Supporting Statement For Paperwork Reduction Act Submissions
Revisions to the Outcomes and Assessment Information Set (OASIS) for Collection by Home Health Agencies – OASIS-C

A. Background

This request is for OMB approval to modify the Outcome and Assessment Information Set (OASIS) data set that home health agencies (HHAs) are required to collect in order to participate in the Medicare program. Proposed revisions to the OASIS data set include: 1) issues raised by stakeholders, including removing items that are not currently used by CMS for payment or quality, adding items to address clinical domains not currently covered, and modifying item wording or response categories for selected items; and 2) the addition of process items that support measurement of evidence-based practices.

Since 1999, the CoP at § 484.55 has mandated that HHAs use the "Outcome and Assessment Information Set" (OASIS) data set when evaluating adult, non-maternity patients receiving skilled services.[1] The OASIS is a patient-specific, comprehensive assessment that identifies each patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs.. CMS sees the OASIS as one of the most important aspects of the HHA's quality assessment and performance improvement efforts.

> "By integrating a core standard assessment data set into its own more comprehensive assessment system, an HHA can use such a data set as the foundation for valid and reliable information for patient assessment, care planning, and service delivery, as well as to build a strong and effective quality assessment and performance improvement program." [2]

HHAs are required to collect OASIS data at specific time points (admission, resumption of care after inpatient stay, recertification every 60 days that the patient remains in care, transfer, and at discharge). HHAs are also required to encode and transmit patient OASIS data to the state OASIS repositories. State survey agencies are responsible for collecting OASIS data from HHAs and making OASIS-based outcome reports available to HHAs. Through the state system, an HHA is able to obtain online outcome reports based on its own OASIS data submissions, and comparative state and national aggregate reports. Individual HHAs thus have on-line access to case mix reports, adverse event reports and annualized risk-adjusted outcome reports based on their own reported OASIS data. CMS regularly collects OASIS data from the states for storage in the national OASIS

[1] In meeting the Conditions of Participation, HHAs are expected to collect OASIS data on all of the patients served by the agency with the following exceptions: 1) maternity patients; 2) those under 18; and, 3) those receiving only personal care services, e.g., housekeeping, chore services. In 2003, Section 704 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) temporarily suspended OASIS collection for non-Medicare/non-Medicaid patients until the outcome of an OASIS Study is presented to Congress. This study was completed in December 2005 and has been submitted to Congress.

[2] Medicare and Medicaid Programs: Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies, 42 CFR Part 484 [Final Rules], *Federal Register*, Volume 64, Number 15, January 25, 1999, Pages 3747-3784.

repository, and measures of patient outcomes are made available to consumers and the general public through the Home Health Compare website maintained by CMS.

Since 2000, elements of the OASIS data have also served as the basis for the Prospective Payment System (PPS) that determines home health reimbursement for Medicare patients. Using the same data elements for both quality monitoring and payment allows CMS to ensure that HHAs are not maximizing profits at the expense of beneficiary outcomes while realizing the efficiency of using a single data source. [3] OASIS is also instrumental in assisting CMS to address the new challenges presented by Pay for Reporting (as mandated in the Dec. 2005 Deficit Reduction Act) which dictates that "for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points."

Need for revision of the OASIS Data Set

Since OASIS data collection was mandated in 1999, CMS has been systematically collecting input on ways to improve the OASIS instrument and reduce the burden of the collection effort. In 2002, CMS introduced the "reduced-burden" OASIS that was a product of the Secretary's Regulatory Reform Advisory Committee to help guide HHS' broader efforts to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. The Advisory Committee studied OASIS and recommended deleting those items and assessments not used for payment, quality measurement or survey purposes in an effort to ease paperwork burden on HHAs and their clinicians. This resulted in a burden reduction of 28% and the revised OASIS was implemented in December 2002.

Since the 2002 revision, CMS has continued to solicit input on potential refinements and enhancements of the OASIS instrument from HHAs, industry associations, consumer representatives, researchers and other stakeholders. Work carried out under a previous contract by University of Colorado Health Sciences Center (UCHSC) included gathering suggestions for OASIS revisions, synthesizing and consolidating suggestions for review by a technical expert panel and CMS staff, data analysis to inform the review process, and development of a series of potential OASIS enhancements for consideration by CMS.

Proposed revisions to OASIS items address issues raised by stakeholders, including removing items that are not currently used by CMS for payment or quality, adding items to address clinical domains not currently covered, and modifying item wording or response categories for selected items. These changes and item deletions are and considered to be high priority by CMS and have implications for outcome measurement, risk adjustment of outcome reports, case mix adjustment for prospective payment, data submission procedures and specifications, reporting systems, and provider paperwork burden.

[3] Sections 4602 and 4603 of the Balanced Budget Act require the implementation of a home health prospective payment system (PPS) to replace an interim payment system. In defining PPS for home health agencies (HHAs), the statute requires the Secretary to consider an appropriate unit of service, the number, type and duration of visits provided within that unit of service, and their cost. Payment for a unit of service was modified by a case-mix adjustor, set by the Secretary, to explain a significant amount of the variation in the cost of different units of services. The home health PPS was implemented October 1, 2000.

In addition, adopting measures of efficient and high-quality care is central to the direction that CMS would like to take in its Quality Initiative. In concordance with long-standing federal objectives, CMS ultimately plans to create a standard patient assessment instrument that can be used across all post-acute care settings. The revision of the OASIS instrument is an opportunity to consider various components of quality care and how patients might be better served as they (and information about them and their care) move among health care settings. For this reason, the OASIS C includes process items that support measurement of evidence-based practices across the post-acute care spectrum that have been shown to prevent exacerbation of serious conditions, can improve care received by individual patients, and can provide guidance to agencies on how to improve care and avoid adverse events. These changes are based on input from various panels of technical experts, stakeholders, industry associations, MedPAC, and the National Quality Forum (NQF) that offered insights and suggestions on what processes of care reflect best practices for patients receiving care in their homes. Emphasis on incorporating NQF recommendations, advancing standardization of OASIS with various tools (including MDS) and promoting use of evidence-based strategies that improve health are all integral to OASIS instrument revisions we are proposing. Based on these revisions, a set of 55 revised/updated and new quality measures have been developed for agencies to use for quality improvement. They have also been proposed to the National Quality Forum (NQF) for consideration for endorsement for public reporting, and we anticipate that a subset will be publicly reported beginning in 2011.

Revision of the OASIS data set

CMS places a high priority on designing a home health assessment instrument with refinements that are responsive to industry concerns. It is also very important that proposed changes to OASIS items result in a data set that does not create additional burden. Therefore, testing of new and revised items with actual users in a home health environment and obtaining their feedback was considered critical to assess the impact of these changes.

Abt Associates and their subcontractors UCHSC and Case Western Reserve University were awarded a contract by CMS in September 2006 to continue the process of refining the OASIS data set, as well as for the testing of the instrument and analysis of the impact of proposed changes. Under this contract, researchers from Abt Associates, UCHSC, and Case Western Reserve University have assisted CMS in carrying out the revisions based on the input described in the previous section. A revised Draft OASIS C data set was developed and published in the Federal Register for public comment July 2007. Modifications to item wording were then made based on public comment and internal review. A revised Draft OASIS C was published in the Federal Register in October 2007 and this version was used for field testing.

Data collection was begun in spring 2008, as soon as OMB approval of the PRA package was received. Eleven health agencies in Colorado, Massachusetts, and Ohio were selected to conduct the field testing, with a range of characteristics including not-for-profit and for-profit, large and small, urban and rural, and those using both paper-based OASIS assessments and electronic data collection. At each of the agencies, a group of RNs and PTs received ½ day training on the new/revised OASIS C items. The agencies were responsible for recruiting patients for the study and were encouraged to select patients with the conditions targeted by the OASIS process items; e.g., diabetes, heart failure and pressure ulcers. Agencies then used paper-based instruments to collect a certain number of "time" assessments (full version of the OASIS C) at each of the required timepoints to estimate time burden. These were done when the patient was normally scheduled for an OASIS. After the OASIS C was

done, the clinician would then continue to assess the patient for any information needed to complete the regularly scheduled OASIS B. Then, in most cases, a second clinician would go back to the patient within 48 hours and complete another version of the OASIS C, with just the new and revised items, to be used to assess inter-rater reliability. By September 2008, the data collection goals of 180 OASIS C time study assessments and 160 pairs of inter-rater assessments were met.

A second round of data collection was then conducted, in which research staff reviewed patient records on-site. Data collection included an assessment of whether information in the home health medical record supported the clinician responses to OASIS C process items. For example, if the OASIS C response said the patient had a multifactor falls risk assessment, whether there was evidence of that in the record. Researchers also collected data from the OASIS B to assess differences in responses between OASIS B and OASIS C that could impact items used for home health reimbursement. For example, the bathing item has a new response option on OASIS C. If the clinician chose that on OASIS C, the response selected on the OASIS B assessment completed at the same time was examined. In addition, focus groups were conducted with the clinicians who collected the OASIS C data to obtain feedback on issues such as usability, burden, and how the revised data set might impact care patterns.

Another round of revision to the OASIS occurred following field testing, based on feedback from clinicians and analysis of the results of the time and inter-rater reliability testing. This version was published in the Federal Register for public comment on November 14, 2008 and 142 comments were received. Each of these comments was reviewed and evaluated and further revisions to the OASIS C data set were made when appropriate. These modifications resulted in the version of OASIS C that is accompanies this submission. A detailed description of proposed modifications to the OASIS data set can be found in the response to question B.12 and are illustrated in Attachment A.

B. Justification

1 . Need and Legal Basis

Section 1861(o) of the Act (42 U.S.C. 1395x) specifies certain requirements that a home health agency must meet in order to participate in the Medicare program. (Regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare CoP.) In particular, section 1861(o)(6) of the Act requires that an HHA must meet the CoP specified in section 1891(a) of the Act and such other CoP as the Secretary finds necessary in the interest of the health and safety of its patients.

Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws. Section 1891(b) of the Act, states that the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA, and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the CoPs. Section 1891(b) of the Act (42 U.S.C. 1395bbb) requires the Secretary to assure that the CoPs and their requirements adequately protect the health and safety of individuals under the care of a home health agency, and 1891(c)(2)(C)(i)(II) requires that a standard HHA survey shall include a survey of the quality of

care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care. In accordance with section 1891(d)(1), we are required to monitor the quality of home health care with a "standardized, reproducible assessment instrument." Based on industry input, we selected the OASIS as the instrument to improve the quality of care and to comply with the law. The use of OASIS is a requirement that HHAs must meet to participate in the Medicare program (See 42 CFR § 484.55).

The conditions of participation (42 CFR §484.200 - §484.265) that require submission also provide for exclusions from this requirement. Generally, the agencies excluded from the OASIS submission requirement do not receive Medicare payments as they either do not provide services to Medicare beneficiaries or the patients are not receiving Medicare-covered home health services. Under the Conditions of Participation, agencies are excluded form the OASIS reporting requirement on individual patients if:

- Those patients are receiving only non-skilled medical services,
- Neither Medicare nor Medicaid is paying for home health care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement).
- Those patients are receiving pre-or post – partum services,
- Those patients are under the age of 18 years.

Section 4603 of the Balanced Budget Act of 1997 (BBA) created section 1895(a) of the Act, which required the development of a prospective payment system (PPS) for HHAs beginning October 1, 2000. Specifically, section 1895(b)(4)(C) of the Act requires the Secretary to establish appropriate case-mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. Section 4601(d) of the BBA provided the statutory authority for the development of a case-mix system by requiring the Secretary to expand research on a PPS for HHAs under the Medicare program that ties prospective payments to a unit of service, including an intensive effort to develop a reliable case-mix adjuster that explains a significant amount of the variances in costs. Further, section 4601(e) of the BBA provides the authority for the submission of data for the case-mix system, effective for cost reporting periods beginning on or after October 1, 1997, by permitting the Secretary to require all HHAs to submit additional information necessary for the development of a reliable case-mix system. Regulations implementing these requirements are codified at 42 CFR 484 Subpart E. We have plans to eventually link beneficiary information across provider settings with other administrative data (for example, payment and utilization data). Beneficiaries may have very complex service delivery histories, moving among various services and benefits. If OASIS data are not collected, it would be difficult to track outcomes and facilitate administrative tasks involved with integrating the care of individuals in our data systems, including the Minimum Data Set (MDS) for nursing home residents.

Under the home health PPS, HHAs have an incentive to provide care more efficiently to maximize the payment they receive. Some have raised concern that the quality of care could suffer as agencies reduce the number of visits provided to patients. With the data, we will be able to support or refute anecdotal information, unsubstantiated opinion, or conjecture, facilitate consensus building, and develop more objective policy decisions. Most importantly, data provides a better opportunity to formulate effective quality driven home health policy in the future.

OASIS is also instrumental in assisting CMS to address the new challenges presented by Pay for Reporting (as mandated in the Dec. 2005 Deficit Reduction Act). Specifically, section 5201(c)(2) of the DRA added section 1895 (b)(3)(B)(v)(II) to the Social Security Act, requiring that "every home health agency [HHA] shall submit to the Secretary [of Health and Human Services] such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause." In addition, section 1895 (b)(3)(B)(v)(I), as also added by 5201 (c)(2) of the DRA, dictates that "for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points."

In accordance with the requirements of the Privacy Act of 1974, we published a notice in the Federal Register July 27, 2007 to announce to the public that we were testing revisions to the OASIS data set and soliciting public comments. We revised the proposed instrument to be tested and published an additional notice in the Federal Register on October 19, 2007 describing the changes and responses to comments received, and soliciting additional public comments. Following the completion of field testing and data analysis, we published a revised version of OASIS C for public comment in the Federal Register on November 14, 2008.

2. Information Users

- HHAs: Individual HHAs use the patient-specific information and continue to conduct patient assessment, care planning, quality assessment, and program improvement activities. Using OBQI reports, HHAs are able to examine their specific care domains and types of patients and can compare present performance to past performance with national performance norms. HHAs use the outcome reports to evaluate the effectiveness of care provided to specific types of patients and, in the context of investigating processes of care, to individual patients. They also use the data from outcome reports to continuously monitor quality improvement outcomes over time, and to objectively assess their own strengths and weaknesses in the clinical services they provide. These outcome reports inform the HHA of the care-related areas, activities, and/or behaviors that result in effective patient care, and alert them to needed improvements. Such information is essential to HHAs in initiating quality improvement strategies. They also serve to improve HHAs' financial planning and marketing strategies. The addition of process items to the OASIS will allow agencies to assess the degree to which their agency has implemented best practices related to assessment, proactive care planning and implementation in their care of patients with common clinical conditions such as diabetes and heart failure or who are at risk for falls, depression or pressure ulcers. Many HHAs have already incorporated these processes into their agency practices as part of their efforts to reduce the rate of acute care hospitalization.

- State agencies/CMS: Agency profiles are used in the survey process to compare the HHA's results with past performance. The availability of performance data enables State survey agencies and CMS to identify opportunities for improvement in the HHA, and to evaluate more effectively the HHA's own quality assessment and performance improvement program. CMS and State agency surveyors use the reports off-site in a pre-survey protocol to target areas of concern for the on-site survey. The surveyors look at

how the HHA uses OASIS data internally, and uses the information to more effectively target survey activities. The addition of process items to OASIS will allow state survey agencies to measure the frequency with which processes of care that are recognized as optimal practice are followed by agencies.

- Accrediting Bodies: Upon specific request, national accrediting organizations such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) the Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care, Inc. (ACHC) are able to access the information only for the facilities they accredit, and that participate in the Medicare program by virtue of their accreditation (deemed) status. CMS provides OASIS information to these national accrediting bodies to enable them to target potential or identified problems during the organization's accreditation review of that facility. Process items added to the OASIS have incorporated items necessary to measures some best practices already used by accrediting bodies, such as medication reconciliation.

- Beneficiaries/Consumers: Since November 2003, a subset of the 41 OBQI outcomes have been publicly reported on the Home Health Compare website available to consumers on www.Medicare.gov. The website provides information for consumers and their families about the quality of care provided by individual HHAs, allowing them to see how well patients of one agency fare compared to other agencies and to the state and national average. The website presents the quality measures in consumer-friendly language and provides a tool to assist consumers in the selection of an HHA. As with the nursing home quality initiative, the home health agency initiative uses quality measures to assist consumers in making informed decisions when choosing a home health agency; to monitor the care their home health agency is providing; and to stimulate home health agencies to further improve quality. The addition of process items to OASIS will allow consumers another tool to identify agencies that practice processes of care recognized as optimal practice.

3. Use of Information Technology

The OASIS represents uniform formulations for collecting data items that are customarily collected in the course of the clinician's assessment of adult patients receiving skilled home health care in order to create or update the plan of care, or to document the patient's status during an episode of care. The data are generally collected in the patient's home, though some items require consulting of patient records or data received from the patient's previous health care providers (such as the hospital discharge summary.) As such, the OASIS items are integrated into home health agencies' clinical records, and the modality of data collection is dictated by agencies' choices of documentation systems. Many home health agencies utilize electronic point of care technology (laptop computers, handheld devices, or other technology) that allows for assessment data to be entered electronically as it is collected. Other agencies' clinicians utilize a paper form in the home, and the data are later entered into an electronic system.

For purposes of reporting, the Medicare Conditions of Participation for home health agencies (42CFR484.20) require that the OASIS items collected for Medicare or Medicare patients be submitted electronically to the appropriate state agency. CMS provides the HAVEN

software free of charge for agencies to use in electronically encoding and submitting these data, though some agencies have clinical and billing systems or vendors that perform this function for them.

OASIS data do not require a signature from the respondent.

4. Duplication of Efforts

The OASIS C does not duplicate any other collection data sets and the information cannot be obtained from any other source. It uses elements that are currently collected as part of the condition of participation at § 484.55, which has required a standardized assessment to be integrated into the HHA's current patient data collection and care planning processes since July 1999.

5. Small Businesses

Since OASIS data collection was mandated in1999, CMS has taken steps to reduce OASIS-related burden. For example, we provide a hotline for troubleshooting purposes and free software to HHAs. This software, containing all of the OASIS data time points, is available at no charge, and can be downloaded from our website. There is also a training page on the website, along with an OASIS Q&A mailbox. Additionally, the entire OASIS User's Manual is available on our website at no cost to HHAs. CMS has also provided training through its OASIS contractors either directly or via satellite.

6. Less Frequent Collection

Frequency of collection will not change from the currently mandated OASIS time collection requirements. Since one of the purposes of this data collection is to assess patient outcomes, and since outcome quality measures quantify change in patient health status over time, data must be gathered at a minimum of two time points. Therefore, patient health status data obtained through the OASIS are collected at least twice (i.e., at admission and discharge for patients seen by the HHA for less than 60 days), and at 60-day intervals for patients receiving care for longer periods. Sixty-day intervals correspond to other data collection points required by the Medicare program (i.e., for prospective payment). Since the average length of stay in Medicare home health care is less than 60 days, the majority of data collection will be completed at two time points.

7. Special Circumstances

Under the Medicare Conditions of Participation (42CFR484.20), Medicare-certified Home Health Agencies must report OASIS data electronically to the appropriate state agency or CMS OASIS contractor within 30 days of the assessment completion date. This allows OASIS data to be available from the state and national repositories on a timely basis for a number of key CMS functions, thus avoiding separate (and duplicative) data collection efforts:

- OASIS data can be accessed from the repositories by staff from the Regional Home Health Intermediaries (RHHIs) for use in assuring the accuracy of case-mix classification for payment;

- OASIS data can be accessed from the repositories by state survey and certification staff for use in surveys to assure home health agency compliance with the Conditions of Participation;
- OASIS data can be accessed from the repositories by CMS to assess home health agency compliance with the Pay for Reporting requirements of section 5201(c)(2) of the December, 2005 Deficit Reduction Act.

Less frequent reporting of OASIS data would require that separate systems of data collection be established to collect the required data, which would increase the burden on home health agencies.

We continue to believe that if data collection occurs less frequently than the specified time points, as stated in § 484.55, the ability to make proper Medicare payments and to evaluate the quality of care provided by HHAs to Medicare and Medicaid beneficiaries will be compromised.

8. Federal Register/Outside Consultation

Since August 2002, CMS has consulted with various industry associations such as the National Association for Home Care and the Visiting Nurses Associations of America to solicit input on proposed changes to the OASIS instrument. A CMS Technical Evaluation Panel composed of home health agency professionals, experts in quality measurement, payment indicators, and systems, and a beneficiary representative also provides advice on OASIS refinement. Researchers from UCHSC, Case Western Reserve University and Abt Associates have assisted CMS in designing the proposed OASIS C instrument and conducted the field testing of the revised OASIS instrument and analysis of the results. In addition, comments from clinicians who participated in the field testing of OASIS C were obtained via debriefing and discussion groups following data collection during the fall of 2008, and their recommendations were incorporated into the OASIS C. In October-November 2008, a set revised/updated and new quality measures calculated using items from the proposed OASIS C data set were submitted for review and endorsement by the National Quality Forum (NQF). Based on feedback from the NQF Steering Committee, some additional changes were made to the OASIS C items in order to support the generation and public reporting of endorsed quality measures. Finally, the publication of the proposed OASIS C in the Federal Register for public comment on November 14, 2008 resulted in the submission of comments from numerous individuals, providers, state associations, professional associations, and home health industry organizations. All of these comments were reviewed and further modifications were made to OASIS C where appropriate. A summary of the public comments, both general and item-specific, and CMS' response is included in the accompanying document, "Response to Public Comments on the Revised OASIS C Instrument for Home Health Quality Measures & Data Analysis.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We pledge confidentiality of patient-specific data as provided by the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Summary of Changes to the OASIS data set

As described previously, revisions to the OASIS data set include: 1) responding to issues raised by stakeholders, including removing items that are not currently used by CMS for payment or quality, adding items to address clinical domains not currently covered, and modifying item wording or response categories for selected items; and 2) the addition of process items that support measurement of evidence-based practices. We have also made changes which 3) "harmonize" the OASIS data items (and resultant quality measures) with other post-acute data collection and quality measurement initiatives, such as the Minimum Data Set (MDS) version 3.0 for skilled nursing facilities, the Continuity Assessment Record and Evaluation (CARE) tool developed as part of the Post Acute Care (PAC) Payment Demonstration, and the National Voluntary Consensus Standards for Development of Framework for Measuring Quality for Prevention and Management of Pressure Ulcers ("NQF Pressure Ulcer Framework ").

The motivation for specific changes can be found in the accompanying "Response to Public Comments on the Revised OASIS C Instrument for Home Health Quality Measures & Data Analysis." The types of changes include:

- deletion of the items not used for payment, quality or risk adjustment such as the Medicaid Identifier and the item related to Intractable Pain;
- consolidation and streamlining the questions related to caregivers, to change in functional status relative to baseline, and to proactive care planning;
- improving the wording of items related to pressure ulcers to be consistent with recommendations from the National Pressure Ulcer Advisory Panel, including definitions of stages, re-epithelialized versus healed, identifies deep tissue injuries in evolution, and documentation of length and width;
- deletion of the "14-day prior status" column from all items related to activities of daily living (ADLs) and instrumental activities of daily living (IADLs;
- elimination of IADLS including shopping, laundry, transportation, housekeeping and caregiver management of equipment; and
- improving the capacity to show improvement in ambulation, bathing, and oral medication, e.g.:
    - for ambulation, a new response category enables the item to show progress from a two-handed assistive device like a walker to one-handed device like a cane;
    - for bathing, a new response category enables the item to show progress when a patient is able to bathe independently at the sink;

    - for oral meds, a new response category enables the item to show progress when a patient is no longer requires a person to provide reminders, but can take meds if someone else prepares doses in advance;
- separating out functions that are complex and confusing to report together (e.g.; transferring item now excludes transfers related to toilet and tub and shower and focuses on bed and chair transfers.);
- adding an item measuring improvement in toileting hygiene;
- modifying items related to patient prognosis; and
- rewording of the reason for emergency care question so that it addresses the patient going to the emergency room, not for unplanned physician visits, and improves the list of reasons for emergency care and hospitalization.

Process items were added for measurement of the following:

- whether care was provided in a timely manner;
- whether the plan of care establishes parameters for notifying the physician of changes in patient status;
- whether patients received recommended immunizations;
- whether assessment and proactive care planning were conducted for patients with pain, depression, falls and pressure ulcers;
- whether planned interventions for conditions of interest including diabetes, heart failure and pressure ulcers were implemented;
- whether a complete drug regimen review was done and if the patient's physician (or other primary care practitioner) was contacted promptly if review indicated any potential clinically significant adverse effects or drug reactions; and
- whether the patient/caregiver received teaching on high risk medications at start of care and if medication teaching was done during the episode

Based on the field testing, public comments received, and input from NQF, further efforts have been made to consolidate and reduce the number of OASIS items to be collected at each time point. The current number of items is as follows:

	Start of care	Resumption of care	Follow up/ recertification	Transfer to inpatient	Discharge	Death at Home
OASIS-B1 Total Items by Time Point	**94**	**78**	**30**	**11**	**72**	**4**
OASIS-C Total Items by Time Point	**96**	**81**	**32**	**24**	**73**	**5**

When assessing the impact of these changes on burden, it must be remembered that many of the items added to OASIS C are condition-specific. For example, there are a number of questions related to pressure ulcers that apply only to the home health population with pressure ulcers, estimated to be less than 5 per cent. At Start of Care (SOC) the OASIS C would contain a minimum of 17 tracking items plus 70 clinical items if the patient did not have conditions such as diabetes, pain or wounds/ulcers. In contrast, the existing OASIS B1 would require 18 tracking items plus 58 items for a similar patient, including a requirement for both current and prior status on 14 ADLs/IADLs. In addition, field testing identified that some agencies have already incorporated many of the OASIS process items into their agency-specific assessment, particularly falls risk and pain assessment. These factors may help to

explain why clinicians in the field testing reported that the time required for the OASIS C was not greater than required for OASIS-B1 at most time points.

Burden estimation: Since the implementation of the OASIS, many HHAs have conducted their own time studies. Although minimal, we acknowledge that there is a small burden associated with the on-going use of the existing OASIS instrument when collecting OASIS information as part of the comprehensive assessment, and collecting the information for PPS. As part of the field testing of OASIS-C, we developed both qualitative and quantitative estimates of the time required to complete the assessment at various time points. While the samples are relatively small, none of the data indicates that any additional time would be required to complete the OASIS-C. Qualitatively, clinicians who participated in the field testing reported that the OASIS-C took about the same time to complete as the OASIS-B1. This is partially because, while some items were added, many apply only to small populations. In addition, many collect information that home health agency clinicians were already collecting in the course of their comprehensive assessment (e.g., pain assessments or falls risk assessments) and recording the information on the OASIS did not require additional time.

Our estimates of time, cost, average HHA size, and staff salaries are calculated as indicated below, based on historical information from the industry, consultation with the University of Colorado, assistance with statistical information from our contractors at Stepwise Systems, as well as use of updated information from additional sources, as noted.

For the period July 2007 through June 2008, there were a total of 13,891,200 OASIS assessment submissions. We estimate that there were approximately 9,565 agencies active during that period (average of total for 2007 and 2008). Therefore we estimate HHAs submit, on average (13,891,200/9,565 =) 1,453 assessments @per HHA, on an annual basis. (Note, this is about the same as the 1,447 assessments per agency estimated for 2004-2005 in the previous OASIS PRA submission.)

Based on the most recent available salaries for home health clinicians from the Bureau of Labor Statistics, and the distribution of OASIS completion across disciplines, we estimate an average hourly salary of $29.47 per clinician.

In 2008, there were about 9729 HHAs participating in the Medicare program. Based on trends in increase over the past 5 years, we estimate that there will be an additional 441 providers in 2009, for a total of 10,170 providers in 2009.

Since the number of assessments completed per agency has remained essentially constant, we retain the previous PRA package's estimate of the average-sized HHA as having 18 clinicians.

Startup Training: Training clinicians in newly certified HHAs, and new staff in existing HHAs on the use of OASIS is an ongoing process, but we recognize that the significant number of updates and improvements in OASIS-C will likely require agency-wide training of all staff. We estimate 4 hours per staff member for 1-time OASIS-C training, for a total of 18 clinicians * 4 hours= 72 hours per agency. With an estimated 10,170 agencies, this translates to 10,170 * 72 = **732,240** total hours for startup training (in the first year only).

In subsequent years, we would see the previously-estimated 8 hours per year per agency (8*10,170 =) 81,360 hours per year for ongoing training.

Data collection: The total annual burden of completing assessments and training clinicians per facility is estimated to be: 1,453 assessments @ 1 hr/assessment = 1,453 hrs + 8 hours per year per agency for training new staff = 1,461 hours per agency per year, or overall 1.005506 hrs./assessment.

The total ongoing annual burden of completing assessments and training clinicians in 2009 is 1,453 assessments/agency * 1.005506 hrs/assessment * 10,170 agencies = **14,858,370 hours.**

The total burden for start up training, assessment data collection, and training new staff in 2009 is estimated to be (732,240+14,858,370=) **15,590,610 hours.**

13. Capital Costs

At the time of the OASIS implementation, there was a one-time start-up cost for HHAs in the first year. After the first year of OASIS implementation, existing HHAs experience an ongoing cost of reporting the gathered information to the State or OASIS contractor. We continue to acknowledge that the time frames required by § 484.55 serve as a strong performance expectation for HHAs. In identifying standardized data elements that fit within the HHA's overall comprehensive assessment responsibilities, the OASIS includes only information necessary to measure outcomes of care for quality indicators and for HHAs to continue to receive payment through the prospective payment system. Therefore, we require that HHAs use the current version of the OASIS as specified in §484.55(e). We believe this requirement is necessary to continue to build a valid, reliable, comparable data set of outcomes.

We do not believe that the upgrade to OASIS-C will require new capital expenditures on the part of home health agencies. The equipment and systems in use for OASIS-B1 can handle OASIS-C as well. Software will require updating, as it does in most years to deal with incidental changes, and CMS will provide the updated HAVEN software free of charge for agencies that do not wish to update their proprietary systems.

14. Cost to Federal Government

We believe that the shift to OASIS-C will require a number of changes in systems that will result in costs to CMS. These would include the costs to:

Conduct State OEC training	*$50,000*
Update OASIS training	*$225,000*
Updating OASIS Q&A	*$100,000*
Make other systems changes	*$1,700,000*
TOTAL	*$2,075,000*

15. Changes to Burden

We estimate that the elimination, simplification, and revision of existing OASIS items as well as the addition of process and a few other items, will have no net burden impact. We dropped 25 items, plus the 11 prior ADL/IADL items, from OASIS-B1, a total of 36 items. We added 39 items, a number of which are process items that will be collected only on small subpopulations or during specific months of the year (e.g., flu season). Therefore, the total impact of the proposed OASIS revisions, including both elimination, revision and addition of items, changes the estimated burden of the OASIS very little while incorporating process measures needed to support evidence-based practices across the post-acute care spectrum. In fact, our field testing found that the time required to collect the OASIS-C data was no greater than that required for OASIS-B1, and qualitative reports from clinicians who participated in the field test corroborated this finding. A table showing how the proposed OASIS-C differs from the OASIS-B1 is included as Attachment A to this document.

16. Publication/Tabulation Dates

There are no publication or tabulation dates. These information collection requirements do not employ sampling techniques or statistical methods.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

Attachment A
Comparison of OASIS-B1 (Current Version) to OASIS-C version 12.0 (Proposed Data Collection)