

# Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) Clearance Package

## Supporting Statement – Part A

### Outcome and Assessment Information Set OASIS-E2 (CMS-10545)

#### **A. Background**

This request is for the Office of Management and Budget (OMB) approval to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect to participate in the Medicare program. The current OASIS version, OASIS-E1, OMB control number 0938-1279, was approved by the OMB on December 11, 2024, and implemented on January 1, 2025. We are seeking OMB approval for the proposed revised OASIS data set, referred to hereafter as OASIS-E2, scheduled for implementation in the HH QRP on April 1, 2026. The changes in OASIS-E2 include the removal of the A1250 Transportation item, which will be replaced by the revised A1255 Transportation item (1 data element [DE]) to align with a similar item used in other CMS programs. The item O0350 Patient's COVID-19 vaccination is up to date (1 DE) will be removed to align with removal of the associated quality measure. Subregulatory changes include adding the B1000 Hearing, B0200 Vision, and A1110 Language items to the resumption of care (ROC) timepoint. The item A0810 Sex will replace the M0069 Gender item (no change in DE).

#### ***1. Collection and Use of OASIS Data***

Effective July 19, 1999, the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS), now CMS, mandated that HHAs use the OASIS data set when evaluating adult patients receiving skilled services, excluding those patients under age 18, patients receiving pre- & post-partum maternity services, and patients receiving only chore and housekeeping services.<sup>1</sup> In the [Calendar Year \(CY\) 2023 Home Health Prospective Payment System \(HH PPS\) final rule](https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/oasis/downloads/june18restart.pdf), refinement of the language describes patient exemptions for OASIS data collection as: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.<sup>2</sup>

OASIS is a standardized set of assessment items agencies incorporate into their own patient-specific comprehensive assessment. The comprehensive assessment required by the HH Conditions of Participation (COPs) must include the current version of the OASIS data elements using the language and groupings of the OASIS instrument, as specified by the Secretary.<sup>3</sup>

<sup>1</sup>Health Care Financing Administration (HCFA). (1999, June 18). Medicare and Medicaid Programs; Mandatory Use, Collection, Encoding, and Transmission of Outcome and Assessment Information Set (OASIS) for Home Health Agencies [HCFA-3020-N]. *Federal Register*, 64(117). <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/oasis/downloads/june18restart.pdf>.

<sup>2</sup>Center for Medicare and Medicaid Services (CMS). (2022, November 4). Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements [CMS-1766-F], 42 CFR Part 484. *Federal Register*, 87(213). <https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-23722.pdf>.

<sup>3</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR

Part 484.55 Comprehensive assessment of patients. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>.

HHAs are required to collect the OASIS at specific time points: start of care, resumption of care after a qualifying inpatient stay, follow-up (including recertification every 60 days that the patient remains in care of the HHA), transfer to an inpatient facility, and discharge from agency not to an inpatient facility (including death at home).<sup>4</sup> To clarify, home health episodes begin with either a start of care or a resumption of care, corresponding to admission in other PAC settings.

CMS sees 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, service delivery, and improvement efforts.”*<sup>5</sup>

HHAs can obtain on-demand electronic quality measure reports based on their own OASIS data submissions and compare their agency's quality measure results to national aggregate measure results. Individual HHAs have on-line access to case mix reports, potentially avoidable event reports, outcome reports, process measure reports, review and correct reports, and provider preview reports based on their own reported OASIS data. CMS makes available measures of patient quality to consumers and to the general public through the [Care Compare](#) website (previously Home Health Compare) and the [Provider Data Catalog](#) maintained by CMS.

Since 2000, elements of the OASIS data set also serve as the basis for the Prospective Payment System (PPS) that determines home health reimbursement for Medicare patients. Using some of the same data elements for both quality measurement 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.<sup>6,7</sup> CMS also uses OASIS data to address Pay for Reporting requirements, as mandated in the Deficit Reduction Act of 2005, which dictate:

*“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.”*<sup>8</sup>

Section 2(a) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of

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<sup>4</sup>HCFA. (1999, January 25). Medicare and Medicaid Program: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies [HCFA-3007-F], 42 CFR Part 484. *Federal Register*, 64(15), pp.3764-3784. <https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1449.pdf>

<sup>5</sup>HCFA. (1999, January 25). Medicare and Medicaid Program: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies [HCFA-3007-F], 42 CFR Part 484. *Federal Register*, 64(15), pp.3764-3784. <https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1449.pdf>

<sup>6</sup>105<sup>th</sup> Congress of the U.S.A. (1997, July 30). Balanced Budget Act of 1997, Public Law 105-217, 42 USC, H.R. 2015. <https://www.govinfo.gov/content/pkg/CRPT-105hrpt217/pdf/CRPT-105hrpt217.pdf>

<sup>7</sup>CMS. (2005, December 23). Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies [CMS-3006-F], 42 CFR Part 484. *Federal Register*, 70(246). <https://www.govinfo.gov/content/pkg/FR-2005-12-23/pdf/05-24389.pdf>

<sup>8</sup>109<sup>th</sup> Congress of the U.S.A. (2006, February 8). Deficit Reduction Act of 2005, Public Law 109-171, 42 USC. <https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf>

2014<sup>9</sup> amended Title XVIII of the Social Security Act (the Act)<sup>10</sup>, in part, by adding a new section 1899B, requiring the submission of standardized post-acute care (PAC) assessment data for quality, payment, and discharge planning by Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs).<sup>11</sup>

## ***2. Resumption of All-Payer OASIS Data Collection***

The CY 2023 HH PPS final rule ended the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients and established the requirement for HHAs to submit all-payer OASIS data for purposes of the HH QRP. The policy does not change the current OASIS data collection patient exemptions, i.e., patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.<sup>12</sup>

## ***3. Prior OASIS Refinement Efforts***

Given the significant development work and advanced vendor and provider communication required for each updated version, the OASIS is only updated approximately every two years, or earlier to align with major policy changes.

### **OASIS-B**

Following the initial implementation of OASIS in 1999, CMS introduced the first major revision in 2002 with the “reduced-burden” OASIS (OASIS-B).<sup>13</sup> CMS developed the reduced burden OASIS in response to recommendations from the HHS Secretary’s Regulatory Reform Advisory Committee,<sup>14</sup> as part of a larger HHS initiative to streamline unnecessarily burdensome or inefficient regulations that interfere with the quality of health care. The Advisory Committee studied OASIS and recommended deleting items and time point assessments not used for payment, quality measurement, or survey purposes to ease paperwork burden on HHAs and their clinicians. This resulted in a burden reduction of 28 percent, and CMS implemented the revised OASIS in December 2002.

### **OASIS-B1**

Data collection using the next version of OASIS began January 1, 2008. In OASIS-B1, OASIS item wording was modified to reduce complexity, and items were added to address clinical

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<sup>9</sup>113<sup>th</sup> Congress of the U.S.A. (2014, October 6). Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, Public Law 113-185, H.R. 4994. <https://www.govinfo.gov/content/pkg/BILLS-113hr4994enr/pdf/BILLS-113hr4994enr.pdf>

<sup>10</sup>CMS. (1965). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, 42 U.S.C. [https://www.ssa.gov/OP\\_Home/ssact/title18/1800.htm](https://www.ssa.gov/OP_Home/ssact/title18/1800.htm)

<sup>11</sup> CMS. (2014). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, Section 1899B. Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning, 42 U.S.C. 1395lll. [https://www.ssa.gov/OP\\_Home/ssact/title18/1899B.htm](https://www.ssa.gov/OP_Home/ssact/title18/1899B.htm)

<sup>12</sup>CMS. (2022, November 4). Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements [CMS–1766–F], 42 CFR Part 484. *Federal Register*, 87(213). <https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-23722.pdf>.

<sup>13</sup> The Office of Management and Budget (OMB). (1980, amended 2002). Paperwork Reduction Act, Public Law 96-511, 94 Stat. 2812. [https://sourcebook.acus.gov/wiki/Paperwork\\_Reduction\\_Act/view\\_](https://sourcebook.acus.gov/wiki/Paperwork_Reduction_Act/view_)

<sup>14</sup>OMB. (2014, November 7). Revised Supporting Statement A OASIS-C1 ICD-9 11\_7\_14, OASIS Collection Requirements as Part of the COPs for HHAs and Supporting Regulations [OMB: 0938-0760]. <https://omb.report/icr/201502-0938-004/doc/53526001>

domains not currently covered by deemed essential for patient assessment. Additionally, OASIS process items to support evidenced-based practices were added, and items not required for payment, quality, or risk adjustment were eliminated.<sup>15</sup>

## OASIS-C

CMS continued soliciting input on potential refinements and enhancements to OASIS from HHAs, industry associations, consumer representatives, researchers, and other stakeholders. CMS developed and tested OASIS-C in 2008. OASIS-C increased clarity in measurement, replaced needed items that had been eliminated, and integrated process items into the OASIS, allowing for calculation of process quality measures in addition to outcome measures. 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. Data collection using OASIS-C began on January 1, 2010.<sup>16</sup>

## OASIS-C1/ICD-9-CM and OASIS-C1/ICD-10-CM

The OASIS-C1, initially planned for implementation on October 1, 2014, revised diagnosis items for coding using ICD-10-CM.<sup>17</sup> This version also addressed issues raised by stakeholders to update clinical concepts and modify item wording and response categories for clarification. Additionally, items were revised to harmonize them with data items collected in other settings, such as nursing homes and rehabilitation facilities. Burden was reduced with removal of items no longer used for payment, quality, or risk adjustment.

Enactment of the Protecting Access to Medicare Act (PAMA) of 2014<sup>18</sup> delayed the planned October 1, 2014, implementation date for OASIS-C1 since PAMA required that CMS not implement ICD-10 prior to October 1, 2015. An interim version, OASIS-C1/ICD-9-CM, was implemented October 1, 2014. The 2014 version included all revisions planned for OASIS-C1, except for the diagnosis items that used ICD-9-CM coding, which were retained. The OASIS-C1/ICD-10-CM instrument, effective October 1, 2015, replaced the diagnosis items with those that used ICD-10 coding to align with the system-wide transition to ICD-10-CM.<sup>19</sup>

## OASIS-C2

The OASIS-C2, approved on December 6, 2016, was implemented on January 1, 2017, to comply with requirements pursuant to the IMPACT Act of 2014 for standardized data collection, by adding new cross-setting standardized items in required domains and revising other items to align across the PAC settings. Testing (2016-2017) included inter-rater reliability of paired

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<sup>15</sup>CMS. (2007, August 29). Medicare Program; Home Health Prospective Payment System Refinement and Rate Update for Calendar Year 2008 [CMS-1541-FC], 42 CFR Part 484. *Federal Register*, 72(167). <https://www.govinfo.gov/content/pkg/FR-2007-08-29/pdf/07-4184.pdf>

<sup>16</sup>CMS. (2009, November 10). Medicare Program; Home Health Prospective Payment System; Rate Update for Calendar Year 2010 [CMS-1560-F], 42 CFR Part 484. *Federal Register*, 74(216). <https://www.govinfo.gov/content/pkg/FR-2009-11-10/pdf/E9-26503.pdf>

<sup>17</sup>CMS. (2013, December 2). Medicare and Medicaid Programs; Home Health Prospective Payment System Rate Update for CY 2014, Home Health Quality Reporting Requirements, and Cost Allocation of Home Health Survey Expenses [CMS-1450-F], 42 CFR Part 431. *Federal Register*, 78(231). <https://www.govinfo.gov/content/pkg/FR-2013-12-02/pdf/2013-28457.pdf>

<sup>18</sup>113<sup>th</sup> Congress of the U.S.A. (2014, April 1). Protecting Access to Medicare Act (PAMA) of 2014, Public Law 113-93, H.R. 4302. <https://www.govinfo.gov/content/pkg/PLAW-113publ93/pdf/PLAW-113publ93.pdf>

<sup>19</sup>CMS. (2014, November 6). Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies [CMS-1611-F], 42 CFR Part 484. *Federal Register*, 79(215). <https://www.govinfo.gov/content/pkg/FR-2014-11-06/pdf/2014-26057.pdf>

assessments, medical record review, and clinician focus groups to evaluate validity, reliability, burden, feasibility, and usability.

### OASIS-D

In the CY 2018 HH PPS proposed rule, CMS proposed that OASIS items, or data elements within OASIS items, which do not meet specific criteria would no longer be collected beginning January 1, 2019. The criteria included use in the calculation of quality measures already adopted in the HH QRP, or use for previously established purposes, including payment, survey, the Home Health Value Based Purchasing (HHVBP) Model or fulfilling a data category as part of the COPs. Following the consideration of public comment, and to align with measure removals in CY 2017, CMS finalized changes to 33 OASIS items for the OASIS-D version that resulted in the collection of 235 fewer data elements at specific time points within a home health episode.<sup>20</sup>

The OASIS-D, approved on December 6, 2018, was implemented on January 1, 2019 to further comply with the IMPACT Act mandate to collect standardized data, by addition of new cross-setting standardized items in required domains, some of which supported standardized quality measurement, i.e., Application of Percent of Residents Experiencing One or More Falls with Major Injury (CBE 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 (CBE 2631).<sup>21</sup>

An additional change introduced in OASIS-D was the modification to OASIS item M1311 to support the new standardized cross-setting pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, that replaced the previous standardized cross-setting pressure ulcer measure, Percent of Residents or Patients With Pressure Ulcers that are New or Worsened.

### OASIS-D1

Per the OASIS Update for CY 2020, minor revisions were made to the OASIS for version D1, effective January 1, 2020.<sup>22</sup> Two existing OASIS items, M1033 Risk for Hospitalization and M1800 Grooming, were added to the follow-up assessment time point for use in the Patient-Driven Groupings Model (PDGM), a case-mix classification and payment model. In OASIS-D1, data collection was made optional for 23 existing OASIS items at Start of Care/Resumption of Care (SOC/ROC), Follow-up (FU), Transfer (TOC, and Discharge (DC).

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<sup>20</sup> CMS. (2017, November 7). Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements [CMS-1672-F], 42 CFR Part 484. *Federal Register*, 82(214). <https://www.govinfo.gov/content/pkg/FR-2017-11-07/pdf/2017-23935.pdf>

<sup>21</sup> CMS. (2018, November 13). Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations [CMS-1689-FC], 42 CFR Part 484. *Federal Register*, 83(219). <https://www.govinfo.gov/content/pkg/FR-2018-11-13/pdf/2018-24145.pdf>

<sup>22</sup> CMS. (2019, May 14). OASIS-D1: OASIS Update for CY 2020. [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D1-Update-Memorandum\\_Revised\\_May-2019.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D1-Update-Memorandum_Revised_May-2019.pdf)

## OASIS-E

The OASIS-E was implemented January 1, 2023, following a 2-year delay due to the Coronavirus Disease 19 (COVID-19) Public Health Emergency (PHE). Revisions in the OASIS- E version complied with additional requirements of the IMPACT Act, as provided in the CY 2020 HH PPS final rule and additional changes noted in the CY 2022 and CY 2023 HH PPS final rules.

The CY 2020 HH PPS final rule (84 FR 60478) added cross-setting standardized data elements to OASIS to facilitate care coordination and interoperability, and improve Medicare beneficiary outcomes across PAC settings. In the CY 2020 HH PPS final rule, CMS 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 reflected 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.<sup>23</sup> Due to the COVID-19 PHE, the proposed effective date of OASIS-E reflecting these changes, January 1, 2021, was delayed and home health agencies (HHAs) continued using OASIS-D1.

During the PHE, the CY 2022 HH PPS final rule (86 FR 62240) finalized, effective January 1, 2022, updates to the HH QRP including removal of the Drug Education on All Medications Provided to the Patient/Caregiver During All Episodes of Care (CBE ID 0520) measure and its associated data element M2016 Patient/Caregiver Drug Education Intervention. The CY 2022 HH PPS final rule also permitted an occupational therapist to conduct a home health initial assessment visit and complete a SOC comprehensive assessment under the Medicare program when specific criteria are met.<sup>24</sup>

In the CY 2023 HH PPS final rule (87 FR 66790), CMS finalized the codification of measure removal factors, and ended the suspension of the OASIS data collection from non-Medicare/non-Medicaid patients.<sup>25</sup>

## OASIS-E1

The OASIS-E1 was implemented on January 1, 2025. The OASIS-E1 includes changes related to addition of one item supporting an assessment-based quality measure (QM), removal of one item due to retirement of a QM, and removal of two data elements no longer used in the HH QRP or for other purposes in CMS programs.

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<sup>23</sup>CMS. (2019, November 8). Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements [CMS–1711–FC], 42 CFR Part 484. *Federal Register*, 84(217). <https://www.govinfo.gov/content/pkg/FR-2019-11-08/pdf/2019-24026.pdf>

<sup>24</sup>CMS. (2021, November 9). Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities [CMS–1747–F and CMS–5531–F], 42 CFR Part 484. *Federal Register*, 86(214). <https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf>

<sup>25</sup>CMS. (2022, November 4). Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements [CMS–1766–F], 42 CFR Part 484. *Federal Register*, 87(213). <https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-23722.pdf>.



## **B. Justification**

### **1. Need and Legal Basis**

Conditions that an HHA must meet to participate in the Medicare program are established in Sections 1861(o) and 1891 of the Social Security Act (the Act). These requirements and the regulations at Conditions of Participation (COPs) 42 CFR Part 484.1 Basis and scope are considered necessary to ensure the health and safety of patients.<sup>26</sup>

Section 1861(o) of the Act describes an HHA for the purposes of participation in the Medicare program.<sup>27</sup> Section 1891(a) establishes specific requirements for HHAs participating in the Medicare program in several areas, including patient rights, home health aide training and competency, and compliance with applicable federal, state, and local laws. Section 1891(b) requires the Secretary to assure that the COPs for Home Health Agencies and their requirements adequately protect the health and safety of individuals under the care of a home health agency, and Section 1891(c) 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.<sup>28</sup>

In accordance with Section 1891(d) of the Act, CMS is required to monitor the quality of home health care with a “standardized, reproducible assessment instrument.” CMS identified OASIS as the instrument to improve the quality of care and to comply with the law. The incorporation of the current version of OASIS items into the comprehensive assessment using the language and groupings of the OASIS items is a requirement, as specified by the Secretary. The OASIS items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.<sup>29</sup>

Section 1895(a) of the Act was created by Section 4603 of the Balanced Budget Act (BBA) of 1997 and required the development of a home health prospective payment system (PPS). The PPS for home health services was launched October 1, 2000. Section 1895(b)(4)(C) requires the Secretary to establish appropriate case-mix adjustment factors for home health services in a

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<sup>26</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.1 Basis and scope. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

<sup>27</sup>CMS. (1965). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, Section 1861 Definitions of Services, Institutions, Etc., 42 U.S.C. 1395x (b)(o). [https://www.ssa.gov/OP\\_Home/ssact/title18/1861.htm](https://www.ssa.gov/OP_Home/ssact/title18/1861.htm)

<sup>28</sup>CMS. (1965). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, Section 1891 Conditions of Participation for Home Health Agencies; Home Health Quality, 42 U.S.C. 1395bbb. [https://www.ssa.gov/OP\\_Home/ssact/title18/1891.htm](https://www.ssa.gov/OP_Home/ssact/title18/1891.htm)

<sup>29</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.55 Comprehensive assessment of patients. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>.



manner that explains a significant amount of the variation in cost among different units of services.<sup>30</sup>

Section 4601(d) of the BBA of 1997 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) 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.<sup>31</sup>

Regulations implementing these requirements are codified in the Medicare Program Prospective Payment System for Home Health Agencies final rule (42 CFR 484 Subpart E).<sup>32</sup> CMS anticipates eventually linking beneficiary information across provider settings with other administrative data (for example, payment and utilization data). Beneficiaries may have complex service delivery histories, moving among numerous services and benefits. The collection of OASIS data facilitates efforts by CMS to support tracking outcomes and conducting administrative tasks involved with integrating the care of individuals.

Section 704 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 temporarily suspended OASIS data collection for non-Medicare and non-Medicaid patients until the outcome of an OASIS study was presented to Congress.<sup>33,34</sup> The Secretary conducted the required study from 2004 to 2005 and submitted it to Congress in December 2006.<sup>35</sup>

The IMPACT Act of 2014 amended Title XVIII of the Act by adding Section 1899B(a)(1) which mandated a revision to the OASIS item set. Specifically, all covered providers must submit data reporting for the following domains across settings for the purpose of cross-setting measures:

- Patient assessment data standardized across PAC settings in accordance with subsection (b).
- Data on quality measures, including functional status, cognitive function, skin integrity, incidence of falls, medication reconciliation, and care coordination, under subsection (c)(1); and

<sup>30</sup>CMS. (1997). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, Section 1895 Prospective Payment for Home Health Services, 42 U.S.C. 1395fff. [https://www.ssa.gov/OP\\_Home/ssact/title18/1895.htm#:~:text=1895,the%20Secretary%20under%20this%20section](https://www.ssa.gov/OP_Home/ssact/title18/1895.htm#:~:text=1895,the%20Secretary%20under%20this%20section).

<sup>31</sup>105<sup>th</sup> Congress of the U.S.A. (1997, July 30). Balanced Budget Act of 1997, Public Law 105-217, 42 USC, H.R. 2015. <https://www.govinfo.gov/content/pkg/CRPT-105hrpt217/pdf/CRPT-105hrpt217.pdf>

<sup>32</sup>HCFA. (2000, July 3). Medicare Program; Prospective Payment System for Home Health Agencies [HCFA-1059-F], 42 CFR Part 484 Comprehensive assessment of patients. *Federal Register*, 65(128). <https://www.govinfo.gov/content/pkg/FR-2000-07-03/pdf/00-16432.pdf>

<sup>33</sup>108<sup>th</sup> Congress of the U.S.A. (2003, December 8). Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, 42 USC, 117 Stat. 2066. <https://www.govinfo.gov/content/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf>

<sup>34</sup>CMS. (2022, November 4). Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements [CMS-1766-F], 42 CFR Part 484. *Federal Register*, 87(213). <https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-23722.pdf>.

<sup>35</sup>CMS. (2006). The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients – Report to Congress. <https://www.cms.gov/files/document/cms-oasis-study-all-payer->

[data- submission-2006.pdf](#)

- Data on resource use and other measures, e.g., discharge to community, and preventable hospital readmission rates, under subsection (d)(1).<sup>36</sup>

Further, Section 1899B(1)(B) 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 the assessment instrument,
- Comparison of quality and data across PAC settings, and
- Improved discharge planning, exchangeability of data, and coordinated care between settings.

In 2015, to align with Section 1899B of the Act, CMS undertook a comprehensive reevaluation of all 81 Home Health Quality Measures (HH QM), some of which were used only in the Home Health Quality Initiative (HHQI) and others that were also used in the HH QRP. The review of all the measures was performed in accordance with the guidelines from the CMS Measure Management System (MMS). The goal was to streamline the measure set, consistent with CMS MMS guidance and in response to stakeholder feedback. This effort included the development of recommendations for measure retention, removal, and replacement. As a result, effective January 1, 2017, CMS removed six publicly reported process measures and announced the removal of an additional 28 measures that had not been previously finalized through rulemaking.<sup>37</sup>

CMS continues to evaluate the need for and use of home health quality measures and the associated OASIS data elements. Changes are proposed and finalized through the annual CMS rule-making process.

## **2. Information Users**

### **HHAs:**

- OASIS data are collected as part of the comprehensive assessment required by the Medicare COPs.<sup>38</sup> The comprehensive assessment must include the exact use of the current version of the OASIS items in the data set. However, OASIS is not intended to represent a comprehensive assessment but to be part of an HHA's comprehensive assessment. 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, but the item content, skip patterns, and OASIS number must remain the same. Individual

<sup>36</sup> CMS. (2014). The Social Security Act, Title XVIII-Health Insurance for the Aged and Disabled, Section 1899B. Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning, 42 U.S.C. 1395lll. [https://www.ssa.gov/OP\\_Home/ssact/title18/1899B.htm](https://www.ssa.gov/OP_Home/ssact/title18/1899B.htm)

<sup>37</sup> CMS. (2016, November 3). Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements [CMS-1648-F], 42 CFR Part 484. *Federal Register*, 81(213). <https://www.govinfo.gov/content/pkg/FR-2016-11-03/pdf/2016-26290.pdf>

<sup>38</sup> CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.55 Comprehensive assessment of patients. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

HHAs also use OASIS as part of care planning, quality assurance and program improvement activities.

- On-demand reports, based on OASIS data collection, can be used by HHAs for performance monitoring and to help guide quality assurance and performance improvement efforts. OASIS data are used to provide information in several types of CMS on-demand reports including a) Outcome Reports; b) Potentially Avoidable Event Reports; c) Agency Patient-Related Characteristics (case mix) Reports; d) Patient Tally Reports, and e) Review and Correct Reports. CMS provides these reports to HHAs for use in comparing 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. HHAs 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 quality assessment and performance improvement component of the COPs, as mandated in §485.65 Condition of participation: Quality assessment and performance improvement (QAPI).<sup>39</sup>

### **Beneficiaries/Consumers:**

- o Currently, quality measure information is presented in consumer-friendly language on the CMS [Care Compare](#) (formerly Home Health Compare) website. Since the introduction of the website in 2003, a subset of quality measures derived from OASIS data has provided 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 averages. The home health measures reported on the website include process of care and outcome measures based on OASIS data. Since July 2015, CMS has used OASIS data to calculate measures publicly reported in an HHA's Quality of Patient Care (QoPC) Star Rating.

### **State Survey Agencies – [CMS Quality, Safety & Oversight Group \(QSOG\)](#):**

- o State Survey Agencies, under agreements between the State and the Secretary, carry out the Medicare certification process. CMS maintains oversight for compliance with the Medicare health and safety standards for facilities serving Medicare and Medicaid beneficiaries, and makes information about these activities available to beneficiaries, providers/suppliers, researchers, and state surveyors.
- o The survey is conducted on behalf of CMS by the individual State Survey Agencies. Surveyors review how the HHA uses OASIS data internally, and use this information to focus the survey activities. CMS and state surveyors use the reports off-site in a

<sup>39</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.65 Quality assessment and performance improvement. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

pre-survey protocol to target areas of concern for the on-site survey. HHA 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 QAPI program.

### **HHVBP Model**

- o The CMS Innovation Center implemented the original Home Health Value-Based Purchasing (HHVBP) Model in nine (9) states from January 1, 2016, through December 31, 2021. The HHVBP Model was expanded nationwide in the CY 2022 HH PPS rule.<sup>40</sup> The [expanded HHVBP Model](#) began on January 1, 2022 with a pre-implementation year, and includes Medicare-certified HHAs in all fifty (50) states, District of Columbia, and the U.S. territories. The Model uses CMS's existing home health data collection, quality reporting, and payment systems. The Model measure set includes OASIS-based, claims-based, and HHCAHPS survey-based measures, and currently uses data already reported by HHAs through the HH QRP requirements. Under the Model, HHAs receive adjustments to their Medicare fee-for-service payments based on their performance against a set of quality measures, relative to their peers' performance. Performance on these quality measures in a specified year (performance year) impacts payment adjustments in a later year (payment year).

### **Accrediting Organizations**

- o Upon specific request, national accrediting organizations such as [The Joint Commission](#), the [Community Health Accreditation Partner](#) (CHAP), and the [Accreditation Commission for Health Care](#) (ACHC) are able to obtain OASIS 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.

#### **A. Consideration of Burden of Information Collection Requests**

CMS continually looks for opportunities to minimize burden associated with the collection of the OASIS for information users through strategies that (1) simplify collection and submission requirements, (2) improve OASIS comprehension, and (3) enhance communication and outreach, (4) minimize learning costs, and (5) provide flexible time frames for data submission.

First, interviews are conducted with information users before novel items are introduced. The interviews provide valuable evidence to ensure the item(s) are precise and result in meaningful

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<sup>40</sup> CMS. (2021, November 9). Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities [CMS-1747-F and CMS-5531-F], 42 CFR Part 484. *Federal Register*, 86(214). <https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf>

information.

Second, improving OASIS comprehension is a priority. A number of strategies are used, including standardizing the collection instructions across all HHAs, ensuring that all instructions and notices are written in plain language, and by providing step-by-step examples for completing the OASIS. Human-centered design best practices are used, such as prioritizing key communication in headings, text boxes, and bold text. Close attention is paid to the amount of information required in the forms so that only the necessary data is collected on the OASIS.

Third, CMS looks for opportunities to improve communication with users and conducts outreach. CMS provides a dedicated help desk to support users and respond to questions about data collection. Additionally, an HH QRP webpage houses the OASIS user manual and links to OASIS Q&As and the HH QRP training webpage, which supports understanding of the OASIS, and can be used by current and assist new users of the OASIS. CMS utilizes a listserv to facilitate outreach to users, such as communicating timely and important new material(s), as well as reminders and alerts related to the OASIS completion. Finally, CMS provides a free internet-based system through which users can access on-demand reports for feedback on the collection of the OASIS associated with their agency.

Fourth, CMS is aware of the learning costs that HHAs may incur when new data collection is required. CMS provides multiple free training resources and opportunities for HHAs to use, reducing the burden to HHAs in creating their own training resources. These training resources include live training, online learning modules, tip sheets, and/or recorded webinars and videos. Having the materials online and on-demand gives HHAs the flexibility to use the materials in a group setting or on an individual basis at times that work for them.

Fifth, CMS allows up to 30 days for HHAs to submit all data required in this information collection, providing ample time for data submission. CMS acknowledges that some small providers may experience difficulties complying with data collection requirements, and having additional time may reduce the stress and anxiety HHA providers may experience.

### ***3. Use of Information Technology***

The OASIS items are integrated into an HHA's clinical records, and the data collection mode is dictated by an agency's choice of documentation systems. Many HHAs use electronic point of care technology (e.g., laptop computers, handheld devices, or other technology) that allows for OASIS data to be entered electronically as it is collected. Other HHAs use a paper form in the home, and the data are later entered into an electronic system. CMS requires all OASIS assessments to be submitted to the [internet Quality Improvement and Evaluation System \(iQIES\)](#).

CMS uses information technology to decrease the burden associated with data collection of the OASIS. This is accomplished through strategies that (1) streamline information and submission processes, (2) minimize costly documentation requirements, and (3) utilize information technology for improving communication.

First, CMS creates data collection specifications for HHA electronic health record (EHR) software with ‘skip’ patterns to ensure the OASIS is limited to the minimum data required to meet quality reporting requirements. These specifications are available free of charge to all HHAs and their technology partners. Further, these minimum requirements are standardized for all users of the OASIS assessment forms. CMS also provides flexibility to HHAs by giving them the option of recording the required data on a printed form and later transferring the data to electronic format or they can choose to directly enter the required data electronically to the CMS designated submission system, which is currently used by Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs) and Home Health Agencies (HHAs).

Second, CMS has minimized costly documentation requirements by allowing HHAs to electronically self-attest to the accuracy of the data in the OASIS prior to transmitting the OASIS, eliminating the need for supportive documentation to be submitted with the OASIS. CMS has also developed customized software that allows HHAs to encode, store and transmit the OASIS data. The software is available free of charge on the CMS Website at [jHAVEN | CMS](#). Additionally, the software delivers real-time warnings to the HHA when the data is incomplete. HHAs receive warnings when the data is accepted by the system but may be incomplete for purposes of quality reporting submission. HHAs receive fatal warnings when the data collection form is not accepted by the system for any reason.

Third, we provide customer support for software and transmission problems encountered by the providers. HHAs can self-select their preferred method of communication. For example, we have dedicated help desks to respond to questions about issues HHAs may encounter with the software. We also offer HHAs the ability to sign up for listservs that send out timely and valuable information, reminders, and alerts via electronic mail related to the software. CMS has also established a website to assist providers with questions regarding the OASIS, at [OASIS Data Sets | CMS](#). This website publishes the latest information related to the OASIS, houses archived versions of the tool, and is available at all times to HHAs.

#### **4. *Duplication of Efforts***

The OASIS data set collection does not duplicate any other data collection by HH providers, and the information cannot be obtained from any other source. OASIS uses data elements that are collected pursuant to the COPs at 42 CFR § 484.55 Condition of participation: Comprehensive assessment of patients<sup>41</sup>, which has required a standardized assessment to be integrated into the HHA's current patient assessment and care planning processes since July 1999<sup>42</sup>.

#### **5. *Small Businesses***

Since OASIS data collection was first mandated in 1999, CMS has taken steps to reduce HHA burden related to OASIS data collection, which includes burden in HHAs considered to be small

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<sup>41</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.55 Comprehensive assessment of patients. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

<sup>42</sup>Health Care Financing Administration (HCFA). (1999, January 25). Medicare and Medicaid Programs: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies. [HCFA-3007-F]. *Federal Register*, 64(15). <https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1449.pdf>



businesses. For example, CMS provides free software to HHAs which contains the data items to be completed at each of the OASIS data time points. This software is available for download from the [CMS Home Health Quality Reporting Program](#) website free of charge. Small business HHA providers that cannot afford the expense of an electronic health records or computer programming vendor can use this software free of charge as the means by which to submit their OASIS data to CMS.

CMS provides up-to-date OASIS training resources on the [Home Health Quality Reporting Training](#) page located on the [Home Health Quality Reporting Program](#) website. The website offers many informational and educational tools that can be used by small business HHA providers. CMS provides OASIS training through its contractors either in person or virtually. HHA providers can send questions regarding OASIS coding, OASIS documentation, and data reported in quality reports to the [CMS HH QRP Help Desk](#) by emailing [homehealthqualityquestions@cms.hhs.gov](mailto:homehealthqualityquestions@cms.hhs.gov).

## **6. *Less Frequent Collection***

Since one of the purposes of OASIS 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. HHAs must collect OASIS data as part of the comprehensive assessment for Medicare and Medicaid patients at five specific time points during the home health episode:

- admission to home care (SOC),
- resumption of care after a qualifying inpatient stay (ROC),
- recertification every 60 days that the patient remains in care of the HHA (FU),
- death at home (DAH), and
- end of care (TOC or DC).<sup>43</sup>

Therefore, patient health status data obtained through OASIS are collected at least twice (i.e., admission and discharge), and at 60-day intervals for patients receiving home health care for periods exceeding 60 days. The average length of stay in HH care has been found to be less than 60 days<sup>44</sup>, and therefore OASIS data collections are completed at two time points (the beginning and end of care) and the recertification data collection would not be conducted.

## **7. *Special Circumstances***

Under the COPs at 42 CFR § 484.45 Condition of participation: Reporting OASIS information, HHAs must report OASIS data electronically within 30 days of the assessment completion

<sup>43</sup>Health Care Financing Administration (HCFA). (1999, January 25). Medicare and Medicaid Programs: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies. [HCFA-3007-F]. *Federal Register*, 64(15). <https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1449.pdf>

<sup>44</sup>Schade CP, Brehm JG. (2010, June). Improving the home health acute-care hospitalization quality measure. *Health Services Research*, 45(3), 712-727. doi: 10.1111/j.1475-6773.2010.01106.x. Epub 2010 Apr 6. PMID: 20403057; PMCID: PMC2875756. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2875756/>

date.<sup>45</sup> This allows OASIS data to be available on a timely basis for several key CMS functions, thus avoiding separate (and duplicative) data collection efforts:

- Home Health and Hospice [Medicare Administrative Contractors](#) (HH&H MACs) can access OASIS data for use in assuring the accuracy of case-mix classification for payment.
- State survey agencies can utilize the survey and certification functions of [iQIES](#) to access OASIS data. The data is used in surveys to assure HHA compliance with the COPs.
- CMS can access OASIS data to assess HHA compliance with the Pay-for-Reporting Performance Requirement described in the CY 2015 HH PPS final rule<sup>46</sup>, and developed
- to meet requirements of Section 5201(c)(2) of the Deficit Reduction Act (DRA) of 2005.<sup>47</sup>
- CMS can access OASIS data to generate agency-specific quality reports, which are available to Medicare-certified HHAs through the [iQIES](#). HHAs use these reports as a source of information for their patient care quality monitoring and improvement programs.
- As stated in the CY 2022 HH PPS final rule, CMS relies partly on OASIS data to inform and implement the expanded HHVBP Model.<sup>48</sup>

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

We continue to believe that if OASIS data collection occurs less frequently than the time points specified in COPs 42 CFR § 484.55 Condition of participation: Comprehensive assessment of patients<sup>49</sup>, 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.

## Statistical Policy Directive No. 15 (SPD-15) Implementation Update

We support implementing the latest SPD-15 directive that requires the use of one combined question for race and ethnicity. For the FY/CY2027 Rulemaking seasons, we intend to discuss our plans to implement Figure 3, the Minimum Categories Only as depicted in 2024-06469 (89

<sup>45</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.45 Reporting OASIS information. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

<sup>46</sup>CMS. (2014, November 6). Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies [CMS-1611-F], 42 CFR Part 484. *Federal Register*, 79(215). <https://www.govinfo.gov/content/pkg/FR-2014-11-06/pdf/2014-26057.pdf>

<sup>47</sup>109<sup>th</sup> Congress of the U.S.A. (2006, February 8). Deficit Reduction Act of 2005, Public Law 109-171, 42 USC. <https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf>

<sup>48</sup>CMS. (2021, November 9). Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities [CMS-1747-F and CMS-5531-F], 42 CFR Part 484. *Federal Register*, 86(214). <https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf>

<sup>49</sup>CMS. (2017, January 13). Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies [CMS-3819-F], 42 CFR Part 484.55 Comprehensive assessment of patients. *Federal Register*, 82(9). <https://www.govinfo.gov/content/pkg/FR-2017-01-13/pdf/2017-00283.pdf>. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484>

FR 22182) with the expectation to implement in our 5 PAC Programs beginning in 2028. The implementation of this standard sooner would be a significant burden for the following reasons –

- Existing patient assessment instruments (PAIs) collect information on patients' race and/or ethnicity using an earlier standard. By statute, all PAIs must propose the data items, including race/ethnicity via notice and comment rulemaking. This means that to add the race/ethnicity from SPD-15, we would need to propose the time, place, and manner of adding the SPD-15 race/ethnicity in each of its rules.
- While we have begun preliminary conversations with our Information Systems Group (ISG) colleagues for implementation following rulemaking, adoption of this standard (like any new work) requires adequate time for vendors, States, other CMS components, and federal agencies to implement updates to their respective systems, databases, finder files, etc.
- We need to allow for the 12-month period allotted prior to implementation of any updates and related trainings to the assessment tools and technical data specifications, our various data bases, and impacted reports. We plan to incorporate the Race and Ethnicity Question with Minimum Categories only (no examples or write-ins) (as shown in Figure 3 of the Federal Register posting)
- The new Race and Ethnicity Question has a longer list of race/ethnicity options, which may be more difficult to administer by PAC staff, due to the age and comorbidities of the Medicare-aged population. The Minimum Categories only question (figure 3) reduce provider burden and patient/resident/family confusion since the staff must read the questions to the patient/resident for their response. We also consider the translations for patients who need staff to ask the questions in a language other than English. CMS has tested write-in options for assessment items and that data cannot be used. Aside from spelling issues and how many write-ins should be allowed, we seek inter-operability, and write-ins do not allow for this.

## **8. *Federal Register/Outside Consultation***

The 60-day Federal Register notice published as part of the proposed rule that published July 2, 2025 (90 FR 29108).

CMS uses the [Federal Register](#), Technical Expert Panels (TEPs), and the CMS consensus-based entity (CBE) to receive information regarding potential changes to the quality measures used in home health. As a result, refinements to the OASIS data elements and data set are also considered and finalized as appropriate.

Through its contractors, CMS recruits and convenes TEPs to advise CMS on quality measure refinement. TEP members may include home health and other healthcare professionals, beneficiary representatives, and experts in quality measurement and payment.

The CMS consensus-based entity (CBE) oversees measure endorsement for use in CMS programs. Feedback from the CMS CBE has led to changes in OASIS item to support the generation and public reporting of endorsed quality measures.

## **9. *Payments/Gifts to Respondents***

There are no payments or gifts to respondents.

## **10. *Confidentiality***

CMS pledges confidentiality of patient-specific data consistent with the Privacy Act of 1974 (The Privacy Act), as amended at Title 5 U.S.C. §552a.<sup>50</sup> [The Privacy Act](#) establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies.

As required by The Privacy Act, HHS publishes [System of Records Notices](#) (SORNs) to provide public notice of the records it maintains about individuals which are retrieved by personal identifier. The types of information contained in the records, the legal authority for collecting and maintaining the records, how the records are used within HHS, and the purposes (referred to as “routine uses”) for which HHS may disclose the records to non-HHS parties without the individual record subject’s consent are described in each SORN. Also indicated is whether any records are exempt from certain Privacy Act requirements. For more information about systems of records and exemptions, see [OMB Circular A-108 \(Dec. 2016\) - PDF](#).<sup>51</sup>

In 1999, CMS established an additional requirement of the COPs for HHAs approved to participate in Medicare and/or Medicaid to encode and report OASIS electronically into a national database for the purposes of quality of care and reimbursement.<sup>52</sup> Also in 1999, CMS established a new System of Records (SOR) containing data on the physical, mental, functional, and psychosocial status of all patients receiving the services of the HHAs.<sup>53,54</sup> The [SORNs 09-70-0522](#) were updated for the HHA Outcome and Assessment Information Set (OASIS), and published November 13, 2007 ([72 FR 63906](#)), April 23, 2013 ([78 FR 23938](#)), May 29, 2013 ([78 FR 32257](#)), and February 14, 2018 ([83 FR 6591](#)). Data will be kept private to the extent allowed by law.

## **11. *Sensitive Questions***

There are no sensitive questions on OASIS.

## **12. *Burden Estimates (Hours & Wages)***

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<sup>50</sup>Records maintained on individuals, U.S. Code 5 (2021), § 552a. [5 USC 552a: Records maintained on individuals](#)

<sup>51</sup>OMB. (2016, December). Circular No. A-108. To the Heads of executive Departments and agencies: federal agency Responsibilities for review, Reporting, and Publication under the Privacy Act. <https://www.hhs.gov/sites/default/files/omb-circular-a-108-dec-2016.pdf>

<sup>52</sup>HCFA. (1999, January 25). Medicare and Medicaid Program: Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies [HCFA-3007-F], 42 CFR Part 484. *Federal Register*, 64(15), pp.3764-3784. <https://www.govinfo.gov/content/pkg/FR-1999-01-25/pdf/99-1449.pdf>

<sup>53</sup>HCFA. (1999, June 18). Privacy Act of 1974; Report of New System, FR 99-15530. *Federal Register*, 64(117), pp.32992-32998. <https://www.govinfo.gov/content/pkg/FR-1999-06-18/html/99-15530.htm>

<sup>54</sup>Office of the Federal Register, National Archives and Records Administration. (2001, December 27). *Federal Register*, 66(248). <https://www.govinfo.gov/content/pkg/FR-2001-12-27/pdf/FR-2001-12-27.pdf>

## Part I. Background Information

The total data elements in the current version, OASIS-E1, are displayed in Table 1. The number of data elements added and removed for the proposed version OASIS-E2, are noted with the net change between versions. Because there are a different number of data elements collected at each time point, we present itemized burden estimates by time point for this section, rather than for the entire data set.

**Table 1. Number of Data Elements Added and Removed for OASIS-E2**

Time Point	#DE in OASIS-E1	#DE added for OASIS-E2	#DE removed for OASIS-E2	Net change (+/-)	#DE in OASIS-E2
SOC	200	1	1	0	200
ROC	169	4	1	+3	172
FU	43	0	0	0	43
TOC	23	0	1	-1	22
DAH	10	0	1	-1	9
DC	147	0	2	-2	145

Notes: DE = data element(s), SOC = Start of Care, ROC = Resumption of Care, FU = Follow-up, TOC = Transfer of Care, DAH = Death at Home, DC = Discharge.

The OASIS-E1 item A1250. Transportation (1 DE) is collected at SOC, ROC and DC. For OASIS-E2, this item is being removed. A modified item, A1255 Transportation (1 DE), is being added to the SOC and ROC time points. The item O0350 Patient's COVID-19 vaccination is up to date (1 DE) is being removed from the TOC, DC and DAH time points. The following changes were completed subregulatory, so they were not included in the Final Rule: In OASIS-E1, the Hearing, Vision, and Language items were only collected at SOC. These items will be collected at the ROC timepoint in addition to SOC, for OASIS-E2 (no change in DE). A0810 Sex will replace the M0069 Gender item (no change in DE).

In our estimations, we assume that data elements require 0.15, 0.25 or 0.3 minutes of clinician time to complete. The number of data elements at each level of burden are listed in Table 2, for each time point.

**Table 2. Number of Data Elements at Each Level of Burden by Time Point for OASIS-E2**

Level of Burden (Minutes)	SOC	ROC	FU	TOC	DAH	DC
0.15	21	21	0	0	0	21
0.25	9	9	0	0	0	9
0.3	170	142	43	22	9	115
<b>Total # DE/time point</b>	<b>200</b>	<b>172</b>	<b>43</b>	<b>22</b>	<b>9</b>	<b>145</b>

Notes: DE = data element(s), SOC = Start of Care, ROC = Resumption of Care, FU = Follow-up, TOC = Transfer of Care, DAH = Death at Home, DC = Discharge.

We calculate burden by timepoint by looking at the number of data elements in each time point

assessment and multiplying that by the level of burden for those data elements.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates ([Bureau of Labor Statistics](#)). To account for overhead and fringe benefits we have doubled the hourly wage. These amounts are detailed in Table 3.

**Table 3. U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates**

A	B	C	D	E	F	G
Occupation title	Occupation Code	Median Hourly Wage (\$/hour)	Fringe Benefit (100%) (\$/hour)	Adjusted Hourly Wage (\$/hour) (C + D)	% of Assessments completed	Weighted hourly wage (E x F)/100
<b>Registered Nurse (RN)</b>	29-1141	\$45.00	\$45.00	\$90.00	75.42%	\$67.88
<b>Physical Therapist (PT)</b>	29-1123	\$48.57	\$48.57	\$97.14	23.71%	\$23.03
<b>Speech-Language Pathologist (SLP)</b>	29-1127	\$45.87	\$45.87	\$91.74	All other therapists combined (\$91.74 (SLP) + \$94.56 (OT) = 186.30/2 = <b>93.15</b> )  0.29% (SLP) + 0.58% (OT)= 0.87%	\$0.81 (=93.15 x 0.87/100)
<b>Occupational Therapist (OT)</b>	29-1122	\$47.28	\$47.28	\$94.56	N/A	N/A
<b>Miscellaneous Health Technologists and Technicians (Administrative )</b>	29-2090	\$23.84	\$23.84	\$47.68	N/A	N/A
						\$91.72 weighted clinician hourly

						wage
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The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2023 show that for 12,135 **Medicare-certified HHAs active as of December 31, 2023**, the SOC/ROC OASIS was completed by RNs approximately 75.42 percent of the time, PTs approximately 23.71 percent of the time, and other therapists, including OTs and SLP/STs approximately 0.87 (=0.29% SLP + 0.58% OT) percent of the time. Based on these data we estimated a **weighted clinician average hourly wage of \$91.72**, inclusive of fringe benefits, using the hourly wage data in Table 3. The average hourly wage for health technologists and technicians, **\$47.68**, is used to calculate estimated **administrative cost**. The formula for the weighted clinician average hourly wage is  $0.7542 \times \$90.00 + 0.2371 \times \$97.14 + 0.0087 \times \$93.15 = \$91.72$ . Individual providers determine the staffing resources necessary.

Table 4 shows the total number of assessments submitted in CY 2023 by time point. These numbers are used in the burden calculations that follow.

**Table 4. Calendar Year (CY) 2023 OASIS Submissions by Time Point**

<b>Time Point</b>	<b>CY 2023 Assessments Completed</b>
Start of Care	6,627,538
Resumption of Care	911,192
Follow-up	3,520,347
Transfer to an inpatient facility	1,818,914
Death at Home	48,398
Discharge from agency	5,389,311
<b>TOTAL</b>	<b>18,315,700</b>

## **Part II. Estimated Hourly Burden and Estimated Cost**

CMS uses a standard process to calculate estimated clinical and administrative hourly burden and estimated cost for the OASIS PRA.

- 1) Calculate the estimated clinician time spent completing data entry for each OASIS time point assessment.
  - a) **Clinician minutes** = data elements (N) x 0.15, 0.25, or 0.3 minutes per data element. (See Table 2 for level of burden by time point).
- 2) Calculate the estimated administrative staff time spent submitting each OASIS time point assessment.
  - a) **Administrative minutes**= assessments (N) x 5 minutes. (See Table 4 for number of assessments per time point).
- 3) Calculate the estimated hourly burden for all HHAs for each OASIS time point assessment. (See Table 5, below).



- a) **Clinician hours** for all HHAs = (clinician minutes per time point assessment x assessments [N])/60 minutes per hour.
  - b) **Administrative hours** for all HHAs = (administrative minutes per time point assessment x assessments [N])/60 minutes per hour.
- 4) Calculate the estimated cost for all HHAs for each OASIS time point assessment. (See Table 6, below).
- a) **Clinical cost** for all HHAs = (weighted clinician average hourly wage [\$91.72 x hours per time point assessment])
  - b) **Administrative cost** for all HHAs = (administrative hourly wage [\$47.68] x hours per time point assessment)

### A. Estimated Hourly Burden

The estimated clinical and administrative hourly burden for all HHAs for OASIS-E2 are displayed in Table 5, below.

**Table 5. Estimated hourly clinical and administrative burden for all HHAs for OASIS-E2**

	SOC	ROC	FU	TOC	DAH	DC	Total hours/ occupation
Clinical							
		728,9	756,874.61	200,0	2,17	3,585,8	11,501,864.1
	6,229,8	5		8	7	91.	9
	85	3.		0.	.	82	
	.7	6		5	9		
	2	0		4	1		
Administrative	552,294.83	75,93	293,362.25	151,5	4,03	449,109.25	1,526,308.33
		2		7	3		
		.		6.	.		
		6		1	1		
		7		7	7		
Total hours/ time point	6,782,1	804,8	1,050,236.86	351,6	6,21	4,033,0	13,028,172.5
	80	8		5	1	01.	2
	.5	6.		6.	.	07	
	5	2		7	0		
		7		1	8		

Notes: SOC = Start of Care, ROC = Resumption of Care, FU = Follow-up, TOC = Transfer of Care, DAH = Death at Home, DC = Discharge.

### B. Estimated Cost

The estimated clinical and administrative costs for all HHAs for OASIS-E2 are displayed in Table 6.

**Table 6. Estimated clinical and administrative cost for all HHAs, and total estimated cost for OASIS-E2**

	SOC	ROC	FU	TOC	DAH	DC	Total cost/ occupation
Clinical	\$571,406,980.97	\$66,859,842.15	\$69,420,765.08	\$18,351,446.95	\$199,758.56	\$328,715,628.86	\$1,054,954,422.56
Administrative	\$26,333,417.65	\$3,620,469.55	\$13,987,512.08	\$7,227,151.63	\$192,301.39	\$21,413,529.04	\$72,774,381.33

Total cost/ time point	\$57,740,398.63	\$70,480,311.70	\$83,408,277.16	\$25,578,598.58	\$392,059.94	\$350,129,157.90	\$1,127,728,803.90
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### C. Thirty (30) Percent Adjustment for All Payer

As specified in the Calendar Year (CY) 2023 HH Prospective Payment System final rule HHAs will collect and submit OASIS data for eligible patients regardless of payer effective January 1, 2025 (with OASIS-E1). Table 7 represents an estimated 30 percent increase in hourly and cost burden. For this PRA application, 30 percent is added to the overall total hours (Table 5) and overall total cost (Table 6) calculated for OASIS-E1, and displayed in Table 7, below.

**Table 7. All Payer Adjustment to total estimated hourly burden and cost for OASIS-E2**

	<b>Total hourly burden</b>	<b>Total cost</b>
Totals from Tables 5 and 6	13,028,172.52	\$1,127,728,803.90
30 percent adjustment	3,908,451.76	\$338,318,641.17
<b>Final totals</b>	16,936,624.28	\$1,466,047,445.07

**Table 8. Summary of Hours and Cost Burden for OASIS-E2**

<b>Category</b>	<b>Estimated Hours</b>	<b>Estimated Cost</b>
Clinicians	11,501,864.19	\$1,054,954,422.56
Administrative	1,526,308.33	\$72,774,381.33
Adjustment for All Payer	3,908,451.76	\$338,318,641.17
<b>Totals (from Table 7)</b>	16,936,624.28	\$1,466,047,445.07

The total burden hours are 16,936,624.28. The total cost is \$1,466,047,445.07

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### **13. Capital Costs**

There are no capital costs.

### **14. Cost to Federal Government**

The Department of Health & Human Services (DHHS) will incur costs associated with the administration of the HH QRP including costs associated with the IT system used to process OASIS submissions to CMS and analysis of the data received.

CMS has engaged the services of an in-house CMS contractor to create and manage an online reporting/IT platform for OASIS. This contractor works with the CMS Center for Clinical Standards and Quality, Division of Post-Acute and Chronic Care (DCPAC) in order to support the IT needs of multiple quality reporting programs. When HHAs transmit the data contained within the OASIS to CMS it is received by this contractor. Upon receipt of all data sets for each quarter the contractor performs some basic analysis which helps to determine each provider's compliance with the reporting requirements of the HH QRP. The findings are communicated to the HH QRP lead in a report. Contractor costs include the development, testing, roll-out, and maintenance of the software that is made available to HHAs free of charge, providing a means by which HHAs can submit the required data to CMS.

DCPAC also retains the services of a separate contractor for the purpose of performing a more in-depth analysis of the HHA quality data, as well as the calculation of the quality measures, and for future public reporting of the HHA quality data. Said contractor is responsible for obtaining

the HHA quality reporting data from the in-house CMS contractor. They will perform statistical analysis on this data and prepare reports of their findings, which will be submitted to the HH QRP lead.

DCPAC retains the services of a third contractor to assist with provider training and help desk support services related to the HH QRP.

In addition to the contractor costs, the total includes the cost of the following Federal employees:

- GS-13 (locality pay area of Washington-Baltimore-Northern Virginia) at 100% effort for 3 years, or **\$336,315.**
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or **\$132,368.**

The estimated annual cost to the federal government is as follows:

CMS in-house contractor – Maintenance and support of IT platform that Supports the OASIS	\$ 750,000
Data analysis contractor.....	\$1,000,000
Provider training & help desk contractor.....	\$1,000,000
GS-13 Federal Employee (100% x 3 years at \$112,105 annually).....	\$ 112,105
GS-14 Federal Employee (33% x 3 years at \$132,368 annually).....	\$ 132,368
<b>Total Cost to Federal Government .....</b>	<b>\$2,994,473</b>

## 15. *Changes to Burden*

### Summary of Additions to and Removals from the OASIS data set for version E2.

The OASIS-E2 is scheduled for implementation on April 1, 2026, to comply with changes noted in the CY2025 HH Final Rule and subregulatory changes. The changes in OASIS-E2 include the removal of the A1250 Transportation item, which will be replaced by the revised A1255 Transportation item (1 DE) to align with a similar item used in other CMS programs. The item O0350 Patient's COVID-19 vaccination is up to date (1 DE) will be removed in OASIS-E2. Subregulatory changes include CMS adding the B1000 Hearing, B0200 Vision, and A1110 Language items to the ROC timepoint (No change in DE). A0810 Sex will replace the M0069 Gender item (no change in DE).

### Change in Burden from OASIS-E1 to OASIS-E2

The change in burden from OASIS-E1 to OASIS-E2, in hours and cost, is displayed in Table 9 below.

**Table 9. Change in Burden from OASIS-E1 to OASIS-E2**

<b>A</b>	<b>B</b>	<b>C</b>	<b>D (C – B)</b>
	<b>OASIS-E1</b>	<b>OASIS-E2</b>	<b>Change from OASIS-E1 to OASIS- E2</b>
<b>Hourly burden</b>	<b>16,683,290</b>	<b>16,936,624.28</b>	<b>253,334.28</b>
<b>Cost</b>	<b>\$1,294,803,517.77</b>	<b>\$1,466,047,445.07</b>	<b>\$171,243,927.30</b>

Hourly burden has increased 253,334.28 hours from OASIS-E1 to OASIS-E2.

Cost has increased \$171,243,927.30 from OASIS-E1 to OASIS-E2.

#### **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 Care 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. 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 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**

OASIS-E1 to OASIS-E2 Change Table

**Attachment B**

All Items Version of OASIS-E2 (Proposed Data Collection)

**Attachment C**

Itemized List of time points and OASIS-E2 assessment items (Proposed Data Collection)