PUBLIC SUBMISSION

As of: January 20, 2009
Received: January 13, 2009
Status: Posted
Posted: January 15, 2009
Category: Health Care Provider/Association - Home Health Facility
Tracking No. 8081cbc1
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-2008-0141-0085
ME

Submitter Information

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Organization: Visiting Nurses Of Aroostook

General Comment

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

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

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

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

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

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

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

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

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

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

5. The burden estimate is likely low but even so is very considerable.
The Supporting Statement estimates the total burden for 2009 at 15,590,610 hours and the average salary at $29.47 per clinician. Thus, CMS estimates the annual burden at nearly $460 million. This estimate likely understates the actual burden given:
- The burden estimate is based on the assumption that OASIS-C will not increase the burden.
- As discussed above, this assumption is unsupported.
- The average salary does not reflect agency overhead. The true cost to the agency of a $29.47 hourly rate would be about $44 per hour.
- The training estimate does not account for annual turnover of new staff.
- The burden estimate does not reflect the fact that almost all agencies have clinical staff to over see the OASIS process and clerical staff to assist in the effort.

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

Attachments

CMS-2008-0141-0085.1: ME

VISITING NURSES
OF AROOSTOOK
A part of the Eastern Maine HomeCare Family

#85

January 12, 2009

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

We are writing to comment on the proposed changes to the Outcome and Assessment Information Set, referred to as
OASIS-C, noticed in the November 14, 2008 Federal Register. Document Identifier: CMS–R–245 (OMB# 0938–0760)
We support the use of OASIS as a comprehensive assessment tool and the OASIS reports as an effective measure to improve quality care to patients. However, we have the following comments regarding the OASIS-C changes.

Concern: M0102 Date of Referral
Suggestion for Change: Define the date of referral. Suggestions include altering item to read "Indicate the ordered date the agency is to initiate homecare." Differentiate between an inquiry about services and an actual referral for services. Not all referrals come from a physician so eliminate the word physician.
Rationale: .Clarification is necessary for consistent practice among agencies. Starting the services is not always within the home care provider's control. For example, providers may be waiting for authorization from Medicare Advantage programs which may delay the start of care; sometimes referrals are made while the patient is still hospitalized and home
care is not able to start care for an extended period of time; and sometimes patients make the request not be seen on a certain day, also delaying the start of services. Provide direction for how agencies are to answer this question when the initial physician's order start of care is delayed. Does the date an agency updates the physician on the patient's availability for start of care become the referral date?
Concern: M1010 & 1012 Inpatient Diagnosis and ICD Code
Suggestion for Change: Eliminate this requirement. If CMS needs the data it is available from the hospitals.
Rationale: Not all institutions make this information available in a timely manner. Home health providers do not have access to this information without the timely cooperation of the institution from which the patient is discharged. This is an undue burden and unrealistic expectation because final hospital coding often does not occur until the hospital generates
the bill. It is not realistic for home care clinicians to have knowledge of the coding requirements for inpatient facilities; requiring them to enter this information with insufficient or completed data from referrals sources will result in errors in apatient's medical record.
Concern: M1014 Medical or Treatment Regimen Change
Suggestion for Change: Eliminate this item
Rationale: This information is collected in other M0 items
Concern: M1032 Frailty Indicators
Suggestion for Change: Define unstable vital signs and clarify what is debilitating pain, recent mental health change and what constitutes a decline in functional status. Include items identified from home health agencies' work with the QIOs as included on the Hospitalization Risk Assessment Form at www.homehealthquality.org web site. The presence of

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

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

Concern: M1034 Stability Prognosis

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

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

Concern: M1038 Guidelines for Physician Notification

Suggestion for Change: Delete this item

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

Concern: M1040 through M1055 Vaccinations

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

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

Concern: M1242 Formal Pain Assessment

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

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

Concern: M1300 - M1306 - Pressure Ulcer Assessment

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

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

Concern: M1312 - M1314 Pressure Ulcer Length & Width
Suggestion for Change: Eliminate both items
Rationale: Requiring length and width of the wound does not meet the guidelines for measurement and assessment as established by the Wound, Ostomy and Continence Nurses Society (WOCN). This question does not ask for the components of a complete wound assessment; therefore clinicians will be required to complete redundant documentation
in order to accurately document the wound condition. Providing only a length and width of a wound does not provide an accurate accounting of a wound status and is not best clinical practice. WOCN guidelines for wound measurement include a length that is measured at 12 o'clock to 6 o'clock with 12 o'clock always being toward the patient's head. Width is
measured side to side from 3 o'clock to 9 o' clock. Simply asking for length and width does not support the guidelines.
Concern: M1320 Status of Most Problematic Pressure Ulcer
Suggestion for Change: Clarify that this pertains only to stages 3 and 4
Rationale: A healed stage 1 or 2 would no longer be considered a pressure ulcer.
Concern: M1326 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item.
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings.
Concern: M1328 Pressure Ulcer Intervention
Suggestion for Change: Eliminate this item
Rationale: Moisture retentive dressings are noted on the 485 as supplies. It is in the home care clinician's area of expertise to recommend a wound treatment; however, the physician makes the final determination regarding orders for moisture retentive dressings. Physicians need be responsible for ordering such dressings. It is not the home care clinician's area of expertise or scope of practice to determine the use of moisture retentive dressings. Physicians need be
responsible for ordering such dressings.
Concern: M1360 Diabetic Foot Care Plan
Suggestion for Change: Do not collect this at start of care.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.
Concern: M1500 Symptoms of Heart Failure
Suggestion for Change: Clarify what heart failure guidelines include, one symptom or combination of all symptoms referred to in question?
Rationale: Improve data collection by having all clinicians doing the same type of assessment.
Concern: M1730 Depression Screening
Suggestion for Change: Offer suggestions for specific screening tools
Rationale: Clinicians need to use a standardized screening tool in order to collect and report on standardize data. Comparison across patients will be less accurate if individual providers are using a wide variety of screening tools.
Concern: M1734 Depression Intervention Plan
Suggestion for Change: Eliminate this from SOC.
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.
Concern: M1880 Change in Mobility
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at transferring but not at ambulation – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need
of home care services. What if they are worse as a result of surgery – is that considered an injury or illness onset? Various aspects of this item are unclear and likely will result in confusion and inaccurate answers.
Concern: M1890 Change in Self-care Ability

Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at dressing but not at bathing – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. Various aspects of this item are unclear and likely will result in confusion and inaccurate answers
Concern: M1910 Ability to use Telephone
Suggestion for Change: Eliminate this item
Rationale: This assessment is covered in an emergency plan and safety assessment.
Concern: M1920 Change in Ability to Perform Household Tasks
Suggestion for Change: Eliminate this item
Rationale: What if the patient is better at meal preparation but not at laundry – how should the question be answered? This is a very subjective assessment. Patients most likely will be worse than prior level of functioning if they are in need of home care services. The question is too broad to achieve consistent and meaningful data.
Concern: M1930 Has patient had multi-factor Falls Risk Assessment
Suggestion for Change: Recommend a standardized falls risk assessment.
Rationale: In order to have consistent data collection and comparison across patients and agencies, it is important for clinicians to collect data in a consistent manner.
Concern: M1940 Falls Risk Assessment Intervention
Suggestion for Change: Do not require this at SOC
Rationale: The physician-ordered plan of care is not yet established at the time of SOC OASIS assessment since this time is actually a data-gathering time on which the clinician bases the plan of care.
Concern: M2002 Medication Follow-up
Suggestion for Change: Eliminate the need to contact the physician within one day and clarify what is considered "contacted" – does that mean a message has been left via phone, a fax has been sent, the home care clinician contacted the physician's nurse or other staff? Define clinically significant. Does "contacted within one calendar day to resolve clinically significant medication issues" imply that both contact and resolution is expected in one day, or is the intent of
the question to show contact within one day?
Rationale: What if the person completing the OASIS assessment isn't the same person doing the follow-up – does this result in 2 clinicians completing the OASIS assessment? What if the physician is contacted but nothing is resolved – what is the CMS expectation? Consider the discharge disposition for patients in assisted living facilities. The risk adjustment is
inadequate. Patients move to assisted living BECAUSE they can't manage their medications and/or ADLs. It is unlikely they will recover the abilities and show improvement during a Medicare episode. This is especially problematic if the Assisted Living facility has a policy requiring the AL staff to administer all medications. This skews outcomes for this population. Is a pharmacist considered a primary care practitioner? What about weekend admissions – it is unlikely that
the issue would be resolved in one day. Ability to "resolve" is dependent upon willingness and availability of practitioners outside of the home care provider's control. Providers should not be expected to resolve something that is outside of the scope of practice (ordering medications).
Concern: M2004 Medication Interventions
Suggestion for Change: Eliminate this item
Rationale: It is unrealistic to expect the discharging or transferring clinician to know all of this without reviewing the entire medical record including looking at previous OASIS assessments. This is burdensome and time consuming to have to review an entire episode to make this determination. Additionally, previous instructions did not allow a "look-back" on OASIS – are those instructions no longer valid?
Concern: M2020 Management of Oral Medications
Suggestion for Change: Go back to the question asking only about prescription medications (not all medications) and eliminate previous instructions to mark the patient as independent if taking the majority of medications. Further clarify how to answer the item choices – what if both 1 and 2 pertain – how should the question be answered?
Rationale: The actual medication has an impact on the patient's health status. For example, if a patient is taking Colace and a vitamin and remembers to take them but is also taking Digoxin but forgets to take it, the current assessment instructions would be to mark the patient as independent. In general, compliance with

and ability to take prescription medications impacts the outcome far greater than over-the-counter medications. Additionally, M2040 refers to all
prescribed medications (including oral) when assessing a change in the management of medications. The difference in M02020 and M02040 is confusing and inconsistent.
Concern: M2110 Types and Sources of Assistance Matrix
Suggestion for Change: Clarify how to answer this question. For example, in item a, what if the patient can do some of the tasks and not others? If they need help, does frequency impact the patient?
Rationale: Lack of direction will result in inconsistent and unreliable data.
Other general comments and concerns: We are concerned that there were only 11 pilot agencies. This is not statistically significant. There are over 9,000 Medicare-certified providers. We suggest pilot studies on a much larger scale in order determine the feasibility and usefulness of the proposed OASIS changes. Please also clarify what previous instructions still apply or no longer apply (i.e.: majority of the time, day of assessment etc.) Expand the time frame for OASIS assessment completion to 7 days. Completion of OASIS assessment is burdensome for the patient in its current form and will become increasingly exhausting for the patient as all of the other assessments are added. Additionally, allow the recertification to be completed within the last 2 weeks of the certification period. This is less intrusive for the patient and more realistic for the provider. Excessive unbillable visits are being made in order to complete the assessment within the last five days of the certification period. The five-day completion requirement is
burdensome to the provider in this time of worker shortages. It will take considerable time and resources, initially and long-term, to implement these changes. With all of the other
home care changes, this change will be overwhelming to clinicians. Already we are seeing clinicians leaving home care due to excessive paperwork. Adding length and completion time to an already cumbersome document is not acceptable. Any future changes to the OASIS assessment should be done in a more comprehensive manner, across care settings, and in conjunction with CMS implementation of the tool and process for the Post Acute Care Assessment. Instead of asking if standardized assessment tools have been completed to assess pain and risks for skin breakdown, add a tool into the assessment that is approved by nationally recognized experts. This will prevent the need to duplicate documentation in more than one area of the clinical record since many agencies already have tools like the Braden scale and pain assessment scales as requirements in their documentation. This would also be beneficial for national bench marking.

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

Sincerely,

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PUBLIC SUBMISSION

As of: January 20, 2009
Received: January 13, 2009
Status: Posted
Posted: January 15, 2009
Category: Home Health Facility - HPA25
Tracking No. 8081cbe8
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-2008-0141-0086
NH

Submitter Information

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General Comment

We have a concern about the new MO Items that are supposed to address process measures. OASIS was meant to be an assesment tool done to assess the patient in the home.

Are M items and MO items utilized the same way?

M1730 asks about a standard depression screening tool . Who does the screeening and who provides the tool? Will everyone use the same tool? Are they expected to be done on admission?
Who will provide all of these assesment tools??

Are there going to be skip items?

Re: M1308 .. what is the definition of unhealed . Whats the time frame?

M1012 are we responsible to know each inpatient procedure? Why are these even in the OASIS?

Are we responsible for what the MD should be ordering?

What is the time frame for M1032 answers? ie the unstable vital signs? And who decides they are unstable

who decides what are "high risk" meds? Shouldnt the DR and or pharmacist be responsible for this???

M1034 what is the defintion of "fragile health" these are subjective questions.

M2000 potential adverse effects ... what is the DR.s responsibilty in this?

will the time frame to complete the OASIS be extended. A lot of the new questions do not pertain to the patient in the home. They will be unknown at the time of admission.
the process ones in particular.

Re: the burden..... An OASIS done correctly even now doesnt take an hour.. It takes longer than that now to do a good and complete job and also be attentive to the patient (the reason we are even in there)

The burden has been grossly underestimated....

Its not about the paperwork its supposed to be about the patient.

We understand improving quality but not at the expense of the patient.

PUBLIC SUBMISSION

As of: January 20, 2009
Received: January 13, 2009
Status: Posted
Posted: January 15, 2009
Category: Home Health Facility - HPA25
Tracking No. 8081cdc9
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-2008-0141-0087
IN

Submitter Information

Name: Bonnie Dixon
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General Comment

After reviewing the proposed OASIS-C tool, we see changes that are welcome and some that are concerns. Regarding the depression items-M1730 to M1736; what type of professional will be expected to complete a depression screen? Most general nurses have had minimal pshychiatric trainnig and few Home Care agencies have Psychiatric Nursing Services; so the question is what type of screening tool will be expected to be used - will there be guidance; and is this an area that an agency could use the MSW to complete?

Regarding the expected assessments for Falls, Hospitalization, Pressure Ulcers, Pain etc., we would like to see standardized assessments incorporated into the OASIS-C tool; or at the very least guidance regarding the assessment tools recommended to be used. This would allow for everyone to be working from the same page - so to speak.

Many of new questions require definitions in order to accurately answer the questions - what would be 'unstable' vital signs for a newly assessed patient at SOC? What constitutes 'frailty'? And doesn't this information get caught in the Hospitlization assessment questions?

There are many references to physician ordered plans of care - the initial OASIS assessement performed at Start of Care is a part of the comprehensive assessement used to determine a patient's needs and to help determine a plan of care developed in consultation with the physician. The plan of care is not in place at the time of the SOC OASIS - so many of these questions would be NA.

Thank you for considering these concerns.

PUBLIC SUBMISSION

As of: January 20, 2009
Received: January 13, 2009
Status: Posted
Posted: January 15, 2009
Category: Health Care Provider/Association - Home Health Facility
Tracking No. 8081ce06
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-2008-0141-0088
MN

Submitter Information

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General Comment

see attachment

Attachments

CMS-2008-0141-0088.1: MN

GUARDIAN ANGELS ELIM HOME CARE

#88

January 8, 2009

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

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.

Please know that most home care clients are in a weakened vulnerable state upon admission to home care. If a clinician has to complete the task of all the required data collection as well as perform actual SKILLED needs such as med teaching or set up, wound care, vitals sign assessment, making sure they have their meds and food in the house, are able to arrange follow-up medical appointments and transportation, the client AND clinician will be overwhelmed and exhausted. A reasonable expectation would be that some of the assessments be done within the EPISODE of care and not on the initial assessment. In a time where client care is so important it seems counterproductive to hold a client hostage for so long in an admission process. These are vulnerable frail people who are probably in their most weakened state having to answer questions that will now take another 1 to 11/2 hours longer. I realize we all want the best care possible but under these circumstances I urge you to reconsider what his means to all of us. Health Care is expensive enough without adding to the cost. I am certain it will cost us more but CMS will not pay for it another unfunded mandate for health care.

Concern: **M0102** Date of Referral
Suggestion for Change: 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 or in the nursing home 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 places a patient at risk for rehospitalization and speaks to the fragility of their overall status. These include the diagnoses of CHF, diabetes, COPD, and chronic ulcers. Antibiotic resistant infections are an increasing challenge and should be included in this category. Environmental conditions or personal attributes such as low socioeconomic status, low literacy, inadequate support network, poor prognosis, shortened life expectancy, inability to manage own medications are all common in the home care population and are contributing factors to the frailty of the patients served. **Eliminate this item from SOC**
Rationale: **As providers, we 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:

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.) 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 my concerns before proceeding with the plan to change the OASIS as proposed.

Sincerely,

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PUBLIC SUBMISSION

As of: January 20, 2009
Received: January 13, 2009
Status: Posted
Posted: January 15, 2009
Category: Nurse - HC065
Tracking No. 8081ce76
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-2008-0141-0090
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General Comment

Although I believe the OASIS has become an excellent tool for identifying patient problems and, in turn, improving patient outcomes, the changes proposed in OASIS-C have the potential to put the value on paperwork instead of the patient. With so many additional questions, the clincian will have to spend so much more time research data in order to provide accurate answers that the focus will be shifted from patient to paperwork. The OASIS-C will also be a financial burden for the home health agencies since it will increase the amount of time the clinician will be spending in the home thus leading to clinician's wanting more money for their OASIS visits, plus require more data entry and QI audit time.