

**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 V2.00.0
FOR THE COLLECTION OF DATA
PERTAINING TO THE
HOSPICE QUALITY REPORTING PROGRAM

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Exhibit A

FY 2017 Hospice PRA Burden Estimate Calculation Worksheet

Exhibit B

FY 2014 Hospice PRA Burden Estimate Calculation Worksheet

Supporting Statement A
For Paperwork Reduction Act Submissions

***Hospice Item Set For the Collection of Data Pertaining to the
Hospice Quality Reporting Program
(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. This item set is used for the collection of quality measure data related to the Hospice Quality Reporting Program (HQRP). This Paperwork Reduction Act submission is for HIS V2.00.0. The HIS V2.00.0 will include the items as the HIS V1.00.0, with the addition of several new items for use in new measures, measure refinement, patient record matching, and future public reporting.

The HIS V2.00.0 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
- Visits when Death is Imminent

The HIS was developed specifically for use by hospices and contains data elements that can be used by CMS to collect patient-level data to calculate six National Quality Forum (NQF) endorsed quality measures, a modification of one NQF-endorsed measure, and two measures that are not yet NQF endorsed under the HQRP (see Table 1).

Table 1. NQF-Endorsed Measures Corresponding to the Hospice Item Set

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 (modified)	Beliefs/values addressed
(not yet NQF endorsed)	Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission
(not yet NQF endorsed)	Visits when Death is Imminent

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 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 Hospice Quality Reporting Program (HQRP) in the FY 2012 Hospice Wage Index Final Rule (76 FR 47318 through 47324, and 47325 through 47326).² 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 the first reporting period, hospices were required to gather data pertaining 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 National Quality Forum (NQF)-endorsed #0209 pain measure. Hospice providers were then required to report their data between 01/01/2012 and 04/01/2012.

In the CY 2013 HH PPS final rule (77 FR 67132 through 67136),³ 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),⁴ CMS finalized the specific collection of data items that support six NQF endorsed measures and one modified measure for hospice. Data for the 7 measures is collected via the HIS V1.00.0.

In the FY 2017 Hospice Wage Index Proposed Rule, CMS retains 7 measures that were previously adopted in the FY 2014 rule and proposes two new quality measures. The Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission is a composite measure created from components, which are currently adopted HQRP measures and calculated using existing items on the HIS V1.00.0; thus, no new data collection is required. The Hospice Visits when Death is Imminent Measure Pair would use data collected via 4 new HIS items. For one existing measure, NQF #1637 measure refinement requires the implementation of one new HIS item. Public reporting of hospice quality data is targeted for CY 2017. As such, the HIS v2.00.0 includes two new administrative items intended to support public reporting.

¹ Patient Protection and Affordable Care Act. Pub. L. 111-148. Stat. 124-119. 23 March 2010. Web. <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>.

² Medicare Program; Hospice Wage Index for Fiscal Year 2012; Final Rule, Federal Register/Vol. 76, No. 150 August 4, 2011. <http://www.gpo.gov/fdsys/pkg/FR-2011-08-04/pdf/2011-19488.pdf>

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. <https://www.gpo.gov/fdsys/pkg/FR-2012-11-08/pdf/2012-26904.pdf>

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. <https://www.gpo.gov/fdsys/pkg/FR-2013-08-07/pdf/2013-18838.pdf>

The HIS V2.00.0 contains items to calculate the 7 adopted NQF measures (and thus the composite measure), the Hospice Visits when Death is Imminent measure pair, as well as administrative items for patient record matching and future public reporting of hospice quality data.

Use of the HIS allows collection of standardized, patient-level data collection for quality reporting purposes as part of the HQRP. The use of this HIS is necessary in order to allow CMS to collect quality data from hospices in compliance with Section 3004 of the Affordable Care Act.

Section 3004 of the Affordable Care Act requires that the Secretary establish procedures for making the data submitted for the HQRP available to the public. In general, any measures selected for the HQRP be endorsed by the consensus-based entity, which holds a contract regarding performance measurement with the Secretary. This contract is currently held by NQF.

Implementation of the HIS V2.00.0 fulfills both of these requirements – the item set allows for standardized, patient-level data collection of data elements required to calculate the aforementioned quality measures. Secondly, data collection through the HIS has resulted in standardized data, which can be used to calculate the aforementioned quality measures in a manner consistent with the scientific methods required to create a publicly reported quality measure under the HQRP. There are no other reasonable or currently available alternatives for CMS to use for the collection of patient-level quality data from hospices that would fulfill the requirements of publicly reporting quality measures, set forth in the Affordable Care Act.

2. Purpose and Use of the Information Collection

All hospices providers must submit the specified type and amount quality data for participation in the Hospice Quality Reporting program to avoid a 2 percentage point reduction in the market basket update for FY 2014 and beyond.

There are two primary users of the Hospice QRP data. The first user is CMS, which collect 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 Hospice QRP, and at a later date for public reporting.

The second primary group of data users is the public, who will have access to this data after it is made available by posting on the CMS website. Public reporting of the Hospice Quality Reporting Program data will begin no earlier than spring/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 that is also used by HHAs for the Outcome and Assessment Information Set, Version C (OASIS-C), SNFs for the Minimum Data Set (MDS 3.0), and 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 effort, and the standardized data elements in the HIS to collect data on pain, respiratory status, medications, patient preferences, beliefs/values, and visits when death is imminent 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. The HIS V2.00.0 will replace the HIS V1.00.0.

5. Impact on Small Businesses or Other Small Entities

In order to minimize burden to 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 ICR places on the provider. CMS is asking hospices to collect and submit data elements that can be used to calculate six NQF-endorsed quality measures, a modification of one NQF-endorsed measure, and two measures that are not yet NQF endorsed. A pilot test of the data collection for new items showed 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 will be used in hospices to collect quality data specific to the six NQF-endorsed quality measures, a modification of one NQF-endorsed measure, and two measures that are not yet NQF endorsed. 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, reduce the market basket update by 2 percentage points for any hospice that does not submit quality data submission for a fiscal year. CMS did begin collection hospice QRP data on 10/01/2012. 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

The 60-day Federal Register notice was published on April 28, 2016 and the comment period ended on June 20, 2016.

Since 2014, CMS has consulted with various industry associations such as the National Hospice and Palliative Care Association, the National Association for Home Care and Hospice, and the Visiting Nurses Associations of America to solicit input on proposed changes to the HIS instrument. CMS also recruits and convenes Technical Evaluation Panels (TEPs) composed of hospice professionals, experts in quality measurement, and beneficiary representatives to provide advice on HIS measure refinement. Feedback from the above mentioned entities has led to HIS item changes to support the generation and future public reporting of endorsed quality measures. In addition to the public comment period included in the federal register process as above, the HIS V2.0.0 data set was informed by comments from numerous individuals, providers, state associations, professional associations, and the hospice industry in response to publication for public comment in the Federal Register as part of prior OMB PRA review processes to create HIS V2.0.0. Public comments received via the Federal Register did not result in additional modifications, as of the close of the 60-day comment period.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts as a condition of complying with these ICRs.

10. Assurance of Confidentiality Provided to Respondents

The patient-level data collected using the HIS 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 his/her 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. A System of Records will be established for this ICR prior to the time that it is implemented.

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 = 4,259⁵

Total number of admissions to all hospices per year = 1,248,419⁶

Total number of admissions to all hospices over three years = 3,745,257

⁵ Quality Improvement and Evaluation System (QIES) List of Hospice Providers, January 2016

⁶ The discharge number was calculated using the number of HIS discharge assessments submitted October 1, 2014 – September 30, 2015.

Estimated average number of admissions to each hospice:

- **per year:** 1,248,419 admissions to all hospices / 4,259 hospices = 293 admissions per hospice per year
- **per month:** 1,248,419 admissions to all hospices / 4,259 hospices / 12 months per year = 24 per month
- **over 3 years:** 3,745,257 admissions to all hospices over 3 years / 4,259 hospices = 879 per 3 years

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

- **per year:** 1,248,419 admissions to all hospices per year x 2 Hospice Item Set records (1 Admission Record and 1 Discharge Record) per patient = 2,496,838 records per year
- **per month:** 2,496,838 Hospice Item Set records per all hospices per year / 12 months per year = 208,070 per month
- **over 3 years:** 2,496,838 Hospice Item Set records per all hospices per year x 3 years = 7,490,514 per 3 years

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

- **per year:** 2,496,838 Hospice Item Set records per all hospices / 4,259 hospices = 586 records per hospice per year
- **per month:** 208,070 Hospice Item Set records per all hospices per month / 4,259 hospices = 49 per month
- **over 3 years:** 7,490,514 Hospice Item Set records per all hospices per 3 years / 4,259 hospices = 1,759 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 @ \$67.10/hr.⁷

9 minutes nursing/clinical staff time to abstract data for Discharge Record – paid @ \$67.10/hr.

5 minutes administrative/clerical staff time to upload Assessment Record data – paid @ \$32.24/hr.⁸

5 minutes administrative/clerical staff time to upload Discharge Record data – paid @ \$32.24/hr.

Nursing Time:

⁷ The adjusted hourly wage of \$67.10 per hour for a Registered Nurse was obtained using the mean hourly wage from the May 2015 U.S. Bureau of Labor Statistics, \$33.55. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See <http://www.bls.gov/oes/current/oes291141.htm>

⁸ The adjusted hourly wage of \$32.24 per hour for a Medical Secretary was obtained using the mean hourly wage from the May 2015 U.S. Bureau of Labor Statistics, \$16.12. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See <http://www.bls.gov/oes/current/oes436013.htm>

- 23 minutes x 293 Hospice Item Sets per each hospice per year / 60 minutes per hour = 112.36 nursing hours per each hospice per year
- 112.36 hours per year x \$67.10 per hour = \$7,539.66 nursing wages per each hospice per year
- \$7,539.66 per each hospice per year x 4,259 hospice providers = \$32,111,417.38 nursing wages per all hospices per year
- \$7,539.66 per each hospice per year x 3 years = \$22,618.98 nursing wages per each hospice over 3 years
- \$32,111,417.38 per all hospices per year x 3 years = \$96,334,252.13 nursing wages for all hospices over 3 years

Administrative Assistant Time:

- 10 minutes x 293 Hospice Item Sets per each hospice per year / 60 minutes per hour = 48.85 administrative/clerk hours per each hospice year
- 48.85 hours per year x \$32.24 per hour = \$1,575.06 administrative/clerk wages per each hospice per year
- \$1,575.06 per each hospice per year x 4,259 hospice providers = \$6,708,171.43 administrative/clerk wages per all hospices per year
- \$1,575.06 per each hospice per year x 3 years = \$4,725.17 administrative/clerk wages per each hospice over 3 years
- \$6,708,171.43 per all hospices per year x 3 years = \$20,124,514.28 administrative/clerk wages per each hospice over 3 years

Total annualized cost to each hospice provider:

\$7,539.66	Nursing wages per each hospice per year
\$1,575.06	Administrative assistant wages per each hospice per year
\$9,114.72	Total

Total annualized cost to all hospice providers:

\$32,111,417	Nursing wages per all hospice providers per year
\$6,708,171	Administrative assistant wages per all hospice providers per year
\$38,819,589	Total

Total 3-year cost to each hospice provider:

\$22,618.98	Nursing wages per each hospice over 3 years
\$4,725.17	Administrative assistant wages per each hospice over 3 years
\$27,344.16	Total

Total 3-year cost to all hospice providers:

\$96,334,252	Nursing wages per all hospice providers over 3 years
\$20,124,514	Administrative assistant wages per all hospice providers over 3 years
\$116,458,766	Total

PART 3. Additional Calculations

Average monthly cost to each individual hospice provider:

\$38,819,589 for all Hospices per year / **4,259** hospices / **12** months per year = **\$759.56**

Cost to provider per each individual hospice patient:

\$38,819,589 for all hospices per year / **1,248,419** Hospice Item Sets per year = **\$31.10**

Table 2 – Summary of Burden Hours and Costs

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Cost (\$)
Hospice Item Set Admission Assessment (CMS-10390)	0938-1153	4,259	1,248,419 per year	0.233 clinician hours; 0.083 clerical hours	395,333 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$22,900,166
Hospice Item Set Discharge Assessment (CMS-10390)	0938-1153	4,259	1,248,419 per year	0.150 clinician hours; 0.083 clerical hours	291,298 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$15,919,423
3-year total	0938-1153	4,259	7,490,514	0.55 hours	2,059,891 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$116,458,766

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 V2.00.0 for provider training, preparation of HIS V2.00.0 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. 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 Hospice Quality

Reporting Program. In addition, the federal government will also incur costs for help-desk support that must be provided to assist Hospice 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 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. Explanation for Program Changes or Adjustments

We estimate the annualized yearly burden per each hospice to be 161 hours, or \$9,114.72, and the annualized burden across all hospices to be 686,630 hours, or \$38,819,589.

In a previous PRA package, which was published in the Federal Register on August 7, 2013,⁹ we estimated that the total annualized burden to each hospice for the reporting of hospice quality measure data would be \$3,818.26 and the annualized burden across all hospices in the U.S. would be \$14,287,929. (See Exhibit B).

We have noted that there will be some increase in burden associated with the use of the HIS V2.00.0. We estimate that the increase to each individual hospice will be approximately 21 hours, or \$5,296, and the total increase in burden across all 4,259 hospices will be approximately 160,803 hours, or \$24,531,660. (See Exhibit A, Appendix 4). We believe that this increase in burden can be attributed to several factors. First, the burden calculation used in the previous PRA package was based on the use of the HIS v1.00.0. HIS V2.00.0 includes 17 additional items for response: 3 new items in the Admission assessment, and 14 new items in the Discharge assessment. These additional items will be used for:

- Data collection for a set of two paired quality measures under development to assess hospice visits when death is imminent
- Refinement of quality measure NQF #1637

⁹ <https://www.gpo.gov/fdsys/pkg/FR-2013-08-07/pdf/2013-18838.pdf>

- Additional administrative items for patient record matching and future public reporting of hospice quality data

In addition, the numbers of patients and hospices have increased. We use updated information from the Center for Medicare regarding the current number of Medicare-participating hospices in the U.S. to inform our burden calculations. This figure has increased since the previous PRA submission and thus has increased the burden calculation included in this package.

Finally, this burden estimate uses new wage calculations as compared to the HIS V1.00.0 calculations. We have adjusted all wage estimates by a factor of 100 percent to include fringe benefits. Because of this increase in the input wages, the change in cost to hospices appears to be much larger than the change in burden hours.

This quality reporting program was mandated by Section 3004(c) of the Affordable Care Act, (1814(i)(5)(A)(i) of the Social Security Act) and therefore, this burden is statutorily mandated:

- In order for CMS to meet the requirements set forth in section added by section 3004 (c) of the Patient Protection and Affordable Care Act) which states that the Secretary of the Department of Health and Human Services should establish a quality reporting program for hospices by Fiscal Year 2014.
- In order for each hospice to comply with the reporting requirements of ACA Section 3004(c).
- In order for each hospice to be entitled to receive their annual market basket for update beginning in Fiscal Year 2014.

16. Plans for Tabulation and Publication and Project Time Schedule

At this time, CMS is making plans for the public reporting of Hospice quality measure data as required by ACA 3004(c)(5)(E). This public reporting is tentatively planned to begin no earlier than spring/summer 2017.

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

CMS requests an exemption from displaying the expiration date of this PRA package approval, as these forms are to be used on a continuing basis for hospices' compliance with the requirements of the HQR. P.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certifications statement.