U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

OFFICE OF MANAGEMENT AND BUDGET PAPERWORK REDUCTION ACT CLEARANCE PACKAGE

SUPPORTING STATEMENT-PART A

HOSPICE OUTCOMES AND PATIENT EVALUATION (H.O.P.E.)

FOR THE COLLECTION OF DATA
PERTAINING TO THE
HOSPICE QUALITY REPORTING PROGRAM

<u>SUPPORTING STATEMENT-PART A</u> H.O.P.E. FOR THE COLLECTION OF DATA PERTAINING TO THE HOSPICE QUALITY REPORTING PROGRAM

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<u>Supporting Statement, A</u> For Paperwork Reduction Act Submissions

Hospice Outcomes and Patient Evaluation (HOPE) for the Collection of Data Pertaining to the Hospice Quality Reporting Program (CMS-10390 - OMB Control Number – 0938-1153)

A. Background

On July 1, 2014, hospices began using a newly created data collection instrument, titled the "Hospice Item Set" (HIS). The HIS was developed specifically for use by hospices and contains data elements used by the Center for Medicare & Medicaid Services (CMS), to collect patient-level data to calculate seven process quality measures for the HQRP. Although the seven HIS process measures were removed from public reporting in the FY 2022 Hospice Final Rule, these component quality measures are still used to calculate the Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission (Consensus Based Entity [CBE] #3235).

CMS has been developing the Hospice Outcomes & Patient Evaluation (HOPE), a new patient assessment instrument.. This tool is intended to help hospices better understand care needs throughout the patient's dying process and contribute to the patient's plan of care. HOPE will provide assessment-based quality data to enhance the HQRP through standardized data collection and provide additional clinical data that could inform future payment refinements. CMS intends for HOPE to include key items from the HIS and continue to collect information to inform the Comprehensive Assessment at Admission (CBE #3235) while gathering additional data to support new quality measures.

While the HIS collects data only at hospice admission and discharge, HOPE aims to collect quality data throughout the patient stay by introducing an additional timepoint, the HOPE Update Visit (HUV). This additional timepoint enables CMS to gather patient level data during their hospice stay. Hospice providers are required to submit up to two HUVs depending on the length of the hospice stay.

CMS will also require hospice providers to return after an assessing visit to reassess a patient's symptoms during a stay. This Symptom Reassessment (SRA) can occur three times during a hospice stay, once during admission and twice during the HUV, each time triggered only if the patient has rated a listed symptom as moderate or severe. SRA is not its own separate timepoint, the SRA items are included in the Admission and HUV timepoints. Between the new HUV timepoint and the new Symptom Reassessment requirement, CMS anticipates greater burden for hospice providers in order to collect and report these new data points.

CMS intends to develop at least two HOPE-based quality measures. Additional quality measures may be developed in the future based on data elements added to future versions of the tool.

HOPE is expected to provide hospices with information to help them identify opportunities to adjust their practices and improve patient- and agency-level decisions about the care they provide. Furthermore, patients and their families will be more informed about the hospice they choose based on potential public reporting of the HOPE assessment-based QMs.

B. Justification

1. Circumstances Making the Collection of Information Necessary

Section 3004(c) of the Affordable Care Act (ACA), which added section 1814(i)(5)(A)(i) to the Social Security Act (The Act), authorized the establishment of a new quality reporting program for hospices. ¹ Section 3004(c)(5)(C) of the ACA requires that hospices must submit quality data in a form, manner, and time specified by the Secretary. Section 3004(c)(5)(A)(i) further provides that, beginning with FY 2024, the Secretary shall apply a reduction in the amount of four (4) percentage points to the market basket percentage increase for any hospice that fails to submit data to the Secretary in accordance with requirements established by the Secretary for that fiscal year. In addition, statutory language at section 1861(aa)(2)(G) of the Social Security Act permits the Secretary to impose "such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services."

CMS established the HQRP in the FY 2012 Hospice Wage Index Final Rule (76 FR 47318 through 47324, and 47325 through 47326). ²

In the FY 2014 Hospice Wage Index final rule (78 FR 48257), ³ CMS finalized the specific collection of data items that support seven CBE-endorsed measures for hospice. Data for the seven measures were collected via the HIS V1.00.0.

In the FY 2017 Hospice Wage Index final rule, CMS retained the seven measures that were previously adopted in the FY 2014 rule and adopted two new quality measures: The Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission, and the Hospice Visits when Death is Imminent Measure Pair. Data for each of these measures is collected using the HIS which is the data collection instrument currently approved and in use.

Since the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), CMS provided updates related to the process for identifying high priority areas of quality measurement and improvement and for developing quality measures that address those priorities. In this rule, CMS identified the need for a new data source to support the development of new HQRP QMs, particularly outcome measures. CMS therefore provided notice of development of a new hospice measurement tool, Hospice Outcomes and Patient Evaluation (HOPE) through the FY 2024 Hospice Wage Index and Payment Update final rule (88 FR 51164).

After initial information gathering activities, CMS conducted extensive testing on HOPE and its potential data elements from October 2019 to November 2022 prior to finalizing the data elements in HOPE V1.0. CMS completed four phases of HOPE testing: cognitive, pilot, alpha, and beta. Results of the first three tests informed the content and design of the beta test, which aimed to confirm the reliability, validity, and feasibility of administering the HOPE assessment items. CMS has published an extensive report about HOPE testing from cognitive to beta. ⁴

¹ Patient Protection and Affordable Care Act. Pub. L. 111-148. Stat. 124-119. 23 March 2010. Web. Government Publishing Office.

² Medicare Program; Hospice Wage Index for Fiscal Year 2012; Final Rule, Federal Register/Vol. 76, No. 150 August 4, 2011. Government Publishing Office

³ Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Final Rule, Federal Register/Vol. 78, No. 152 August 7, 2013. Government Publishing Office

⁴ [INSERT LINK TO HOPE TESTING REPORT]

In the FY 2025 Hospice Wage Index and Payment Rate Update proposed rule, CMS proposed requiring implementation of a hospice patient-level item set to be used by all hospices to collect and submit standardized data on each patient admitted to hospice. HOPE will be used to support the standardized collection of the requisite data elements to calculate quality measures. Hospices will be required to complete and submit HOPE admission and HOPE discharge for each patient, as well as a HOPE Update Visit (HUV) assessment, when applicable, starting October 1, 2025, for FY 2027 APU determination. At this time, HIS elements will carry over into HOPE. A HIS to HOPE item change table will be included with this package.

2. Purpose and Use of the Information Collection

All hospice providers must submit the specified type and amount of quality data in a timely manner for participation in the HQRP to avoid a 4 percentage point reduction in the market basket update for FY 2024 and beyond.

There are two primary users of the HQRP data. The first user is CMS, which collects this data as required by Section 3004(c)(5)(A)(i) of the ACA (which added section 1814(i)(5)(A)(i) to the Social Security Act). CMS uses the hospice quality data collected for the purpose of calculation of quality measures, for determining provider compliance with the data reporting requirements of the HQRP, and for public reporting.

The second primary group of data users is the public, who have had access to hospice data since public reporting of the HQRP data began during the summer of 2017.

3. Use of Improved Information Technology and Burden Reduction

Hospices have 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. Hospices currently use the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system for data submission but will eventually be transitioning to the Internet Quality Improvement and Evaluation System (iQIES) system which is currently used by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), Long Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs).

CMS requires that the collected data be transmitted to CMS electronically. HOPE manner is similar to the process also used by HHAs for the Outcome and Assessment Information Set (OASIS), SNFs for the Minimum Data Set (MDS), IRFs for Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), and LTCHs for the LTCH Care Data Set. Hospices are required to attest to the accuracy of the data collected for HOPE. However, if electronic signatures were to be required at a future date, CMS could accommodate HOPE as well.

4. Efforts to Identify Duplication and Use of Similar Information

HOPE data collection does not duplicate any other efforts, and the standardized data elements in HOPE to collect data on pain, respiratory status, symptom impact, patient preferences, and beliefs/values, cannot be currently obtained from any other existing data source. There are no other data sets that will provide comparable and standardized information on patients receiving hospice care.

5. Impact on Small Businesses or Other Small Entities

To minimize the burden on hospices that qualify as small business entities, CMS is using a web-based

data submission process so that hospices can submit the specified data electronically. HOPE minimizes the burden that Information Collection Requests (ICRs) places on the provider.

The type of quality data specified for participation in the HQRP is already currently collected by hospices as part of their patient care processes.

6. Consequences of Collecting the Information Less Frequently

HOPE will be used in hospices to collect quality data for multiple quality measures. Data is required for every hospice patient admitted at admission and upon discharge. Data for the two HUV timepoints, each at specified timeframes are subject to the length of the hospice stay. Hospices are required to submit HOPE data to CMS on a periodic basis, as directed by CMS.

Section 3004 (C) (which added 1814(i)(5)(A)(i) to the "Act") required the Secretary to establish a quality reporting program for hospices. HOPE statute further required that, beginning with FY 2014, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not submit quality data submission for a fiscal year. In FY 2024, the reduction increased to 4 percentage points. CMS began collection of HQRP data on October 1, 2012. To remain in compliance with the ACA Section 3004 and 1814(i)(5)(A) of the Act, we must continue to collect hospice quality measure data and add new quality measures as appropriate.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances apply to these collections.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

A Notice of Proposed Rulemaking published on April 4, 2024 (89 FR 23778).

No outside consultation was sought.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts as a condition of complying with HOPE information collection request.

10. Assurance of Confidentiality Provided to Respondents

The patient-level data collected using HOPE will be kept confidential by CMS. Data will be stored in a secure format meeting all federal privacy guidelines. Data will be collected using a secure platform for electronic data entry and secure data transmission. The electronic system will be password protected, with access limited to CMS and project staff. To protect patient confidentiality, the patient's name will not be linked to their individual data. For identification purposes, a unique identifier will be assigned to each sample member.

All patient-level data is protected from public dissemination in accordance with the Privacy Act of 1974, as amended. The information collected is protected and held confidential in accordance with 20 CFR 401.3. The System of Record number is 0970-0548.

11. Justification for Sensitive Questions

This data collection does not incorporate any questions that would be considered sensitive in nature.

12. Estimates of Incremental Burden Hours and Costs

CMS estimates the burden increase for hospice facilities to be calculated as follows:

PART 1. Time Burden

Estimated number of hospice admissions and HOPE record submissions

Total number of Medicare-participating hospices = **5,640**⁵

Total number of admissions to all hospices per year = $2,763,850^6$

Total number of admissions to all hospices over three years = **8,291,550**

PART 1. Time Burden

Estimated Number of Admissions and Records per Hospice

	Admissions/Records	Hospices	Per Year	Per 3 Years
Admissions	2,763,850	5,640	490	1,470
Total HOPE Records	8,291,550	5,640	1,470	4,410

Estimated Number of Admissions and Records for all Hospices

	Admissions/Records	Hospices	Per 3 Years
Admissions	2,763,850	5,640	8,291,550
Total HOPE Records	8,291,550	5,640	24,874,650

Estimated HOPE Burden Hours per Year, by Time Point

Burden Hours per year (HOPE Admission)			
Discipline	Records	Hours	Total time
Clinical	2,763,850	0.45 (27 minutes)	1,243,733 hours
Clerical	2,763,850	0 (0 minutes)	0 hours
Total (HOPE Admission)			1,243,733 hours

⁵ Medicare-participating hospices were calculated using 100 percent of Medicare hospice claims data for fiscal year 2022

⁶ Reflects the number of HOPEs using 100 percent of Medicare hospice claims data for fiscal year 2022

Burden Hours per year (HOPE HUV)			
Discipline	Records	Hours	Total time
Clinical	2,763,850	0.37 (22 minutes)	1,013,411 hours
Clerical	2,763,850	0.083 (5 minutes)	230,321 hours
Total (HOPE HUV)			1,243,733 hours
Burden Hours per year (HOPE Discharge)			
Discipline	Records	Hours	Total time
Clinical	2,763,850	0 (0 minutes)	0 hours
Clerical	2,763,850	0 (0 minutes)	0 hours
Total (HOPE Discharge)			0 hours

PART 2. Cost/Wage Calculation

Note that this analysis of HOPE costs presents rounded inputs for each calculation and based on the incremental increase of burden from the HIS timepoints. The actual calculations were performed using unrounded inputs, so the outputs of each equation below may vary slightly from what would be expected from the rounded inputs.

Time for All Hospices

Discipline	Hours	Records	Total time
Nursing	0.82 (49 minutes)	2,763,850	2,257,144 hours
Administrative Assistant	0.08 (5 minutes)	2,763,850	230,321 hours
Total			2,487,465 hours

Aggregate Cost Calculations

Aggregate Annual Cost Per Hospice			
Discipline	Hours	Wages ⁷	Total cost
Clinical	400.17	\$78.10	\$31,253.02
Clerical	40.83	\$37.02	\$1,511.65
Total			\$32,764.67
Aggregate Annual Cost For All Hosp	ice Providers		
Discipline	Hours	Wages	Total cost
Clinical	2,257,144	\$78.10	\$176,282,998
Clerical	230,321	\$37.02	\$8,526,477
Total			\$184,792,739

⁷ The adjusted hourly wage of \$78.10 per hour for a Registered Nurse was obtained using the median hourly wage from the May 2022 U.S. Bureau of Labor Sta tistics, \$39.05. The adjusted hourly wage of \$37.02 per hour for a Medical Secretary was obtained using the median hourly wage from the May 2022 U.S. Bureau of Labor Statistics, \$18.51. HOPE median hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See Bureau of LaborStatistics.

Aggregate 3-Year Cost Per Hospice			
Discipline	Hours	Wages	Total cost
Clinical	1205.4	\$78.10	\$93,760
Clerical	117.6	\$37.02	\$4,534
Total			\$98,294
Aggregate 3-Year Cost For All Hospi	ice Providers.		
Discipline	Hours	Wages	Total cost
Clinical	6,711,432	\$78.10	\$528,848,994
Clerical	690,963	\$37.02	\$25,579,431
Total			\$554,428,425

PART 3. Additional Calculations

Average monthly cost to each individual hospice provider:

\$184,792,739 for all Hospices per year / **5,640** hospices / **12** months per year =**\$2,730.39**

Cost to provider per each individual hospice patient

\$184,792,739 for all hospices per year / **2,763,850** admissions per year = **\$66.86**

TABLE 2 – Summary of Burden Hours and Costs

Regulation Section(s)	Number of Respondents	Number of Responses (per year)	Burden per Response (hours)	Total Annual Burden (hours)	Median Hourly Labor Cost of Reporting (\$)	Total Cost (\$)
HOPE Admission Timepoint	5,640	2,763,850	Clinicia n: 0.45 Clerical: 0	Clinicia n: 1,243,733	Clinicia n at \$78.10 per hour; Clerica l staff at \$37.02 per hour	\$97,135,547
HUV Timepoint	5,640	2,763,850	Clinicia n: 0.37 Clerica l:	Clinicia n: 1,013,411 Clerica l: 230,321	Clinicia n at \$78.10 per hour; Clerica l staff at \$37.02 per	\$87,657,192
					Clinicia n at \$78.10 per	

HOPE Discharge Timepoint	5,640	2,763,850	Clinicia n: 0 Clerica 1: 0	Clinicia n: 0 Clerica l: 0	hour; Clerica l staff at \$37.02 per hour	\$0
TOTAL IMPACT	5,640	2,763,850	Clinician: 0.82 Clerical: 0.083	Clinician: 2,257,144 Clerical: 230,321	Clinician at \$78.10 per hour; Clerical staff at \$37.02 per hour	\$184,792,739

The incremental burden increase for HOPE (1,243,733 + 1,243,733 + 0) is 2,487,466 hours

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No anticipated capital costs since a web-based interface is available to all providers to submit the requisite information.

14. Annualized Cost to the Federal Government

The federal government will incur costs related to HOPE for provider training, preparation of HOPE manuals and materials, receipt and storage of data, data analysis, and upkeep of data submission software.

There are costs associated with the maintenance and upkeep of a CMS-sponsored web-based program that hospice providers will use to submit their HOPE data. The work to maintain HOPE web-based data submission platform will be performed by a CMS IT group known as the Division of Quality Systems for Assessment & Surveys (DQSAS), or groups under contract with DQSAS, to perform HOPE work. DQSAS will use approximately 0.5 FTE's at a grade 13 or higher to manage the technology aspect of the HQRP. In addition, the federal government will also incur costs for help-desk support that must be provided to assist hospices with the data submission process.

After hospice providers submit HQRP data to CMS, HOPE data is 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 hospice data by these CMS contractors.

Also, pursuant to §1814 (i)(5)(A)(i) of the Act, hospices that do not submit the required data will receive a 4 percentage point reduction of their annual market basket increase. The federal government will incur additional costs associated with aggregation and analysis of the data necessary to determine provider compliance with the reporting requirements for any given fiscal year.

The total annual cost to the federal government for the implementation and ongoing management of HOPE data is estimated to be \$1,583,500. These costs are itemized below:

ESTIMATED ANNUAL COSTS TO FEDERAL GOVERNMENT:

Create and Conduct Provider Web-based Training	\$ 8,500
Prepare and Update HOPE Manuals and Materials	\$ 25,000
Contractor Costs for Receipt and Storage of HOPE Data	\$550,000
Cost for Aggregation & Data Analysis	\$500,000
Costs for Upkeep & Maintenance of HOPE Data Submission	
Software by CMS/DQSAS	\$500,000

TOTAL COST TO FEDERAL GOVERNMENT:

\$1,583,500

15. Changes in Burden

Because HOPE contains a new timepoint and several new data elements in its admission timepoint, the burden hours and costs have increased from the previous Hospice Item Set. Burden increases mainly stem from the addition of the HUV timepoint, which adds an additional 22 minutes of clinical time and 5 minutes of administrative time. The expansion of the HOPE Admission timepoint (when compared to HIS Admission) also accounts for an increase in burden hours (27 additional minutes).

Regulation	Total # of	# of Submitted	Burden Per	Total Incremental	Hourly	Total Costs (\$)
Sections	Hospices	Assessments	Assessment	Burden across all	Labor	, ,
	•			Hospices (hours)	Costs (\$)	
HOPE	No change	+2,763,850	+0.9 hours	+2,487,466 hours	No change	+\$184,792,739
Burden						
Increase						

16. Plans for Tabulation and Publication and Project Time Schedule

As required by ACA 3004(c)(5)(E), CMS launched the Care Compare web site⁸ in beginning of 2021 to publicly report hospice quality measurement data, including quality measures calculated from HQRP data.

17. Expiration Date

The expiration date appears in the top right corner of the first page of each instrument.

18. Certification Statement

There is no exception to HOPE certification.

⁸ Care Compare web site: <u>Ca re Compare</u>