

Revised Supporting Statement A for
Paperwork Reduction Act Submissions

Revision to the Outcome and Assessment Information Set (OASIS)
for Collection by Home Health Agencies
(Update from OASIS C to OASIS-C1)

A. Background

This request is for OMB approval to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect in order to participate in the Medicare program. The current version of the OASIS (OASIS-C) was originally approved by OMB on July 27, 2009, and has been in use since January 2010. OMB approval was renewed effective July 2012. The proposed revisions to the OASIS, referred to hereafter as OASIS-C1, include: 1) revising OASIS items to enable the coding of diagnoses using the ICD-10-CM coding set which goes into effect October 1, 2014; 2) addressing issues raised by stakeholders, such as updating clinical concepts and modifying item wording and response categories to improve item clarity; and 3) reducing burden associated with OASIS data collection by removing items not currently used by CMS for payment, quality, or risk adjustment.

Collection and Use of OASIS Data

Since 1999, the Conditions of Participation (CoPs) at § 484.55 have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services.¹ The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care 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

1 In meeting the CoPs, 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.

HHAs are required to collect the 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, potentially avoidable 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 repository, and measures of patient outcomes are made available to consumers and to 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.” Additional information about the legal basis for OASIS data collection is presented in Section B.1: Need and Legal Basis; additional information about OASIS data use is presented in Section B.2: Information Users.

Prior OASIS Refinement Efforts

In 2002, CMS introduced the “reduced-burden” OASIS that was a product of the Secretary’s Regulatory Reform Advisory Committee to help guide HHS’s 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 percent, and the revised OASIS was implemented in December 2002.

After the 2002 revision, CMS continued soliciting input on potential refinements and enhancements of the OASIS instrument from HHAs, industry associations, consumer representatives, researchers, and other stakeholders. A revised version of the OASIS (OASIS-C)

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.

was developed in and field tested in 2008. Testing included time analysis and inter-rater reliability of paired assessments, medical record review, and clinician focus groups to evaluate validity, reliability, burden, feasibility, and usability. The resulting modifications were incorporated in the version of OASIS-C that is currently approved by OMB. Data collection using OASIS-C began on January 1, 2010.

OASIS-C1 Refinement Efforts

As stated above, the current proposed revisions are based on three needs: 1) the need to enable the coding of diagnoses using the ICD-10-CM coding set which goes into effect October 1, 2014; 2) the need to address issues raised by stakeholders, such as updating clinical concepts and modifying item wording and response categories to improve item clarity; and 3) the need to reduce burden associated with OASIS data collection by removing items not currently used by CMS for payment, quality, or risk adjustment. As part of the OASIS-C1 development process, CMS obtained input from home health providers by enlisting representatives from nine home health agencies in Massachusetts, Colorado and Ohio to review the draft OASIS-C1 and provide feedback via paper forms and interviews. Participating agencies were provided with an annotated version of OASIS-C1 for review, and a feedback form to record their comments on each of the revised items. The study team (consisting of Donna Hurd MS RN and Deborah Deitz, RN BSN of Abt Associates Inc., Angela Richard MS, RN from University of Colorado at Denver and Elizabeth Madigan PhD, RN of Case Western Reserve University) conducted in-person interviews to obtain verbal feedback on the suggested revisions. These data collection activities took place in the fall of 2011. In addition, an Expert Work Group was convened to review the proposed revisions and make recommendations in January 2012.

The OASIS-C1 draft data set has been further revised based on public comments received during the 60-day public comment period. These changes are discussed in Section 15 of this Supporting Statement and itemized in an attached document—“crosswalk” document titled “Revisions to Initial Proposed Draft OASIS-C1 in Response to Public Comments & CMS Review.” A detailed comparison between the OASIS-C data item set and the OASIS-C1 data item set is provided in [Attachment A titled “OASIS-C to Revised Draft OASIS-C1 – Items, Timepoints & Uses Crosswalk.”](#)

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 §484.20 and §484.55) that require OASIS collection and reporting also provide for exclusions from this requirement. Under the CoPs, agencies are excluded from 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, or
- 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. It would be difficult to track outcomes and facilitate administrative tasks

involved with integrating the care of individuals in our data systems if OASIS data were not collected.

OASIS is also instrumental in assisting CMS to address the challenges presented by Pay for Reporting (as mandated in the Dec. 2005 Deficit Reduction Act [DRA]). 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.”

2. Information Users

- **HHAs:** Individual HHAs use the patient-specific information in the OASIS data set to conduct patient assessment, care planning, quality assessment, and program improvement activities. Using Outcomes-based Quality Improvement (OBQI) reports based on the OASIS data set, 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 can also be used to improve HHAs’ financial planning and marketing strategies.
- **State Agencies/CMS:** Agency profiles are used in the survey process to compare an HHA’s results with its 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. Quality assessment and performance improvement programs are not currently required under the regulations, but surveyors look at how the HHA uses OASIS data internally, and they use the information to more effectively target survey activities.
- **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 obtain the information only for the facilities they accredit and that participate in the Medicare program by virtue of their accreditation (deemed) status. The accrediting bodies do not have direct access to the system, but CMS provides the OASIS information to enable them to target potential or identified problems during the organization's accreditation review of that facility.

- **Beneficiaries/Consumers:** Since November 2003, a subset of the OBQI outcomes has 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 home health measures reported on the website include process of care measures, outcome measures and measures of care utilization, all calculated based on OASIS-C data and presented in consumer-friendly language. 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 identify agencies that practice processes of care recognized as optimal practice; to monitor the care their home health agency is providing and; and to stimulate home health agencies to further improve quality.

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 (42 CFR § 484.20) require that the OASIS items collected for Medicare or Medicaid 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. 100% of responses are submitted electronically.

OASIS data do not require a signature from the respondent.

4. Duplication of Efforts

The OASIS dataset collection does not duplicate any other data set collection, 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 42 CFR § 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 in 1999, CMS has taken steps to reduce OASIS-related burden to all providers, including those that are small businesses. For example, we provide a hotline for troubleshooting purposes and free software to HHAs. This software, which contains the data items to be completed at each of the OASIS data time points, is available for download from the CMS website free of charge. Small business home health providers that cannot afford the expense of an electronic health records/computer programming vendor can use this software free of charge as the means by which to submit their OASIS-C1 data to CMS.

CMS also offers an OASIS training page on the cms.gov website. The OASIS webpage offers many great informational and educational tools that can be used by small business home health providers such as the OASIS Q&A mailbox which publishes answers to provider questions on a quarterly basis and the OASIS User's Manual. CMS also provides 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 is completed at two time points (the beginning and end of care).

7. Special Circumstances

Under the Medicare Conditions of Participation (42 CFR § 484.20), 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 Home Health and Hospice Medicare Administrative Contractors (HH&H MACs) 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 CoPs;
- 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 42 CFR § 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

The 60 day PRA notice was published in the Federal Register on Friday June 21, 2013 (78 FR 37542). The 60 day comment period ran from Friday, June 21, 2013 through Tuesday, August 20, 2013. A total of ten (10) public comments were received during this comment period. A summary of the comments received and our responses thereto are discussed in a document, titled “Responses to Public Comments in the OASIS-C1 Data Set for Home Health Quality Measures & Data Analysis” which is included with the PRA package.

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. Feedback from the National Quality Forum Steering Committee has led to OASIS item changes to support the generation and public reporting of endorsed quality measures. Researchers from University of Colorado Denver, Case Western Reserve University and Abt Associates Inc. assisted CMS in designing, conducting field testing, and analyzing results of testing the OASIS-C instrument. For the current revision, comments on proposed changes from home health clinicians were obtained via interviews during the fall of 2011, and an Expert Panel their recommendations were incorporated into the OASIS-C1. Quality measures calculated using items from the OASIS data set are submitted for review, endorsement and ongoing maintenance by the National Quality

Forum (NQF). In addition, the OASIS data set has been revised based on comments from numerous individuals, providers, state associations, professional associations, and home health industry organizations in response to publication for public comment in the Federal Register as part of prior OMB PRA review processes.

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 as amended at 5 U.S.C. 552a. The System of Records Notice associated with this data collection effort (09-70-0522) was published 2007-11-13.⁴

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Part 1. Estimated Time Burden

Average Number of HHA in U.S. = **12,014**

Average Number of OASIS-C1 Assessments Submitted Per All HHAs per Year = **17,268,890**

Average Number of OASIS-C1 Assessments Submitted Per Each HHA per Year = **1,437**

Average Number of OASIS-C1 Assessments Submitted Per Each HHA per Month = **119.75**

(The above figures were calculated as follows:

17,268,890 OASIS submissions per all HHAs per year/**12,014** HHAs in U.S. = **1,437** OASIS submissions per ALL HHAs per year

1,437 OASIS submissions per HHA per year / 12 months per year = **119.75** OASIS submissions per each HHA per month)

⁴ <http://www.cms.gov/Regulations-and-Guidance/Guidance/PrivacyActSystemofRecords/downloads/0522.pdf>

Part II. Estimated Cost/Wage Calculation

A. Time Estimates

Average time spent per each OASIS-C1 Assessment/Patient = 52.8 minutes

47.8 minutes of clinical time spent to perform the OASIS-C1 assessment

5.0 minutes of administrative time to submit data from each OASIS-C1 assessment to CMS

Estimated Annual Hourly Burden per each HHA for OASIS-C1 = 1267.2 hours per HHA

119.75 OASIS-C1 assessments per HHA per month x 52.8 min/assessment = **6,322.8** min per HHA per month.

6,322.8 min per HHA per month / 60 minutes per hour = 105.38 hours per HHA per month.

105.38 hours per HHA/mo. x 12 months per year – 1264.56 hours per each HHA per year

Estimated Annual Hourly Burden for all HHA for OASIS-C1 = 15,224,141 hours

119.76 OASIS-C1 assessments per HHA per month x 52.8 min/assessment = **6,322.8** min per HHA per month.

6,322.8 min per HHA per month / 60 minutes per hour = 105.38 hours per HHA per month.

105.38 hours per HHA/mo. x 12 months per year – 1264.56 hours per each HHA per year

1,264.56 hours per HHA per year x 12,014 HHAs = 15,224,141 hours for all HHAs per year.

4. Estimated Annual Hour Burden per ALL HHAs per year for ongoing OASIS-C1 Training

8 hours of training per each HHA per year x 12,014 HHAs = 96,112 training hours

B. Wage Costs for Completion of OASIS-C1 Assessments

Average Time/Cost per OASIS-C1 Assessment per HHA = 52.8 minutes

47.8 minutes clinician’s time to collect clinical data – paid @ \$32.41 per hour =

\$25.82

5.0 minutes administrative time paid @ \$14.01 per hour =

\$ 1.17

\$26.99

Medical Clinician’s Time:

Calculation Method #1

47.8 minutes x 1,437 OASIS forms per HHA per year = 68,689 minutes per HHA per year

68,689 minutes per HHA per year / 60 minutes = 1,145 hours per HHA per year

1,145 hours per HHA per year x \$32.41 per hour = **\$37,109.45** clinical wages/ per each HHA/year

\$37,109.45 x 12,014 HHAs = **\$445,832,932** per all HHAs per year

Calculation Method #2

47.8 minutes of clinical/nursing time x 119.75 OASIS forms per HHA per year = 5,724 min per HHA monthly

5,724 minutes per each HHA monthly x 12 months per year = 68,688 minutes per HHA yearly

68,688 minutes per HHA yearly / 60 minutes per hour = 1144.8 hours per HHA yearly

1145 hours per HHA yearly x **\$32.41** per hour = **\$37,109.45** nursing wages per HHA yearly

\$37,109.45 x 12,014 HHAs = **\$445,832,932** per all HHAs per year

Administrative Assistant Time:

Calculation Method #1

5 minutes per OASIS form x 1,437 OASIS forms per HHA per year = 7,185 minutes per HHA per year
7,185 minutes per HHA per year / 60 minutes = 119.75 hours per HHA per year
119.75 hours per HHA per year x \$14.01 per hour = **\$1,677.70** admin assistant wages per HHA per year
\$1,677.70 x 12,014 HHA HHAs = **\$20,155,888** per all HHA HHAs/year

Calculation Method #2

5 minutes of Admin. staff time x 119.75 OASIS forms per HHA per year = 598.75 min per HHA monthly
598.75 minutes per each HHA monthly x 12 months per year = 7,185 minutes per HHA yearly
7,185 minutes per HHA yearly / 60 minutes per hour = 119.75 hours per HHA yearly
119.75 hours per HHA yearly x **\$14.01** per hour = **\$1,677.70** nursing wages per HHA yearly
\$1,677.70 x 12,014 HHAs = **\$20,155,887** per all HHAs per year

Total Annualized Staff Wages for Time Required to Complete OASIS Assessments per Each HHA:

\$37,109.45	Clinical/Nursing wages per each HHA per year
\$ 1,677.70	Administrative assistant wages per each HHA per year
\$38,787.15	Total Annualized Cost to Each HHA Provider

Total Annualized Staff Wages for Time Required to Complete OASIS Assessment Across All HHAs

\$445,832,932	Clinical/Nursing wages per all HHA providers per year
\$ 20,155,887	Administrative assistant wages per all HHAs per year
\$465,988,819	Total Annualized Cost to <u>All</u> HHAs Providers

A. Training Costs:

2 hours of OASIS-C1 update training per each HHA x 18 staff members = 36 total training hrs. per HHA
36 hours of training per HHA x 12,014 HHAs = 432,504 hrs. OASIS-C1 update training/year for all HHAs

13 Clinical staff persons per HHA to attend 2 hour training = 26 hours

5 Administrative Staff members attending 2 hour training session = 10 hours

Clinical Staff Training Wage Estimate

26 hours x \$32.41 per hour = **\$842.66** for training clinical staff at each HHA per year
\$842.66 x 12,014 HHAs = **\$10,123,717** for training clinical staff in all HHAs/per year

Administrative Staff Training Wage Estimate

10 hours x \$14.01 per hour = **\$140.10** for training clinical staff at each HHA per year
\$140.10 x 12,014 HHAs = **\$1,683,161** for training clinical staff in all HHAs/per year

Wages for One-Time Training Wages for Each Individual HHA

\$842.66 Clinical Staff Training Wages per each HHA

\$140.10 Administrative Staff Training Wages per each HHA

\$982.76 **Total Combined Wages for one-time Staff Training**

Wages for One-Time Training Wages for ALL HHAs
 \$10,123,717 Clinical Staff Training Wages per each HHA
 \$1,683,161 Administrative Staff Training Wages per each HHA
\$11,806,878 Total Combined Wages for one-time Staff Training

B. Summary of Estimated Costs

\$37,109.45	Nursing wages per each HHA per year
\$ 1,677.70	Administrative assistant wages per each HHA per year
\$ 982.76	Wages for One-time OASIS-C Update Staff Training for each HHA
\$39,769.91	Estimated Total Annualized Cost to Each HHA Provider

\$445,832,932	Nursing wages per all HHA providers per year
\$ 20,155,887	Administrative assistant wages per all HHAs per year
\$ 11,806,879	Wages for One-time OASIS-C Update Staff Training for ALL HHAs
\$477,795,698	Estimated Total Annualized Cost to All HHAs Providers

PART C. Additional Calculations:

1. Average Yearly Cost to Each HHA
 $\$477,795,698 - \text{Cost for all HHAs per year} / 12,014 \text{ HHAs in U.S.} = \mathbf{\$39,770}$

2. Estimated Average Monthly Cost Across All HHAs
 $\$477,795,698 - \text{Total annual cost to all HHAs per year} / 12 \text{ months per year} = \mathbf{\$39,816,308}$

3. Estimated Average Monthly Cost to Each Individual HHA
 $\$477,795,698 - \text{Total annual cost to all HHAs/year} / 12 \text{ months per year} / 12,014 \text{ HHAs} = \mathbf{\$3,314}$

4. Estimated Cost per Each OASIS-C1 Assessment
 $\$477,795,698 - \text{Total annual cost to all HHAs/year} / 17,268,890 \text{ OASIS-C1 assessments per year} = \mathbf{\$27.67}$
 per each OASIS-C1 assessment

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-C1 will require new capital expenditures on the part of home health agencies. The equipment and systems in use for OASIS-C can handle OASIS-C1 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

CMS will incur costs associated with the collection and handling of OASIS-C1 data for several reasons. First, providers can submit their OASIS data using a CMS sponsored web-based program known as HAVEN. The federal government will incur costs associated with the maintenance and upkeep of this web-based computer program. In addition, the federal government will also incur costs for the help-desk support that must be provided to assist providers, not only with the OASIS data collection process, but also the data submission process.

Secondly, once OASIS data has been submitted by HHA providers, it is then transmitted to a CMS contractor for processing and analysis. Thereafter, the data is stored by another CMS contractor for future use. There are costs associated with the transmission, analysis, processing and storage of the OASIS data by the CMS contractors.

Thirdly, pursuant to §1895 (b)(3)(B)(v)(I) of the Social Security Act, HHAs that do not submit OASIS-C1 data will receive a 2 percentage point reduction of their home health market basket percentage increase. There are costs associated with the tabulation of the data necessary to determine provider compliance with the reporting requirements mandated by §1895 (b)(3)(B)(v)(I) of the SSA.

It is important to note that these costs are not new, but have been associated with the use of the OASIS data collection instrument since it was first introduced in 1999.

The total estimated annual cost to the federal government for the implementation and ongoing management of OASIS-C1 data is \$1,500,000. These costs are itemized below:

<u>ESTIMATED ANNUAL COSTS TO FEDERAL GOVERNMENT:</u>	
Conduct State OEC Training	\$100,000
Update OASIS-C1 Web-Based Training	\$150,000
Update OASIS-C1 Q&As	\$100,000
Update OASIS-C1 Manuals and Materials	\$100,000
Contractor Costs for Receipt and Storage of OASIS-C1 Data	\$550,000
Costs for Upkeep & Maintenance of HAVEN Software by CMS/DNS	\$500,000
TOTAL COST TO FEDERAL GOVERNMENT:	\$1,500,000

15. Changes to Burden

Summary of Changes to the OASIS-C data set

As described previously, revisions to the OASIS data set include: 1) revision of OASIS items to enable the coding of diagnoses using the ICD-10-CM coding set which goes into effect October 1, 2014; 2) addressing issues raised by stakeholders, such as updating clinical concepts and modifying item wording and response categories to improve item clarity; and 3) reducing burden associated with OASIS data collection by removing items not currently used by CMS for payment, quality, or risk adjustment. We have also made efforts to have these changes increase “harmonization” between the OASIS data items (and resultant quality measures) and other post-acute data collection and quality measurement initiatives, such as the Minimum Data Set (MDS) for skilled nursing facilities, the Continuity Assessment Record and Evaluation (CARE) tool developed as part of the Post-Acute Care (PAC) Payment Demonstration. **ICD-10 related changes** - Items in the OASIS-C that report patient diagnoses (M1010, M1016, M1020, M1022, and M1024) have been revised to accommodate ICD-10-CM coding. These items now have space to enter 7-digit codes, and references to prior ICD-9 “E” and “V” codes were removed.

Modifying and clarifying item wording – Wording changes designed to clarify questions, responses or directions were made to 44 items in OASIS-C1. These include clarification of data collection time periods and spelling out abbreviations such as “e.g.” and “i.e.” with clearer language such as “for example” and “specifically”.

Increased Harmonization – Column 2 on M1308 was eliminated at all time points and replaced with M1309 at Discharge to collect information on worsening pressure ulcer status using wording harmonized with the MDS and CARE instruments.

Updated clinical concepts – M1032, Risk for Hospitalization, was revised to collect data on factors that have been identified in the literature as predictive of hospitalization, and to order responses based on length of the appropriate look-back period.

Burden reduction – In order to minimize the burden related to collection of the OASIS data set, CMS and its contractors identified opportunities to eliminate collection of eight items at various time points:

- Item M1012, Inpatient Procedures, is an item that agencies have previously reported to be time-consuming and burdensome as this information may not be readily available at the time of home health intake. CMS announced in April 2011 that the response to M1012 was not used for payment, quality measure development, or risk adjustment so any response including “unknown” was acceptable to report, but the item cannot be left blank. However, agency interviews conducted as part of OASIS-C1 development in late 2011 indicated that clinicians are not uniformly aware of the CMS announcement. Therefore, the deletion of M1012 from the OASIS will result in a decrease in burden to all OASIS users (in that a response will no longer be required) and will provide an even greater decrease in burden for those users who have continued to collect and report the information on inpatient procedures to complete the item.

M1012 is eliminated in OASIS-C1; this change impacts OASIS assessments conducted at start and resumption of care.

– Items M1310, M1312 and M1314 report the length, width and depth of the pressure ulcer with the largest surface dimension. If the patient has more than one pressure ulcer, the clinician must determine the longest length and width of each pressure ulcer and make a determination of which ulcer has the largest dimensions, then measure and report the length, width and depth of that ulcer, rounding to the nearest centimeter. The intention of including these items in OASIS was to provide data for a measure reporting on improvement in the patient’s pressure ulcer status between start/resumption of care and discharge. However, the information is not currently being used for that purpose and analysis of 2010 and 2011 data indicate problems with the validity (accuracy) of the data being reported. These three pressure ulcer dimension items have been deleted from the OASIS-C1; this change impacts OASIS assessments conducted at start and resumption of care and at discharge.

– Item M1350 reports whether the patient has a skin lesion or open wound that is receiving intervention from the home health agency, other than a surgical wound, pressure or stasis ulcer. This item is currently used only for risk adjustment of quality measures. In OASIS-C1 this item will still be collected at start and resumption of care (which is when risk adjustment takes place), but is deleted at discharge.

– Item M1410 reports the types of respiratory treatments (oxygen, ventilator etc) the patient is receiving at home. This item is currently used only for risk adjustment of quality measures. In OASIS-C1 this item will still be collected at start and resumption of care (which is when risk adjustment takes place), but is deleted at discharge.

– Item M2110 reports how frequently the patient receives assistance with activities of daily living from caregivers other than the home health agency. This item is currently used only for risk adjustment of quality measures. In OASIS-C1 this item will still be collected at start and resumption of care (which is when risk adjustment takes place), but is deleted at discharge.

– Item M2440 is collected at the time of transfer from home health to a skilled nursing facility to identify the reason that a patient was transferred. This item has been deleted from the OASIS-C1 as it is not used for payment, quality measure development, or risk adjustment.

Changes following the initial 60-day public comment period

CMS received comments on the Draft OASIS-C1 data set (published in the Federal Register on June 21, 2013) from a total of 10 home care clinicians, agencies and organizations. Many commenters addressed multiple topics and items. Most commenters expressed their support for proposed changes to the OASIS data set and offered a number of useful recommendations for modifications to improve the OASIS-C1 that CMS has incorporated into the Final Proposed Draft OASIS-C1.

Three documents , which are included with this PRA package, detail changes made to the Draft OASIS-C1 following the initial 60-day public comment period accompany this Revised Supporting Statement A. They are:

- A Revised Draft OASIS-C1 data set with changes based on internal review following public comments;
- A crosswalk from the Initial Draft OASIS-C1 to Final Proposed Draft OASIS-C1, titled “Revisions to Initial Proposed Draft OASIS-C1 in Response to Public Comments & CMS Review” that identifies all changes to the OASIS-C1 data set following the initial 60-day public comment period;
- A document titled “Response to Public Comments on the OASIS-C1 Data Set for Home Health Quality Measures & Data Analysis (Form# CMS–R–245/OMB# 0938– 0760), September 2013” which summarizes positive feedback, addresses general comments, and responds to item-specific comments and suggestions.

A total of 27 items were revised based on public comment and internal review following the 60-day comment period. Of these, 23 were minor wording changes or additions to clarify item questions, responses and/or instructions. There were substantive changes to 4 items:

- M1033 – Risk for Hospitalization – based on a public comment, response 7 was changed from “Currently taking 6 or more medications” to “Currently taking 5 or more medications”. A literature review indicates this change reflects a conservative and evidence-based cut-point to identify patients at risk for hospitalization.
- M1309 – Worsening in Pressure Ulcer Status since SOC/ROC – based on public comments and expert guidance, the item has been modified to improve instructions for item completion and to permit clinicians to record pressure ulcers that are unstageable due to slough/eschar and that are new or previously Stage I or Stage II at the most recent start or resumption of care.
- M1910 – Falls Risk Assessment – based on public comment, we revised the language used in Response 1 and 2 to more closely reflect the responses currently used in OASIS-C. Response 1 now reads: “Yes, and it does not indicate a risk for falls”. Response 2 now reads: “Yes, and it does indicate a risk for falls.”
- M2250 – Plan of Care Synopsis – d. Depression interventions has been modified to include the phrase, “and/or physician notified that patient screened positive for depression” to enable agencies to receive credit for appropriate interventions that are reported in the new NQF-endorsed measure “Depression Assessment Conducted with Follow-up Plan”.

We do not believe that any of the changes made to the OASIS item set will have an impact on the estimated burden of OASIS-C1 on HHA providers that was describes stated in our 60 day PRA package.

Impact of Item Deletion

The impact of item deletion on the number of items in the OASIS data set is shown in Table 2.

Table 2: Number of Items in OASIS-C and C-1, by Assessment Reason/Timepoint

Dataset	Total Items	Start of Care (SOC)	Resumption of Care (ROC)	Recertification/ Other Follow-up	Discharge	Death at Home
OASIS-C	114	95	80	32	62	5
OASIS-C1	110	91	76	32	56	5

The total number of items in the OASIS dataset decreases from 114 in OASIS-C to 110 in OASIS-C1. The number of items collected at Start of Care decreases from 95 to 91, at Resumption of Care there is a decrease from 80 to 76, at Transfer it decreases from 19 to 18 and at Discharge the number of items collected drops from 62 to 56. The number of items collected at Recertification/Follow-up is anticipated to remain the same despite the deletion of one item (M1350) at that time point. This is because of the anticipated need to begin collecting another item (M1011) at that time point for the purposes of case-mix adjustment used in the payment system.

CMS supports the deletion of OASIS items at any time points where the information collected is not currently being used for payment, quality measurement or risk adjustment. We believe the item deletions being proposed for OASIS-C1 meet that goal. Table 2 in Section 12 – Burden Estimate (Hours & Wages), shows that the total number of items in the OASIS dataset decreases from 114 in OASIS-C to 110 in OASIS-C1. The number of items collected at Start of Care decreases from 95 to 91, at Resumption of Care there is a decrease from 80 to 76, at Transfer it decreases from 19 to 18 and at Discharge the number of items collected drops from 62 to 56.

Our estimate of the hours of respondent burden to be reduced by the proposed changes to the OASIS data set was calculated using the methodology described in Section 12 – Burden Estimate (Hours & Wages). Because different number of items are collected at different time points (start of care, recertification, inpatient transfer, etc.), the total burden estimate for a year is calculated by multiplying (a) the number of each type of assessment conducted in a year by (b) the number of items in each type of assessment by (c) the average length of time per item. Since we lack information on the specific time required to complete each OASIS item, we use a standard average length of time per item. The estimate of average time per item used in the calculation is 0.9 minutes per item.⁵ Calculations for all burden estimates are shown in Section 12 above.

⁵ This is slightly higher than the 0.7 minutes per item included in the OMB notice printed on the OASIS-C, but it is more consistent with the estimated average burden per assessment of 60 minutes (55 minutes of data collection and 5 minutes of data entry) which has been used in estimating total burden for OASIS-C.

Table 3 shows the frequency number of items and the total minutes and hours estimated for each assessment type, based on the average of 0.9 minutes per item.

Table 3: Calculation of Burden Reduction Impact

Reason for Assement	Frequency	Freq %	# Items OASIS C	# Items OASIS C1	# Deletions	Avg. Mins per item	Avg. Mins saved per Admin	Total Mins saved	Total hours saved
1 – SOC	5647110	32.7%	95	91	4	0.9	3.6	20,329,596	33,8827
3 – ROC	1071622	6.2%	80	76	4	0.9	3.6	3,857,839	6,4297
4 – FU	4054919	23.5%	32	32	0	0.9	0	0	0
5 - FU (other)	65109	0.4%	32	32	0	0.9	0	0	0
6 - TF w/o DC	1641621	9.5%	19	18	1	0.9	0.9	1,477,459	2,4624
7 - TF w/DC	234749	1.4%	19	18	1	0.9	0.9	211,274	3521
8 - Death at home	39182	0.2%	5	5	0	0.9	0	0	0
9 – DC	4514578	26.1%	62	56	6	0.9	5.4	24,378,721	406,312
Totals	17268890	100.0%					2.9	50,254,889	837,581

The reduction in burden is the difference between the total estimated burden for the current version of OASIS (OASIS-C) and the projected burden of the proposed OASIS-C1. Based on these calculations, we estimate an overall reduction in burden for data collection and entry of 837,581 hours per year when OASIS-C1 is implemented in October 2014.

16. Publication/Tabulation Dates

These information collection requirements do not employ sampling techniques or statistical methods. While the patient-level OASIS data is not published, CMS does publish a set of quality measures derived from OASIS assessments on the Medicare Home Health Compare web site. The OASIS data used to calculate the quality measures are updated quarterly and represent a rolling 12 months of data. Data for all episodes of care that end within that 12-month period are included regardless of when the episode of care began. The most recent update occurred on January 17, 2013 and includes episodes ending between October 2011 and September 2012. Additional details about the measures are available on the CMS Home Health Quality Initiative web site: https://www.cms.gov/HomeHealthQualityInits/10_HHQIQualityMeasures.asp

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

OASIS-C to Revised Draft OASIS-C1 – Items, Timepoints & Uses Crosswalk