Supporting Statement A

Outcome and Assessment Information Set
OASIS-E (CMS-10545)

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-D (0938-1279) data item set was approved by the Office of Management and Budget (OMB) on December 6, 2018 and implemented on January 1, 2019. We are seeking OMB approval for the proposed revised OASIS item set, referred to hereafter as OASIS-E, scheduled for implementation on January 1, 2023. The OASIS E includes changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act); and, to accommodate data element removals to reduce burden; and improve formatting throughout the document.

1. 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 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 elements.

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 elements 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 or death). HHAs can obtain on-demand electronic outcome reports based on their own OASIS data submissions, and comparative 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 makes available measures of patient outcomes to consumers and to the general public through the Home Health Compare website maintained by CMS.

Since 2000, elements of the OASIS data also served as the basis for the Prospective Payment System (PPS) that determined 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 requirements for 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-E 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-E is presented in Section B.1; additional information about OASIS-E data use is presented in Section B.2: Information Users.

2. 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.

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")

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 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-C1 had 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 mandated that CMS may not implement ICD-10 prior to October 1, 2015. As a result, CMS was not 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 was an interim version of the OASIS-C1 data item set that was created in response to the legislatively mandated ICD-10 delay. The 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 in OASIS-C1 that use ICD-10 codes were replaced with the corresponding items from OASIS-C that use ICD-9 codes. In addition, OASIS-C1/ICD-9 fixed some typographical errors and clarified skip patterns relative to OASIS C1.

OASIS-C1/ ICD-10 Version

OASIS-C1/ICD-10 Version replaced the OASIS-C1/ICD-9 version 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, approved on December 6, 2016, was implemented on January 1, 2017 to comply with requirements 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.

OASIS-D Version

The OASIS D, approved on December 6, 2018, was implement on January 1, 2019 to comply with requirements summarized below.

- Changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) included:
    - New standardized items (GG0130, GG0170a-b, d-s, J1800, J1900) to support measurement domains mandated by the Act -Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF # 0674); and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
    - Modification to OASIS item M1311 to support a new standardized pressure ulcer measure that replaced the current standardized pressure ulcer measure. The new measure is Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- New items added to OASIS for standardization to align with the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI), the Long-term Care Hospital (LTCH) Long Term Care Data Set (LCDS), and the Minimum Data Set (MDS).
    - GG0100 Prior Functioning
    - GG0110 Prior Device Use
- Item removals, including the removal of data elements at different time points. This resulted in largely different assessments by time point, reducing burden for HHAs.

OASIS-D1 Version

Per the OASIS Update for CY2020 (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D1-Update-Memorandum_Revised_May-2019.pdf), minor revisions were made to the OASIS for version D1, effective January 1, 2020. Two existing OASIS items were added to the Follow-up assessment time point (M1033 Risk for Hospitalization and M1800 Grooming), and data collection was made optional for 23 existing OASIS items at Start of Care/Resumption of Care (SOC/ROC), Transfer (TRN), Discharge (DC), and Follow-up (FU).

OASIS E Version

The OASIS E is designed to be implemented on January 1, 2023 to comply with additional requirements of the IMPACT Act (per the CY2020 HH final rule), and additional changes noted in the CY2022 HH final rule, and changes intended for the CY2023 HH NPRM

I. Changes per the CY2020 rule

- The addition of standardized assessment data elements to OASIS E to facilitate care coordination and interoperability and improve Medicare beneficiary outcomes across PAC settings.

Standardized items to Assess Cognitive Function

- C0100 Should Brief Interview for Mental Status (C0200-C0500) be Conducted?
- C0200 Repetition of Three Words
- C0300 Temporal Orientation
- C0400 Recall
- C0500 BIMS Summary Score
- C1310. Signs and Symptoms of Delirium (from CAM)
- D0150 Patient Health Questionnaire-2 to 9 (PHQ-2 to 9)
- D0160. Severity Score

Standardized items to Assess for Special Services, Treatments, and Interventions

- O0110 Special Treatment, Procedures, and Programs
- K0520 Nutritional Approaches
- N0415 High-Risk Drug Classes: Use and Indication

Standardized items to Assess Medical Conditions and Co-Morbidities

- J0510 Pain Effect on Sleep
- J0520 Pain Interference with Therapy Activities
- J0520 Pain Interferences with Day-to-Day Activities

Standardized items to Assess Impairments

- B0200 Hearing
- B1000 Vision

Standardized items to Assess Social Determinant of Health, A New Category

- A1005 Ethnicity
- A1010 Race
- A1110 Language
- B1300 Health Literacy
- A1250 Transportation
- D0700 Social Isolation

- The removal of one quality measure Improvement in Pain Interfering with Activity (NQF #0177) and the associated data element M1242 Frequency of Pain Interfering with Patient's Activity or Movement.
- The addition of two quality measures, Transfer of Health Information to Provider-Post-Acute Care and Transfer of Health Information to Patient Post-Acute Care and its associated data elements including:
  - A2121 Provision of Current Reconciled Medication List to Subsequent Provider at Discharge,
  - A2120 Provision of Current Reconciled Medication List to Subsequent Provider at Transfer,
  - A2122 Route of Current Reconciled Medication List Transmission to Subsequent Provider,
  - A2123 Provision of Current Reconciled Medication List to Patient at Discharge, and A2124 Route of Current Reconciled Medication List Transmission to Patient
- Item removals and additions, including the removal and addition of data elements at different time points.
  - M0140 Race/Ethnicity, removed and replaced
  - M1200 Vision, removed and replaced
  - M1730 Depression Screening, removed and replaced
  - M1910 Has the patient had a Multi-factor Falls Risk Assessment using a standardized validated assessment? - complete removal
  - M1030 Therapies the Patient Receives, removed and replaced
  - M1051 Pneumococcal Vaccine, complete removal
  - M1033 Risk of Hospitalization, added to Follow up
  - M1800 Grooming, added to Follow up
  - M1056 Reason Pneumococcal Vaccine Not Received, complete removal
  - M2401 Intervention Synopsis, removal of row a
  - Voluntary in 2020 and Removed in 2021 from Follow up time point:
    - M1610 Urinary Incontinence or Urinary Catheter Presence
    - M1620 Bowel Incontinence Frequency
    - M1630 Ostomy for Bowel Elimination

        - M1021 Primary Diagnosis, ICD-10 CM and Symptom Control
        - M1023 Other Diagnoses, ICD-10 CM and Symptom Control Rating
        - M1400 When is the patient dyspneic or noticeable Short of Breath?
        - M1311 Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage?
        - M1322 Current Number of Stage 1 Pressure Ulcers
        - M1324 Stage of Most Problematic Unhealed Pressure Ulcer/Injury that is Stageable
        - M1332 Current Number of Stasis Ulcer(s) that are Observable
        - M1334 Status of Most Problematic Stasis Ulcer that is Observable
        - M1340 Does the Patient have a Surgical Wound?
        - M1342 Status of Most Problematic Surgical Wound that is Observable
        - M2030 Management of Injectable Medications: Excludes IV Medications
        - M2200 Therapy Need
- Modification to text:
    - M0102 Date of Physician Ordered Start of Care
    - M1000 Inpatient Facilities
    - A2122 Route of Current Reconciled Medication List Transmission to Subsequent Provider
    - A2124 Route of Current Reconciled Medication List Transmission to Patient
    - GG0100 Prior Functioning: Functioning Everyday Activities
    - GG0130 Self Care
    - GG0170 Mobility
    - M1620 Bowel Incontinence Frequency

II. Changes per the CY2022 rule

- The removal of one quality measure Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care (CMS ID 2705-10) and its associated data element M2016 Patient/Caregiver Drug Education Intervention.
- Subsequent to publishing the CMS-10545 OASIS-E 60-day Federal notice we removed eight GG activities items from the Follow-up time point, which resulted in a decrease in the burden hours.

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), CMS is 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 CoPs (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 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 requirements for 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 sub-clause (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, federal law under section 1899B(a)(1) of the Act mandates a revision to the OASIS item set. Specifically, 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 CoPs (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.

Starting in 2015, CMS began a process of evaluating the HH Quality Measures (HH QM) set, this included comprehensive analysis of the entire HH QM set to develop recommendations for retention, removal and replacement. As a result of this effort, CMS removed six publicly reported measures via the final CY17 HH PPS rule, and announced the removal of an additional 28 measures that had not been previously finalized through rulemaking, effective January 1, 2017. In the CY 2018 HH PPS proposed rule (82 FR 35342) we proposed to remove 247 data elements from 35 OASIS items collected at specific time points during a home health episode. Public comment was sought both on the proposed and announced removals and was favorable towards the changes. These data elements were not used in the calculation of quality measures already adopted in the HH QRP, nor were they being used for previously established purposes unrelated to the HH QRP, including payment, survey, the Home Health Value Based Purchasing (HH VBP) Model or care planning. Given the significant development work and advance vendor and provider communication required for each new version, the OASIS is only updated approximately every two years, or earlier to align with major policy changes (such as roll-out of ICD-10). Therefore, changes to the items underlying the measures removed in CY2017, and the item removals were finalized in the CY 2018 HH PPS final rule (82 FR 35342), from the version of the OASIS effective in January 2019, with the release of OASIS-D.

In the CY 2020 HH PPS final rule (84 FR 60478) we finalized, effective January 1, 2021, the addition of 144 data elements and removal of 20 data elements for a net addition of 124 data elements. This included the removal of one quality measure, the adoption of two quality measures, the modification of an existing measure, and the addition of standardized assessment data elements across five assessment categories. The proposed effective date of the OASIS-E that reflected these changes, January 1, 2021, was delayed due to the Coronavirus Disease 19 (COVID-19) Public Health Emergency (PHE). Home health agencies (HHAs) continued using OASIS-D. During this time while the PHE was ongoing, the CY2022 HH PPS final rule (86 FR 62240) finalized, effective January 1, 2022, removal of the Drug Education on All Medications Provided to the Patient/Caregiver During All Episodes of Care (CMS ID 2705-10) and its associated data element M2016 Patient/Caregiver Drug Education Intervention.

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 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.

  On-demand 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 on-demand reports including a)

Outcome Reports; b) Potentially Avoidable Event Reports; c) Agency Patient-Related Characteristics (formerly case mix) Reports; and d) Patient Tally Reports. CMS provides these reports to HHAs for them to use to compare present performance to past performance with national performance norms. These 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 the on-demand 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 the on-demand 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 outcome and process measures derived from OASIS data have been publicly reported on the Home Health Compare website available to consumers on www.Medicare.gov. The website provides information for consumers and their families about the quality of care provided by individual HHAs, allowing them to see how well patients of one agency fare compared to other agencies and to the state and national average. The 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. 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.

- 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.

- HHVBP: CMS has implemented a 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).

- 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 data items that are collected at specified time points throughout the home health episode of care, including start of care, resumption of care following an inpatient stay, at least every 60 days of continuous service or for a significant change in clinical condition, at transfer to an inpatient facility, discharge from home health or death at home. Data are collected of adult patients receiving skilled home health care, ordered and overseen by a physician, in order to create or update the plan of care, or to document the patient's status during an episode of care. The OASIS items are integrated into home health agencies' clinical records, and the modality of data collection is dictated by agencies' choice 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 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 CMS-designated data submission system.

4. Duplication of Efforts

The OASIS data set 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

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).

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 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. CMS also provides training through its OASIS contractors either in-person or virtually.

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 five specific time points during the home health episode:

- admission to home care (SOC)
- resumption of care after an inpatient stay (ROC)
- recertification every 60 days that the patient remains in care (FU),
- death at home (DAH)
- end of care (TOC or DC).

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. Since the average length of stay in Medicare home health care is less than 60 days, most 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 within 30 days of the assessment completion date. This allows OASIS data to be available on a timely basis for a number of key CMS functions, thus avoiding separate (and duplicative) data collection efforts:

- OASIS data can be accessed 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 by state survey and certification staff for use in surveys to assure home health agency compliance with the CoPs.
- OASIS data can be accessed 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 have allowed CMS to generate agency-specific quality reports since January 2001. These reports are available to Medicare-certified HHAs through the internet Quality Improvement and Evaluation System (iQIES). Agencies depend on these reports as a source of information for their patient care quality monitoring and improvement programs.
- As stated in the 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 relies 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 published 02/09/2022 (87 FR 7457).

We received comments from home care providers and organizations Commenters asked about the burden associated with training, completing, and submitting OASIS-E. They mentioned nursing staff shortages and other challenges associated with the COVID-19 Public Health Emergency (PHE), and training required for the national expansion of the Home Health Value-Based Purchasing (HHVBP) Model. Two commenters recommended removal of M0110 Episode Timing and M220 Therapy Need. Commenters recommended removing unnecessary documentation to adjust for the increased number of items in the OASIS-E, adjusting burden estimates and delaying implementation of OASIS-E.

In response, CMS recognizes the competing challenges that HHAs have been facing in recent years. However, we believe at this time home health agencies should be able to carry out their operations to meet regulatory requirements related to OASIS-E data collection, while also addressing any issues related to COVID-19. While it is true the items referenced by the commenters no longer influence payment by CMS, they may be used other payers in their PPS-like payment models. Even though the HHVBP model is being expanded it leverages OASIS

items used by HHAs for many years and are not changing with the implementation of OASIS-E. For more details see the Response to Public Comments document.

CMS estimates burden for the time to complete each data element, and that each OASIS item comprises one or more data elements, depending on the complexity of the item. The CMS estimates for training burden are intended as hours and cost for ongoing OASIS training for new and current clinical staff, not a one-time update only for OASIS-E. This has been corrected in Section 15 of this Supporting Statement. Only clinical, not administrative staff are included in these estimates. Training burden estimates are based on what an HHA may need to provide in addition to all other OASIS training provided by CMS, including national provider training. CMS estimates burden for OASIS submission as the time needed for the submission activity by an administrative staff person. These estimates do not include time the HHA may spend in review of the OASIS assessments.

In summary, CMS has made no changes to OASIS items or burden estimates in response to public comments. Subsequent to publishing the CMS-10545 OASIS-E 60-day Federal notice we removed eight GG activities items from the Follow-up time point, which resulted in a decrease in the burden hours.

Since August 2002, CMS has consulted with various industry associations such as the National Association for Home Care and Hospice and the Visiting Nurses Associations of America to solicit input on proposed changes to the OASIS instrument. Through its contractors, 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. Public comment on the changes to the OASIS-E data set were solicited from providers, state associations, professional associations, and the home health industry and reported in the Federal Register as part of CY 2020 HH PPS final rule.

The 30-day Federal Register notice published May 19, 2022 (87 FR 30498).

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)

Part I. Estimated Time Burden

This OASIS version reflects a net increase of 135 data elements (DE) across all time points (Table 1) from OASIS-D/D1.

Table 1. Number of Data Elements Added and Removed for OASIS-E

Time Point	#DE in OASIS-D (D1)	#DE added for OASIS-E	#DE removed for OASIS-E	Net change (+)	#DE in OASIS-E
SOC	158	59	14	45	203
ROC	131	49	8	41	172
FU	37	0	0	0	37
TOC	22	1	1	0	22
DAH	9	0	0	0	9
DC	97	51	2	49	146
Totals	444	168	25	**135**	588

In our estimations, we assume that data elements require a range of 0.15-0.3 minutes of clinician time to complete (Table 2). To better reflect the differing required number of data elements at each time point, we present itemized burden estimate by time point for this section. This itemization includes the total number of each time point assessment administered by HHAs annually, based on 2020 data (the most recent year for which data are available).

Table 2. Number of Data Elements at Each Level of Burden by Time Points for OASIS-E

Level of Burden	SOC	ROC	FU	TOC	DAH	DC
0.15	21	21	0	0	0	21
0.25	9	9	0	0	0	9
0.3	173	142	37	22	9	116
Total # DE	**203**	**172**	**37**	**22**	**9**	**146**

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or

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

speech language pathologists (SLP/ST). Data from 2020 show that the SOC/ROC OASIS is completed by RNs (approximately 76.50 percent of the time), PTs (approximately 20.78 percent of the time), and other therapists, including OTs and SLP/STs (approximately 2.72 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $79.41, inclusive of fringe benefits, using the hourly wage data in Table 3 below. Individual providers determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates (Bureau of Labor Statistics). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 3.

Table 3. U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates

Occupation title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$38.47	$38.47	$76.94
Physical therapists HHAs	29-1123	$44.08	$44.08	$88.16
Speech-Language Pathologists (SLP)	29-1127	$40.02	$40.02	$80.04
Occupational Therapists (OT)	29-1122	$42.06	$42.06	$84.12
Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other	29-2098	$23.21	$23.21	$46.42

Table 4 shows the total number of assessments submitted in CY 2020; these numbers will be used in the calculations below.

TABLE 4. CY 2020 OASIS SUBMISSIONS BY TIME POINT

Time Point	CY 2020 Assessments Completed
Start of Care	6,393,366
Resumption of Care	930,910
Follow-up	3,652,940
Transfer to an inpatient facility	1,796,827
Death at Home	50,493
Discharge from agency	5,206,230
TOTAL	18,030,766

Part II. Estimated Cost

START OF CARE

Estimated time spent per each OASIS-E SOC Assessment/Patient = 57.3 clinician minutes
203 data elements x 0.15-0.3 minutes per data element = 57.3 minutes of clinical time spent to complete data entry for the OASIS-E SOC assessment.

- 21 DE counted as 0.15 minutes/DE (3.15)
- 9 DE counted as 0.25 minutes/DE (2.25)
- 173 DE counted as 0.30 minutes/DE (51.9)

Clinician

Estimated hourly burden for all HHAs (11,354) for OASIS-E SOC assessments = 6,105,664 hours
57.3 clinician minutes per SOC assessment x6,393,366 assessments =366,339,872 minutes/60 minutes per hour = 6,105,664 hours for all HHAs

Estimated Cost for all HHAs for OASIS-E SOC assessments= $484,850,778.24 for all HHAs
$79.41/hour x6,105,664 hours for all HHAs = $484,850,778.24 for all HHAs

Administrative
Estimated hourly burden for all HHAs for OASIS-E SOC assessments = 532,781 hours
5 administrative minutes per SOC assessment x 6,393,366 assessments= 31,966,830 minutes/60 minutes per hour = 532,780.5 hours

Estimated Cost for all HHAs for OASIS-E SOC assessments =$24,731,670.81
$46.424/hour[8] x 532780.5 hours = $24,731,670.81 for all HHAs

RESUMPTION OF CARE

Estimated time spent per each OASIS-D ROC Assessment/Patient = 48 minutes
172 data elements x 0.15 - 0.3 minutes per data element = 48 minutes of clinical time spent to complete data entry for the OASIS-D ROC assessment

- 21 DE counted as 0.15 minute/DE (3.15)
- 9 DE counted as 0.25 minute/DE (2.25)
- 142 DE counted as 0.30 minute/DE (42.6)

Clinician
Estimated Hourly Burden for all HHAs for OASIS-E ROC assessments =744,728 hours
48clinician minutes per ROC assessment x930,910 ROC assessments =44,683,680 minutes/60 minutes =744,728 hours for all HHAs

Estimated Cost for all HHAs for OASIS-E ROC assessments =$59,138,850.48 for all HHAs
$79.41/hour x 744,728 hours =$59,138,850.48 for all HHAs

Administrative
Estimated hourly burden for all HHAs for OASIS-E ROC assessments = 77,575.83 hours
5 administrative minutes per SOC assessment x 930,910 assessments= 4,654,550 minutes/60 minutes per hour =77,575.83 hours

Estimated Cost for all HHAs for OASIS-E ROC assessments =$3,601,070.03
$46.42/hour x 77,575.83 hours = $3,601,070.03 for all HHAs

FOLLOW UP

Estimated time spent per each OASIS-E FU Assessment/Patient = 11.1 minutes

8 Occupation used for administrative time: 29-2098 Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians: Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, May 2020, U.S. Government Printing Office, Washington, DC, , loaded 100%.

37data elements x 0.15 -0.3 minutes per data element = 11.1 minutes of clinical time spent to complete data entry for the OASIS-D FU assessment.

- 37 DE counted as 0.30 minutes/DE

Clinician

Estimate Hourly Burden for all HHAs for OASIS-E FU assessments = 675,793.9 hours
11.8 clinician minutes for OASIS-E FU assessments x 3,652,940 FU assessments = 40,547,634 minutes/60 minutes = 675,793.9 hours for all HHAs

Estimated Costs for all HHAs for OASIS-E FU assessments = $53,664,793.6 for all HHAs
$79.41/hour x 675,793.9 hours = $53,664,793.6 for all HHAs

Administrative

Estimated hourly burden for all HHAs for OASIS-E FU assessments = 304,411.67 hours
5 administrative minutes per FU assessment x 3,652,940 assessments= 18,264,700.00 minutes/60 minutes per hour = 304,411.67 hours

Estimated Cost for all HHAs for OASIS-E FU assessments = $14,130,789. 72
$46.42/hour x 304,411.67 hours = $14,130,789.72 for all HHAs

TRANSFER OF CARE

Estimated time spent per each OASIS-E TOC Assessment/Patient = 6.6 minutes
22 data elements x 0.15-0.3 minutes per data element = 6.6 minutes of clinical time spent to complete data entry for the OASIS-D TOC assessment

- 22 DE counted as 0.30 minutes/DE

Clinician

Estimated Hourly Burden for all HHAs for OASIS-E TOC assessments = 197,650.97 hours
6.6 clinician minutes x 1,796,827 TOC assessments = 11,859,058.20 minutes/60 minutes = 197,650.97 hours

Estimated costs for all HHAs for all OASIS-E TOC assessments = $15,695,483.53 for all HHAs
$79.41/hour x 197,650.97 hours = $15,695,483.53 for all HHAs

Administrative

Estimated hourly burden for all HHAs for OASIS-E TOC assessments = 149,735.58 hours
5 administrative minutes per TOC assessment x 1,796,827 assessments = 8,984,135.00 minutes/60 minutes per hour = 149,735.58 hours

Estimated Cost for all HHAs for OASIS-E FU assessments = $6,950,725.62
$46.42/hour x 149,735.58 hours = $6,950,725.62 for all HHAs

DEATH AT HOME

Estimated time spent per each OASIS-E DAH Assessment/Patient = 2.7 minutes
9 data elements x 0.15-0 .3 minutes per data element = 2.7 minutes of clinical time spent to complete data entry for the OASIS-E DAH assessment.

- 9 DE counted as 0.30 minutes/DE

Clinician
Estimated Hourly Burden for all HHAs for OASIS-E DAH assessments = 2,272.19 hours
2.7 clinician minutes x 50,493 DAH assessments = 136,331.10 minutes/60 minutes = 2,272.19 hours

Estimated Costs for all HHAs for OASIS-E DAH assessments = $180,4344.61 for all HHAs
$79.41 x 2,272.19 hours = $180,434.61for all HHAs

Administrative
Estimated hourly burden for all HHAs for OASIS-E DAH assessments = 4,207.75 hours
5 administrative minutes per DAH assessment x 50,493 assessments = 252,465.00 minutes/60 minutes per hour = 4,207.75 hours

Estimated Cost for all HHAs for OASIS-E DAH assessments = $195,323.76
$46.42/hour x 4,207.75 hours = $195,323.76 for all HHAs

DISCHARGE

Estimated time spent per each OASIS-E DC Assessment/Patient = 40.2 minutes
146 data elements x 0.15-0.3 minutes per data element = 40.2 minutes of clinical time spent to complete data entry for the OASIS-E DC assessment.

- 21 DE counted as 0.15 minutes/DE
- 9 DE counted as 0.25 minutes/DE
- 116 DE counted as 0.30 minutes/DE

Clinician
Estimated Hourly Burden for all HHAs for OASIS-E DC assessments = 3,488,174.1 hours
40.2 clinician minutes x 5,206,230 DC assessments = 209,290,446 minutes/60 minutes = 3,488,174.1 hours

Estimated costs for all HHAs for OASIS-E DC assessments = $276,995,905.28 for all HHAs
$79.41/hour x 3,488,174.1 hours = $276,995,905.28 for all HHAs

Administrative
Estimated hourly burden for all HHAs for OASIS-E DC assessments = 433,852.50 hours

5 administrative minutes per DC assessment x 5,206,230 assessments = 26,031,150.00 minutes/60 minutes per hour = 433,852.50 hours

Estimated Cost for all HHAs for OASIS-E DC assessments = $20,139,433.05
$46.42/hour x 433,852.50 hours = $20,139,433.05 for all HHAs

Table 5. Summary of Clinician Hourly Burden and Costs

Assessment	**Clinician Estimated Hourly Burden**	**Clinician Estimated Cost**
SOC	6,105,664	$484,850,778.24
ROC	744,728	$59,138,850.48
FU	675,793.9	$53,664,793.6
TOC	197,650.97	$15,695,483.53
DAH	2,272.19	$180,434.61
DC	3,488,174.10	$276,995,905.28
TOTAL	11,214,283.16	$890,526,245.74

Table 6. Proposed Change in Clinician Burden Costs*

OASIS-E	OASIS-D	DIFFERENCE
$890,526,245.74	$559,827,580.49	$ 330,698,665.25 ($ 29,126.18 per HHA)

Table 7. Summary of Administrative Hourly Burden and Cost

Assessment	Administrative Estimated Hourly Burden	Administrative Estimated Cost
SOC	532,781	$24,731,670.81
ROC	77,575.83	$ 3,601,070.03
FU	304,411.67	$14,130,789.72
TOC	149,735.58	$6,950,725.62
DAH	4,207.75	$195,323.76
DC	433,852.50	$20,139,433.05
TOTAL	1,502,564.33	$69,749,012.99

Clinician Training Costs for ongoing OASIS training:

13 Clinical staff persons per HHA to attend 2-hour training = 26 hours
26 hours x 11,354 HHAs = 295,204 training hours for all HHAs
295,204 training hours for all HHAs x $ 79.41/hour = $23,442,149.64 for all HHAs

Table 8. Summary of Total Burden-Clinician, Administrative, and Training

Category	Estimated Hourly Burden	Estimated Cost
Clinician Burden	11,214,283.16	$890,526,245.74
Administrative Burden	1,502,564.33	$69,749,012.99
Clinician Training	295,204	$23,442,149.64
TOTAL	13,012,051.49	$983,717,408.37

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. 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 patient-driven groupings model. 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-E 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 D) can easily support the OASIS-E as well. Software will require updating and CMS will provide 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. 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 with 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 E 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 E data is $1,500,000. These costs are itemized below:

ESTIMATED ANNUAL COSTS TO FEDERAL GOVERNMENT:	
Update OASIS-E Manuals and Materials	$300,000
Contractor Costs for Receipt and Storage of OASIS-D Data	$550,000
Costs for Upkeep & Maintenance of Software by CMS/DNS	$500,000
TOTAL COST TO FEDERAL GOVERNMENT:	**$1,350,000**

15. Changes to Burden

Summary of Changes to the OASIS-E data set

The OASIS E is scheduled for implementation on January 1, 2023 to comply with requirements for the IMPACT Act. Changes pursuant to the IMPACT Act include:

- The addition of standardized assessment data elements to OASIS E to facilitate care coordination and interoperability, and improve Medicare beneficiary outcomes across PAC settings.

Standardized items to Assess Cognitive Function

- C0100 Should Brief Interview for Mental Status (C0200-C0500) be Conducted?
- C0200 Repetition of Three Words
- C0300 Temporal Orientation
- C0400 Recall
- C0500 BIMS Summary Score
- C1310. Signs and Symptoms of Delirium (from CAM)
- D0150 Patient Health Questionnaire-2 to 9 (PHQ-2 to 9)
- D0160. Severity Score

Standardized items to Assess for Special Services, Treatments, and Interventions

- O0110 Special Treatment, Procedures, and Programs
- K0520 Nutritional Approaches
- N0415 High-Risk Drug Classes: Use and Indication

Standardized items to Assess Medical Conditions and Co-Morbidities

- J0510 Pain Effect on Sleep
- J0520 Pain Interference with Therapy Activities
- J0520 Pain Interferences with Day-to-Day Activities

Standardized items to Assess Impairments

- B0200 Hearing
- B1000 Vision

Standardized items to Assess Social Determinant of Health, A New Category

- A1005 Ethnicity
- A1010 Race
- A1110 Language
- B1300 Health Literacy
- A1250 Transportation
- D0700 Social Isolation

The removal of one quality measure Improvement in Pain Interfering with Activity (NQF #0177) and the associated data element M1242 Frequency of Pain Interfering with Patient's Activity or Movement.

The addition of two quality measures, Transfer of Health Information to Provider-Post-Acute Care and Transfer of Health Information to Patient Post-Acute Care and its associated data elements including:

- A2121 Provision of Current Reconciled Medication List to Subsequent Provider at Discharge,
- A2120 Provision of Current Reconciled Medication List to Subsequent Provider at Transfer,
- A2122 Route of Current Reconciled Medication List Transmission to Subsequent Provider,
- A2123 Provision of Current Reconciled Medication List to Patient at Discharge, and A2124 Route of Current Reconciled Medication List Transmission to Patient

- Item removals and additions, including the removal and addition of data elements at different time points.
  - M0140 Race/Ethnicity, removed and replaced
  - M1200 Vision, removed and replaced
  - M1730 Depression Screening, removed and replaced
  - M1910 Has the patient had a Multi-factor Falls Risk Assessment using a standardized validated assessment? - complete removal
  - M1030 Therapies the Patient Receives, removed and replaced
  - M1051 Pneumococcal Vaccine, complete removal
  - M1033 Risk of Hospitalization, added to Follow up
  - M1800 Grooming, added to Follow up
  - M1056 Reason Pneumococcal Vaccine Not Received, complete removal
  - M2401 Intervention Synopsis, removal of row a
  - Voluntary in 2020 and Removed in 2021 from Follow up time point:

- M1610 Urinary Incontinence or Urinary Catheter Presence
- M1620 Bowel Incontinence Frequency
- M1630 Ostomy for Bowel Elimination
- M1021 Primary Diagnosis, ICD-10 CM and Symptom Control
- M1023 Other Diagnoses, ICD-10 CM and Symptom Control Rating
- M1400 When is the patient dyspneic or noticeable Short of Breath?
- M1311 Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage?
- M1322 Current Number of Stage 1 Pressure Ulcers
- M1324 Stage of Most Problematic Unhealed Pressure Ulcer/Injury that is Stageable
- M1332 Current Number of Stasis Ulcer(s) that are Observable
- M1334 Status of Most Problematic Stasis Ulcer that is Observable
- M1340 Does the Patient have a Surgical Wound?
- M1342 Status of Most Problematic Surgical Wound that is Observable
- M2030 Management of Injectable Medications: Excludes IV Medications
- M2200 Therapy Need

- Modification to text:
  - M0102 Date of Physician Ordered Start of Care
  - M1000 Inpatient Facilities
  - A2122 Route of Current Reconciled Medication List Transmission to Subsequent Provider
  - A2124 Route of Current Reconciled Medication List Transmission to Patient
  - GG0100 Prior Functioning: Functioning Everyday Activities
  - GG0130 Self Care
  - GG0170 Mobility
  - M1620 Bowel Incontinence Frequency

III. Changes per the CY2022 rule

- The removal of one quality measure Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care (CMS ID 2705-10) and its associated data element M2016 Patient/Caregiver Drug Education Intervention.

IV.

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V. Change in Burden from OASIS-D to OASIS-E

The total burden hours have increased from 9,984,576 to 13,012,051.49 for a net change (increase) of 3,027,475.49 hours.

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 quality measures based on OASIS data 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 23, 2020 and includes episodes between October 2018 and September 2019. Additional details about the measures are available on the CMS Home Health Quality Initiative web site: Centers for Medicare & Medicaid Services

17. Expiration Date

CMS intends to publish the expiration date within the OASIS-E Guidance Manual and on the OASIS assessments, as well as on its website: Centers for Medicare & Medicaid Services.

18. Certification Statement

There are no exceptions to the certification statement.

Attachment A
Changes Made to OASIS-D to create OASIS-E

Attachment B

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

Attachment C

Itemized table of time points and assessment items of OASIS-E (Proposed Data Collection)