Supporting Statement A

Outcome and Assessment Information Set
OASIS-C2
(OMB control number: 0938-1279)

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-C1/ICD-10 (0938-1279) data item set was approved by the Office of Management and Budget (OMB) on May 26, 2015 and implemented on October 1, 2015. We are seeking OMB approval for the proposed revised OASIS item set, referred to hereafter as OASIS-C2, scheduled for implementation on January 1, 2017. The OASIS C2 is being modified to include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), and formatting changes throughout the document.

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 data set 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[2]. The comprehensive assessment must include the exact use of the current version of the OASIS data set.

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." [3]

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 (not skilled) 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 § 484.55 specifically requires that a patient receive from the HHA a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must (1) identify the patient's continuing need for home care; (2) meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs; and (3) for Medicare patients, identify eligibility for the home health benefit, including the patient's homebound status.

3 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.[4] 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."

Section 2(a) of the IMPACT Act, (hereafter "the Act"; Pub. L. 113-185, enacted on Oct. 6, 2014) amended Title XVIII of the Social Security Act[5], in part, by adding a new section 1899B, requiring the submission of standardized data by Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs). The proposed changes to the OASIS C2 are part of CMS's overall efforts to implement the Act's data reporting and data standardization requirements for the assessment instrument that is mandated for use in HHAs participating in Medicare. Additional information about the legal basis for OASIS C2 presented in Section B.1; additional information about OASIS-C2 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

4 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.

5 Title XVIII of the Social Security Act established regulations for the Medicare program, the reporting of quality data by home health agencies (HHAs) is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act ("the Act")

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) 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. Data collection using OASIS-C began on January 1, 2010.

OASIS-C1

Significant revisions were made to the OASIS-C data item set to create the OASIS-C1. The original version of OASIS-C1 was created mainly because of the need to enable the coding of diagnoses using the ICD-10-CM coding. In addition, OASIS-C1 was also designed to address issues raised by stakeholders, to update clinical concepts and modify item wording and response categories to improve item clarity. OASIS-C1also incorporated a significant reduction in provider burden through removal of items, used in OASIS-C, that are not useful for payment, quality, or risk adjustment purposes.

OASIS-C1had been scheduled for implementation on October 1, 2014. However, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted. This legislation mandates that CMS may not implement ICD-10 prior to October 1, 2015. As a result, CMS will not be able to implement OASIS-C1 prior to October 1, 2015 and was faced with the dilemma of how to handle the collection of OASIS data during the ICD-10 delay.

OASIS-C1/ ICD-9 Version

OASIS-C1/ICD-9 Version is an interim version of the OASIS-C1 data item set that was created in response to the legislatively mandated ICD-10 delay. OASIS-C1/ICD-9 Version incorporates the updated clinical concepts, modified wording and improved item clarity that was incorporated into OASIS-C1. However, the data items inOASIS-C1 that use ICD-10 codes were been replaced with the corresponding items from OASIS-C that use ICD-9 codes. In addition, OASIS-C1/ICD-9 fixes some typographical errors and clarifies skip patterns relative to OASIS C1.

OASIS-C1/ ICD-10 Version

OASIS-C1/ICD-10 Version replaced the OASIS-C1/ICD-9 version in order to support the system wide implementation of the ICD-10. This version retained all the updated clinical concepts, modified wording, and improved clarity included in OASIS-C1/ICD-9, as well as the typographical fixes, and reinstated the ICD-10 codes from OASIS-C1. Specifically, the OASIS-C1/ICD-10 version replaced the five ICD-9-CM-based items in the OASIS-C1/ICD-9 data set

(M1010, M1016, M1020, M1022, M1024) with the corresponding ICD-10 items (M1011, M1017, M1021, M1023, M1025). The OASIS-C1/ICD-10 data item set was approved by the Office of Management and Budget (OMB) on May 26, 2015 and implemented on October 1, 2015.

OASIS-C2 Version

The OASIS C2 is scheduled for implementation on January 1, 2017 in order to comply with requirements for the Act as summarized below.

- Changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), including
    - three new standardized items (M1028, M1060, GG0170c);
    - modification to and renumbering of select medication and integumentary items to standardize with other post-acute settings of care (M1311, M1313, M2001, M2003, and M2005).

- Additional, non-standardized changes include the following:
    - Changes to the lookback period and item number was changed in five items (M1500, M1510, M2015, M2300 and M2400).

- Formatting changes throughout the document, including
    - converting multiple check boxes to a single box for data entry where responses are mutually-exclusive, and
    - changing the numbering for pressure ulcer staging from Roman to Arabic numerals.

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."

As has been previously discussed, a revision to the OASIS item set has been mandated by federal law under section 1899B(a)(1) of the Act. All covered providers must submit data reporting for the following domains across settings (cross setting measures):

- patient assessment data standardized across PAC settings (section 1899B(b) of the Act);
- quality measures, including functional status, cognitive function, skin integrity, incidence of falls, medication reconciliation, and care coordination (section 1899B(c)(1) of the Act); and
- measures of resource use, discharge to community, and preventable hospital readmission rates (section 1899B(d)(1) of the Act).

Further, section 1899B(b)(3) of the Act requires that PAC settings standardize their patient assessment datasets across settings, such that the following conditions are met:

- data element uniformity in assessment instrument;
- comparison of quality and data across PAC settings; and
- improved discharge planning, exchangeability of data, and coordinated care between settings.

The conditions of participation (42 CFR §484.20 and §484.55) require a comprehensive assessment for each HHA patient covered under Medicare and that assessment must include the exact use of the current version of the OASIS data set. The Act mandates data standardization requirements for the OASIS item set as part of the overall standardization of quality reporting and patient assessment in PAC settings.

In compliance with both of these laws, the OASIS item set must be revised.

2. Information Users

- HHAs: OASIS data are collected as part of the comprehensive assessment required by the Medicare CoPs – and the comprehensive assessment must include the exact use of the current version of the OASIS data set. However, OASIS is not intended to represent a comprehensive assessment but to be part of an HHA's comprehensive assessment documentation. Consequently, the information gathered here is used by every HHA participating in Medicare for eligible patients. Agencies are free to rearrange OASIS item sequence in a way that permits logical ordering within their own forms, as long as the actual item content, skip patterns, and OASIS number remain the same. Individual HHAs also use the OASIS as part of care planning, quality assessment, and program improvement activities.

Outcomes-based Quality Improvement (OBQI) reports - based on the OASIS data set – can be used by HHAs for performance monitoring and to help guide quality/performance improvement efforts. OASIS data are used to calculate several types of OBQI reports including a) Risk Adjusted Outcome Reports; b) Potentially Avoidable Reports; c) Agency Patient-Related Characteristics (formerly case mix) Reports; and d) Patient Tally Reports. CMS has provided these reports to HHAs for them to use to compare present performance to past performance with national performance norms. The OBQI 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 use the data from OBQI reports to continuously monitor quality improvement initiatives over time, and to objectively assess staffing needs, as well as strengths and weaknesses in the clinical services they provide. The information in OBQI reports can also be used in satisfying the annual evaluation component of the CoPs as mandated in §484.52(a).

- Beneficiaries/Consumers: Since November 2003, a subset of the OBQI outcomes, as well as selected process measures derived from OASIS data, have been publicly reported on the Home Health Compare website available to consumers on https://www.medicare.gov/homehealthcompare/search.html. 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, calculated based on OASIS data or Medicare claims 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. In 2015, CMS added a Quality of Patient Care star rating to Home Health Compare, which summarized results of nine quality measures, eight of which are calculated using OASIS data.

- 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.

  CMS has implemented a Home Health Value-Based Purchasing (HHVBP) Model in nine states. The Model utilizes Medicare's existing HH data collection, quality reporting, and payment systems. This model relies heavily on information gathered from OASIS data

collections (either directly via home health pay for reporting[6] or indirectly via quality report systems such as OBQI and HH compare, as discussed above). Under the HHVBP Model, CMS will measure the performance of home health agencies based on a set of measures, and adjust payments to agencies based on their performance. The program uses a broad set of performance measures that captures the multiple dimensions of care that HHAs provide. Most of the performance measures are derived from the OASIS assessment instrument. The OASIS-based measures used in HHVBP include three process measures (drug education, flu vaccine ever received, and pneumococcal vaccine) and seven outcome measures (improvement in bathing, improvement in bed transfer, improvement in ambulation, improvement in oral medications, improvement in dyspnea, improvement in pain, and discharge to the community). The set of measures used in HHVBP is not static, and CMS is currently considering changes to the performance measures used in the program. These potential changes include new OASIS-based performance measures that are currently not publicly reported or part of the Home Health Quality Reporting program as well as measures that are being developed as part of the IMPACT Act.

- 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.

3. Use of Information Technology

The OASIS item set 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, however, like other comprehensive assessment documentation, OASIS data can be collected using a variety of strategies, including observation, interview, review of pertinent documentation (for example, hospital discharge summaries) discussions with other care team members where relevant (for example, phone calls to the physician to verify diagnoses), and measurement (for example, intensity of pain).

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

6 Section 5201(c)(2) of the DRA added Section 1895(b)(3)(B)(v)(II) to the Act in 2005, requiring that "every [HHA] shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of healthcare quality (e.g. OASIS data to the state repository)." Since 2007, Section 1895(b)(3)(B)(v)(I) has given CMS the authority to reduce market rate payment adjustments by up to 2 percentage points for failure to submit data for the reporting year. CMS established the quantity of OASIS assessments each HHA must submit to meet this requirement in the CY2015 Home Health Final Rule (effective July1, 2015, increases incrementally each additional year).

agencies' clinicians utilize a paper form in the home, and the data are later entered into an electronic system. OASIS data do not require a signature from the respondent.

For purposes of reporting, the CoPs (42 CFR §484.20 and §484.55) require that 100% of completed 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.

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 in1999, 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 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

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. By law, OASIS data must be collected for patients at four? specific time points during the home health episode:

- admission to home care (start of care, or SOC)
- resumption of care after an inpatient stay (resumption of care, or ROC)
- recertification every 60 days that the patient remains in care,
- end of care (EOC, e.g. transfer to an inpatient facility or discharge from home care).

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). Frequency of collection will not change from the currently mandated OASIS time collection requirements.

7. Special Circumstances

Under the Medicare CoP (§ 484.20), HHAs 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.
- The OASIS data collected and transmitted by HHAs to their respective state agencies has allowed CMS to generate agency specific quality reports since January 2001. These reports are available to Medicare-certified HHAs through the Certification and Survey Provider Enhanced Report (CASPER) system and the CMS's Quality Improvement and Evaluation System (QIES). Agencies depend on these reports as a source of information for their patient care quality monitoring and improvement programs.
- As stated in the C CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule (42 CFR Part 409, 424, & 484, FR 2015-27931), CMS intends to rely partly on the data gathered by OASIS to inform and implement the HH VBP.

Less frequent reporting of OASIS data would require that separate systems of data collection be established to collect the required data and transmit 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 Federal Register notice was published on April 1, 2016 and the comment period ended on May 31. 2016. There were no public comments received.

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. CMS also recruits and convenes Technical Evaluation Panels (TEPs) composed of home health agency professionals, experts in quality measurement, payment indicators, and systems, and beneficiary representatives to provide advice on OASIS measure 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. In addition to the public comment period included in the federal register process as above, The OASIS-C2 data set was informed by 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 to create OASIS C2. Public comments received via the Federal Register did not result in additional modifications, as of the close of the 60-day comment period.

The 30-day Federal Register notice published on June 30, 2016 and ended August 1, 2016. No public comments were received.

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.[7]

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

This section estimates the burden of implementing the OASIS-C2, based on: the number of active home health agencies nationally; the time to complete the item set and; the wages of staff involved in implementation. First we estimate the average number of assessments per month per agency. Then we estimate the number of hours required for compliance, both to complete the assessment and conduct any necessary training, per agency and nationally. This is followed by the estimated labor costs, based on national wage data, for completing the assessment and

7 http://www.cms.gov/Regulations-and-Guidance/Guidance/PrivacyActSystemofRecords/downloads/0522.pdf

conducting the training, which factors in the hours estimates. Finally we calculate the per agency cost, both annually and monthly, as well as the average per assessment cost.

Part 1. Estimated Monthly Burden
Average Number of HHA in U.S. = 12,198
Average Number of OASIS-C2 Assessments Submitted All HHAs per Year = 17,900,000
Average Number of OASIS-C2 Assessments Submitted Per Each HHA per Year = 1,467
Average Number of OASIS-C2 Assessments Submitted Per Each HHA per Month = 122

The above figures were calculated as follows:

- 17,900,000 OASIS submissions per all HHAs per year/12,198 HHAs in U.S. = 1,467 OASIS submissions per ALL HHAs per year
- 1,467 OASIS submissions per HHA per year / 12 months per year = 122 OASIS submissions per each HHA per month)

Part II. Estimated Cost/Wage Calculation

A. Time Estimates

Average time spent per each OASIS-C2Assessment/Patient = 52.8 minutes[8]
- 47.8 minutes of clinical time spent to perform the OASIS-C2 assessment
- 5.0 minutes of administrative time to submit data from each OASIS-C2 assessment to CMS

Estimated Annual Hourly Burden per each HHA for OASIS-C2= 1288.32 hours per HHA
- 122 OASIS-C2 assessments per HHA per month x 52.8 min/assessment = 6,441.6 min per HHA per month.
- 6,441.6 min per HHA per month / 60 minutes per hour = 107.36 hours per HHA per month.
- 107.36 hours per HHA/mo. x 12 months per year – 1288.32 hours per each HHA per year.

Estimated Annual Hourly Burden for all HHA for OASIS-C2= 15,714,927 hours
- 1288.32 hours per HHA per year x 12,198 HHAs = 15,714,927 hours for all HHAs per year.

Estimated Annual Hour Burden per ALL HHAs per year for ongoing OASIS-C2Training
- 8 hours of training per each HHA per year x 12,198 HHAs = 97584 training hours.

B. Wage Costs for Completion of OASIS-C2Assessments

Per recent HHS guidelines, labor cost estimates include an assumed overhead rate of 100 percent of pre-tax wages. As such, estimates include multiplying the hourly wages by 2. As no readily available, national data exist, this represents the rough mid-point of varying estimates of overhead costs. This estimate does not include time for training.

8 See explanation, Section 15. Changes to Burden.

Average Time per assessment per HHA = 52.8 minutes

Clinician's time to collect clinical data – paid @ $33.55*2= $67.10 per hour, $67.10/60=$1.12 per minute[9].
Administrative time paid @ $16.36*2 =32.72 per hour, $32.72/60=$0.55 per minute.

- 47.8 minutes of clinicians time =47.8*$1.12=$53.46
- 5.0 minutes of administrative time=5.0*$0.55= $2.73
- Cost per assessment=$56.18

Cost estimates are provided monthly and annualized in the estimates below.

1. Medical Clinician's Time:

Calculation Method #2 (monthly)

- 47.8 minutes of clinical/nursing time x 122 OASIS forms per HHA per month = 5,845 min per HHA monthly.
- 5,845 minutes per each HHA monthly x 12 months per year = 70,144.29 minutes per HHA yearly
- 70,144.29 minutes per HHA yearly / 60 minutes per hour = 1169 hours per HHA yearly
- 1169 hours per HHA yearly x $67.10 per hour = $78,439. 90 nursing wages per HHA yearly
- $78,439.90 x 12,198 HHAs = $956,809,900.20 per *all* HHAs per year

2. Administrative Assistant Time:

Calculation Method #2 (monthly)

- 5 minutes of Admin staff time x 122.3OASIS forms per HHA per year = 611 min per HHA monthly
- 611 minutes per each HHA monthly x 12 months per year = 7,337 minutes per HHA yearly
- 7,337 minutes per HHA yearly / 60 minutes per hour = 122.3hours per HHA yearly
- 122.3 hours per HHA yearly x $32.72 per hour = $4001.66 nursing wages per HHA yearly
- $4001.66 x 12,198 HHAs = $48,812,199.89 per *all* HHAs per year

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

$78,439.90	Clinical/Nursing wages per each HHA per year
$ 4,001.66	Administrative assistant wages per each HHA per year
$82,441.56	Total Annualized Cost to Each HHA Provider

9 Occupations used: 29-1141 Registered Nurses (medical clinician) and 29-2050 Health Practitioner Support Technologists and Technicians (administrative) Source: Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, May 2014, U.S. Government Printing Office, Washington, DC, [2015].

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

$956,809,900.20 Clinical/Nursing wages per all HHA providers per year
$ 48,812,199.89 Administrative assistant wages per all HHAs per year

$1,005,622,100.09 Total Annualized Cost to All HHAs Providers

C. **Training Costs:** Please note, there is no structured training manual. Each agency implements provider training at their own discretion. However, there is an online guidance manual that may answer many questions. The manual can be accessed here: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-6-29-16.pdf

- 2 hours of OASIS-C2 update training per each HHA x 18 staff members = 36 total training hrs. per HHA.
- 36 hours of training per HHA x 12,198 HHAs = 43,9128 hrs. OASIS-C2 update training/year for all HHAs

Clinical Staff Training Wage Estimate

- 13 Clinical staff persons per HHA to attend 2 hour training = 26 hours
- 5 Administrative Staff members attending 2 hour training session = 10 hours
- 26 hours x $67.10 per hour = $1,744.60 for training clinical staff at ***each*** HHA per year
- $1,744.60 x 12,198 HHAs = $21,280,630.80 for training clinical staff in ***all*** HHAs/per year

Administrative Staff Training Wage Estimate

- 10 hours x $32.72 per hour = $327.20 for training clinical staff at *each* HHA per year
- $327.20 x 12,198 HHAs = $3,991,185.60 for training clinical staff in *all* HHAs/per year

Wages for One-Time Training Wages for Each Individual HHA

- $1,744.60 Clinical Staff Training Wages per each HHA
- $ 327.20 Administrative Staff Training Wages per each HHA
- $2,071.80 Total Combined Wages for one-time Staff Training

Wages for One-Time Training Wages for ALL HHAs

- $21,280,630.80 Clinical Staff Training Wages per each HHA
- $ 3,991,185.60 Administrative Staff Training Wages per each HHA
- $25,271,816.40 Total Combined Wages for one-time Staff Training

D. Summary of Estimated Costs

$78,439.90 Nursing wages per each HHA per year

$ 4,001.66	Administrative assistant wages per each HHA per year
$ 2,071.80	Wages for One-time OASIS-C2 Update Staff Training for each HHA
$84,513.36	Estimated Total Annualized Cost to Each HHA Provider

$956,809,900.20	Nursing wages per all HHA providers per year
$ 48,812,199.89	Administrative assistant wages per all HHAs per year
$ 25,271,816.40	Wages for One-time OASIS-C2 Update Staff Training for ALL HHAs
$1,030,893,916.49	Estimated Total Annualized Cost to All HHAs Providers

PART C. Additional Calculations:

Average Yearly Cost to Each HHA

- $1,030,893,916.49– Cost for all HHAs per year /12,198 HHAs in U.S. = $84,513.36

Estimated Average Monthly Cost Across All HHAs

- $1,030,893,916.49– Total annual cost to all HHAs per year / 12 months per year = $85,907,826.37

Estimated Average Monthly Cost to Each Individual HHA

- $1,030,893,916.49– Total annual cost to all HHAs/year /12 months per year /12,198 HHAS = $7,042.78

Estimated Cost per Each OASIS-C2 Assessment

- **$**1,030,893,916.49– Total annual cost to all HHAs/year / 17,900,000 OASIS-C2 assessments per year = $57.59 per each OASIS-C2 assessment

13. Capital Costs

At the time of the initial 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-C2 will require new capital expenditures on the part of home health agencies. The equipment and systems to support the current version of the OASIS (OASIS C1/ICD-10) can easily support the OASIS-C2 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 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 C2 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 C2 data is $1,500,000. These costs are itemized below:

ESTIMATED ANNUAL COSTS TO FEDERAL GOVERNMENT:	
Conduct State OEC Training	$100,000
Update OASIS-C2 Web-Based Training	$150,000
Update OASIS-C2 Q&As	$100,000
Update OASIS-C2 Manuals and Materials	$100,000
Contractor Costs for Receipt and Storage of OASIS-C2 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-C2 data set
The OASIS C2 is scheduled for implementation on January 1, 2017 in order to comply with requirements for the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) IMPACT Act.

Changes pursuant to the Act include:

- three additional standardized items (M1028, M1060, GG0170c);

- modification to and renumbering of select medication and integumentary items to standardize with other post-acute settings of care (M1311, M1313, M2001, M2003, and M2005); and
- changing the numbering for pressure ulcer staging from Roman to Arabic numerals to further standardize cross-setting items.

Modifications not as a result of the IMPACT act include formatting changes throughout the document, and modification to five existing items. Specifically:

- converting multiple check boxes to a single box for entering response values, where responses are mutually-exclusive;
- converting spaces for data entry into boxes; and
- changing the item wording on the lookback period from "previous OASIS assessment" to "most recent SOC/ROC assessment" and item number in five items (M1500, M1510, M2015, M2300 and M2400).

All new items added to the OASIS C2 item set are either used to calculate or risk adjust a standardized, cross-setting quality measure required by the IMPACT Act. As the provisions of the Act include exemption from Paperwork Reduction Act requirements, we have not calculated the additional burden associated with these new items. Other OASIS C2 item changes are formatting and minor wording change to existing items. We do not estimate that these refinements will result in any additional burden beyond the estimates previously submitted for the OASIS-C1/ICD-10 version; therefore, the estimates have not been modified. There has been a slight change in the burden estimate due to an increase in the number of active HHAs (184 new HHAs). The burden hours have increased from 15,320,253 to 15,812,511.

16. Publication/Tabulation Dates

These information collection requirements do not employ sampling techniques or statistical methods. While the patient-level OASIS data are 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 28, 2015 and includes episodes ending between July 2014 and June 2015. 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

CMS will display the PRA disclosure statement and expiration date on the cover page of the item set guidance manual.

18. Certification Statement

There are no exceptions to the certification statement.

Attachment A
Changes Made to OASIS C1/ICD-10 to create OASIS-C2

Attachment B

All Time Points Version of OASIS-C2 (Proposed Data Collection)