Supporting Statement for the Information Collection Requirements
in 42 CFR 485 Critical Access Hospital Conditions of Participation
CMS-10239

INTRODUCTION
This information collection package is being submitted as a revision of the currently approved collection. We are adding a new information collection requirementthat is based upon the conditions for participation (CoP) contained in CMS-3228-F, Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients, published by CMS on November 19, 2010 (75 FR 70831-70844).

We are not including burden associated with most patient-related activities (such as healthcare plans, patient records, and clinical records) in this information collection request because these activities would take place in the absence of the Medicare and Medicaid programs. These activities are considered usual and customary business practices and as stated in 5 CFR 1320.3(b)(2) are exempt from the PRA.

A. BACKGROUND
Section 1820 of the Act, as amended by section 4201 of the Balanced Budget Act of 1997 (Pub. L.105-33) provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFP), under which individual States may designate certain facilities as CAHs. The MRHFP replaced the Essential Access Community Hospital (EACH)/Rural Primary Care Hospital (RPCH) program.

This document represents all CAH CoPs currently effective. Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2006 National Occupational Employment and Wage Estimates found at www.bls.gov.

The information collection requirements described herein are needed to implement the Medicare and Medicaid CoPs for 1,189 (1,290 minus the 101 CAHs with DPUs) CAHs.

485.618(d)(2)(iii)- Emergency Services – The State must maintain documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency. This information is included in each State's rural healthcare plan and is maintained by the State. Therefore, no burden is being attributed to this task.

485.631(b)(2)- Responsibilities of the Doctor of Medicine or Osteopathy- A doctor of medicine or osteopathy must be present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide medical direction, medical care services, consultation, and supervision. The extraordinary circumstances must be documented in the CAH's records. We believe that this can be documented in the monthly meeting notes of the board. No burden is being assessed for

this requirement, as minutes of meetings (board and staff level) are common and practical activities for the industry.

The salary estimates contained in this package are based on the following healthcare personnel:

“Clerical person” refers to the BLS 2006 median salary for healthcare support workers, all healthcare workers not listed separately. The estimated median annual salary of $26,990 for all healthcare support workers at www.bls.gov was used to calculate an estimated hourly rate of $12.98 per hour (i.e., $26,990 divided by 52 weeks per year divided by 40 hour per week).

“Records technician” refers to medical records and health information technicians, who, according to the BLS, have a median annual income in 2006 of $28,030. Thus, the hourly rate used in this report is $13.48
(i.e., $28,030 divided by 52 weeks per year divided by 40 hours per week).

“Clinician” refers to the BLS 2006 national median salary for a registered nurse ($27.54 per hour), annual salary $57,280.

“Coordinator” refers to the BLS 2006 national median salary for nurse managers ($35.26 per hour, $73,340 annual salary).

The “physician” salary is based on the median hourly wage of the U.S. Department of Labor’s 2006 BLS. The wage is equal to or greater than $70 per hour or $145,600 per year.

“Administrator” refers to the BLS 2006 national median wage for management occupation, chief executives. The wage is equal to or greater than $70 per hour or $145,600 per year.

These CAH requirements allow CAHs greater flexibility in the utilization of their staff and resources while increasing quality control requirements to assure patient health and safety.

2010 Revisions for §482.635(f)

On April 15, 2010, the President issued a Presidential memorandum on Hospital Visitation to the Secretary of Health and Human Services. The memorandum may be viewed on the web at: http://www.whitehouse.gov/the-press-office/presidential-memorandum-hospital-visitation. As part of the directives in that memorandum, the Department, through the Office of the Secretary, tasked CMS with developing proposed requirements for hospitals, including critical access hospitals (CAHs) that would address the right of a patient to choose who may and may not visit him or her. In the memorandum, the President pointed out the plight of individuals who are denied the comfort of a loved one, whether a family member or a close friend, at their side during a

time of pain or anxiety after they are admitted to a hospital. The memorandum indicated that these individuals are often denied this most basic of human needs simply because the loved ones who provide them comfort and support do not fit into a traditional concept of "family." The President also emphasized the consequences that restricted or limited visitation has for patients. Specifically, when a patient does not have the right to designate who may visit him or her simply because there is not a legal relationship between the patient and the visitor, physicians, nurses, and other staff caring for the patient often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions, medications, and allergies, particularly if the patient has difficulties recalling or articulating, or is totally unable to recall or articulate this vital personal information. Many times, the individuals who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to the CAH staff. In addition, the President noted that many States have already taken steps to ensure that a patient has the right to determine who may and may not visit him or her, regardless of whether the visitor is legally related to the patient.

The existing CAH CoPs at 42 CFR part 485 do not contain a specific CoP regarding a patient's visitation rights. Therefore, we added a new standard on visitation rights for patients at §485.635(f). In addressing the President's directive to ensure patient visitation rights, we focused on developing requirements to ensure that CAHs protect and promote patient visitation rights in a manner consistent with that in which CAHs are currently required to provide services.

The information collection requirements described herein are needed to implement the Medicare and Medicaid CoPs for the 1,314 CAHs that we estimate will need to take steps to comply with the ICR requirements in this final rule. The information collection requirements for CAHs have been reported in a separate package under CMS-10239.

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2009 National, State, Metropolitan, and Nonmetropolitan Area occupational Employment and Wage Estimates found at www.bls.gov. The salary estimates contained in this package are based on the following healthcare personnel:

"Administrator" refers to the BLS 2009 national median wage for management occupation, chief executives. The wage was $59.05 per hour, or $122,824 per year.

B. JUSTIFICATION

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR Part 485. These regulatory requirements implement sections 1102, 1138, 1814(a)(8), 1820(a-f), 1861 (mm), 1864, and 1871 of the Social Security Act (the Act). Section 1861(e) of the Act authorizes promulgation of regulations in the interest of the health and safety of individuals who are furnished services by a hospital. The Secretary may impose

additional requirements if the requirements are necessary and in the interest of the health and safety of the individuals who are furnished services by hospitals.

Sections 1820 and 1861 (mm) of the Act provide that critical access hospitals participating in Medicare meet certain specified requirements. CMS has implemented these provisions in 42 CFR Part 485 Conditions of Participation for Critical Access Hospitals (CAHs). The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in CAHs.

CMS deems CAHs to meet the conditions if they are accredited by the Joint Commission on Accreditation of Health Organizations (JCAHO) or the American Osteopathic Association (AOA). The JCAHO and AOA establish standards that CAH health care professionals use to measure their performance and health care delivery.

Under the authority of Section 1865 of the Act, CMS does not survey for the CoPs at the 234 JCAHO and AOA accredited CAHs. These accrediting organizations are granted deemed status because their standards have been determined to be at least equivalent to or more stringent than CMS's CoPs for CAHs. To the extent that the JCAHO and the AOA have higher standards than the Medicare CAH CoP, CMS is not concerned with such "higher" requirements. However, in the instances where the JCAHO or AOA CAH accreditation standards are less stringent than the Medicare CoPs, CMS works with the accreditation organization to assure:

- Appropriate changes are made to their standards, or
- The accrediting organization notifies the accredited CAHs that they must meet Federal requirements that may be more stringent than the accrediting organizations' standards.

Federal standards and the standards of an accrediting body may deviate from one another as outlined at 1865(a)(4) of the Act. It states an accrediting body must demonstrate that all of the applicable conditions or requirements of the title are met or exceeded. The Act further provides at 1865(b)(2), that the Secretary shall also consider the following, "The accrediting body requirements for accreditation, survey procedures, ability to supply information for use in enforcement activity, monitoring procedures for providers found to be out of compliance with our requirements, and the ability to provide the Secretary with the necessary data for validation."

There are 1,183 CAHs that must meet the CAH CoPs and 101 CAHs with DPUs that must meet the hospital CoPs in order to receive program payment for services provided to Medicare or Medicaid patients. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 restrained the growth of the program by terminating the State's authority to designate a CAH as a necessary provider as of January 1, 2006. As a result, CMS has certified very few additional CAHs in 2006 because almost all hospitals that meet the distance and size criteria have already converted to CAH status. Therefore, we anticipate that no more than 2 new CAHs per year will become certified

under Medicare and Medicaid. The total number of CAHs for purposes of this information collection request will be 1189 (1183 existing + 6 over a 3-year period).

We believe many of the requirements applied to these CAHs will impose no burden since a prudent institution would self-impose them in the course of doing business. Regardless, we have made an attempt to estimate the associated burden for a CAH to engage in these standard industry practices.

However, statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating CAHs require the inclusion of these requirements in standards for care provided in CAHs. The information requirements contained within the regulations are comparable to those of JCAHO and are necessary safeguards against potential overpayments, excessive utilization, and poor health care that may occur when such standards are loose or non-existent.

2010 Revisions for §482.635(f)

These regulatory requirements implement the directives contained in the Presidential Memorandum on Hospital Visitation dated April 15, 2010. As part of the directives of this memorandum, the Department of Health and Human Services, through the office of the Secretary, tasked CMS with developing proposed requirements for hospitals, including CAHs, that would address the right of a patient to choose who may and may not visit him or her.

The current CAH CoPs do not address visitation rights for patients. Thus, to implement the directives contain in the Presidential Memorandum on Hospital Visitation, it was necessary to develop a separate CAH CoP to ensure a patient's visitation rights.

2. Information Users

The CoPs and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a CAH qualifies for a provider agreement under Medicare and Medicaid. CMS and the healthcare industry believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

2010 Revisions for §482.635(f)

The ICRs contained in this regulation are designed to assure that CAHs have written policies and procedures regarding a patient's visitation rights. Surveyors use this CoP and the accompanying requirements specified in this regulation as a basis for determining whether a CAH qualifies for a provider agreement under the Medicare and Medicaid programs.

3. Improved Information Technology

CAHs may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Similar Information

These requirements are specified in a way that does not require a CAH to duplicate its efforts. If a facility already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one facility to another acceptable.

5. Small Business

These requirements do affect small businesses. However, the general nature of the requirements allows facilities the flexibility to meet the requirements in ways that are consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information, or require its collection on a routine basis. Nor does the rule prescribe the manner, timing, or frequency of the records or information required to be available. CAH records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on June 28, 2010.

9. Payment/Gift To Respondent

We do not plan to provide any payment or gifts to respondents for the collection of this information.

10. Confidentiality

Normal medical confidentiality practices are observed. Information will be help private to the extent provided by law.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates

485.610 – Standard: Relocation of CAHs with a necessary provider designation

A CAH that has a necessary provider designation and relocates its facility can continue its designation only if the relocated facility in its new location serves at least 75 percent of the same service area; provides at least 75 percent of the same services and is staffed by 75 percent of the staff at its original location.

Prior to any relocation of a necessary provider CAH, the CAH must send a letter of intent to the State Agency and to the CMS Regional Office. The letter should state that the CAH plans to relocate and must attest that it will continue to be essentially the same provider serving the same community but at a new location. The Administrator, or other appropriate person, would have to draft an attestation letter stating that the facility meets the conditions to relocate and continue its necessary provider designation. We estimate that approximately 5 facilities a year will relocate and that it would take one hour to draft the letter and 30 minutes for clerical personnel to put it into a final form.

As stated in 5 CFR 1320.3(c)(4), this information collection requirement is exempt from the PRA as it will impose burden on less than 10 entities on an annual basis.

485.616 Standard: Agreements with network hospitals.
Each CAH must have an agreement with respect to credentialing and quality assurance with at least one hospital that is a member of the network; one QIO or equivalent entity; or one other appropriate and qualified entity identified in the State rural health care plan. The agreement should include patient referral and transfer. The initial development of the agreement will take approximately two hours. We estimate that no more than two CAHs a year become certified under Medicare and Medicaid.

485.618(c) – Standard: Blood and blood products.

The CAH must update policy agreements with blood collection establishments to ensure prompt notification about potentially infected blood and blood products. We estimate that CAH will utilize one coordinator and one clerical person for one hour each to update the policy agreements.

Hours/Est. Salary/#of CAH	Annual Burden Hours	Annual Cost Estimate
1 coordinator x 1,189CAHs x 1 hr x $35.26	1,189	$41,924.14
1 clerical person x 1,189 CAHs x 1 hr x 12.98 hrs	1,189	$15,433.22
TOTAL	2,378	$57,357.36

485.618(e) – Standard: Coordination with emergency response systems.

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hour a day basis to receive emergency call, provide information on treatment of emergency patients and refer patients to the CAH or other appropriate locations for treatment.

The burden associated with this requirement is the time and effort necessary to establish procedures to respond to emergencies on a 24-hour basis. While this requirement is subject to PRA, we believe that the burden associated with this requirement is exempt from the PRA as defined in both 5 CFR 1320.3(b)(2) and (b)(3). As stated in 5 CFR 1320.3(b)(2), the burden imposed by this requirement is exempt from the PRA as it is considered to be usual and customary business practice. In addition, the burden imposed by this requirement would exist even in the absence of the Federal requirement. As stated in 5 CFR 1320.3(b)(3), the burden is exempt from the PRA since the information is collected on the State or local level as well.

485.623 (d)(4) – Standard: Life Safety for fire.

The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association. If CMS finds that the State has a fire and safety code imposed by the State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC if waiving the provisions of the LSC does not adversely affect the health and safety of patients. This regulation requires a CAH to maintain written evidence of regular inspections and approval by State fire control agencies. We estimate that the burden associated with maintaining written evidence of State inspections and approval would be an average of 30 minutes for clerical personnel to file the documentation.

Hours/Estimated Salary/ Number of CAHs	Annual Burden Hours	Annual Cost Estimate
1 clerical person at $12.98/hr. x .5 hr.	595	$7,716.61

x1,189 CAHs		

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Section 485.631-Staffing and staff responsibilities

The CAH's professional health staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes. The burden associated with this requirement is the time it takes a physician and physician assistant, nurse practitioner, or clinical nurse specialist to review the CAH's written policies and make appropriate changes or updates.

Hours/Estimated Salary/ Number of CAHs	Annual Burden Hours	Annual Cost Estimate
1 physician at $70 x 1 hrs. x 1189CAHs	1,189	$82,810
1 Physician assistant, nurse practitioner, or clinical nurse specialist at $36.05 x1 hrs x 1189 CAHs	1,189	42,647.15
1 clerical staff at $12.98/hr x ½ hr x 1189CAHs	594.5	7,716.61
Totals	2,973	$133,173.76

Section 485.635(a) – Patient care policies; 485.638 – Clinical Records

The CAHs health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law. The policies include a description of the services the CAH furnishes directly and those furnished through agreement or arrangement; policies and procedures for emergency medical services and guidelines for medical management of health problems that include the conditions requiring medical consultation and/or patient referral and the maintenance of health care records.

Healthcare industry organizations establish standards that healthcare professionals use to measure their performance and the health care provided in CAHs. The information requirements contained within these regulations are comparable to such industry standards and are necessary safeguards against potential overpayments and poor health care procedures, which may occur when standards are insufficient.

We are not including burden associated with certain patient related activities such as healthcare plans, patient records, clinical records, etc., because prudent institutions already incur this burden in the course of doing everyday business. As stated in 5 CFR 1320.3(b)(2), the burden associated with usual and customary business practices is exempt from the PRA. Further, state laws require providers to maintain patient records. (For example, the annotated Code of Maryland (¶ 10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law requires record information that should include: documentation of personal interviews;

diagnosis and treatment recommendations; records of professional visits and consultations; consultant notes which shall be appropriately initialed or signed.

486.635 (c)(3) – Standard: Services provided through agreements or arrangements

The CAH must maintain a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided. The person principally responsible for the operation of the CAH is also responsible for services furnished in the CAH whether or not they are furnished under arrangements or agreements. The burden associated with this requirement is the time it takes for the administrator to ensure that the list is updated and a clerical person to maintain the list. We estimate that it will take an administrator and a clerical staff each an hour annually to update the list.

Hours/Estimated Salary/ Number of CAHs	Annual Burden Hours	Annual Cost Estimate
1 hr x 1,189 CAHs	1,189	
1 Administrator @ 70 x 1 hr x 1,189		$83,230
1 Clerical @ $12.98 x 1 hr x 1,189	1,189	$15,433.22
Total	2,378	$98,663.22

Section 485.635(f) Condition of participation: Provision of services

Section 485.635(f) requires a CAH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in §485.635(f) (1) through (f)(4).

The ICR burden associated with this requirement is the time and effort necessary for a CAH to develop written policies and procedures with respect to visitation rights of patients and to distribute that information to the patients. The CAH administrator or other appropriate person would draft the policies and procedures and ensure that the information was distributed to the patients in his or her facility. The Administrator could accomplish this task in 15 minutes.

Hours /Est. Salary/ # of CAHs (1,314)	Annual Burden Hours	Annual Cost Estimate
1 Administrator @ $59.05/hr X .25 hrs X 1 a yr. X 1,314	329	$19,398
SUB-TOTAL	**329**	**$19,398**

485.641 – Standard Periodic evaluation and quality assurance review

CAHs that participate in the Medicare or Medicaid programs shall evaluate its total program annually and the evaluation includes a review of the utilization of the CAH services. The purpose of the evaluation is to determine whether the utilization of services was appropriate, if the established policies were followed and if any changes are needed. The CAH must have an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. We believe that the writing of internal policies governing the CAH's approach to the development, implementation, maintenance, and evaluation of the quality assurance program will impose minimal burden. We estimate that it will take 3 hours annually for the existing CAHs to update their policies and document the outcome of all remedial action. If the nurse coordinator does the updating or writing of the policies, we estimate the cost at $125,772.42 per year.

Hours/Estimated Salary/Number of CAHs	Annual Burden Hours	Annual Cost Estimate
Updating policies: 1 coordinater @ $35.26 per hr. x 3 hrs annually x 1,189 CAHs	3,567	$125,772.42
Totals	3567	$125,772.42

485.643(a) and (b) - CoP: Organ, tissue, and eye procurement

CAHs are required to have and implement written protocols that:
(1) Incorporate an agreement with an OPO under which it must notify the OPO in a timely manner of all deaths or imminent deaths;
(2)_Incorporate an agreement with at least one tissue bank and at least one eye bank to ensure that all usable tissues and eyes are obtained from potential donors.

Based on 2005 data from the Medicare Provider and Analysis Review (MEDPAR) hospital records, 13,145 deaths occurred in CAHs. There are approximately 1,189 CAHs (excluding the 101 CAHs that have a DPU). If the average call to an OPO to report a death takes 5 minutes and the total number of calls made equals 13,145, the annual burden is approximately 1,095 hours. If each call is made by a clinician who is paid $27.54 per hour, the annual cost burden would be $30,155.70.

Hours /Est. Salary/ # of CAHs	Annual Burden Hours	Annual Cost Estimate
1 clinician @ $27.54/hr. x .0833 hours per call x 13,145 calls	1,095	30,155.70
TOTALS	**1,095 (454,400)**	**$30,155.70**

485.645 (d) SNF Services

CAHs that provide long term care (swing bed) services (SNF level care) must comply with section 483.12 (a) – Standard: Transfer and discharge rights.

The facility must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare. Before a facility can transferor discharge a resident the facility must notify the resident of the actions to be taken in writing and in a language and manner they understand. The burden associated with this requirement is the time and effort necessary to disclose the notice requirement referenced above to each patient. The 2005 MEDPAR data reported that 1,221 CAHs had a total of 398,565 discharges. . Based on this data, we estimate that on average, a third of the discharges were from swing beds. Therefore, we estimate a total of 132,855 annual discharges from CAHs.

We estimate that it will take a clerical staff at each CAH 5 minutes to notify each patient receiving SNF level care of the transfer or discharge. On average, we have estimated that a CAH that provides "swing-bed care" will transfer or discharge 104 residents annually (1,189 CAHs x 104 residents x .0833 minutes) with annual burden hours of 10,300.5 and an annual cost estimate of $133,701.

Hours/ Est. Salary/ # of CAHs	Annual Burden Hours	Annual Cost Estimate
1 Clerical @ 12.98/hr. x .0833 hours x 104 notices x 1189 CAHs	10,305	$133,701
Total	10,305	$133,701

Distinct Part Units (DPU)

To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a DPU, the facility provides no more than 10 beds in the DPU and must comply with the same CoPs as acute care hospitals.

Based on 2007 data from HRSA, 81 CAHs have psychiatric DPUs and 20 CAHs have rehabilitation DPU. CAHs that provide inpatient psychiatric and rehabilitation services in a DPU must comply with the hospital requirements specified in Subpart A, B, C, and D of part 482 on those units. The burden associated with the 101 CAH with DPUs is reported in CMS-R- 48.

13. Capital Costs

There are no capital costs.

14. Cost To Federal Government

Although the Federal Government does not collect this information, there are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to CAH compliance. Once state survey agencies have completed their surveys and if a final decision to terminate a CAH for noncompliance is to be made, such decisions are made by the RO.

15. Adjustments/ Program Changes

We are revising the currently approved information collection request to include the burden associated with the requirements in §485.635(f). We have adjusted the burden accordingly. No other changes have been made to this information collection request.

16. Publication and Tabulation Data

We do not plan to publish any of the information collected.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods were not used in developing this collection.