessment**
***Suggestion for Change*:** Make suggestions and list appropriate standardized assessment tools for pain. Benchmarking will be difficult and inconsistent if agencies use different standardized assessment tools that may vary on what indicates "severe pain". Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools, such as 0-10 scale and Wong-Baker Faces pain scale, will help decrease data variance that is collected by providers.

***Concern:* M1300 - M1306 - Pressure Ulcer Assessment**
***Suggestion for Change*:** Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen. Please clarify how this question should be answered if I use a standardized tool and an evaluation of clinical factors to assess.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? Is it realistic to get all of this done in the 5-day time frame? Consultation with staff outside the homecare agency, for example a wound ostomy clinic, is often necessary to gather all pertinent clinical information.

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

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

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

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

M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is not the homecare clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

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

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

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

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

Concern: **M1880 Change in Mobility**
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of homecare services. What if they are worse as a

result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

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

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

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

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

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

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

should not be expected to resolve something that is outside of the scope of practice (ordering medications).

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

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

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

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

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

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient as is and will become increasingly exhausting for the patient as all of the other assessments are added. I know of instances where patients have decided that it just wasn't worth having homecare during the initial start of care visit due to the burdensome paperwork involved. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive non-billable visits are being made in order to complete the assessment within

the last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Several items on the proposed OASIS-C document would require the clinician to review the medical record documentation for the entire previous episode of care, which would be extremely time consuming. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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

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

Sincerely,

Jennifer Stark, RHIA
Health Information & Compliance Coordinator
St. Luke's Home Health Services
220 North 6th Avenue East
Duluth, MN 55805

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Document: CMS-2008-0141-0035
MN

Submitter Information

Name: Kris Stark
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Duluth, MN, 55811

General Comment

See attached

Attachments

CMS-2008-0141-0035.1: MN

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

#33

January 9, 2009

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

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

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

I support the use of OASIS in home health as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, I have the following comments/concerns regarding the OASIS-C changes.

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

Concern: **M1010 & 1012 Inpatient Diagnosis and ICD Code**
Suggestion for Change: Eliminate this requirement. If CMS needs the data, the information should be obtained from the inpatient facility.
***Rationale*:** Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final coding often does not occur until the hospital generates their bill. It is not realistic for

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

***Concern:* M01014 Medical or Treatment Regiment Change**
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

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

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

***Concern:* M1038 Guidelines for Physician Notification**
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a

physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

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

***Concern:* M1242 Formal Pain Assessment**
***Suggestion for Change*:** Make suggestions and list appropriate standardized assessment tools for pain. Benchmarking will be difficult and inconsistent if agencies use different standardized assessment tools that may vary on what indicates "severe pain". Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools, such as 0-10 scale and Wong-Baker Faces pain scale, will help decrease data variance that is collected by providers.

***Concern:* M1300 - M1306 - Pressure Ulcer Assessment**
Suggestion for Change: Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen. Please clarify how this question should be answered if I use a standardized tool and an evaluation of clinical factors to assess.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? Is it realistic to get all of this done in the 5-day time frame? Consultation with staff outside the homecare agency, for example a wound ostomy clinic, is often necessary to gather all pertinent clinical information.

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

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

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

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

M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is not the homecare clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

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

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

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

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

Concern: **M1880 Change in Mobility**
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of homecare services. What if they are worse as a

result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

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

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

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

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

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

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

should not be expected to resolve something that is outside of the scope of practice (ordering medications).

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

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

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

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

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

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient as is and will become increasingly exhausting for the patient as all of the other assessments are added. I know of instances where patients have decided that it just wasn't worth having homecare during the initial start of care visit due to the burdensome paperwork involved. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the

last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Several items on the proposed OASIS-C document would require the clinician to review the medical record documentation for the entire previous episode of care, which would be extremely time consuming. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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

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

PUBLIC SUBMISSION

As of: January 15, 2009
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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-2008-0141-0036
MN

Submitter Information

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Minneapolis, MN, 55407
Organization: Allina Hospitals and Clinics-Allina Home Care, Hospice & Palliative Care

General Comment

Please review our attached response and recommendations for change to the proposed OASIS-C tool.
Nancy Payne
Director Compliance and Regulatory Affairs

Attachments

CMS-2008-0141-0036.1: MN

Allina Hospitals & Clinics
Compliance and Regulatory Affairs
PO Box 43 Mail Route 10105
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January 9, 2009

#36

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulation Development
Attention: Document Identifier/OMB Control Number 09380760
Room CA2605
7500 Security Boulevard
Baltimore, MD 212441850

RE: CMS–R–245

On behalf of Allina Hospitals & Clinics (Allina), I appreciate the opportunity to comment on the proposed changes to the Outcome and Assessment Information Set, referred to as OASIS-C, as released in the November 14, 2008, Federal Register.

Allina is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, retail pharmacy, home health and hospice services, as well as home oxygen and medical equipment. Allina serves communities throughout Minnesota and western Wisconsin. Our interest in the proposed changes to the OASIS are significant in that our Allina Homecare, Hospice and Palliative Care (AHHCP) provides comprehensive home based services for over 2000 Medicare patients per year with strong growth expected in the future.

While we support the role the OASIS as a comprehensive assessment tool and as a quality measurement and improvement tool, we have numerous concerns and recommendations regarding the OASIS-C changes CMS proposes.

Concern: M0102 Date of Referral
Recommendation: 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

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 and M1012 Inpatient Diagnosis and ICD Code
Recommendation: Eliminate this requirement. If CMS needs the data it is available from the hospitals.
Rationale: Not all institutions make this information available in 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 patient's medical record.

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

Concern: M1032 Frailty Indicators
Recommendation: Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes 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 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, and 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: All providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. Additionally, for consistent practice within the industry, it is imperative to have concise definitions for stable vital signs, debilitating pain, mental health changes and functional decline. Unclear instructions and definitions will result in unreliable data. Of concern also is that the frailty indicators are not measurable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

Concern: M1034 Stability Prognosis
Recommendation: Eliminate # 3-The patient has serious progressive conditions that could lead to death within 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
Recommendation: 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 will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is physician responsibility and therefore not controllable by provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify 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
Recommendation: 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.

Concern: M1242 Formal Pain Assessment
Recommendation: 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 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
Recommendation: 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 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 wound healing clinic, is often necessary to gather all pertinent clinical information.

Concern: M1312-M1314 Pressure Ulcer Length &Width
Recommendation: 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 complete wound assessment;

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

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

Concern: M1326 Pressure Ulcer Intervention
Recommendation: 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 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
Recommendation: 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 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
Recommendation: 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 data gathering time upon which the clinician bases the plan of care.

Concern: M1500 Symptoms of Heart Failure
Recommendation: 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
Recommendation: Offer suggestions for specific screening tools.
Rationale: Clinicians need to use standardized screening tool in order to collect and report on standardize data. Comparison across patients will be less accurate if individual providers are using wide variety of screening tools.

Concern: M1734 Depression Intervention Plan
Recommendation: 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 data gathering time on which the clinician bases the plan of care.

Concern: M1880 Change in Mobility
Recommendation: Eliminate this item.
Rationale: What if the patient is better at transferring but not at ambulation how should the question be answered? This is 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 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
Recommendation: Eliminate this item.
Rationale: What if the patient is better at dressing but not at bathing how should the question be answered? This is 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
Recommendation: Eliminate this item.
Rationale: This assessment is covered in an emergency plan and safety assessment.

Concern: M1920 Change in Ability to Perform Household Tasks
Recommendation: 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 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 multifactor Falls Risk Assessment?
Recommendation: Utilize 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 consistent manner.

Concern: M1940 Fall Risk Assessment Intervention
Recommendation: 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 data gathering time on which the clinician bases the plan of care.

Concern: M2002 Medication Follow-Up
Recommendation: Eliminate the need to contact the physician within one day and clarify what is considered "contacted". Does that mean message has been left via phone, 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 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 Medicare episode. This is especially problematic if the Assisted Living facility has policy requiring the 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
Recommendation: 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 "look-back" on OASIS are those instructions no longer valid?

Concern: M2020 Management of Oral Medications
Recommendation: 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 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 change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.

Concern: M2110 Types and Sources of Assistance Matrix
Recommendation: 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 much larger scale in order determine the feasibility and usefulness of the proposed OASIS changes.

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 un-billable 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 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.

In summary, Allina appreciates the opportunity to provide comments on the proposed changes to the OASIS-C. We hope that CMS will consider our recommendations as you move ahead to finalize this tool. If you have any questions, please feel free to contact me at 612-262-4912.

Sincerely,

Nancy G. Payne

Nancy G. Payne, RN, MA
Director Compliance and Regulatory Affairs
Allina Hospitals & Clinics

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-2008-0141-0037
MN

Submitter Information

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Address:
Chisago City, MN, 55013
Organization: Fairview Lakes HomeCaring & Hospice

General Comment

Please review letters before finalizing OASIS-C. Very good and legitimate comments to help make OASIS the best, most reliable and useful it can be.
Thank you,
Debra Solomon

Attachments

CMS-2008-0141-0037.1: MN

FAIRVIEW
LAKES HEALTH SERVICES

HomeCaring & Hospice
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January 8, 2009

#37

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 on behalf of our Home Care agency 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 measurable and "other" data would be clinically significant to the patient's home care episode but would not be retrievable from a text field.

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

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

Concern: **M1040** through M1055 Vaccinations
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 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

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.

<u>Other general comments and concerns:</u>
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,

Debra Solomon, RN, MSN, FNP-BC
Clinical Coordinator
Fairview Lakes
HomeCaring & Hospice

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-2008-0141-0038
MN

Submitter Information

Name: Nancy Jordan
Address:
Duluth, MN, 55805
Organization: St. Luke's Home Health Services

General Comment

Please see attached comment letter.

I have reveiwed the OASIS-C in depth. As a nurse I am concerned about the time it would require for me to gather all the data on the 1st visit. Our patients are often very ill and the amount of data that is required on the OASIS C will be hard for our patients.

Attachments

CMS-2008-0141-0038.1: MN

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

#38

January 9, 2009

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

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

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

I support the use of OASIS in home health as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, I have the following comments/concerns regarding the OASIS-C changes.

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

Concern: **M1010 & 1012 Inpatient Diagnosis and ICD Code**
Suggestion for Change: Eliminate this requirement. If CMS needs the data, the information should be obtained from the inpatient facility.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final coding often does not occur until the hospital generates their bill. It is not realistic for

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

Concern: **M01014 Medical or Treatment Regiment Change**
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

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

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

Concern: **M1038 Guidelines for Physician Notification**
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a

physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

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

***Concern:* M1242 Formal Pain Assessment**
***Suggestion for Change*:** Make suggestions and list appropriate standardized assessment tools for pain. Benchmarking will be difficult and inconsistent if agencies use different standardized assessment tools that may vary on what indicates "severe pain". Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools, such as 0-10 scale and Wong-Baker Faces pain scale, will help decrease data variance that is collected by providers.

***Concern:* M1300 - M1306 - Pressure Ulcer Assessment**
Suggestion for Change: Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen. Please clarify how this question should be answered if I use a standardized tool and an evaluation of clinical factors to assess.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? Is it realistic to get all of this done in the 5-day time frame? Consultation with staff outside the homecare agency, for example a wound ostomy clinic, is often necessary to gather all pertinent clinical information.

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

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

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

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

M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is not the homecare clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

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

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

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

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

***Concern:* M1880 Change in Mobility**
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of homecare services. What if they are worse as a

result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

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

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

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

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

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

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

should not be expected to resolve something that is outside of the scope of practice (ordering medications).

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

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

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

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

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

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient as is and will become increasingly exhausting for the patient as all of the other assessments are added. I know of instances where patients have decided that it just wasn't worth having homecare during the initial start of care visit due to the burdensome paperwork involved. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the

last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Several items on the proposed OASIS-C document would require the clinician to review the medical record documentation for the entire previous episode of care, which would be extremely time consuming. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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

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

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Document: CMS-2008-0141-0039
MN

Submitter Information

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Address:
Walker, MN, 56484
Organization: Cass County Health, Human & Veteran's Services

General Comment

OASIS-C comment letter

Attachments

CMS-2008-0141-0039.1: MN

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

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Date: 1/9/2009

#39

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

I am 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)

I 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, 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 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: All 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 multifactor 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 un-billable 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. In addition we are having difficulty finding qualified clinicians to replace those leaving. Shortages in healthcare workers will soon overwhelm the system. Finally the state of the current economy is forcing small agencies such as ourselves to evaluate whether they can afford to remain in the home care industry.
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,

Jeri Seegmiller PHN
Clinical Quality

PUBLIC SUBMISSION

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Comment On: CMS-2008-0141-0001
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Document: CMS-2008-0141-0040
CA

Submitter Information

Name: Mary Dete
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Organization: Angeles Home Health Care, Inc.

General Comment

I think Medicare has evolved from being a payer to a player. It is influenced by its illusion of control supported by an excess of regulations and a fondness for hyper-research and false starts in the implementation of quality standards. It has yet to deliver a working efficient model that balances patient and Provider rights, regulations, reimbursement and realistic outcomes expectations as evidenced by the increased collection burden in the proposed OASIS C document. It swings from confusion to inspiration. I think the potable or electronic Medicare Beneficiary Health Record should be the platform for reform. Don't keep tinkering with assessment tools. Instead, have a centralized assessment with event tabs for specific Providers (hospital, SNF, Rehab, Physician, HHC etc.). Use assessment "across the continuum." Currently we have more UN than continuum. I think members of the NQF should only be Medicare beneficiaries, Medicare Providers with over 10 years of recent experience and exemplary Meicare compliance surveyors. I suggest this membership to illustrate that reform, like evolution (or revolution) comes from those who have walked the walk. There should be a transparency of the relatedness of the Medicare Conditions of Participation, OASIS system and the reality findings of Surveys and assessments of care by recipients or their spokespersons.

My analysis of the proposed OASIS C changes is driven by this preamble.

1. Process Items belong in the Medicare COP. The "best practices" have proven their worth. They belong in the COP. HHC Agencies will then be required to incorporate them in their policies and procedures. State Surveyors will monitor their compliance and the outcomes recorded in the Medical Record, including the OASIS data will be "auditable." Various States require pain assessment and intervention as an integral part of patient vital signs.
2. The additional specificity in the functional limitations assessments is welcome. Attempting to quantify "frailty, stability and risk factors" is somewhat improved. The tool misses the mark in the area of medication compliance and the underlying factors: cognitive, compliance, financial, physical.
3. Assessment related to patient instruction don't fit in OASIS. They are process and the real meat is What the patient Learns and Does. The questions should

capture the SOC medication plan knowledge and compliance and the Discharge would reassess it. Transfers would look for more information on WHAT and WHO drove the rehospitalization.
4. Psychiatric Nursing involvement MO seems to imply this plus medication is the antidote for depression. Don't tretment modalities belong on the 485/POT and in the Policy Manual directives, not on the OASIS? (And what about the clinical gifts of Geri-Psych evaluations, MSW interventions, Parish Nurses, Volunteers, Adult Day Care, partial hospitalization resources, to name a few?)

Therefore, I suggest the following deletions as these MO items belong in the MCOP:
M1038, 1040, 1045, 1050, 1055, 1242, 1246, 1304, 1306, 1326, 1360, 1365, 1500, 1510, 1600, 1730, 1732, 1734, 1736, 1750, 2002, 2004, 2010, 2015

Improvement needed in the following to add more specificity:
M1740, 2310, 2430.

Submitted: Mary K. Dete, RN, PHN, BSN Director of Professional Services
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Document: CMS-2008-0141-0041
IA

Submitter Information

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General Comment

Please, scour the tool for relative terminology the users will define differently, for ex: M1032 terms: major decline, unstable, debilitating, decline in mental status; M1034 high health risks, fragile health. The questions need to be specific and measurable with terminology that is inherent in the question.

M1880, M1890: What time frame are we looking at for prior and how do we answer if there has been a change from the prior ability for ADL's when the question includes multiple tasks however expects one response.

Please seek the guidance of OASIS Answers team (Deb Chishom and Linda Krulish). Who better to spot those questions ripe for confusion, they have answered thousands!!! Otherwise we will end up with a document whose questions lead to constant confusion about how to interpret effecting the reliability of the tool and added rules that apply to one specific question that are latter retracted and a new rule or interpretation applied.

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Document: CMS-2008-0141-0042
KS

Submitter Information

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General Comment

I am responding to the addition of process items that support measurement of evidence based practices. My expertise is pressure ulcer process and outcome indicators in acute and home health care. I am very concerned about the proposed OASIS items M1304 and M1306. I recommend that "physician-ordered" be removed from both items. Rationale #1) Pressure ulcer prevention is multidisciplinary. Use of the word "physician-ordered" implies that only the physican is important to a pressure ulcer prevention plan of care. However, nurses and physical therapists initiate and implement pressure ulcer prevention in this setting as both complete OASIS assessments (as do occupational therapists). Nursing and these other disciplines have interventions that can be independently implemented but both interact with physicians to assure appropriate prevention is provided. A no response to this question can mean that a pressure ulcer prevention plan of care is being implemented by nurses and other disciplines or it can mean that no pressure ulcer prevention is being provided. Therefore, the data item as written will not enable assessment of pressure ulcer prevention quality of care. Rationale #2) The NQF Home Health Care Initiative does not mention "physician ordered". Rather it asks if a pressure ulcer plan of care was implemented without specifying discipline. Retention of "physician ordered" will leave OASIS inconsistent with NQF measures.

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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-2008-0141-0043
KS

Submitter Information

Address:
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General Comment

Regarding OASIS items M1244, M1246, M1360, M1365, M1734, M1736, M1940, M1945 - I recommend that the words "physician ordered" be removed from these questions. Rationale: the plan of care and implementation of the plan of care referenced in these OASIS items are multidisciplinary. A no response to these items will mean that the physician did not order the interventions. However another discipline such as nursing may be monitoring or assessing for foot lesions, depression, falls, providing education on proper foot care etc If the purpose of the question is to evaluate quality of care, then a question for each discipline should be included - else exclude the reference to "physician -ordered" altogether to imply that all disciplines are involved.

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Document: CMS-2008-0141-0044
MN

Submitter Information

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Rochester, MN, 55901
Organization: Stanley Jones & AssociatesI

General Comment

We are writing to comment on the proposed changes to the OASIS-C ,
noticed on November 14, 2008, Federal Register Document Identifier: CMS-R-245.

Thank you for the opportunity to express our opinion.

Following are our comments.

Attachments

CMS-2008-0141-0044.1: MN

#44

Concern: M0102 Date of Referral
Suggestion for Change: Eliminate this requirement.
Rationale: Starting services is not always within an agency's control. An agency may be waiting for authorization from Medicare Advantage programs, the referral may have come from the hospital well before the actual discharge date; a patient a family member may request services to begin on a certain day (for instance following a scheduled surgery). Also, not all referrals come from a physician.

Concern: M0903 Date of Last (Most Recent) Home Visit
Suggestion for Change: Eliminate this requirement
Rationale: This information may be unreliable if obtained from the client. If the last home care agency has not billed, this information will not be present in the Common Working File.

Concern: M1010 & 1012
Suggestion for Change: Eliminate this requirement
Rationale: If CMS needs this information, it is available from the hospital. Not all hospitals make this information readily available to providers in a timely manner. Final coding in hospitals may not occur until billing occurs, making obtaining this information a difficult task in some instances. It is not realistic for home care clinicians to have knowledge of the coding requirements for inpatients facilities; requiring them to enter this information with insufficient or incomplete data from referral sources will result in errors in patient's medical records.

Concern: M01014
Suggestion for Change: Eliminate this requirement
Rationale: This information is collected in other M0 items

Concern: M1034
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 with the exception of the predicted time of death. Clinicians should not have to guess if a client is going to live or die with in a year's time. Also, there will be difficulty differentiating between number 2 and 3 resulting in useless data.

Concern: M1038
Suggestion for Change: Eliminate the requirement
Rationale: This seems burdensome for both physicians and providers. Doctors already report having excessive paper work requirements from the home care industry. Physicians will most likely not provide this for all patients. This parameter is decided by the physician, not the provider and therefore, not controllable by the provider. Home care clinicians are already required to notify a physician about changes in the patient's condition 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-M1055
Suggestion for Change: Clarify instructions that providers will not be mandated to provide vaccinations. Eliminate "from your agency".

Rationale: It is important to verify vaccinations, however why is it important that the agency who is providing the current service give the vaccination? Why should providers assume the financial and resource burden of vaccination administration? There are more efficient ways to ensure vaccinations.

Concern: M1242
Suggestion for Change: Formal Pain Assessment
Rationale: The physician-ordered plan of care I not yet established at the time of SOC OASIS assessment. This time is a data gathering time for the clinician to base the plan of care on. Also, standardized tools would assist in gathering data that would be statistically accurate.

Concern: M1300-M1306
Suggestion for Change: Extend the SOC OASIS assessment time for five to seven days to allow collaboration between disciplines and to determine ability and availably of caregivers as well as the most effective wound care regime.
Rationale: It may be unrealistic to get all of this done in a five day window if a wound care clinic needs to by consulted or other staff, especially if the assessment is done on a weekend or by a physical therapist that is not trained in wound care.

Concern: M1312 – M1314
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 and accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measurement 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
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**
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
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: Diabetic Foot Care Plan
Suggestion for Change: Do not collect this at the start of care.
Rationale: The physician ordered plan of care is not yet established at the tome of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.

Concern: M1730
Suggestion for Change: Offer suggestion for a standardized tool
Rationale: Improve the validity of the OASIS results.

Concern; Depression Intervention Plan
Suggestion for Change: Eliminate this item
Rationale: The physician ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is a data gathering time on which the clinician basis the plan of care.

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

Concern: 1940 Falls Risk Assessment Intervention
Suggestion for Change: Do not require at the 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 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, and 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 two clinicians completing the OASIS assessment? What if the physician is contacted but nothing is resolved, what then does CMS expect. Consider the discharge disposition for patients in assisted living facilities. The risk adjustment is inadequate. Patients move to assisted livings because they can't manage their medications or ADLs. It is unlikely they will recover the abilities and show improvement during a Medicare episode. It becomes more problematic if the assisted living has a policy that does not allow the resident to administer their own medications. This skews medications for these populations. If it is a weekend admission, it is highly unlikely the issue would be resolve in one day. Providers should not be expected to resolve something that is outside of their scope of practice (ordering medications).

Concern: M2004 Medication Intervention
Suggestion for Change: Eliminate this item
Rationale: It is unrealistic to expect the clinician to all of this without reviewing an entire medical record and the previous OASIS (have the rules changed and is it okay to do so?) This would be extremely time consuming.

Other General Comments and Concerns

1) Expand the time frame to complete the OASIS

   With the number and complexity of the OASIS questions increasing, allow 7 days for the SOC. This will be less burdensome on both the clinician and the patient. Increase the timeframe for recertifications. Allow the recertification to be completed within the last 2 weeks of the certification period.

2) Add a standardized tool to assess pain and risks for breakdown that is nationally recognized. This would be beneficial for national benchmarking.

   Thank you for considering our concerns before proceeding with the plan to change the OASIS as proposed.

   Sincerely,

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Document: CMS-2008-0141-0045
FL

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General Comment

Interim HealthCare Inc. appreciates the work devoted to the revision of the OASIS document and consideration of recommendations for change submitted by the industry over the past 8 years. For reasons of efficiency, we are representing the comments of our Network related only to those items which we believe need further refinement or deletion. The comments are stated in numeric order of the OASIS items and are uploaded here as a separate attachment.

Attachments

CMS-2008-0141-0045.1: FL

#45

Aggregate Comments on Proposed OASIS-C Respectfully Submitted by Interim HealthCare Inc.– 110 Medicare Certified Home Health Agencies in 30 States

We appreciate the work devoted to the revision of the OASIS document and consideration of recommendations for change submitted by the industry over the past 8 years. For reasons of efficiency, we are representing the comments of our Network related only to those items which we believe need further refinement or deletion. The comments are stated in numeric order of the OASIS items.

M1032 (Frailty Indicators)
Recommendation: Delete from OASIS; abstract from other existing sources

Comments: The majority of items included among the response choices are already collected elsewhere in the OASIS document:

a) Debilitating pain is M1240;

b) Recent functional decline is M1880 Change in Mobility, M1890 Change in Self-care Ability and M1920 Change in Ability to Perform Routine Household Tasks

c) History of falls is part of the Fall Risk Assessment (see our comment for M1930 Fall Risk Assessment)

Another response item, "multiple hospitalizations", is an item that is more accurately collected through the CMS database rather than through the recall of a stressed patient/family.

The response "unstable vital signs" is impossible for the clinician to answer upon SOC or ROC since the clinician will have only one set of vital signs at that time—unable to determine stability.

Overall this question appears to be a research question, and it does not contribute any additional useful information to the home care agency to plan or provide efficient and effective care to the patient. Home care should not be responsible to aggregate this information.

Finally, if this question is retained, please advise the home care industry of the importance of a "frailty" indicator: a)how it should be used in planning patient care: and b) is it any one response that attributes the designation of "frailty" to a patient or a particular combination? Without this information, the question is a research project that we believe is most efficiently conducted on a sample of patients, and not at the cost of time of clinicians and patients nationwide.

Recommendation: Delete the frailty question

M1034 (Stability Prognosis)
Recommendation: Delete from OASIS

Comments: This item contains very imprecise and subjective language, such as "heightened" risk, "serious" complications, "high" health risk, "likely" to return, "typical of the patient's age", "fragile" health, "serious" progressive conditions. Unless these terms are clearly and specifically defined, the interpretation from one clinician to another will be so inconsistent as to make this question useless and a waste of time for the clinician and the patient.

The term "typical of the patient's age" is actually somewhat offensive as it reinforces stereotypical thinking regarding the elderly. We know and we are constantly reminded that each senior is an individual; that there is no such thing as a "typical" 80 year old, for instance.

Critically, it is the opinion of our nursing leaders nationwide that the types of conclusions listed as responses in this question go beyond the nurse's or therapist's scope of practice. Our training provides no basis for answering this question; we believe these are best relegated to physician practice.

This question will cause stress and anxiety among the clinicians responsible for completing OASIS while at the same time it does not contribute to the clinical care that must be planned and provided to the patient. Again, additional information is requested from home care without advising the industry what it does to improve care and there is no evidence-based research that supports the need or the value of establishing a "stability" index for home care patient.

Recommendation: Delete this question from the OASIS.

M1038 (Guidelines for Physician Notification)
Recommendation: Delete this measure – "high risk" is inadequately defined to implement in day-to-day process, and the references to the content of the Plan of Care and documentation to transfer or discharge is best incorporated into the certification survey process

Comments: The term "high risk medication" is imprecise and requires interpretation on the part of the clinician; the two examples provided (hypoglycemics and anticoagulants) are inadequate to apply the label of "high risk" to other medications an individual patient may take. If a high risk medication classification and list exists, CMS should advise the industry, otherwise the variation in interpretation will not result in a positive improvement in patient care. This question also seems to be redundant of M2015 Patient/Caregiver Drug Education Intervention. Finally, does the label of "high risk" apply to over-the-counter medications also? Home care typically collects a medical profile that includes prescribed drugs, OTC medication and herbs and supplements in view of the at-risk problems of the combinations of many of these substances.

These process questions related to verifying that all appropriate interventions have been implemented throughout the episode. Although simple in concept, this is actually quite complex to operationalize in current home care practice.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which may be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these particular standards relating to clinician behavior and work flow.

Recommendation: Remove process questions related to the Plan of Care and the record of intervention from the OASIS and use them to establish clear, measurable and objective performance expectations used during the certification survey process; and either identify "high risk" medications, including OTC and supplements and herbal products or delete the question.

M1050 (Pneumococcal Vaccine) and M1055 (Reason PPV Not Received)
Recommendation: Delete from OASIS; move the measure to the physician PQRI data set.

Comments: We believe there is an issue of patient recall for a vaccine only recommended once in a lifetime after age 65. We typically initiate home health following an acute exacerbation and

the patient is just returning home - a stressful situation only contributing to recall problems. Although a second pneumococcal vaccine injection would not harm the patient, it is a waste of Medicare resources. The only repository of accurate knowledge of the patient having received the vaccine is the physician practice. We support greater integration of preventive care in home health care, but when the implementation of such is practical.

Recommendation: The receipt of the pneumococcal vaccination should be relegated to PQRI measures as the physician practice has the best history of vaccination.

M1100 (Patient Living Situation)
Recommendation: Modification by defining terms used in the item

Comments: Please better define "regular daytime", "regular nighttime" and "occasional/short term" as interpretation will vary widely and the resulting data will be of questionable value. These are not standardized terms in home care with accompanying standardized definitions.

M1242 (Frequency of Pain)
Recommendation: Modify Words in bold face to emphasize meaning of the Item

Comments: As this item is currently worded, "**Frequency of pain** interfering with patient's activity or movement", the emphasis is placed on the frequency of pain as reflected by the bolded words "Frequency of Pain". Unfortunately, many clinicians do not read the complete question to realize that it is asking about how often pain interferes with activity or movement. We would like to see the emphasis of the question to be changed as follows "Frequency of **Pain Interfering with Patient's Activity or Movement**" (notice the change in which words are bolded).

M1242-(Formal Pain Assessment)
Recommendation: Modification

Comments: While we support requiring the use of a standardized pain assessment as expected practice in home care, we question the validity of an item that does not specify the scale or scales to be used. We would recommend that CMS select one or more scales to be used and incorporate such into the OASIS instead of this measure. We believe any outcomes related to pain management could then be better correlated to the use of a known instrument rather than the randomly selected assessment by a variety of providers and clinicians. There is not even the assurance that the clinicians in any one agency use the same assessment. If a standardized assessment is used, we believe that the results could also contribute to the home health industry's knowledge of effective care. We encourage CMS to be bold, make a substantial change and make more rapid progress in care improvement than can be offered by "yes, no" questions.

Also, the responses currently offered provide no standardized definition of "severe". If a standardized scale(s) was used, the definition of "severe" could be noted on the scale(s) providing improved inter-rater reliability on this item and more uniform focus by clinicians on addressing "severe" pain.

Recommendation: Modify the question by requiring the use of a CMS selected pain assessment scale and define "severe".

M1244 (Planned Pain Intervention) and M1246 (Pain Intervention)
Recommendation: Delete both measures, and incorporate both into the certification survey process.

Comments: These process questions related to including interventions on the Plan of Care and verifying that all appropriate interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which may be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud CMS' effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards of clinician behavior.

Recommendation: Remove process questions related to the content of the Plan of Care and the presence/absence of interventions from the OASIS, and use them to establish clear, measurable and objective performance expectations during the certification survey process.

M1300 (Pressure Ulcer Assessment)
Recommendation: Modification

Comments: We commend CMS for addressing pressure ulcer risk screening in this population. However, we also recommend that the item be modified to require the sue of a standardized screen such as the Braden Scale in the OASIS document. We question the validity of an item that does not specify the scale or scales to be used. The results of the standardized scale could contribute to the home health industry's knowledge of effective care. We encourage CMS to be bold, make a substantial change and make more rapid progress in care improvement than can be offered by "yes, no" questions.

In addition, the use of a standardized screen would negate the need of M1302 (Risk of Developing Pressure Ulcers) and reduce the burden of the OASIS by one more question.

Recommendation: Modify the item by requiring a particular standardized scale, such as the Braden Scale.

M1304 (Planned Pressure Ulcer Prevention) and M1306 (Pressure Ulcer Prevention)
Recommendation: Delete both measures, and incorporate both into the certification survey process.

Comments: These process questions related to including interventions on the Plan of Care and verifying that all appropriate interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which may be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review,

again, to answer honestly if all interventions were appropriately implemented over the course of an episode.

- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards and change traditional clinical behavior in home health agencies with no presentation of research indicating this as a best practice.

Recommendation: Remove process questions related to the Plan of Care and the intervention history from the OASIS, and use them to establish clear, measurable and objective performance expectations that are used during the survey process.

M1312 (Pressure Ulcer Length) and M1314 (Pressure Ulcer Width)
Recommendation: Modification

Comments: The requirement for measurement of a wound is essential. However, the question as currently written focuses solely on the longest ulcer. When more than one ulcer is present, all ulcers may be healing but not at the same rate—this is not uncommon. The longest ulcer at SOC may have progressed rapidly through the healing process but at discharge a different ulcer may have healed more slowly. Because the slower healing ulcer is now the "Longest", it becomes the point of measurement. The results may not reflect the true outcome for the patient.

We request that you consider an alternate method for measuring an ulcer. Namely, request the total area covered by ulcers to be recorded (in square cm). This is achieved by adding the area of all pressure ulcers (length in cm X width in cm). The question would again be repeated at discharge. Although this method requires some basic math, it does present us with a much better measurement of improvement.

Recommendation: Modify the measurement to reflect the total area affected by all ulcers, not a single ulcer, at SOC, ROC and at discharge.

M1326 (Pressure Ulcer Intervention) and M1328 (Pressure Ulcer Intervention)
Recommendation: Delete from OASIS; move the measures to the physician PQRI data set.

Comments: These questions focus on the standard of practice related to moist wound healing. All of our home care nurses want ALL of their wound care patients to receive moist wound treatment. However, it is the physician who is the decisionmaker regarding wound treatment. They write the orders for the dressing, and the nurse must follow this order (assuming it is not detrimental to the patient's health). Although our nurses attempt to influence the physician, they are not always successful. These questions are clearly outside of the scope of nursing practice. It appears to be research on physician practice, not assessing home care practice.

Recommendation: Move the questions to the PQRI data set to focus on improvement of physician practice which home care nurses are not able to directly impact in each instance in which a patient would receive appropriate care with moist wound healing treatment.

M1360 (Diabetic Foot Care Plan) and M1365 (Diabetic Foot Care Plan Follow Up)
Recommendation: Delete both measures, and incorporate both into the certification survey process.

Comments: These process questions related to including interventions on the Plan of Care and verifying that all appropriate interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which often may be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care.. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards.

Recommendation: Remove process questions related to the Plan of Care and the intervention history from the OASIS, and use them to establish clear, measurable and objective performance expectations that are used during the certification survey process.

M1500 (Symptoms of Heart Failure) and M1510 (Heart Failure Follow-Up)
Recommendation: Delete both measures, and incorporate both into the certification survey process.

Comments: These process questions related to including interventions on the Plan of Care and verifying that all disease-specific interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which often may be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care.. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards.

Recommendation: Remove process questions related to the Plan of Care and the intervention from the OASIS and use them to establish clear, measurable and objective performance expectations that are used during the survey process.

M1730 (Depression Screening)
Recommendation: Modification by selecting a standardized scale(s) for use in the OASIS

Comments: We commend CMS for addressing depression screening in this population. However, we recommend that the item be modified to include a specific screen such as the Geriatric Depression Screen in the OASIS document. The PHQ may also be included for patients aged 18-64. We question the validity of an item that does not specify the scale or scales to be used. Using a standardized scale, the results could also contribute to the home health industry's knowledge of effective care. We encourage CMS to be bold, make a substantial change and make more rapid progress in care improvement than can be offered by "yes, no" questions.. In addition, the use of a standardized screen would negate the need of M1732 (Depressive Symptoms Reported) and reduce the OASIS by one more question.

Also, please clarify in the instructions how the question is answered should the patient already be diagnosed with a depressive disorder and is being treated.

Recommendation: Insert a standardized depression screen in the OASIS, and define how the question is answered if the patient has been diagnosed with a depressive disorder and is being treated.

M1734 (Depression Intervention Plan) and M1736 (Depression Intervention Implementation)
Recommendation: Delete both measures, and incorporate both into the certification survey process.

Comments: These process questions related to including interventions on the Plan of Care and verifying that all appropriate interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the questions do not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (often by someone else) to answer honestly if all appropriate interventions are on the Plan of Care.. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, these questions also require the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards..

Recommendation: Remove process questions related to the Plan of Care and the intervention from the OASIS, and use them to establish clear, measurable and objective performance expectations that are used during the survey process.

M1860 (Ambulation/Locomotion)
Recommendation: Modification of Response #2 to address ability to climb stairs

Comments: Clinicians have struggled with the accurate response to this question since the inception of OASIS. Thank you for the modifications you have made to the responses. We would

additionally recommend in response item #2 the elimination of the "and/or" option and only allow "and". As a #2 response actually requires a patient to be able to negotiate stairs, the "and/or" option is confusing and misleading. As currently written, it allows the option for the patient to be a #2 without being able to climb stairs

Recommendation: Modify response No. 2 by eliminating "and/or" and use only "and" to ensure that this response clearly indicates that the patient can climb stairs.

M1930 (Fall Risk Assessment)
Recommendation: Modification by use of standardized fall risk assessment

Comments: While we support requiring the use of a standardized fall risk assessment as expected practice in home care, we question the validity of an item that does not specify the scale or scales to be used. We would recommend that CMS select one or more scales to be used and incorporate such into the OASIS instead of this item. A comprehensive scale for home care does not currently exist. Interim HealthCare has extracted a number of fall risk assessment elements from several evidence-based tools to create a home care specific tool (See attached). We would like to see a similar tool incorporated into the OASIS, rather than allowing the "yes/no" responses currently proposed.

We believe any outcomes related to fall risk assessment could then be better correlated to the use of a known instrument rather than an individual clinician's use of a randomly choice. The results could also contribute to the home health industry's knowledge of effective care. We encourage CMS to be bold, make a substantial change and make more rapid progress in care improvement than can be offered by "yes, no" questions.

Recommendation: Insert a standardized multi-faceted fall risk assessment, example attached.

M1940 (Falls Risk Intervention) and M1945 (Falls Risk Intervention)
Recommendation: Delete these items and incorporate these into the certification survey process

Comments: This is another process question related to verifying that all appropriate interventions have been implemented throughout the episode, although simple in content, are actually quite complex to operationalize.

- First, the question at the SOC does not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (which may often be by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care.. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, this type of question also requires the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards.

Recommendation: Remove process questions related to the Plan of Care and the intervention history from the OASIS and use them to establish clear, measurable and objective performance expectations that are used during the survey process.

M2002 (Medication Follow Up)
Recommendation: Modification-define "clinically significant"

Comments: Please provide your definition of "clinically significant".

M2010 (Patient/Caregiver Drug Education) and M2015 (Patient/Caregiver Drug Education Intervention)
Recommendation: Delete both measures and incorporate them into the certification survey process; if retained, define "high risk" and denote if such extends to OTC and herbal supplements.

Comments: The term "high risk medication" is imprecise and requires interpretation on the part of the clinician; the two examples provided (hypoglycemics and anticoagulants) are inadequate to provide sufficient guidance to apply the classification to other medications. If a high risk medication classification and list exists, CMS should advise the industry, otherwise the variation in interpretation will not result in positive improvement in patient care. This question also seems to be redundant of M2015 Patient/Caregiver Drug Education Intervention.

In addition, this is another process question related to verifying that all appropriate interventions have been implemented throughout the episode, although simple in concept, are actually quite complex to operationalize.

- First, the question at the SOC does not represent usual home care workflow. The clinician who completes the SOC assessment will be required to wait until the Plan of Care is completed (often by someone else) in order to answer honestly if all appropriate interventions are on the Plan of Care.. In addition, the clinician who completes the discharge or transfer assessment is virtually required to conduct a patient chart review, again, to answer honestly if all interventions were appropriately implemented over the course of an episode.
- Second, this type of question also requires the clinician to work outside of the usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step.

We are seriously concerned that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to complete the assessment. Obviously this approach is not helpful to the agency, the patient or the healthcare system.

We applaud the effort to clearly establish standards of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards.

Recommendation: Remove process questions related to the Plan of Care and the intervention history from the OASIS, and use them to establish clear, measurable and objective performance expectations that are used during the survey process. If the item is retained, "high risk" must be clearly defined and clarification provided as to its application to OTC and herbal supplements.

M2110 (Types and Sources of Assistance)
Recommendation: Modification to define and simplify; delete "supervision and safely" item as repetitive of other OASIS items; "advocacy", "facilitate" need to be defined.

Comments: There are so many items included in any one category (e.g., ADLs) that it makes it difficult for the clinician to choose just one response. This item requires clear instruction to "score" the level of assistance based on the item requiring the most assistance to complete the activity **safely**". Additionally, the items included under each category should be indicated as "i.e.", not "e.g." By using "e.g." you are allowing the clinician to look outside of the categories listed and randomly include other activities, thus compromising the integrity of the information gathered.

There is no need for the "supervision and safety" category because these are addressed on other OASIS questions (M1800 – M1910).

The scope of the meaning of "advocacy" and "facilitation" needs to be better defined to enhance the inter-rater-reliability in the responses.

Recommendation: Modification of complexity of items to improve inter-rater reliability; delete the "safety and supervision" item as this is established in several other OASIS questions; "advocacy" and "facilitate" are inadequately defined for inter-rater reliability.

Issue: Value vs Burden of Proposed Changes

We appreciate CMS' review of our expressed concerns about several of the OASIS items in this statement and over the past several years. We can see that CMS has put effort into improving many of the OASIS measures and making each more practical for use with the home care patient to improve the delivery of home care.

However, we remain seriously concerned that the number of questions in two data sets has increased dramatically:

OASIS data set	B1	C
SOC/ROC	~81	102 (an increase of ~26%)
Transfer	~11	27 (an increase of ~145%)

This increase will result in extended visit time for the assessing clinician, increased cost for the agency and increased stress for the patient family, adding at least an additional 30 to 45 minutes for the SOC and ROC visit, which is already 90 to 120 minutes. If CMS does not consider the extra burden on the home health agency (i.e., the time of the clinician and the extra data entry burden), the additional stress for the patient and family caregiver(s) cannot be overlooked. Here is a direct comment from one of our field clinicians: "Patients hate all the questions we ask now, boy they are really going to hate us and not want us now." We remain concerned that our patients will be lost in the midst of our efforts to "help" them by gathering all of this information. We acknowledge that items on the OASIS are important, but among the new proposed questions we believe that as currently worded more are interesting from the standpoint of analysis of post-acute care and not necessarily demonstrated as important to patient care.

In particular, we are concerned about the value of the agency process questions related to including to asking if interventions are stated on the Plan of Care and verifying that all appropriate interventions have been implemented throughout the episode. Although the items appear simple in concept, they are actually quite complex to operationalize. They fall outside of the usual workflow that occurs in a typical home care agency. The assessing clinician may not be the clinician who provides care throughout the episode nor the clinician who creates the Plan of Care. In addition, the clinician who completes the discharge or transfer assessment will be required to conduct a patient chart review to answer honestly if all interventions were appropriately implemented. These particular items also require the clinician to work outside of their usual clinical process (i.e., assess, analyze, plan, implement, evaluate). Our clinicians perceive that they are being asked to combine assessing, analyzing and planning in the same step. In the absence of evidence-based findings that clinical process be changed, these items do appear to add to quality of patient care.

We fear that clinicians will become frustrated with the difficulty of collecting the information for these questions and just answer "Yes" to all of them in order to get the assessment completed

and off their to-do list. Obviously this approach will not be helpful to the agency, the patient or the healthcare system.

We are pleased that these questions are clearly establishing a standard of practice—something that has been lacking in home health—but we believe that the OASIS assessment is not the effective place to try to enforce these standards.

Recommendation: Remove from the OASIS all of those items related to the Plan of Care and a history of interventions, and use these to establish clear, measurable and objective performance expectations that are used during the certification survey process.

Respectfully submitted,

Barbara A. McCann Chief Clinical Officer, Interim HealthCare Inc.

Karen Carnes, Vice President Clinical Services, Interim HealthCare Inc.

Members of the Interim HealthCare National Nurses Council

Attachment: Recommended multi-faceted fall risk assessment using OASIS items.

Interim HEALTHCARE

SureSteps℠ Fall Prevention Program

Fall Risk Analysis Tool
For Patients Receiving Skilled Care

Patient Name: _____ Date of analysis: _____

Functional Analysis:

Indicator	Yes	No
1. History of falls (2 or more falls or any fall with injury in last year)?	1	0
2. Patient demonstrates agitated or disruptive behavior (M0610 = 3, 4, or 5)?	1	0
3. Vision is at least partially impaired (M0390 = 2 or 3)?	1	0
4. Patient experiences urinary incontinence (M0530 = 1 or 2)?	1	0
5. Patient requires assistance with ambulation **AND** transferring (M0700 = 1 or 2 **AND** M0690 = 1, 2, or 3)?	1	0
Risk Analysis Score		

❒ ***My patient has scored greater than 2 and is at high risk for falls.***

Pharmacy Analysis:

Indicator	Yes	No
1. Total number of high risk diagnoses*		
2. Total number of high risk medications**		
3. Is your patient taking 4 or more medications	1	0
4. Is your patient taking 8 or more medications	1	0
5. Is your patient taking 12 or more medications	1	0
6. Is your patient being treated by more than one physician	1	0
Risk Analysis Score		

❒ ***My patient has a total score greater than 10 and is at high risk for falls.***

***High-risk diagnoses:**

- ❒ cerebrovascular disease
- ❒ cardiac arrhythmia
- ❒ dementia
- ❒ altered mental status
- ❒ Parkinson's disease
- ❒ seizure disorder
- ❒ diabetic neuropathy
- ❒ osteoporosis
- ❒ cataracts
- ❒ previous fracture (LE)
- ❒ altered gait
- ❒ acute illness such as infection, fever

****High-risk medications:**

Drugs which act on the central nervous system:

- ❒ tricyclic antidepressant
- ❒ trazadone
- ❒ monoamine oxidase inhibitor
- ❒ antidepressant
- ❒ antipsychotic
- ❒ barbiturate
- ❒ benzodiazepine.

Drugs which can cause abnormal movements,

- ❒ sedating antihistamine

Drugs which act on the cardiovascular system:

- ❒ beta blocker
- ❒ calcium channel blocker
- ❒ reserpine
- ❒ methyldopa
- ❒ vasodilator
- ❒ digoxin

Drugs which lower blood sugar:

- ❒ oral hypoglycemic
- ❒ insulin

If your patient has a functional score or a pharmacy score that indicates the patient is at high risk for falls, refer the patient to your office's Fall Prevention Program: complete *Patient's Risk of Falls Report to Physician* and incorporate appropriate interventions into POC.

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Document: CMS-2008-0141-0046
MN

Submitter Information

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General Comment

see attached comment letter

Attachments

CMS-2008-0141-0046.1: MN

St. Luke's
Home Health Services
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Duluth, Minnesota 55805

#46

January 9, 2009

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

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

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

I support the use of OASIS in home health as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, I have the following comments/concerns regarding the OASIS-C changes.

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

***Concern:* M1010 & 1012 Inpatient Diagnosis and ICD Code**
Suggestion for Change: Eliminate this requirement. If CMS needs the data, the information should be obtained from the inpatient facility.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final coding often does not occur until the hospital generates their bill. It is not realistic for

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

***Concern:* M01014 Medical or Treatment Regiment Change**
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items

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

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

***Concern:* M1038 Guidelines for Physician Notification**
Suggestion for Change: Delete this item
Rationale: Physicians already report excessive paperwork from the home care industry. Parameters will likely be different for each patient, depending on history and current health status. Physicians most likely will hesitate to provide this for individual patients. This seems excessively burdensome for providers and physicians. Additionally, surveyors are likely to use this as a reason for survey citation if it is not available on all patients. Ultimately, deciding parameters for individual patients is a physician responsibility and therefore not controllable by a provider. Eliminate the need for parameters for each patient. Home care clinicians are already required to notify a

physician about changes in patient conditions that may impact the plan of care. There is no regulatory requirement for parameters. Not every patient requires parameters, and, if they are necessary, it can take time to establish them making it unrealistic to establish them at the start of care.

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

***Concern:* M1242 Formal Pain Assessment**
***Suggestion for Change*:** Make suggestions and list appropriate standardized assessment tools for pain. Benchmarking will be difficult and inconsistent if agencies use different standardized assessment tools that may vary on what indicates "severe pain". Eliminate this question on SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care. Additionally, the use of one or two standardized assessment tools, such as 0-10 scale and Wong-Baker Faces pain scale, will help decrease data variance that is collected by providers.

***Concern:* M1300 - M1306 - Pressure Ulcer Assessment**
Suggestion for Change: Extend the SOC OASIS assessment time frame from 5 days to 7 days to allow collaboration between disciplines and to determine ability and availability of caregivers as well as the most effective wound care regimen. Please clarify how this question should be answered if I use a standardized tool and an evaluation of clinical factors to assess.
Rationale: What if PT or a weekend person is admitting – does the assessment need to be done right away at SOC? Is it realistic to get all of this done in the 5-day time frame? Consultation with staff outside the homecare agency, for example a wound ostomy clinic, is often necessary to gather all pertinent clinical information.

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

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

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

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

M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is not the homecare clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be responsible for ordering such dressings.

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

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

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

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

Concern: **M1880 Change in Mobility**
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of homecare services. What if they are worse as a

result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.

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

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

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

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

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

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

should not be expected to resolve something that is outside of the scope of practice (ordering medications).

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

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

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

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

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

Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient as is and will become increasingly exhausting for the patient as all of the other assessments are added. I know of instances where patients have decided that it just wasn't worth having homecare during the initial start of care visit due to the burdensome paperwork involved. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the

last five days of the certification period. The five-day completion requirement is burdensome to the provider in this time of worker shortages.

It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Several items on the proposed OASIS-C document would require the clinician to review the medical record documentation for the entire previous episode of care, which would be extremely time consuming. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment.

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

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

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Document: CMS-2008-0141-0047
IA

Submitter Information

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General Comment

The time to collect the proposed Oasis C-1 data will be significantly increased because of the following:

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

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

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

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

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

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

G. Management of Oral medications M2020 Recommend response 1 a and b be two different responses. This is significant improvement for a patient to go from " (a) dosages are prepared in advance by another person to (b) another person develops a drug diary or chart. Please give us room to capture our improvement that we assist the clients in achieving.

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

Thank you for your immediate attention this very timely and potentially highly impactful topic

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Document: CMS-2008-0141-0048
MN

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General Comment

To Whom It May Concern,

We are writing to notify CMS of our concerns about the proposed OASIS -C assessment.

Our agency has concerns with the following areas:

M1012 Inpatient Procedure Codes
This places an undo burden of resources on the HHA to research what procedures were completed in the hospital and the correct code for every procedure. Clients are not reliable historians about the procecures they experience in the hospital and often the history and physical does not address all procedures completed. Our agency receives referrals from as far as 300 miles away. They come from different healthcare systems and information is difficult to obtain. HHA are to code for the diagnoses and co-morbidities they are monitoring, teaching, or have the potential to monitor/teach. These codes often include "after care for.." which is more appropriate than listing the actual procedure.

M1040, M1045, M1050, M1055 Immunizations
These questions imply to the HHA and the client that the HHA is responsible to provide these immunizations. This places another burden of resources related to vaccines and emergency kits for every vaccine administered. These immunizations can be received in the clinic setting at anytime during the season or during the client's follow up visits. This would allow the primary clinical medical record to remain up to date and intact. When the client's primary medical record is intact, their safety is improved through out the health care system. We suggest changing these questions to ask the client if they have received any of these vaccines within the last year or recent season. If the client has not received these, the answers need to reflect the client's choice or simply "yes" or "no."

Please review the OASIS -C comments above. We are striving to improve our services and want to concentrate on client's care.

Sincerely,
Kelly Counihan RN, Quality Compliance Coordinator
Fairview HealthLine HomeCare
Hibbing, MN 55746

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
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Document: CMS-2008-0141-0049
IA

Submitter Information

Name: Debbie Green
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Fort Madison, IA, 52627
Organization: FMCH Home Health

General Comment

MO1010 & MO1012: Estimated time to compile info and document this added information is at least 30 minutes per assessment.

The process questions are just that process. They do not provide quality just documentation. The estimated additional time per assessment with these questions would be about 1 hour. We actually did some to determine the time. They are also duplicative. We do pain these assessments within our comprehensive assessments and when needed based on patient assessment. Why do we have to answer "yes" when we are already doing - just adds one more step to the process which is already lengthy.

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Document: CMS-2008-0141-0050
KS

Submitter Information

Name: Jan Cruz
Address:
Wichita, KS, 67202
Organization: Interim HealthCare

General Comment

I am submitting my comments in the attached file. Thank you.

Attachments

CMS-2008-0141-0050.1: KS

#50

Public Comments on Docket DMS 2008-0141
Medicare and Medicaid Programs OASIS Collection Requirements

I want to take this opportunity to express some concerns I have about the proposed OASIS C changes.

M2110 What is meant by the caregiver not likely ? It would be very subjective and I question the accuracy of our interpretation. We try to teach caregivers but we may not know their ability to perform within the five day window.
M1930 will require all agencies to utilize the same fall risk assessment to come to the same conclusion. This would be an additional cost for some agencies that are not currently utilizing one.
ADL Questions I appreciate the clarification in these questions so everyone understands it is the ability to perform safely, including getting in and out.
M1730 will require all agencies to utilize an universal depression screening tool and that would create more paperwork and cost. Plus this would need to be incorporated into the daily visit notes to have supportive documentation of our intervention.
M2430 Appreciate the additional reasons for hospitalizations.
M0102 I wonder what is the need to have the date of the referral on OASIS. Is OASIS to become patient outcome assessment or an assessment of an agencies compliance with COP. I feel that surveyors have the responsibility to monitor agencies compliance issues. I know if we are late in admission of a client we will notify the referral source and document what caused the delay. That documentation would not show up anywhere on this form so you would not have a total answer to a compliance concern.
M1246 will require the assessing nurse or therapist to review the POC and orders on the chart to verify that pain has been included in the POC for this client.
M1312,1314 I do not understand the importance of the longest length or width. We measure all wounds and the severity has to do with their staging and their amount of drainage and co-morbidities that affect the healing process.
M1326 Some physicians continue to order gauze wound care, wet to dry wound care despite our suggestions for more efficient wound products. We are to follow the physician orders. Are we to be penalized for following a doctor's order? Our purpose is to provide care to the patient, so we would not refuse care based on the type of wound products ordered by a physician.

M1510will require the nurse to audit the chart notes for any notation of interventions or teaching. Also I am unsure of the meaning of "instance of heart failure". Is this only hospitalization for CHF or is it for any weight gain or continued edema? This would need clarification so we would be able to answer accurately.
M1360 will require the nurse to audit the chart for foot assessments in the nurses narratives as this is not included in the typical nurse notes.
M2010 will require the nurse or therapist to review the notes for documentation anytime between the SOC and the ROC. Same for M2015 and 2040. We may have different nurses doing the OASIS at ROC so she would have to review the written chart in order to answer questions that other nurses on the case addressed in their notes.
M2310 Appreciate the availability of more options.

My concern is that the additional questions will create a very lengthy form that may be misinterpreted and therefore have inaccurate results. Also, as it is, the nurse is performing her assessment and the patient is trying to be polite but they have just come out of a skilled facility, are in a weakened state and they are worn out after about 40 minutes…some sooner. This will also be an added burden to the client. You may say the nurse can go out again to finish it up but often times the payor source is not authorizing additional visits. Therefore the burden to pay the nurse falls on the agency alone. Some of the additional assessments will require uniform assessments, which will increase the burden of paper and training of staff. It will also affect the daily notes of our professionals to assure documentation is easily found for the clinician to search for the information they need to complete their OASIS. This affects the cost burden of changing paperwork and paying employees for time spent in office. If CMS is anticipating that agencies become paperless will there be financial assistance to help accomplish this. These changes can greatly affect the small home health agencies, many who are rural and already stressed. We need the small agencies to help meet the needs of all recipients of home health.

I appreciate your consideration of my comments and thank you for your time.

Jan Cruz Director Health Care Services
Interim HealthCare