

**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 ITEM SET V3.00.0  
FOR THE COLLECTION OF DATA  
PERTAINING TO THE  
HOSPICE QUALITY REPORTING PROGRAM

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**Supporting Statement, A**  
**For Paperwork Reduction Act Submissions**

***Hospice Item Set 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) V1.00.0. The HIS is used for the collection of quality measure data related to the Hospice Quality Reporting Program (HQRP), and the HIS V1.00.0 specified the collection of data items that supported seven National Quality Forum (NQF) endorsed Quality Measures (QMs) for hospice. On April 1, 2017, hospices began using an updated HIS V2.00.0, which includes the same items from the HIS V1.00.0 along with the addition of several new items for use in new measures, measure refinement, patient record matching, and future public reporting. Data collected from the HIS are used to calculate the seven NQF-endorsed QMs, the NQF-endorsed Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission QM, and the Hospice Visits when Death is Imminent measure pair.

This information collection request will remove Section O. Service Utilization (hereafter referred to as Section O) of the HIS discharge assessment. Removal of Section O is the sole change from HIS V2.00.0. CMS is requesting to extend the existing expiration date (August 31, 2021) for an additional 3-years.

The HIS V3.00.0 consists of data elements that are designed to collect standardized, patient-level data for the following domains of care:

- Pain
- Respiratory Status
- Medications
- Patient Preferences
- Beliefs & Values

The HIS V3.00.0 was developed specifically for use by hospices, and contains data elements that can be used by the Center for Medicare & Medicaid Services (CMS), to collect patient-level data to calculate eight NQF-endorsed quality measures. (see Table 1).

**Table 1. Measures Corresponding to the Hospice Item Set V3.00.0**

NQF Number	Measure Name
NQF #1634	Hospice and Palliative Care – Pain Screening
NQF #1637	Hospice and Palliative Care – Pain Assessment
NQF #1639	Hospice and Palliative Care – Dyspnea Screening
NQF #1638	Hospice and Palliative Care – Dyspnea Treatment
NQF #1617	Patients Treated With an Opioid who are Given a Bowel Regimen
NQF #1641	Hospice and Palliative Care – Treatment Preferences
NQF #1647	Beliefs/values addressed
NQF #3235	Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission

## **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.<sup>1</sup> 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 2014, the Secretary shall apply a reduction in the amount of two (2) 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.

CMS established the HQRP in the FY 2012 Hospice Wage Index Final Rule (76 FR 47318 through 47324, and 47325 through 47326).<sup>2</sup> In this rule, CMS set forth the initial framework for the HQRP and established that the first reporting period would take place from October 1, 2012 through December 31, 2012. During this first reporting period, hospice providers were required to report their data gathered from January 1, 2012 and April 1, 2012. The data that hospices gathered for this first reporting period pertained to two quality measures: (1) a structural measure titled “Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care” and; (2) the NQF-endorsed #0209 pain measure.

In the CY 2013 HH PPS final rule (77 FR 67132 through 67136),<sup>3</sup> CMS retained the two measures that had previously been adopted in the FY 2012 rule. Hospices continued to collect data for these measures until December 31, 2013. CMS retired these two measures in the FY 2014 final rule (78 FR 48256 through 48257).

In the FY 2014 Hospice Wage Index final rule (78 FR 48257),<sup>4</sup> CMS finalized the specific collection of data items that support seven NQF-endorsed measures for hospice. Data for the seven measures were collected via the HIS V1.00.0.

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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; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies; Final Rule, Federal Register/Vol. 77, No. 217 November 8, 2012. [Government Publishing Office](#)

4 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](#)

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 V2.00.0, which is the data collection instrument currently approved and in use.

The FY 2020 Hospice Wage Index and Payment final rule (84 FR 38484)<sup>5</sup> revealed that measure 2 of the HVWDII measure pair did not meet readiness standards for public reporting. We are replacing the current Hospice Visits when Death is Imminent measure pair from the HQRP measure set with a modified version, Hospice Visits in the Last Days of Life (HVLDDL) based on Medicare hospice claims data. Our analysis found that using Medicare hospice claims data, rather than HIS data, significantly improved testing results compared to the HVWDII measure pair. The HVLDDL measure also contains updated specifications to the numerator to align with available claims data, though the exclusion criteria remain the same as the HVWDII measure. The HVLDDL is a single measure and is based on visits by a RN or Medical Social Worker (MSW) in at least two of the last three days of life.

Our analysis, described below, demonstrates that, compared with the HVWDII measure pair, the HVLDDL demonstrates higher validity and variability testing results. Validity testing and the literature strongly supported the focus on RNs and MSWs in the revised measure construct, which in turn allowed us to consider claims data. Because HVLDDL is based on claims data, using it instead of the HVWDII measure reduces the burden of reporting on hospices, and is responsive to the concerns of the HQRP that OIG and MedPAC expressed in recent reports. In addition, the design of the HVLDDL measure has received the support of stakeholders and, coincidentally, is better aligned with the Service Intensity Add-on (SIA) policy that became effective January 1, 2016 and detailed in the FY 2016 Hospice Wage Index and Payment final rule (80 FR 47142)<sup>8</sup>. The HVLDDL measure, as a replacement, would continue to fill an

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5 Medicare Program: FY 2020 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; Final Rule, Federal Register/Vol.84, No. 151 August 6, 2019. <https://www.govinfo.gov/content/pkg/FR-2019-08-06/pdf/2019-16583.pdf>

6 2019: Vulnerabilities in Hospice Care ([Office of the Inspector General](#) )

7 Report to Congress: Medicare Payment Policy (March 2019) [MEDPAC](#)

8 Medicare Program: FY 2016 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; Final Rule, Federal Register/Vol.80, No. 151 August 6, 2015 [Government Publishing Office](#)

important area in hospice care previously filled by the HVWDII measure pair, which is generally supported by the NQF Measure Application Partnership (MAP) and the HQRP Technical Expert Panel's (TEP). We discussed these findings with a TEP convened by our measure development contractor, Abt Associates, in November 2019 and with the MAP, hosted by the NQF in December 2019 for inclusion in the HQRP. During these meetings, the discussions reflecting on the analysis generally supported the replacement of HVWDII with a claims-based HVLDDL measure. The TEP report can be found in the downloads section at [Hospice QRP Provider Engagement Opportunities](#) and final recommendations and presentation of the HVLDDL measure before the MAP can be found at [Quality Forum - Post-Acute Care](#).

Several organizations and panels have identified care of the imminently dying patient as an important domain of palliative and hospice care and established guidelines and recommendations related to this high priority aspect of healthcare that affects a large number of people. The NQF 2006 report "A Framework for Preferred Practices for Palliative Care Quality" recommends that signs and symptoms of impending death are recognized, communicated, and educated, and care appropriate for the phase of illness is provided<sup>9</sup>. We continue to recognize that the last week of life is typically the period in the terminal illness trajectory with the highest symptom burden. Particularly during the last few days before death, patients experience many physical and emotional symptoms, necessitating close care and attention from the integrated hospice team and drawing increasingly on hospice team resources<sup>10, 11, 12</sup>. Highly specific physical signs associated with death were identified within 3 days of death (Hui et al., 2014)<sup>13</sup>. Hospice responsiveness during times of patient and caregiver need is an important aspect of care for hospice

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9 National Quality Forum. A National Framework and Preferred Practices for Palliative and Hospice Care Quality. 2006; Available from:

[http://www.qualityforum.org/publications/2006/12/A\\_National\\_Framework\\_and\\_PREFERRED\\_Practices\\_for\\_Palliative\\_and\\_Hospice\\_Care\\_Quality.aspx](http://www.qualityforum.org/publications/2006/12/A_National_Framework_and_PREFERRED_Practices_for_Palliative_and_Hospice_Care_Quality.aspx)

10 de la Cruz, M., et al. (2015). Delirium, agitation, and symptom distress within the final seven days of life among cancer patients receiving hospice care. *Palliative & Supportive Care*, 13(2): 211-216. doi: 10.1017/S1478951513001144

11 Dellon, E. P., et al. (2010). Family caregiver perspectives on symptoms and treatments for patients dying from complications of cystic fibrosis. *Journal of Pain & Symptom Management*, 40(6): 829-837. doi: 10.1016/j.jpainsymman.2010.03.024

12 Kehl, K. A., et al. (2013). A systematic review of the prevalence of signs of impending death and symptoms in the last 2 weeks of life. *American Journal of Hospice & Palliative Care*, 30(6): 601-616. doi:

13 Hui D, dos Santos R, Chisholm G, Bansal S, Buosi Silva T, Kilgore K et al. (2014). Clinical Signs of Impending Death in Cancer Patients. *The Oncologist*; 19(6):681-687. Accessible via: [The Oncologist](#).

patients<sup>14</sup>. Although Medicare-certified hospices do not have any mandated minimum number of required visits for patients in routine home care (RHC), the primary level of hospice care, at the end of life, hospices should be equipped to meet the higher symptom and caregiving burdens of patients and their caregivers during this critical period<sup>15</sup>. Highly specific physical signs associated with death were identified within 3 days of death. Further, the American College of Physicians Clinical Practice Guidelines recommend that clinicians regularly assess pain, dyspnea, and depression for patients with serious illness at the end of life<sup>16</sup>. We also believe that research supports that changes in provider behavior that lead to quality of care improvements could be based on several approaches such as a combination of payment incentives, education, oversight, and transparency of quality metrics.

Since the implementation of HVWDII, we appreciate hospices submitting data for the measure pair because it has supported our ability to review measures on a regular basis as encouraged by public comments. We began developing the HVLDL measure based on the HVWDII measure pair definitions and through an iterative process, we developed the different measure specifications based on claims data and further tested the measure based on CAHPS® data. Specifically, we used 100 percent of FY 2018 Medicare hospice claims data (n=1.1 million beneficiaries) to test the reportability, variation (ability to differentiate between hospices), validity (as demonstrated through alignment between the measure and CAHPS® score), and reliability of the measure. Using these data, we identified all Medicare hospice decedents discharged to death who elected and received hospice care at the Routine Home Care (RHC) level of care for the last days of life to mirror the existing exclusions of the HVWDII.

We pursued a re-specification of the HVWDII measure concept using Medicare claims data because claims data also capture RN and MSW visits by hospices, and, as described below, can provide reliable data without imposing additional burden on hospices. Once we learned from these analyses that RN and MSW visits correlate well with the CAHPS® quality measures for “would recommend” the hospice, we were then interested in re-specifying the visit measure to better align with the SIA because we discussed in the FY 2019 Hospice Wage Index and Payment Rate Update proposed rule (83 FR 38622) that patient needs typically surge and more intensive services are warranted, so we expect that the provision of care would proportionately escalate in order to meet the increased clinical, emotional, and other needs of the patient and family. In addition, reports by OIG and MedPAC encouraged us to explore ways to improve the HQRP. CMS believes Medicare claims data may be a source to identify clinical visit intensity when the last days of life are expected to have the highest need for RN and MSW visits.

We tested multiple claims-based measure designs varying in the frequency of visits by hospice staff in the last four or fewer days of life. Among them, we found that the measure with RN or MSW visits in at

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14 Ellington, L., et al. (2016). Interdisciplinary Team Care and Hospice Team Provider Visit Patterns during the Last Week of Life. *Journal of Palliative Medicine*, 19(5), 482-487. doi: 10.1089/jpm.2015.0198

15 Plotzke, et al. (2015). Medicare Hospice Payment Reform: Analysis of How the Medicare Hospice Benefit is Used. Retrieved from [Medicare Fee-for-Service Payment](#)

16 Qaseem, A., et al., Evidence-Based Interventions to Improve the Palliative Care of Pain, Dyspnea, and Depression at the End of Life: A Clinical Practice Guideline from the American College of Physicians. *Annals of Internal Medicine*, 2008.148(2): p. 141-146.

least two of the last three days of life showed strong variability, while also giving hospices time to determine whether an RN or MSW visit is needed and to coordinate and deliver the visits.

When comparing this claims-based measure construct with the HIS measures, we found the new measure with the specifications for claims-based measure demonstrates an improvement in variability testing, with a larger interquartile range (the difference between the 25<sup>th</sup> and 75<sup>th</sup> percentiles) of 0.28, compared to 0.12 and 0.20 for the HIS Measures 1 and 2, respectively. Furthermore, we found that the standard deviation is also higher for the HVLDL, 0.22, compared to 0.15 and 0.17 for measure 1 and measure 2. Both the interquartile range and standard deviation are measures of the spread of the distribution of measures scores. Higher values of these metrics indicate greater variation for a particular measure score and are suggestive of its greater utility as a differentiator.

We also conducted validity testing to understand whether the HVWDII and the HVLDL is correlated with one component of the CAHPS® Hospice Survey quality measure capturing family caregivers who would definitely recommend the hospice agency to friends and family. Higher positive values of the Pearson's correlation coefficient indicate a greater positive relationship between the measure and the CAHPS® Hospice Survey recommendation scores. Testing results showed that the HVLDL had a correlation coefficient of 0.24 when correlated with the CAHPS® Hospice Survey recommendation scores in contrast to coefficients of 0.22 and -0.10 for HVWDII measure 1 and measure 2, respectively.

As these results demonstrate, we found that measure 2 had a negative, or inverse, relationship with the CAHPS® "would recommend" measure; that is, decedents of hospices with higher rates for measure 2 were less likely to recommend the hospice. This finding does not support previous stakeholder assumptions that visits from non-clinical disciplines in the last days of life improve the quality of hospice care as perceived by the family and caregivers. Specifically, these results indicate that, when at least two visits from medical social workers, chaplains or spiritual counselors, licensed practical nurses or hospice aides occurred in the last seven days of life (measure 2), the CAHPS® "would recommend" measure was significantly lower.

In contrast, the strong correlation coefficient between HVLDL and the CAHPS® recommend scores indicate that, when visits by RN or MSW occurred in at least two of last three days of life, family and caregivers agree or positively correlates that they would recommend the hospice more often when compared to the other measure specifications, on average. The results of our analysis demonstrates the strength of the correlation between the HVLDL's specifications and aggregate caregivers' ratings of care quality, as measured by the publicly-available CAHPS® Hospice scores ([Medicare - Hospice Survey Data](#)).

We also conducted reportability testing to determine if the HVLDL claims based measure could include as much data on the population of interest as the HIS measures. We found that there are 3,594 hospices with reportable data for measure 1 and 3,579 hospices with reportable data for measure 2. In comparison, when using FY 2018 Medicare hospice claims data, we found that the modified measure retained a substantial number of hospices (3,569 hospices) with reportable data, which is comparable to the HIS measures.

Based on the analyses discussed above, the HVLDL defined for at least 3 consecutive days before death (at the RHC level of care) and when the hospice served at least 20 such patients in FY 2018 showed higher testing results in terms of variation and validity for measure scores among patients electing hospice than the HVWDII measure pair and all other claims-based constructs.

Claims data are considered accurate and reliable for measure development, as they are used for payment and subject to audit. Claims data are used to calculate quality measures that are implemented and publicly



reported in other CMS quality reporting programs (QRPs), including the post-acute care QRPs. The data needed to calculate this measure are readily available and require no additional data submission beyond what is already collected on claims in the normal course of business. This measure poses no additional data collection burden to hospice providers. CMS issued a memorandum on March 27, 2020. The memorandum grants exceptions and extensions for quality reporting requirements for Medicare quality reporting programs in response to the novel 2019 Novel Coronavirus (COVID-19) pandemic. This guidance specifies that for all claims-based measures, data from encounters occurring during January 1, 2020 – June 30, 2020 will not be used for specific QRP that have claims-based measures. The HVLDL measure will align with this guidance during the COVID-19 public health emergency to exclude claims data occurring during January 1, 2020 – June 30, 2020 for the 2022 Annual Payment Update.

The data elements from Medicare FFS claims are those basic to the operation of the Medicare payment systems and include date of admission, date of discharge (and discharge status; that is, if the patient was alive or deceased), visits received, and levels of hospice care and not subject to the PRA.

We appreciate the one in-scope public comment on our proposal to replace HVWDII measure pair with the Hospice Visits in the Last Days of Life by reducing burden with the removal of Section O of the HIS discharge assessment beginning January 1, 2021; this means patient discharges occurring after December 31 2020 will no longer be reported and start public reporting on or about May 2022.

The HIS V3.00.0 (without Section O of the discharge assessment) reflects the continued efforts to develop meaningful measures without additional hospice burden and allows for the collection of standardized, patient-level data for quality reporting purposes. There are no other reasonable or currently available alternatives for CMS to use to collect patient-level quality data from hospices that would fulfill the requirements of publicly reporting quality measures, set forth in the ACA.

Final Decision: After considering the comment received, CMS is finalizing the claims-based HVLDL measure to replace the HIS-based HVWDII without revisions. This will be effective January 1, 2021.

## **2. Purpose and Use of the Information Collection**

All hospices providers must submit the specified type and amount quality data for participation in the HQRP to avoid a 2 percentage point reduction in the market basket update for FY 2014 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 this data since public reporting of the HQRP data began 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 use the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system for data submission, which is also 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. This manner is similar to the process also used by HHAs for the Outcome and Assessment Information Set, Version C (OASIS-C), SNFs for the Minimum Data Set (MDS 3.0), 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 the HIS. However, if electronic signatures were to be required at a future date, CMS could accommodate this as well.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

This information collection does not duplicate any other efforts, and the standardized data elements in the HIS V3.00.0 to collect data on pain, respiratory status, medications, 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. This minimizes the burden that this Information Collection Requests (ICRs) places on the provider. CMS is asking hospices to collect and submit data elements that can be used to calculate one NQF-endorsed quality measures. When the HIS was under development and after implementation of HIS, data collection shows that hospices of varying sizes (including several very small hospices) were able to find the required data elements in their medical record systems and complete the HIS. There was minimal difference between the burden of finding and recording the required data experienced by small versus medium or large sized hospices. The amount and 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**

The HIS V3.00.0 will be used in hospices to collect quality data specific to the NQF-endorsed quality measure. Data collection is required for every patient admission and discharge. Hospices are required to submit this data to CMS on a periodic basis.

Section 3004 (C) (which added 1814(i)(5)(A)(i) to the “Act”) required the Secretary to establish a quality reporting program for hospices. This 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. 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 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 60-day Notice published in the Federal Register on August 13, 2020. Two comments were received; however one was out-of-scope. The national association’s comments were in support for telehealth. Their main points relate to data, telehealth, and vendor timing to implement the removal of Section O. The data issue raised relates to using one year of data for our analyses and questioned if the same issues

with Measure 2 of the HVWDII would show with more years of data. The data analyzed regardless of year shows that visits by hospice disciplines other than RN and MSW do not correlate with CAHPS. Further, as we described in the FY 2016 Hospice Payment Rate & Wage Index Rule, we are limited from collecting quality data that we cannot publicly report. Consequently, we must end that data collection and through our analyses found that the claim-based measure overcomes the issues found with the HIS-based measure. Our analysis coincidentally aligns with the Service Intensity Add-on payment policy and the effect of removing Section O will reduce provider burden.

The telehealth comment relates to claims data and supports the continued use of telehealth and that we should include those visits in the measure. We agree that there are times when telehealth visits are needed, such as during a public health emergency when in-person visits would not be safe for patients, their families, and caregivers and the plan of care supports such visits. If claims data are revised to include other fields, including telehealth, we may consider whether to include them in this measure. As with all quality measures, we are encouraging quality of care and as such hospices are encouraged to use in-person visits during these critical last days of life when supported by the plan of care, (CMS-1744-IFC & CMS-5531-IFC).

Finally, the vendor issue raised for timely implementation is something CMS also carefully considers. We have sought vendor feedback on implementation and they have not raised concerns with the early January 2021 implementation date.

Final Decision: After considering the comment, CMS is finalizing the claims-based HVLDL measure to replace the HIS-based HVWDII without revisions. This will be effective January 1, 2021.

A 30-day Notice will be published in the Federal Register on October 23 2020 (85 FR 67547).

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 this information collection request.

### **10. Assurance of Confidentiality Provided to Respondents**

The patient-level data collected using the HIS V3.00.0 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 Annualized Burden Hours and Costs**

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

#### **PART 1. Time Burden**

#### **Estimated number of hospice admissions and Hospice Item Set record submissions**

Total number of Medicare-participating hospices = **4,688**<sup>17</sup>

Total number of admissions to all hospices per year = **1,328,417**<sup>18</sup>

Total number of admissions to all hospices over three years = **3,985,251**

#### **Estimated average number of admissions to each hospice:**

- **per year: 1,328,417** admissions to all hospices / **4,688** hospices = **283** admissions per hospice per year

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<sup>17</sup> Medicare-participating hospices were calculated using 100 percent of Medicare hospice claims data for calendar year 2018

<sup>18</sup> Reflects the number of Hospice Item Sets using 100 percent of Medicare hospice claims data for calendar year 2018

- **per month:** 1,328,417 admissions to all hospices / 4,688 hospices / 12 months per year = 24 per month
- **over 3 years:** 3,985,251 admissions to all hospices over 3 years / 4,688 hospices = 850 per 3 years

**Estimated average number of Hospice Item Set records submitted by all hospices**

- **per year:** 1,328,417 admissions to all hospices per year x 2 Hospice Item Set records (1 Admission Record and 1 Discharge Record) per patient = 2,656,834 records per year
- **per month:** 2,656,834 Hospice Item Set records per all hospices per year / 12 months per year = 221,403 per month
- **over 3 years:** 2,656,834 Hospice Item Set records per all hospices per year x 3 years = 7,970,502 per 3 years

**Estimated average number of Hospice Item Set records submitted by each hospice**

- **per year:** 2,656,834 Hospice Item Set records per all hospices / 4,688 hospices = 567 records per hospice per year
- **per month:** 221,403 Hospice Item Set records per all hospices per month / 4,688 hospices = 47 per month
- **over 3 years:** 7,970,502 Hospice Item Set records per all hospices per 3 years / 4,688 hospices = 1,700.19 per 3 years

**PART 2. Cost/Wage Calculation**

Note that this worksheet presents rounded inputs for each calculation. 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 required to complete each Hospice Item Set record**

- 14 minutes nursing/clinical staff time to abstract data for Admission Record – paid @ \$72.60/hr.<sup>19</sup>
- 9 minutes nursing/clinical staff time to abstract data for Discharge Record – paid @ \$72.60/hr.
- 5 minutes administrative/clerical staff time to upload Assessment Record data – paid @ \$35.66/hr.<sup>20</sup>
- 5 minutes administrative/clerical staff time to upload Discharge Record data – paid @ \$35.66/hr.

**Time required to complete each Hospice Item Set record without Section O**

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<sup>19</sup> The adjusted hourly wage of \$72.60 per hour for a Registered Nurse was obtained using the mean hourly wage from the May 2018 U.S. Bureau of Labor Statistics, \$36.30. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See [Bureau of Labor Statistics](#)

<sup>20</sup> The adjusted hourly wage of \$35.66 per hour for a Medical Secretary was obtained using the mean hourly wage from the May 2018 U.S. Bureau of Labor Statistics, \$17.83. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See [Bureau of Labor Statistics](#)

14 minutes nursing/clinical staff time to abstract data for Admission Record – paid @ \$72.60/hr.<sup>7</sup>  
 4.8 minutes nursing/clinical staff time to abstract data for Discharge Record – paid @ \$72.60/hr.  
 5 minutes administrative/clerical staff time to upload Assessment Record data – paid @ \$35.66/hr.<sup>8</sup>  
 5 minutes administrative/clerical staff time to upload Discharge Record data – paid @ \$35.66/hr.

**Nursing Time:**

- 23 minutes x 283 Hospice Item Sets per each hospice per year / 60 minutes per hour = **108.48** nursing hours per each hospice per year
- 108.48 hours per year x \$72.60 per hour = **\$7,875.65** nursing wages per each hospice per year
- \$7,875.65 per each hospice per year x 4,688 hospice providers = **\$36,921,047.20** nursing wages per all hospices per year
- \$7,875.65 per each hospice per year x 3 years = **\$23,626.95** nursing wages per each hospice over 3 years
- \$36,921,047.20 per all hospices per year x 3 years = **\$110,763,141.60** nursing wages for all hospices over 3 years

**Nursing Time without Section O:**

- 18.8 minutes x 283 Hospice Item Sets per each hospice per year / 60 minutes per hour = **89** nursing hours per each hospice per year
- 89 hours per year x \$72.60 per hour = **\$6,461.40** nursing wages per each hospice per year
- \$6,461.40 per each hospice per year x 4,688 hospice providers = **\$30,291,043.20** nursing wages per all hospices per year
- \$6,461.40 per each hospice per year x 3 years = **\$19,384.20** nursing wages per each hospice over 3 years
- \$30,291,043.20 per all hospices per year x 3 years = **\$90,873,129.60** nursing wages for all hospices over 3 years.

**Administrative Assistant Time:**

- 10 minutes x 283 Hospice Item Sets per each hospice per year / 60 minutes per hour = **47.17** administrative/clerical hours per each hospice year
- 47.17 hours per year x \$35.66 per hour = **\$1,682.08** administrative/clerical wages per each hospice per year
- \$1,682.08 per each hospice per year x 4,688 hospice providers = **\$7,885,591.04** administrative/clerical wages per all hospices per year
- \$1,682.08 per each hospice per year x 3 years = **\$5,046.24** administrative/clerical wages per each hospice over 3 years
- \$7,885,591.04 per all hospices per year x 3 years = **\$23,656,773.12** administrative/clerical wages per each hospice over 3 years

**Total annualized cost to each hospice provider:**

<b>\$7,875.65</b>	Nursing wages per each hospice per year
<b>\$1,682.08</b>	Administrative assistant wages per each hospice per year

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\$9,557.73      **Total**

**Total annualized cost to all hospice providers:**

\$36,921,047.20 Nursing wages per all hospice providers per year

\$ 7,885,591.04 Administrative assistant wages per all hospice providers per year

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**\$44,806,638.24 Total**

**Total 3-year cost to each hospice provider:**

\$23,626.95      Nursing wages per each hospice over 3 years

\$ 5,046.24      Administrative assistant wages per each hospice over 3 years

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**\$28,673.19      Total**

**Total 3-year cost to all hospice providers:**

\$110,763,141.60 Nursing wages per all hospice providers over 3 years

\$ 23,656,773.12 Administrative assistant wages per all hospice providers over 3 years

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**\$134,419,914.72 Total**

**Total annualized cost to each hospice provider without Section O:**

\$6,461.40      Nursing wages per each hospice per year

\$1,682.08      Administrative assistant wages per each hospice per year

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**\$8,143.48      Total**

**Total annualized cost to all hospice providers without Section O:**

\$30,291,043.20 Nursing wages per all hospice providers per year

\$ 7,885,591.04 Administrative assistant wages per all hospice providers per year

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**\$38,176,634.24 Total**

**Total 3-year cost to each hospice provider without Section O:**

\$19,384.20      Nursing wages per each hospice over 3 years

\$ 5,046.24      Administrative assistant wages per each hospice over 3 years

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**\$24,430.44      Total**

**Total 3-year cost to all hospice providers without Section O:**

\$ 90,873,129.60 Nursing wages per all hospice providers over 3 years

\$ 23,656,773.12 Administrative assistant wages per all hospice providers over 3 years

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**\$114,529,902.72 Total**

PART 3. Additional Calculations

**Average monthly cost to each individual hospice provider:**

\$44,806,638.24 for all Hospices per year / 4,688 hospices / 12 months per year = **\$796.48**

**Cost to provider per each individual hospice patient:**

**\$44,806,638.24** for all hospices per year / **1,328,417** Hospice Item Sets per year = **\$33.73**

PART 3. Additional Calculations without Section O

**Average monthly cost to each individual hospice provider:**

**\$38,176,634.24** for all Hospices per year / **4,688** hospices / **12** months per year = **\$678.62**

**Cost to provider per each individual hospice patient:** \_\_\_\_\_

**\$38,176,634.24** for all hospices per year / **1,328,417** Hospice Item Sets per year = **\$28.74**



**Table 2 – Summary of Burden Hours and Costs**

<b>Regulation Section(s)</b>	<b>OMB Control No.</b>	<b>Number of Respondents</b>	<b>Number of Responses (per year)</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
Hospice Item Set Admission Assessment (CMS-10390)	0938-1153	4,688	1,328,417	0.233 clinician; 0.083 clerical	419,780	Clinician at \$72.60 per hour; Clerical staff at \$35.66 per hour	\$26,403,058.87
Hospice Item Set Discharge Assessment (CMS-10390)	0938-1153	4,688	1,328,417	0.150 clinician; 0.083 clerical	309,521	Clinician at \$72.60 per hour; Clerical staff at \$35.66 per hour	\$18,398,283.20
Hospice Item Set Discharge Assessment V3 (Without Section O)	0938-1153	4,688	1,328,417	0.080 clinician; 0.083 clerical	216,532	Clinician at \$72.60 per hour; Clerical staff at \$35.66 per hour	\$11,647,268.00
<b>Removal of Section O</b>				<b>-0.07 clinician</b>	<b>-92,989</b>		<b>-\$6,751,015</b>
3-year total for admission and discharge with Section O		4,688	7,970,502	.55	2,187,903	Clinician at \$72.60 per hour; Clerical staff at \$35.66 per hour	\$134,404,024.21
<b>3-year total for admission and discharge without Section O</b>		<b>4,688</b>	<b>7,970,502</b>	<b>.48</b>	<b>1,908,935</b>	<b>Clinician at \$72.60 per hour; Clerical staff at \$35.66 per hour</b>	<b>\$114,150,979.08</b>

**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 the HIS V3.00.0 for provider training, preparation of HIS V3.00.0 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 HIS V3.00.0 data. The work to maintain this 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 this 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, this 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 2 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 HIS V3.00.0 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 HIS Manuals and Materials	\$ 25,000
Contractor Costs for Receipt and Storage of HIS Data	\$ 550,000
Cost for Aggregation & Data Analysis	\$ 500,000
Costs for Upkeep & Maintenance of HIS Data Submission Software by CMS/DQSAS	\$ 500,000

**TOTAL COST TO FEDERAL GOVERNMENT: \$1,583,500**

**15. Changes in Burden**

This information collection request is being submitted as a revision request. Burden hours have been reduced as a result of removing Section O of the discharge assessment and decreasing the time necessary to complete the discharge assessment. The previously approved burden hours are 686,631.

To determine the reduction of burden of hours to reflect removing Section O from discharge assessment, we estimate it would reduce the time to complete the discharge assessment by 4.2 minutes of clinical staff labor. The reduction of burden to collect the revised HIS discharge assessment is 92,989 hours (309,521[current HIS discharge assessment] - 216,532[without Section O]). The total burden hours are 1,908,935; that is divided by 3 years results in the annual burden hours of 636,312.

To determine the cost savings from Section O removal we use the reduced clinician labor hours. The removal of Section O reduces total annualized cost to complete the discharge assessment by

-\$6,751,015<sup>21</sup> (4.2 min\*(72.60/60)\* 1,328,417) compared to retaining HIS. This reflects the updated labor rates and increased number of respondents and responses from the previously approved burden hours.

**Summary of Reduced Burden Hours**

<b>Regulation Section(s)</b>	<b>Total # of Hospices</b>	<b># of Submitted Assessments</b>	<b>Burden per Assessment</b>	<b>Total Burden across all Hospices (hours)</b>	<b>Hourly Labor Costs (\$)</b>	<b>Total Costs (\$)</b>
Discharge Assessment Burden Reduction	4,668	1,328,417	-4.2 minutes for clinical staff	<b>-92,989</b>	Clinical staff at \$72.60 per hour	<b>-\$6,751,015</b>

**16. Plans for Tabulation and Publication and Project Time Schedule**

As required by ACA 3004(c)(5)(E), CMS launched the Hospice Compare web site<sup>22</sup> in beginning of 2021 to publicly report hospice quality measurement data, including seven quality measures calculated from HIS data.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

CMS has no objection to displaying the expiration date. The expiration date appears in the top right corner of the first page of each instrument.

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21 Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017) and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” It has been determined that the FY 2021 Hospice Wage Index proposed rule, if finalized, is considered an EO 13771 deregulatory action. We estimate that this rule generates \$4,813,380.39 in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon.

22 Hospice Compare web site: [Hospice Compare](#)