

Appendix 1 – Comment and Response Document

Comment: CMS received one supportive comment indicating that the additional data sought by CMS for the calculation of the Hospice Visits when Death is Imminent measure pair does not represent a significant burden on providers and may result in useful information. Other commenters stated that CMS's burden estimates underestimate the costs of completing the HIS. One commenter stated that the typical admission assessment time is 45 minutes to 1 hour, and that staff travel can significantly increase costs. Another commenter stated that the costs of training and operational processes to support valid data abstraction should be included in the burden estimate.

Response: We thank the commenters for their feedback regarding the burden of the HIS V2.00.0, and the support of the new items used to collect data for the Hospice Visits when Death is Imminent measure pair. Regarding the cost estimates for the HIS Admission form, the HIS is a set of data elements that can be used to calculate 7 NQF endorsed quality measures and 2 new measures adopted in this rule. The HIS is **not** a patient assessment that would be directly administered to the patient and/or family or caregivers during the initial assessment or comprehensive assessment visit. Since the HIS is not intended to replace the initial/comprehensive assessment, the PRA burden estimates, by definition, do not include the time spent assessing the patient. HIS PRA burden estimates are intended to reflect only the time needed to complete HIS items, independent of clinical time spent assessing the patient. Similarly, PRA burden estimates are not intended to reflect costs of training and operational processes; these costs should be reflected in cost reports. Cost report

data may be considered in future payment reform. Burden estimates for completing the HIS data items were based on the HIS V1.00.0 and HIS V2.00.0 pilot tests. We recognize additional activities and efforts will be required to implement and use the HIS V2.00.0 as part of the quality reporting program.

We agree that it is important for hospices to learn about and understand the new HIS, and we plan to provide hospices with training resources to facilitate implementation of the HIS. We further acknowledge that specific training costs were not identified in the final rule because calculating the training burden is outside the scope of the information collection requirements.

Comment: One commenter stated that the addition of new items to the HIS Discharge record will require vendor software development and testing, hospice implementation, education and training, and internal validation. The commenter stated that the target implementation date of April 1, 2017 may not provide adequate time for implementation.

Response: CMS appreciates the commenter's feedback regarding the timeline for implementation and of the HIS V2.00.0. The HIS V2.00.0 is undergoing review as part of a PRA package under OMB number 0938–1153 and will be implemented April 1, 2017. CMS believes the April 1, 2017 implementation date will allow sufficient time for providers to update their clinical documentation systems and train staff on new HIS items. The timeline for implementation of the HIS V2.00.0 is consistent with the timeline from prior years when the HIS V1.00.0 was implemented. CMS expects training and implementation activities to take considerably less time for the HIS V2.00.0 compared to the HIS V1.00.0 since the HIS V2.00.0 can capitalize on existing infrastructures used by stakeholders for the HIS V1.00.0 and contains only 17 new item components (compared to the 60 item components that were implemented in

the HIS V1.00.0). Moreover, CMS encourages providers to begin preparations for HIS V2.00.0 implementation as soon as possible. The HIS V2.00.0 is currently available for review by software vendors and hospice providers. Some of the activities that are necessary prior to implementation can be done concurrently. For example, hospice education and training on the new items and data abstraction can be conducted at the same time as vendor development of software.

We are aware of the effort hospices and vendors will have to make to prepare for implementation of the HIS. The HIS pilot showed that implementing the HIS is feasible and that hospices are most likely already collecting the information needed to complete the HIS data items. A draft version of the HIS technical data specifications was posted on the CMS Web site on May 19, 2016. Thus, vendors have been provided with more than adequate time to develop products for their clients. We expect vendors to begin reviewing the draft technical data specifications as soon as they are posted. We encourage vendors to submit questions and comments to the HIS technical email box: HospiceTechnicalIssues@cms.hhs.gov. Software vendors should not be waiting for final technical data specifications to be posted to begin development of their own products. Therefore, we believe that vendors have been provided with adequate time and resources to meet the April 1, 2017 implementation date of the HIS.

For providers that currently use a vendor-designed software to complete HIS records, if a provider has concerns about the timeliness of release of HIS V2.00.0 items in vendor-designed software, CMS reminds providers that alternative means of completing HIS records (HART software) are available to all providers free of charge. As described in section III.C.7.c, HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Although

electronic submission of HIS records is required, hospices do not need to have an electronic medical record to complete or submit HIS data. In the FY 2014 Hospice Wage Index, final rule (78 FR 48258) we finalized that to complete HIS records providers can use either the Hospice Abstraction Reporting Tool (HART) software, which is free to download and use, or vendor designed software. HART provides an alternative option for hospice providers to collect and maintain facility, patient, and HIS Record information for subsequent submission to the QIES ASAP system. Once HIS records are complete, electronic HIS files must be submitted to CMS via the QIES ASAP system. Electronic data submission via the QIES ASAP system is required for all HIS submissions; there are no other data submission methods available. Hospices have 30 days from a patient admission or discharge to submit the appropriate HIS record for that patient through the QIES ASAP system. We will continue to make HIS completion and submission software available to hospices at no cost. We provided details on data collection and submission timing under the downloads section of the HIS Web site on the CMS.gov Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.html>.

Comment: One commenter stated that although the burden associated with the HIS assessment may not be unduly burdensome; the collective burden of various reporting requirements makes a large fiscal impact on hospices.

Response: We thank the commenters for taking the time to express their concerns about the burden and cost of data collection for the HQRP and other regulatory requirements. CMS attempts to reduce the regulatory burden of our quality reporting programs to the greatest extent possible. The estimated burden for completing the HIS V2.00.0 can be viewed here:

(<https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/>)

[PRA-Listing.html](#)). Specifically, CMS estimates 19 minutes per response for the Admission HIS and 14 minutes per response for the Discharge HIS. Details regarding the estimate can be found at <http://cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>. Comments concerning the accuracy of the time estimate(s) or suggestions for improving the HIS can be directed to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. With respect to the commenter's concern about additional expenses incurred as part of quality reporting, any additional costs incurred as part of quality reporting programs should be reported on the cost reports. Cost report data may be considered in future payment reform.

Comment: One commenter stated that the addition of the J0905 Pain Active Problem item to the HIS V2.00.0 would be burdensome to hospice providers since it requires an update to the Admission HIS documentation and the item will not be used in calculation of the Pain Assessment measure. The commenter suggested adding the item when a Patient Reported Outcome Pain Measure is implemented or when a Hospice Patient Assessment Instrument is developed.

Response: CMS thanks the commenter for their comments regarding the new item J0905, Pain Active problem. CMS would like to clarify our reasoning and intent behind the addition of the J0905 Pain Active Problem item. Since the HIS V1.00.0 was implemented on July 1, 2014, CMS has received an overwhelming amount of feedback from the provider community regarding the items in Section J: Pain of the HIS V1.00.0 (J0900). Pain Screening and J0910. Comprehensive Pain Assessment). These items correspond to the National Quality Forum (NQF) #1634 Pain Screening quality measure and the NQF #1637 Pain Assessment quality measure, respectively. NQF #1634 calculates the percentage of patients who were screened for pain within two days of

admission. Patients who screen positive for pain are included in the denominator for NQF #1637, which measures the percentage of patients who screened positive for pain who received a comprehensive pain assessment within 1 day.

Under current specifications for NQF #1634 and NQF #1637, if a patient is *not* in pain at the time of the first screening, that patient is not included in the denominator for NQF #1637—even if pain is an active problem for the patient. As such, if a patient is not in current pain at the time of the first pain screening, HIS V1.00.0 skip patterns direct providers to skip Item J0910, the comprehensive pain assessment item. RTI received feedback from the provider community that the measure specifications and associated skip pattern between J0900 and J0910 do not align with clinical practice, as clinicians will often complete a comprehensive pain assessment for patients when pain is an active problem but the patient is not in pain at the time of the screening. Providers further noted that some vendor-designed software built HIS skip patterns into clinical documentation systems and the skip pattern between J0900 and J0910 was thus restricting the ability of clinicians to document comprehensive assessments that were conducted per clinical best practice, but not required for the purposes of the HIS pain quality measures. Due to these factors, CMS has received feedback from the provider community to consider changing items in the pain section to align HIS pain items with current clinical practice.

Thus, directly in response to feedback from providers, CMS added the J0905 Pain Active Problem item to the HIS V2.00.0. We believe this addition will actually reduce burden on providers since it is better aligned with current clinical practice. The addition of J0905 also better aligns items in the pain section with items in Section J: Respiratory Status. CMS plans to analyze data from J0905 to inform future potential refinements to the NQF-endorsed pain quality measures.

