PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Health Care Professional/Association - Nurse
Tracking No. 8081b2be
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0051
IA

Submitter Information

Name: Bonnie Vos
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General Comment

Burden of Collection concerns:

Intake Process: MO102 and MO104 Need clarification for the Date the Physician made the referral, some referrals are received per the family, neighbor of patient.

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. Why do we need the procedure codes on the OASIS as the previous facility should have the procedure code & procedures can not be completed within a home environment?

MO138 Guidelines for physician Notification. Guidelines are appropriate for the care planning process and not obtained when completeing the admission assessment.

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). To complete OASIS responses we have been instructed not to review previous documentation or other clinical responses. This would be difficult to answer without reviewing prior OASIS information and would be difficult for non-primary clinicians to answer accurately thus requiring on ly the primary clinician to answer every OASIS assessment (again within the 5 day window).

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" 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. Need clarification of transferring with bathing.

M1360 diabetic Foor Care Plan: Inappropraite to answer care planning questions during the admission process. This nursing intervention is addressed after obtaining orders from the physician.

Many of the process items added to the OASIS are agency interventions and should not be added to an assessment tool. Agencies should be able to clarify what interventions are appropriate for their specific patieints.

Change in Mobility(M1880)/self care(M1890). These are subjective and do not measure anything. Improvement can be captured in the ADL questions. Again difficult to answer if different clinicians comp[lete the OASIS tool

Medications section: Again these should be agency specific intereventions and not assessment items to complete at the SOC.

Thanks you for your consideration of specific questions. The additional questions are time consuming and difficult for patients to answer during the admission process when they are acutely ill.

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Health Care Professional/Association - Nurse
Tracking No. 8081b373
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0052
MN

Submitter Information

Name: Kimberly Otte
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Robbinsdale, MN, 55422
Organization: North Memorial Home Health and Hospice

General Comment

Please see the attachment regarding the OASIS-C.

Attachments

CMS-2008-0141-0052.1: MN

North Memorial
Medical Center

#52

January 12, 2009

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

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

I support the use of OASIS as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to 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: **MO104** Date of Physician-ordered start of care
Suggestion for change: eliminate this item. It is already recorded on the 485.
Rationale: If MO102 and MO104 are not within the 48 hour time frame, it would set an agency up for an audit without any further documentation that would support going beyond the initial 48 hours as indicated above. Back office operations should not be integrated into patient care.

Concern: **M1010 & 1012** Inpatient Diagnosis and ICD Code

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

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

Concern: **M1032** Frailty Indicators
Suggestion for Change: Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of high risk chronic diagnoses place a patient at risk for rehospitalization and speak to the fraility of their overall status. These include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. Eliminate this item from SOC
Rationale: At providers will not have historical data on vitals signs and it is unlikely that vital signs are monitored and recorded by patients/families. This makes it difficult to determine whether or not the vital signs are stable or unstable. What is stable for one patient may not be for another. 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.
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. This leaves too much room for individual interpretations so data would not be useful.

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. Health Maintenance should be between the patient and physician, Home Health should not be used to drive physician behaviors.

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. This question is about an agency process and comprehensive assessment tools, not about the patient plan of care. If a standardized pain assessment should be used, it should just be mandated to be done using a particular tool and not asked on every SOC assessment

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. Again, this question is about an agency process and comprehensive assessment tools, not about the patient plan of care. If a standardized pressure ulcer assessment should be used, it should be mandated to be done using a particular tool and not asked on every SOC assessment.

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: Eliminate this item.
Rationale: What if a therapist is doing an assessment and the patient has this diagnosis, even if it is not the primary or secondary diagnosis, how would you expect a therapist to have enough knowledge to answer this question, or if the nurse has been discontinued, to

have knowledge of what transpired during that episode of care without doing a chart review.

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

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

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

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

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

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

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

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

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

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

Concern: **M2020** Management of Oral Medications
Suggestion for Change: Go back to the question asking only about <u>prescription</u> medications (not <u>all</u> medications) and eliminate previous instructions to mark the patient as independent if taking the majority of medications. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?
Rationale: The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with and ability to take

prescription medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all prescribed medications (including oral) when assessing a change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.

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

Other general comments and concerns:
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 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,

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PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Health Care Provider/Association - Home Health Facility
Tracking No. 8081b407
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0053
NY

Submitter Information

Name: Phyllis Wang
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East Greenbush, NY, 12061
Organization: New York State Association of Health Care Providers, Inc.

General Comment

See attached comments in PDF

Attachments

CMS-2008-0141-0053.1: NY

#53

New York State Association of Health Care Providers, Inc.
Representing home and community-based care

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January 12, 2009

Re: Medicare and Medicaid Programs OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; OASIS-C; OMB#0938-0760.

On behalf of the members of the New York State Association of Health Care Providers, Inc. (HCP) we are pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the implementation and use of the OASIS-C document.

HCP is a statewide trade association representing home care and community-based providers through advocacy, information, and education. Founded in 1974, HCP represents approximately 500 offices of Certified Home Health Agencies, Long Term Home Health Care Programs, Licensed Home Care Services Agencies, Hospices, and related health organizations throughout New York State. Through a strong network of regional chapters and an active State office in Albany, HCP is a primary authority of the health care industry.

HCP has long been supportive of the use of Outcomes and Assessment Information Set (OASIS) in home care and has been active in seeking modifications to the tool when appropriate. HCP has also consistently advocated that the OASIS tool should not impose undue burdens on Home Health Agencies (HHAs). While there have been several positive changes from OASIS-B1 to OASIS-C, the proposed changes will present new and costly challenges to HHAs during already difficult financial times.

Regardless of what OASIS modifications are adopted, CMS must consider all the costs an agency will incur to comply with proposed changes. In respect to OASIS-C, at a bare minimum, the changes will require agencies to invest in retraining all staff associated with the OASIS process. Additionally, agencies will need to invest in reprinting OASIS-related forms and perform costly modifications to their software systems.

OASIS-C modifies several questions in response to industry input. Modifications include, the deletion of items not used for payment, quality, or risk adjustment. Some questions are consolidated and the wording of other questions is improved. Other changes were made that added measurements to the OASIS process. The current OASIS-B1 has 253 items that must be collected at various time points. OASIS-C

increases the number of measures to 327. HHAs will need to retrain their staff on the entire document given the extensive changes made to the OASIS system. This will be financially costly and will affect resources available for patient care as clinical staff is retrained.

It is also important that CMS consider the timing of changes to OASIS. CMS is currently considering a switch from the ICD-9 coding system to ICD-10, which will put another huge burden on agencies as they learn the new coding system. Furthermore, HHAs will experience rate cuts through at least 2011 as a result of case-mix creep reductions included in the 2008 Prospective Payment System (PPS) refinements. Reimbursement rates for FY 2009 increased approximately .15% after a 2.75% case-mix creep reduction, which was based on a flawed CMS methodology.

In addition, the Medicare Payment Advisory Commission (MedPAC) has again recommended to Congress an HHA payment freeze on top of the existing case-mix creep reductions.

HCP Recommendation

HCP supports modifications needed to improve current systems, and this proposal includes such changes. Unfortunately, the breadth of the proposed change to OASIS-C will result in additional costs to agencies and restricted human resources. Reimbursement policies from CMS, particularly those in the recently released Medicare PPS refinement, simply do not reflect the additional burden of added OASIS items. The new items, on top of reduced reimbursement, only serve to provide new barriers to reaffirming the right of the elderly and disabled to live in their community, and restricting access to home and community-base care.

Thus, HCP recommends that sufficient transition time and commensurate increases in reimbursements be given for providers to update their systems and for assessors to learn the changes.

As always, HCP looks forward to working with CMS to ensure that quality and accurate data is collected both for the sake of reimbursement and research purposes.

Sincerely,

Phyllis A. Wang
President

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Health Care Provider/Association - Home Health Facility
Tracking No. 8081b4ae
Comments Due: January 13, 2009
Submission Type: Web

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

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Document: CMS-2008-0141-0054
MA

Submitter Information

Name: Helen Siegel
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MA, 02116
Organization: Home Care Alliance of MA

General Comment

Please see attached comments from the Home Care Alliance of Massachusetts on OASIS-C

Attachments

CMS-2008-0141-0054.1: MA

#54

January 7, 2009

RE: Revisions to the Outcomes and Assessment Information Set (OASIS) for Collection by Home Health Agencies – OASIS-C

To Whom It May Concern:

The Home Care Alliance of Massachusetts is the trade association in Massachusetts representing 142 home health agencies and allied businesses and individual members. The following comments represent the collective opinions of the clinical managers of our member agencies – those individuals who work with OASIS on a daily basis.

Although the revised OASIS requires that agencies collect more data items than previously, we do believe that the proposed document addresses a number of industry concerns in that it removes certain items not used for quality or payment, modifies wording or response categories to clarify and show progress within a MO item, and adds process items that support evidence-based practice. We are particularly supportive of the proposed expansion on the list of reasons for emergent care and hospitalization and on the re-definition of emergent care as a visit to the ER only.

A lesson-learned in the almost ten years the home care industry has worked with OASIS is that items that are too subjective or allow for agency or regional preference do not promote accurate comparison. We feel the following items still fall into that category:

M1034: Stability Prognosis: Terms such as "heightened," or in M1880 "better/worse," are subjective terms and would need clarification in Chapter 8 or a similar document to promote consistency

M1242: Pain Assessment Since pain as an outcome is an important measure and to fairly compare agencies and their outcomes, we suggest CMS at least recommend an assessment tool so all agencies are assessing the same way. This would also be an important consideration for M1730: Depression Screening and M1930 Falls Risk Assessment. Standardization would allow for comparison in a meaningful way.

M1010/M1012/M1018: Inpatient Procedures; Prior Medical treatments
It is reasonable to expect that the home care industry works in tandem with other health care providers, yet the "silo mentality" still exists when trying to work with other members of the health care team. With hospitals placing less emphasis on discharge

planning and an increase in the use of hospitalists, the information CMS is expecting agencies to access will be difficult to obtain. This was a lesson-learned from MO 175 which was ultimately removed from the OASIS document. If this item is to be retained, the acute care setting needs to accept some of the responsibility for sharing this information and be required to do so as part of their regulatory requirements.

M1038 Guidelines for physician notification. With the exception of very specific situations that require protocols, when to notify the physician falls within the scope of nursing practice, judgment, and agency standards and policies. Most agencies have policies/protocols or standing orders to support nursing practice. We recommend that this item be dropped from the OASIS-C.

This concern also applies to M 1244 Planned Pain Intervention; M1304 Planned Pressure Ulcer Prevention; M1360 Diabetic Foot Care; M1736 Depression Intervention Implementation. With any of these follow-up and/or intervention plan items, we recommend that there should be a response other than a "yes/no" to indicate that treatment was recommended to the patient and/or physician and it was refused, or the patient is knowledgeable or that the MD was notified and that no change in treatment was made. Here, too, many of these planned interventions fall within the scope of nursing practice and nursing judgment.

Furthermore, M1038 Guidelines for Physician notification; M 1244 Pain; M1304 Pressure Ulcer; and M1360 Diabetic Foot Care are all included in the start of care assessment, yet the answer requires action to have been taken before the assessment is completed. Plans of care do not arrive from the physician to the home health agency complete and ready to go, but rather are generated by the agency staff after the comprehensive assessment is completed of which the OASIS is an integral part! Further guidance is needed here.

M2002-2004 Medication Follow-up & Intervention: This measure is a little unclear. If this item seeks to ascertain that the physician was "contacted" within one calendar day, then we do not have a problem with it. However, if the intent is to have a resolution in one day, than it is completely unrealistic. We agree that a significant medication concern should be identified immediately and the physician notified as soon as possible. However, medication reconciliation may not occur within one calendar day especially on a weekend when the Primary MD cannot be reached. The nurse may begin the process but coordinating a primary care MD who may not be available or who is reluctant to accept responsibility for medications ordered by hospitalists or specialists; or a hospitalist or Nursing Home physician who feel their responsibility ends when the patient leaves their physical space for a patient with ten plus medications may take more than 24 hours time to accurately accomplish. The standard should be "within a reasonable length of time.

Finally, we feel that CMS has grossly underestimated the burden of implementing these revisions in time and dollars! Not only do the clinicians need education, but staff educators need time to understand and develop teaching plans for staff education. These plans will be used at OASIS-C implementation but also as part of on-going orientation. Agency policies have to be revised to accommodate the changes and then printed, distributed, and incorporated into educational programs on agency policy and reviewed by the PAC– very different than educating on a specific document. This will require a substantial amount of administrative time to accomplish. At the very least, a full day seminar at a basic cost of $300 per session plus office time away from other responsibilities to prepare will be needed. It will take 4 hours of employee training for which they are paid (an estimated cost of $75 per hour per clinician inclusive of salary, benefits) as well as paying part-time staff to see patients in their absence. There is also administrative time to check the assessments after they are completed which would take about 30 minutes per assessment.

Using your example of 4 hrs x 18 clinicians = 72 hours x $75 = $5400 not $2121. And double it to replace the 72 hours of clinical time for patients that need to be seen while staff are in class. Then add printing costs, software changes, and policy changes to accommodate the process measures and the transition to OASIS- C becomes a significant financial burden.

Currently, it takes most clinicians 21/2 hours to complete an admission and create a plan of care. With the additional data sets and process measures to consider, we estimate that it will add an additional hour. When home care reimbursement is being debated, CMS should recognize that implementation of an assessment tool of this scope does not happen in isolation but effects agency productivity, cost, and staffing in an environment of nursing shortage which we will have for the foreseeable future. To partially alleviate this problem, we recommend that CMS reconsider the policy of "nurses only" in cases where nursing and therapy are ordered.

We appreciate the opportunity to comment on this important issue.

Very truly yours;

Helen Siegel, RN, MS, MBA
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PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Home Health Facility - HPA25
Tracking No. 8081b4f3
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0055
CT

Submitter Information

Name: Carmela Bilodeau
Address:
Watertown, CT, 06795

General Comment

Please see the attached document containing comments from the management staff of VNA Health at Home, Inc., Watertown, CT.

Thank you for the opportunity to express our opinions regarding the proposed OASIS-C document.

Attachments

CMS-2008-0141-0055.1: CT

#55

Docket ID CMS-2008-0141

Docket Title 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 ID CMS-2008-0141-0001

Document Title 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)

After comparing the number of data elements required for collection on the existing OASIS to the proposed number of data elements on the OASIC-C, we are very concerned about the increased paperwork burden that will be imposed on an already over-burdened and understaffed Home Health Agency workforce.

In addition, we question the need for some of the added information that we will be required to collect in OASIS-C and remain unclear as to how this information will benefit patient care. For example, M1040 – M1055 (influenza/pneumovax vaccine data elements) require a response 12 months of the year, but the information it is gathering is pertinent for only 6 months of the year.

Please see the following data elements that require further clarification:

M1032 Frailty Indicators, box 4: what is the definition of "recent"?

M1244 Planned Pain Intervention and **M1304 Planned Pressure Ulcer Prevention**: what is the definition of "current"? For example, is it the treatment plan that was in place prior to this assessment or the POC which this assessment will determine?

M1310 Current Number of Unhealed Pressure Ulcers at Each Stage, d.1-2: Please clarify and provide guidance regarding "known or likely".

M1312 Pressure Ulcer Length and **M1314 Pressure Ulcer Width**: Please clarify and provide guidance for measurement methods.

M1320 Status of Most Problematic (Observable) Pressure Ulcer, box 0: This wording is misleading since "healed" can refer only to stage 3 or 4 pressure ulcers. If stage 1 or 2 pressure ulcers are healed, they are no longer pressure ulcers (per WOCN guidelines).

M1334 Status of Most Problematic (Observable) Stasis Ulcer, box 0: Since "healed" is an option, does this mean that a healed stasis ulcer remains a stasis ulcer and can be included in the count of current stasis ulcers?

M1342 Status of Most Problematic (Observable) Surgical Wound, box 0: Since "healed" is an option, does this mean that a healed surgical wound remains a surgical wound and can be included in the count of current surgical wounds?

M1360 Diabetic Foot Care Plan and M1365 **Diabetic Foot Care Plan Follow-up**, box NA: Since both of these data elements refer to diabetic foot care, why is the wording "...OR Patient does not have a diagnosis of diabetes" included as a choice?

M1410 Respiratory Treatments: Why is BiPAP not included?

M1510 Heart Failure Follow-up, box 2: Is a call to "911" counted as emergent care?

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Home Health Facility - HPA25
Tracking No. 8081b52d
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0056
MN

Submitter Information

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

General Comment

See attached comment letter. In addition to the attached comment letter, I would like to speak on behalf of our home health agency. Because of the continuous reimbursement cuts and increased regulatory burden, the only other hospital-based agency in our metro area has significantly downsized, laying off the majority of their nursing staff. Although there are other home health agencies in the area, we are often the only agency left that will take complex, high-cost patients, daily wound cares, un/underinsured patients, etc.. It is only a short matter of time before we will have to continue with additional cost-cutting measures to survive. The additional burden of the OASIS-C will only increase our costs to provide care to our patients. We cannot afford to continue operations if our costs keep rising and our reimbursement keeps declining.

Attachments

CMS-2008-0141-0056.1: MN

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

#56

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 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Government - State
Tracking No. 8081b7e7
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0057
TX

Submitter Information

Name: Deborah Price
Address:
Haskell, TX, 79521
Organization: Department of Aging and Disability Services

General Comment

The attachment has comments regarding the OASIS C, Form Number: CMS-R-245 (OMB# 0938-0760) submitted by the Texas OEC's. Thank you for the opportunity to submit suggestions.

Attachments

CMS-2008-0141-0057.1: TX

#57

The following comments are submitted regarding:

Form # CMS – R 245
OMB# 0938-0760

1. M0104

Under response NA recommend changing SOC to SOC/ROC.

2. M0110

Recommend adding instructions to skip if completing a RFA 5 or if completing an RFA 3 other than the last 5 days of a current episode.

3. M1014

Recommend adding a space between "M1032 at DC"

4. M1032

Is response #2 Debilitating pain the same as intractable pain? Recommend defining debilitating pain in item by item tips or changing to intractable pain.

The Federal Register indicated one of CMS goals is to create a standardized assessment instrument that can be used across all post acute care settings. The Federal Register also indicated the revision of the OASIS instrument is an opportunity to consider various components of quality care as patients move among health care settings. In other health care settings, nutrition and hydration are important aspects of care. So why would it not be at least an indicator of frailty in the home health setting?
Recommend adding indicators related to a decline in nutrition/hydration, such as loss of appetite, unintended weight loss greater than 5% in a month, dehydration, abnormal lab values, etc.

Response 5: Recommend changing hospitalizations to more than 1 or decrease the time to 6 months versus 12 months.

Responses are very subjective. Please include parameters in item by item tips.

5. M1034

In response 0, 1 and 2 recommend defining "heightened risk(s)" and "high health risk(s).

In response 1 recommend defining "temporarily".

In response 2 recommend defining "fragile".

In response 3 recommend changing "within a year" to 6 months. (Trigger for a referral to Hospice)

6. M1040

Recommend including this item on the RFA 4 (recertification)

7. M1045

In response 5 recommend defining "does not meet age/condition guidelines".

8. M1055

In response 4 recommend defining "does not meet age/condition guidelines".

9. M1100

Recommend changing the "and" to "AND".

Recommend defining regular daytime and regular night time.

10. M1242

Recommend including what is minimally expected on the "standardized pain assessment" or provide an example of a standardized tool to use as was done in M1300 Response 2.

Recommend response 0 be changed to "No standardized pain assessment conducted."

Recommend that define "severe pain" in response 1 and 2.

11. M1310

Recommend adding check box for unknown in rows d.1-3

12. M1320

Recommend adding comment in question or on responses "per WOCN Guidance" for responses 1, 2 and 3.

13. M1324

Recommend adding comment in question or on responses "per WOCN Guidance" for responses 1, 2, 3 and 4.

14. M1326

Recommend giving examples of moisture retentive dressings in question.

15. M1334 and M1342

Recommend adding comment in question or on responses "per WOCN Guidance" for responses 1, 2, 3 and 4.

16. M1360

Recommend changing "…lower extremities and patient…." to "…lower extremities AND patient…".

Recommend adding to recertification.

17. M1365

Recommend adding to recertification.

18. M1500

Recommend defining or giving an example of "clinical heart failure guidelines"? Is the list a finite list or may other items be included?

19. M1510

On response 1 does "contacted the same day" mean they spoke on phone, sent fax, left message, got orders, etc.? The agency may have a patient that develops 2+ edema and the practitioner was contacted but did not call the agency back until the next day. How would the agency respond? Recommend clarification on communication.

20. M1730

If using wording such as "standardized depression screening tool", suggest including what is minimally expected on the standardized depression tool in the item by item tips or provide an example/suggestions of a standardized tool to use.

21. M1732

On response 4 for recurrent thoughts of death, recommend defining recurrent. Is it hourly, daily, weekly, monthly, etc.?

22. M1734

Recommend defining what the standardized depression screening tool is.

23. M1830

On response 2 recommend omitting "(b) to get in and out of the shower or tub, OR" since the intent of the question does not address the transfer in and out of tub or shower.

24. M1880, M1890, and M1920

Recommend defining time frame for prior level of functioning as it is very vague and is open for interpretation.

25. M1930

Recommend adding sensory impairment as multi-factor Fall Risk Assessment.

Recommend that define Fall Risk Assessment.

26. M2002 and M2004

Recommend combining these two items.

27. Recommend defining "high-risk" medications. Is the item limited to hypoglycemics and anticoagulants?

28. M2200

Recommend adding comment to complete item on ROC when completed within last 5 days of recertification. Otherwise it may be marked "NA".

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Home Health Facility - HPA25
Tracking No. 8081b8b1
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0058
MO

Submitter Information

Name: Dyck Mary
Address:
West Plains, MO, 65775
Organization: Riverways Home Care of Ozarks Medical Center

General Comment

RE: M1312 and M1314
These items only allow for measures for one ulcer. If there is more than one, we need specific criteria to answer this item. It may become confusing, because that critiera may select one ulcer for one OASIS assessment and another ulcer for a later OASIS assessment. The question should provide a way to allow specificity in the selection when there is more than one ulcer.

RE: M1365, M1736, M1945 and M2015
Each of these proposed assessment items asks if a portion of the physician-ordered plan of care was implemented since a previous OASIS assessment. These are poor OASIS assessment additions because whether or not an agency fully and completely implemented the plan of care, very few agencies will likely answer that they did not implement the physician-ordered plan of care. These items are only to be completed upon transfer or discharge, so maybe the intent is to determine if the transfer or a discharge that is to a higher level of care happened because the intervention was not implemented, but even then, it would be impossible to tell from an OASIS assessment if there were extenuating circumstances. These items will be difficult for the responsible clinical staff to answer accurately. I recommend that these items be deleted.

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Other - OT001
Tracking No. 8081b8b6
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0059
LA

Submitter Information

Name: Julianne Haydel
Address:
Baton Rouge, LA, 70806
Organization: Haydel Consulting Services LLC

General Comment

Please see attached
Comments from Julianne Haydel, RN Consultant
Alice Posseno, RN Consultant

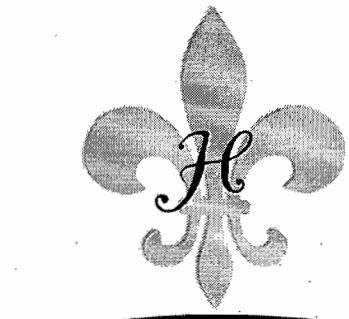
Attachments

CMS-2008-0141-0059.1: LA

HAYDEL Consulting Services, LLC

HAYDEL CONSULTING SERVICES, LLC

#59



HAYDEL
Consulting Services, LLC

In response to the publication of the OASIS-C data set and the solicitation of comments by CMS, Haydel Consulting Services, LLC has prepared the following comments regarding the new data set.

Provided By:

Julianne Haydel & Alice Posseno

1/12/09

HAYDEL Consulting Services, LLC

HAYDEL CONSULTING SERVICES, LLC

In response to the publication of the OASIS-C data set and the solicitation of comments by CMS, Haydel Consulting Services, LLC has prepared the following comments regarding the new data set. Our comments are limited by the fact that many terms contained within the dataset are largely undefined or vague and there is no official guidance as yet. It is our hope that clarification or changes in the language will be considered.

Recertification Assessments

Many of the new questions are asked only at the time of admission and resumption of care. Others are asked at transfer and discharge. However, the greatest potential of change in answers may be at the time of recertification for many of these questions. Questions regarding care plans are omitted at the time of recertification even though care plans are being written. Additionally, it is only on the recertification assessment that many new diagnoses, changes to care plans, etc., are noted.

Tracking Sheet

The Date of Referral question (MO102) may be better suited to the tracking sheet as it is not likely to change. It's inclusion near the Start of Care date will make it easier for agencies and surveyors to assess whether or not time frames for admissions are being met timely.

Frailty Factors

The frailty factors, while critical to assessment of the patient, are vaguely defined without explicit instructions. The reference to 'unstable' vital signs might indicate that over time the patient has significant fluctuations in vital sign data. Upon admission, this kind of instability might not be apparent. Additionally, as nurses, using the framework of 'stable' to describe patients is less than optimal. For instance, a patient with a constant blood pressure greater than 200/100 is 'stable' under the strictest definition of the word. Perhaps a better description might be "Vital signs continually outside of optimal range for patient."

Stability Prognosis

In reviewing this question, it occurs to us that the word, 'stability' could be removed from the question without changing the intention.

Furthermore, a significant portion of the Medicare home health patient population might be considered to have serious, progressive conditions that could lead to death within a year. Because the words, 'fragile', and 'heightened risk(s)' are not clearly defined, it becomes an extremely subjective question. Advanced age, as an example, automatic ally places the patient at higher risk of death within a 12 month period. Additionally, it would difficult for the clinicians at our office to determine if standard treatments carrying risk would qualify e.g. anticoagulant therapy, fluctuating insulin dosages, changes in CHF meds, etc. How does the clinician determine what is heightened risk and fragility vs. expected conditions for these patients of advanced age with corresponding conditions? Additionally, certain patients fluctuate between extremes; e.g. dialysis patients and chemotherapy patients.

The intent of this question is excellent in terms of qualifying outcomes. However, unless clearly objective definitions are put forth upon the introduction of the new dataset, the quality of the data will be subject to individual interpretations by practicing clinicians.

Physician Notification

M1038 investigates whether or not the plan of care has parameters for reporting out of range vital signs and clinical findings. This question is asked only at the time of admission to the agency and at resumption of care after a hospitalization.

Upon admission, at the time of assessment, there is no plan of care.

Upon resumption of care, the prior care plan may be rendered completely or partially obsolete.

Even within our office, there are different opinions regarding about the language of this question.

One opinion is that there is no plan of care upon admission assessment and the plan of care is usually rendered partially or completely obsolete upon resumption of care. Therefore, this question investigates a plan of care that does not exist.

The second opinion is that the completion of these questions is easily done within current OASIS guidelines in the office in the days following the assessment. As an example, ICD-9 codes are typically researched following the initial assessment. In the same way, this question might be answered after the care plan is created. If this is the intent of the question, then we suggest that the language be modified to specify the plan of care that will be created subsequent to the completion of this assessment.

An additional concern with this question is that it suggests a correct answer. In the previous B-1 data set there were no questions relevant to the patient condition in which a clinician assessor could determine a preferred answer. This question, and many others that are similar, actually prompt the clinician to respond in a certain way and write his or her care plan accordingly. While this may improve clinician performance and the quality of care plans, it compromises the quality of data when a correct answer is evident.

Assessment of Pain

A number of questions investigate the plan of care. For purposes of example, the pain assessment is referenced.

(M1240) Frequency of Pain interfering with patient's activity or movement:

☐ 0 - Patient has no pain

☐ 1 - Patient has pain that does not interfere with activity or movement

☐ 2 - Less often than daily

☐ 3 - Daily, but not constantly

☐ 4 - All of the time

(M1242) Has this patient had a formal **Pain Assessment** using a standardized pain assessment tool (appropriate to the patient's a the severity of pain)?

☐ 0 - No standardized assessment conducted

☑ 1 - Yes, and it does not indicate severe pain

☑ 2 - Yes, and it indicates severe pain

(M1244) Planned Pain Intervention: Does the current physician-ordered plan of care include intervention(s) to monitor and mitiga

☐ 0 - No

☐ 1 - Yes

(M1246) Pain Intervention: Since the previous OASIS assessment, have pain management steps in the physician-ordered plan of mented to monitor and mitigate pain?

☐ 0 - No

☐ 1 - Yes

NA - No pain intervention included in physician-ordered plan of care

The first question in the pain assessment (MO1240) is one that has been well discussed as a part of the OASIS B-1 data set.

MO1242 is a new question that addresses the use of a formal pain assessment tool. Without updated instructions on how to answer this question, certain questions come to mind:

It is assumed that what constitutes a formal assessment is left to the agency to determine.

The question is vague as to what time frame this question investigates. Is it limited to the day in question or does it expand to the entire episode of care? If so, what happens to patients whose response to the question varies between visits and services?

MO1244 – As with the question regarding physician notification, there are different opinions regarding about the language of this question even within our office.

One opinion is that there is no plan of care upon admission assessment and the plan of care is usually rendered partially or completely obsolete upon resumption of care. Therefore, this question investigates a plan of care that does not exist.

The second opinion is that the completion of these questions is easily done within current OASIS guidelines in the office in the days following the assessment. If this is the intent of the question, then we suggest that the language be modified to specify the plan of care that will be created subsequent to the completion of this assessment.

An additional concern with this question is that it suggests a correct answer. In the previous B-1 data set there were no questions relevant to the patient condition in which a clinician assessor could determine a preferred answer. This question, and many others that are similar, actually prompt the clinician to respond in a certain way and write his or her care plan accordingly. While this may improve clinician performance and the quality of care plans, it compromises the quality of data when a correct answer is evident.

MO1246 refers to the pain inquires about the interventions taken to manage pain. Again, it is only asked on admission and on resumption of care and investigates the period of time since the last OASIS data was collected. When multiple clinicians are responsible for the care of a patient, it may be difficult to ascertain whether or not the pain interventions were followed according to MD orders. In resumption of care situations where an assessment must be completed within 24 hours and staffing the ROC falls to the first available RN, the best the nurse may be able to do is review the chart. In that case, the question doesn't assess adherence to the plan of care as much as the documentation of adherence.

Furthermore, is the simple inclusion of a pain med in the medication list with an order to 'teach medication regime' sufficient to meet the definition of pain management intervention? Is lack of documentation which is common in our clinical work as serious as an omission as lack of care? Does the presence of documented interventions matter as much as a reduction in pain?

It is sound clinical practice and clearly in the patients' best interests to be seen by agencies with quality assurance plans that assess adherence to MD orders and the presence of pain. Haydel Consulting Services, LLC respectfully questions whether or not this important facet of quality care is appropriate for the initial assessment.

Integumentary Status

The integumentary assessment has been greatly expanded and in many ways improved to include risk factors and measurements. However, like the pain assessment, the integumentary assessment exceeds the scope of patient assessment and investigates the care plan on admission and at resumption of care.

In general the wound care questions are better phrased and allow for a more descriptive portrayal of pressure ulcers. One concern would be the response D3 to MO1310 which asks about ulcers that are 'unstageable: suspected deep tissue injury in evolution'. This extent of wound assessment may be out of reach to the average field nurse with no specialized expertise in wound care and assessment.

Two questions involve the presence and use of moisture retentive dressings on the care plan and in the period of time since last OASIS data was collected. Again, upon admission there is no care plan. In fact, when wounds are involved, it is often advisable for an agency to send out a WOCN or similarly qualified nurse. The need for a nurse with specialized wound care and assessment training is often no evident upon referral and the care plan may not be completed until a second assessment is made. On alternative in the wound care questions is to allow for a nurse to 'defer' assessment until a wound care specialist can see the patient. Although OASIS allows for clinicians to collaborate, it would be inappropriate for two nurses to complete one OASIS form. However, if the wound care was deferred to a specialized wound care and assessment nurse, the care plan could be based upon two different assessments without one nurse signing off on another nurse's assessment.

Because of the time frames in which the questions M1326 and M1328 regarding moisture retentive dressings, a slight change in language would make M1328 more informative. On resumption of care, Instead of asking for the period of time since the last OASIS data was collected, were moisture retentive dressings used, a higher quality of information might be obtained by asking if moisture retentive dressings were used according to orders since the pressure ulcer was initially assessed.

It is greatly appreciated by us that the question regarding the presence of a wound has been edited to specify wound that are receiving assessment and/or intervention (M1350)

Depression

We strongly support the added emphasis on depression in the Medicare home health patient population. However, OASIS-C asks if the patient has been assessed using a formal assessment tool. An investigation shows that many tools are available and that many signs and symptoms of depression may be mimicked by disease processes and therapies. For example, essentially all tools inquire about sleep patterns, fatigue, appetite and loss of interest in activities. All of these symptoms may be side effects of medications. Other symptoms such as feelings of hopelessness, self blame, guilt, etc., are more pointed to depression that is not a result of medications and depression. An alternative to this question would be to list specific symptoms of depression in the elderly and specify that symptoms reported are not related to medication side effects. The danger is that depression will be over rated and under treated if 'formal' tools are used without regard to illness or medications.

M1740 is the same as MO620 in the prior data set. Much confusion existed over the use of 'e.g.' in the examples cited. Many clinicians believed that the questions referred only to the examples listed while others understood the term e.g. to mean 'as an example'. Because of the confusion, Haydel Consulting Services recommending eliminating the use of e.g. and replacing it with 'including but not limited to' to ensure that data collected is consistent throughout home health agencies.

Toileting

The separation of toileting ability from hygiene ability is greatly supported. The word 'safely' added to many of the functional domain questions is felt by us to go a long way to improve data.

Medications

The medication review condition of participation is written separate from the OASIS condition. Traditionally, this has allowed a physical therapist or occupational therapist not comfortable completing a comprehensive medication review to defer the task to a nurse. In the OASIS C data set, questions regarding the comprehensive medication review are present including education on high risk medications. Since most physical therapists do not include general medication teaching in their scope of activity or contractual obligations to agencies, it is possible that many therapists will become unwilling to complete the initial and resumption of care assessments.

The questions M2010 also does not state if the patient has received instruction on ***all*** high risk medications upon admission. For instance, if a therapist or a clinician teaches on Coumadin but defers teaching on insulin until a future visit, has the intent of the question been met? Also, the term 'high risk' varies. Digoxin, a very safe and common drug has a narrow margin of safety. Tylenol, generally assumed to be a very safe medication is listed in the top ten medications responsible for death and the top ten for hospitalizations in the United States. With all due respect, the patient condition upon discharge from the hospital may be such that any medication must be administered with diligence.

Summary

In conclusion, it is refreshing to see changes made to the data set that fully assess the patient's needs and the care given. However, in our experience, the language used must be clearly defined in order to ensure the integrity of the data.

Thank you for your time and attention to our comments.

PUBLIC SUBMISSION

As of: January 16, 2009
Received: January 12, 2009
Status: Posted
Posted: January 14, 2009
Category: Association - Other
Tracking No. 8081b8fc
Comments Due: January 13, 2009
Submission Type: Web

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

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

Document: CMS-2008-0141-0060
MN

Submitter Information

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St. Paul, MN, 55113
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General Comment

Please accept this letter on behalf of the Minnesota HomeCare Association and the Medicare Team thereof.

Attachments

CMS-2008-0141-0060.1: MN

#60

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December, 2008

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

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

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

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

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

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

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

high risk chronic diagnoses place a patient at risk for rehospitalization and speak to the 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,

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