Supporting Statement for the Information Collection Requirements in 42 CFR 482.12, 482.13, 482.21, 482.22, 482.23, 482.24, 482.27, 482.30, 482.41, 482.43, 482.45, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62, 485.616 and 485.631
Hospital Conditions of Participation
CMS-R-48

INTRODUCTION

This information collection package is a request for a revision extension of the currently approved information collection requirements under CMS-R-48 (0938-0328). We have revised the burden estimates to include a new information collection requirement in §482.13(h), 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).

The current information collection requirements for CMS-R-48 are 42 CFR 482.12(d), 482.12(e)(2), 482.12(f)(2), 482.13(a)(1), 482.13(a)(2), 482.13(b), 482.13(d), 482.13(e), 482.13(f), 482.13(g), 482.13(h), 482.21(a), 482.21(b), 482.21(c), 482.21(d), 482.21(e), 482.22(c), 482.23(c)(2), 482.24(c)(2), 482.27(b)(2), 482.27(b)(3), 482.27(b)(5), 482.27(b)(6), 482.27(b)(7), 482.27(b)(8), 482.27(b)(9), 482.27(b)(10), 482.30(c)(1) and (d)(3), 482.41(b), 482.43, 482.45(a)(1), 482.45(b)(3), 482.53(d), 482.53(d)(3), 482.56(b), 482.57(b)(1), 482.60(c), 482.61, 482.62(a), 485.618, and 485.631.

We are not including burden associated with most patient-related activities (such as healthcare plans, patient records, and clinical records) in this package because these activities would take place in the absence of the Medicare and Medicaid programs.

A. BACKGROUND

The majority of the current Medicare hospital CoPs were finalized in 1987. However, in 1997, CMS (formerly HCFA) published a proposed rule to revise all the Medicare hospital CoPs.

Public, industry, and political response to pertinent issues raised in the proposed CoPs led to the finalization of certain portions of the regulation. Thus, this document represents the inclusion of all hospital CoPs currently effective. These hospital requirements allow hospitals greater flexibility in the utilization of their staff and resources while increasing quality control requirements to assure patient health and safety.

The information collection requirements described herein are needed to implement the Medicare and Medicaid CoPs for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. Thus, this package reflects the paperwork burden for a total of 4,991 (i.e., 4,890 hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 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 2006 National Occupational Employment and Wage Estimates found at www.bls.gov. The salary estimates contained in this package are based on the following healthcare personnel:

"Clerical person" refers to the BLS 2006 national average salary for unit clerks, secretaries, and other support staff. The estimated median annual salary of information and record clerks ($26,990), specifically for order clerks reported 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 hours per week).

"Records technician" refers to medical records and health information technicians, who, according to the BLS, had 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 average 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 was $70 per hour, or $145,600 per year.

"Administrator" refers to the BLS 2006 national median wage for management occupation, chief executives. The wage was $70 per hour, or $145,600 per year.

2010 Revisions for §482.13(h)

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 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 hospital 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 hospital CoPs at 42 CFR part 482 do contain a specific CoP regarding the overall rights of hospital patients in §482.13. However, there is no specific requirement regarding a patient's visitation rights. In addressing the President's directive to ensure patient visitation rights, we focused on developing requirements to ensure that hospitals protect and promote patient visitation rights in a manner consistent with that in which hospitals are currently required to protect and promote all patient rights under the current CoPs.

The information collection requirements described herein are needed to implement the Medicare and Medicaid CoPs for 4,860 hospitals 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 482. These regulatory requirements implement sections 1102, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v), and (z), 1864, 1871, 1883, 1902(a)(30), 1905(a) and 1913 of the Social Security Act (the Act). Hospitals receiving payment under Medicaid must meet the Medicare CoPs. 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 for the health and safety of the individuals who are furnished services by hospitals. Section 372 of the Public Health Service Act (42 U.S.C. 274) requires hospitals that perform transplants to be members of and abide by the rules of the Organ

Procurement and Transplantation Network (OPTN). The Medicare requirements at §482.45(b)(3) require reporting of organ-transplant-related data by transplant hospitals to the OPTN, the Scientific Registry, and the OPOs as requested. Transplant hospitals must also provide such data directly to the Department when requested by the Secretary.

Section 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 for the health and safety of the individuals who are furnished services in CAHs.

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

Under the authority of Section 1865 of the Act, CMS does not survey for the CoPs at the JCAHO-and AOA-accredited hospitals, some of which are CAHs. These accrediting organizations are granted deeming authority because their standards have been determined to be at least equivalent to or more stringent than CMS' CoPs for hospitals. To the extent that the JCAHO and the AOA have higher standards than the Medicare hospital CoP, CMS is not concerned with such "higher" requirements. However, in the instances where the JCAHO or AOA hospital 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 its accredited hospitals that they must meet Federal requirements that may be more stringent than the accrediting organization's standards.

Federal standards and JCAHO standards 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 4,991 hospitals, including CAHs with distinct part facilities, that must meet the CoPs in order to receive program payment for services provided to Medicare or Medicaid patients. We expect that no more than two new hospitals a year will become certified under Medicare and Medicaid.

We believe many of the requirements applied to these hospitals will impose no burden since a prudent institution would self-impose them in the normal course of doing

business. Regardless, we have attempted to estimate the associated burden for a hospital 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 hospitals require the inclusion of these requirements in standards for care provided in hospitals. 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 standards are loose or non-existent.

2010 Revisions for §482.13(h)

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 that would address the right of a patient to choose who may and may not visit him or her.

Section 482.13 of the current CoPs for hospitals does address overall patient rights. However, there is no specific CoP that addresses patient visitation rights specifically. Thus, to implement the directives contain in the Presidential Memorandum on Hospital Visitation it was necessary to develop a separate 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 hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care 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.

In terms of the hospital standard for blood and blood products, CMS issued an interim final rule (IFC) to take steps to ensure that hospitals do not make blood and blood products available to patients after they are notified that certain blood and blood products are potentially HIV or HCV infectious. The requirement for patient notification provides an opportunity for counseling, appropriate testing, early treatment, and precautions necessary to prevent further spread of HIV or HCV. The record keeping and reporting requirements ensure that hospital collection of this information serves preventive and remedial purposes. Without this information, CMS would be unable to monitor hospital compliance with these requirements and discharge our responsibility to protect patient health and safety.

2010 Revisions for §482.13(h)

The ICRs contained in this regulation are designed to assure that hospitals 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 hospital qualifies for a provider agreement under the Medicare and Medicaid programs.

3. Improved Information Technology

Hospitals may use various information technologies to store and manage patient medical records as long as they are consistent with existing confidentiality in record-keeping regulations at 42 CFR 482.24. 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.

2010 Revisions for §482.13(h)

The ICRs contained in this regulation are designed to assure that hospitals 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 hospital qualifies for a provider agreement under the Medicare and Medicaid programs.

4. Duplication of Similar Information

These requirements are specified in a way that does not require a hospital 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. Regarding blood and blood product standards, CMS, in concert with the Food and Drug Administration (FDA), has responsibility for review and oversight of potentially infectious HIV or HCV blood and blood products and "look-back" activities. Applicability of the CMS regulation at 482.27(c) is limited to hospitals that participate in the Medicare and Medicaid programs. The FDA regulation impacts blood banks and hospitals that do not participate in CMS programs. There is no overlap of these regulations. CMS and FDA have developed a memorandum of understanding to coordinate surveys of hospitals that have in-house blood banks to minimize the burden on facilities.

2010 Revisions for §482.13(h)

These requirements are specified in a way that does not require a hospital to duplicate its efforts. If a facility has already developed written policies and procedures, regardless of the format they are in, the facility is in compliance with these requirements. 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 the flexibility for facilities to meet the requirements in a way consistent with their existing operations. CMS has taken steps regarding the blood product standard to minimize burden on facilities by coordinating surveys where appropriate.

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. Hospital 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 and provide timely notification for transfusion recipients of the need for testing and counseling, as well as behavioral change to minimize the spread of infections.

2010 Revisions for §482.13(h)

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. Hospital policies and procedures 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 was 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

Documents related to notification become part of the patient's medical record and, therefore, are subject to safeguards for access, information release, patient consent, and other precautions for confidential information, whether in hard copy, film, or computer records. In addition to these existing confidentiality requirements in 42CFR 482.13(d) and 482.27, we are requiring that hospitals establish policies and procedures for notifying patients and documenting medical records regarding potentially HIV or HCV infectious blood and blood products to ensure confidentiality consistent with Federal, State, and local laws.

11. Sensitive Questions

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

12. Burden Estimates

482.12(d)(1), (2) and (4) - Standard: Governing Body-Institutional Plan and Budget
(d)(1) & (2) The facility must have an annual operating budget that includes an item-by-item identification of the anticipated income and expense components. The operating budget identifies the anticipated sources of financing and the objectives of each proposed capital expenditure.

The Administrator or other appropriate person would have to contact the governing body to see if any changes in plans for capital expenditure have been made during the year and to do the necessary paperwork to revise the existing plan. The Administrator could accomplish this task in 30 minutes and one clerical personnel could put it into final form in 15 minutes. The update would then need to be presented to and approved by a committee composed of representatives of the governing body, and the administrative staff. This could involve 3 professional individuals at 15 minutes each, for a total of 45 minutes.

Hours /Est. Salary/ # of Hospitals (6,085)	Annual Burden Hours	Annual Cost Estimate
1 admin.@ $70.00/hr X .50 hrs X 1 a yr. X 4,991 hospitals	2,495.50	174,685.00
Comm. review @ $70.00 X .75 hrs X 1 a yr. X 4,991 hospitals	3,743.25	262,027.50
Clerical @ $12.98/hr X .25 hrs X 1 a yr. X 4,991 hospitals	1,247.75	16,195.80

SUB-TOTAL	**7,486.50**	**$452,908.30**

(d)(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated expenditure in excess of $600,000, (or a lesser amount that is established in accordance with section 1122 (g)(1) of the Act, by the State in which the hospital is located).

Any facility planning capital expenditure of over $600,000 would have the information required by this regulation, such as land survey, building design, and budget. Only facilities with a capital expenditure of $600,000 or more would need to compile this information. It would take the Administrator approximately 3 hours to compile this information and one clerical person 30 minutes to reduce to final form.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 Admin. @ $70.00/hr X 3 hrs X 1 a yr. X 4,991 hospitals =	14,973.00	1,048,110.00
1 clerical @ $12.98/hr X .50 X 1 a yr. X 4,991 hospitals	2,495.50	32,391.59
SUB-TOTAL	**17,468.50**	**$1,080,501.50**

Hospitals are required to review and update the overall capital expenditure plan and the budget at least annually. Facilities adhering to good accounting and planning practice update and generally review their plan and budget on an annual basis. The overall plan and budget reflect the coordination of the hospital's services with other health care facilities and related community resources. It may take the Administrator one hour to review and update the plan and budget, and one clerical person 15 minutes to reduce to final form.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 administrator @ $70.00/hr X 1 hrs X 1 a yr. X 4,991 hospitals	4,991.00	349,370.00
1 clerical @ $12.98 hr X .25 X 4,991 hospitals	1,247.75	16,195.80
SUB-TOTAL	**6,238.75**	**$365,565.80**

Total Annual Hours	**31,193.75**
Total Annual Cost Estimates	**$1,898,975.60**

482.12(e)(2) - Standard: Governing Body-Contracted Services

The hospital must maintain a list of contracted services. The regulations require that a hospital be responsible for assuring that contractors meet all conditions of participation where applicable. Consequently, to be able to determine whether the hospital has done so,

the surveyor must know which services are contracted. We believe that the creation and maintenance of this list by the administrator and one clerical person will take 15 minutes per year.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 administrator @ $70.00/hr X .25 X 1 a yr. X 4,991 hospitals	1,247.75	87,342.50
1 clerical @ $12.98/hr x .25 X 1 a yr. X 4,991	1,247.75	16,195.80
TOTALS	**2,495.50**	**$103,538.30**

482.12(f)(2)- Standard: Governing Body- Emergency Services

When a hospital does not provide emergency services, there must be written policies and procedures governing the medical care provided, which is established by, and is the continuing responsibility of, the medical staff. This is necessary to assure proper treatment of emergencies, especially when a hospital does not provide emergency services. We estimate that at least five physicians and one clerical personnel would be involved in the development and review of these policies and procedures and that it will take a total of 1.5 burden hours. We estimate that 50 hospitals do not offer emergency services.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
5 physicians @ $70.00/hr X .25 X 1 a yr. X 50 hospitals	62.50	4,375.00
1 clerical@ $12.98/hr X .25 X l a yr. X 50 hospitals	12.50	162.25
TOTALS	**75.00**	**$4,537.25**

482.13(a)(1) and 482.13(a)(2)- Standard: Notice of Rights

Standard (a) requires notifying the patient of his rights and of whom to contact to file a grievance. We allow hospitals the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large measure, hospitals already have existing systems for handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with modification will most likely be offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We asked that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in hospitals each year; however, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to disclose the notice requirements referenced above to each patient. We estimate that on average it will take each of the 4,991 estimated hospitals 8 hours to develop the required notice (i.e., 4,991 hospitals x 8 hours = 39,928 hours to develop the notice) and that it will take each hospital 5 minutes (.0833 hours) to provide each notice, with an average of 7,414 hospital admissions annually (37,006,027 per the American Hospital Association's Hospital Statistics, 2007 (AHA) at www.aha.org), and with notices provided per hospital on an annual basis (i.e., 7,414 notices x .0833 hours/notice x 4,991 hospitals = 3,082,372.70 hours to provide notices). Therefore, the total annual burden associated with this requirement is 3,082,372.70 hours (39,928 hours to develop notices and 3,082,372.70 hours to provide notices).

In its resolution of the grievance, a hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each hospital 15 minutes to develop and disseminate the required notice. We further estimated in the final rule that 4,991 hospitals will provide 55 notices on an annual basis, a total annual burden of 68,626.25 hours.

Requirement	Number of Respondents/ Disclosures	Annual Hours per Respondent	Total Annual Burden
Develop notice	4,991 hospitals	8 hours per hospital	39,928.00 hrs
Provide notice	4,991 hospitals	.0833 hours per hospital X 7,414 notices per hospital annually	3,082,372.70 hrs
Inform patient	4,991 hospitals	.25 hrs. X 55 notices	68,626.25 hrs.

of grievance process		X 4,991 hospitals annually	
Annual Cost Estimates			
Develop notice	1 admin. @ $70.00 hr. X 8 hrs. X 4,991	2,794,960.00	
Provide notice	1 clerical person @ $12.98 hr. X .0833 hrs. X 4,991 hospitals X 7,414 notices	40,009,197.65	
Inform patient of the grievance process	1 clerical person @$12.98 hr. X .25 hrs. X 55 notices X 4,991 hospitals	890,768.72	
TOTAL Ann. Burden Hours			**3,190,926.90**
TOTAL Cost Estimates		**$43,694,926.37**	

* While this estimate may appear low, it is based on the fact that this requirement will be bundled and disclosed with other routine hospital admission disclosure requirements.

482.13(d) Standard: Confidentiality of Patient Records

Standard (d), which sets forth the patient's right to access information in his/her records, will involve minimal burden as many States' existing laws cover this point. We have not required disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the hospital can charge. In the preamble of the interim final rule, we deferred to State law and guidance on this point. In the absence of State law, the hospital should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and 1320.3(b)(3) because this requirement is considered standard industry practice and/or is required under State or local law.

In the Patient's Rights CoP final rule (71 FR No. 236) dated Friday, December 8, 2006), we made changes to the requirements in §482.13 that contain information collection

requirements. In this final rule, we combined the requirements set forth in the interim final rule under standard §482.13(e) Standard: Restraint for acute medical and surgical care and §482.13(f) Standard: Seclusion and restraint for management of violent, self-destructive or aggressive behavior into a single standard, §482.13(e) Standard: Restraint and seclusion. This change is designed to address restraint and seclusion use regardless of the treatment setting in which it occurs.

B. Anticipated Effects

1. Effects on Providers

We anticipate the impact of these finalized standards will vary widely among hospitals. Limited data have been gathered in the industry to date regarding the prevalence of restraint and seclusion use. Additionally, we only have estimates on the number of staff per hospital who may have direct patient contact, thus, warranting training. However, among the limited data available, it reflects the use of restraint or seclusion for behavior management only per the current requirement at §482.13(f).

Given these and a variety of other factors, we calculate estimates based on the average of the limited available data. In another example, with respect to training, this rule will have significantly less impact on a hospital that already has a proactive training program in place and has significantly reduced its restraint and seclusion use than it will in a hospital that has not independently taken such an approach. Factors such as size, services rendered, staffing, and patient populations vary as well.

The National Association of Psychiatric Health System (NAPHS) further discussed that there are approximately 250 freestanding specialty hospitals in the United States. This number does not include the approximately 1,400 behavioral health units of general hospitals or government (state and county) psychiatric specialty hospitals. The 1 hour rule applies to all these facilities.

a. Section 482.13(e) Standard: Restraint or seclusion.

Standard 482.13(e), previously entitled “Restraint for acute medical and surgical care” in the interim final rule with comment period, is now entitled “Restraint or seclusion” in this final rule. The existing regulation sets out the patient’s rights in the event he or she is restrained or secluded, and limits when and by whom restraint or seclusion can be implemented. We have combined the existing standards 482.13(e) and 482.13(f) for clarity since it is our goal to reduce the use of restraint or seclusion in all hospital settings.

In the previous §482.13(e)(3)(B), we stated the patient’s “treating” physician be consulted in the event of restraint or seclusion. However, based on comments we have revised the requirement at §482.13(e)(7) to reflect the need to consult the “attending”

physician, instead of the "treating" physician, as soon as possible if the attending physician did not order the restraint or seclusion.

We have revised and expanded §482.13(e)(4) to specify, at §482.13(e)(10), that a physician, other licensed independent practitioner, or trained staff meet the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. We also recognize there will be some impact associated with performing patient assessment and monitoring. However, we view patient assessment and monitoring as a standard component of patient care.

Section 482.13(f)(3)(ii)(c), now §482.13(e)(7), clarifies that the "attending" physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. Although this may minimally increase burden to hospitals, we believe it is a best practice for patient safety.

We have added elements at §482.13(e)(15) that monitoring must occur fact-to-face by trained staff or by using both video and audio equipment, when there is simultaneous use of restraint and seclusion. We have added elements at §482.13(e)(16) regarding the documentation that must be included in the patient's medical record when the patient is restrained or secluded, including the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior, the patient's behavior and intervention used, alternatives or other less restrictive interventions attempted (as applicable), the patient's condition or symptom(s) that warranted restraint or seclusion use, and the patient's response to the use of the restraint or seclusion intervention, including the rational for continued use of restraint or seclusion. We do not believe additional burdens are imposed by this requirement since it is a routine and customary practice to document the circumstances surrounding such an event for comprehensiveness of patient care.

In the interim final rule with comment period at §482.13(f)(3)(ii)(c), we required that the physician or other LIP must see and evaluate the patient's need for restraint or seclusion within 1 hour after the initiation of restraint or seclusion. This 1-hour on-site physician or LIP evaluation was the most controversial provision of the interim final rule with comment.

We anticipate the expansion of who may perform the 1-hour face-to-face evaluation will be less burdensome to hospitals. We believe the training required by this rule will equip staff with appropriate skills for handling escalating or aggressive patient behavior and should reduce overall use of restraints. However, we are aware that the facility's size, progress in reducing the use of restraint or seclusion, and other characteristics will have a varying impact upon each facility's performance of this requirement.

The NAPHS stated their respondents reported that it took an estimated 30 minutes to 1 hour to document all the specific elements required by CMS after a restraint or seclusion episode. This included several elements unique to the rule such as notifying the attending physician if the restraint was ordered by someone other than the patient's attending

physician. Thus, our burden estimate is based on a median timeframe (that is, 45 minutes) that we believe it would take to complete the required documentation in the patient's medical record. However, since we are unable to estimate the prevalence of restraint and seclusion, we can not apply this estimate to assess the associated burden across behavioral health and medical surgical settings.

b. Section 482.13(f) Standard: Staff training requirements.

Standard 482.13(f), previously entitled "Seclusion and restraint for behavior management," has been revised to read "Restraint or seclusion: Staff training requirements." This standard will specifically address the staff training requirements that have been significantly changed or are new.

In §482.13(f), staff training requirements have been expanded to include various training specifications. While we have tried to minimize the burden which will be placed on hospitals in order to meet this requirement, we believe it is important for the provision of safe and effective restraint or seclusion use.

We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded patient, or provide care for a restrained or secluded patient, the staff must be trained and able to demonstrate competency in the performance of these actions. We have revised the staff training requirements to address the following broad areas: training intervals, training content, trainer requirements, and training documentation.

When developing this final rule, we considered public comments regarding the impact associated with the requirement that all staff with direct patient contact be trained in the use of restraint or seclusion. To reduce burden and create a more reasonable requirement while assuring patient safety, we have mandated that only those staff who are involved in the application of restraint or seclusion, or performing associated monitoring and assessment of, or providing care for, restrained or secluded patients have this training. While we expect physicians and LIPs to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospital staff. Thus, we have not included physicians and LIPs in the burden associated with these requirements. Instead, we require the remaining hospital staff who have direct contact with patients must be trained in restraint or seclusion use.

In this final rule, we have specified broad topics to be covered in training, and have not required that staff be trained by an outside organization. We believe that in-house training may be more economical than sending staff off-site for instruction. However, hospitals have the option of sending staff to outside training.

We have based our burden estimate on having the actual number of trainers attend such training from an outside organization one time. We believe that most facilities will have these trained individuals function as program developers and trainers of the appropriate hospital staff. We believe in most instances this professional will be a registered nurse. Thus, we used $27.54 as the nursing hourly rate in this estimate. We used the four day

instructor certification program given by the Crisis Prevention Institute (CPI, INC.) (www.crisisprevention.com), costing $1,200 dollars in tuition plus travel, lodging, and participant salary in our calculations. Since train-the trainer programs are the way many facilities provide staff instruction, we used these estimates in our analysis.

The current JCAHO standards at PC.12.30 which apply to approximately 80 percent of the Medicare-and Medicaid-participating hospitals, address staff training and competence with respect to the use of restraint or seclusion. The current JCAHO standard at PC.11.10 which applies to the hospital leadership's approach to the use of restraint for acute medical and surgical (non-psychiatric) care, refers to staff orientation and education. In effect, these JCAHO standards already require training of this kind for staff involved with the application of restraint or seclusion. Thus, we believe the burden associated with hospitals reimbursing for the associated costs involved in training the trainer would apply only to the remaining 20 percent of hospitals that are not JCAHO accredited.

We estimate, on average, that roundtrip travel for each nurse will cost approximately $400 to cover the need for either local or distant travel, lodging for each nurse will cost approximately $120 per night X 3 nights, and the meals and incidental expenses (M&IE) will be approximately $50 per day depending upon the location within the designated state. Thus, we anticipate the cost to train one nurse per the 998 hospitals to be $1,200 for the course, an estimated $400 airfare based on location, $360 for 3 days lodging, $150 for 3 days M&IE, $112.50 for partial day M&IE, and $1,244.16 for the nurse's salary at $27.54 per hour X 8 hours per day X 4 days. If 20% of the hospitals (i.e., 998) hospitals were to send one nurse to such training, the total cost for the 998 hospitals would be $879,517.44.

Hours/Est. Salary/# of Hospitals	Annual Burden Hours	Annual Costs Estimate
Off-site training of the trainer		
Cost of course x 1 nurse		$1,200.00
Airfare x 1nurse		$400.00
Lodging x 1 nurse		$ 360.00
M&IE x 1 nurse		$262.50
Salary for 1 nurse @ $27.54 per hr. x 8 hrs. day x 4 days each for a one time training (i.e., 32 hours)	32.00	$881.28
Total for 1 nurse per hospital x 998 hospitals (20%) (i.e., 32 hrs. x 998)	31,936.00	$879,517.44

To be responsive to requests for more detail regarding our expectations and to assure staff competency, we have described the content to be covered during training. Given that most facilities already have some type of training program, as noted in many comments

from hospitals, we believe that these requirements will only serve to refine existing programs, not mandate new ones. Thus, there may be only some minimal, initial cost for revising program materials to incorporate the elements specified in the regulation.

Hours/Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Costs Estimate
Developing a new training program (20% of hospitals = 4,991 X 20% = 998)		
1 clinical trainer @ $27.54 hr. x 40 hrs. on average one-time X 998 hospitals	39,920.00	$1,099,396.80
Total	39,920.00	$1,099,396.80

We require that each individual who will potentially be involved in restraint and seclusion of a patient have training in the proper techniques. According to the NAPHS, initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Using data from the American Hospital Association's (AHA) 2005 Annual Survey, the average number of total full-time and part-time clinical employees per hospital are 257 and 116 respectively. While we recognize this does not include clinical staff in such areas as rehabilitation services, this total of 373 persons per hospital should provide an estimate on which to base this analysis. Thus, this estimate reflects the number of staff who may have direct patient contact. We realize that some hospitals will have more or fewer employees to train.

Additionally, the CMS' Online Survey, Certification, and Reporting (OSCAR) data, reveals the average number of beds per hospital is 160. We estimate that an average size hospital may have 373 staff persons who will require this training.

Hours/Est. Salary/# of Hospitals	Annual Burden Hours	Annual Costs Estimate
Attendance in the training program		
1 clinical trainer @ $27.54 hr. x 8 hrs. x 998 hospitals	7,984.00	$219,879.36
373 trainees x 8 hours per hospital x 998 hospitals	2,978,032.00	
Total	2,986,016.00	$219,879.36

We require that each individual receives annual updates to the training and that the annual training is documented. Again, according to NAPHS, annual updates are about 7 hours of staff and instructor time per each employee who has direct patient contact. Again, an average size hospital has 373 employees who have direct patient contact that must be trained in de-escalation techniques.

Hours/Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Costs Estimate
Annual updates in the training program		
1 clinical trainer @ $27.54 hr. x 4 hrs. on average annually x 998 hospitals	3,992.00	$109,939.68
373 trainees x 4 hours per hospital x 998 hospitals	1,489,016.00	
Total	1,493,008.00	$109,939.68

We require recordkeeping for documenting in each trained individual's personnel record that he or she has successfully completed training. We believe that such records are kept by the hospital in the normal course of business. Therefore, we do not believe that these requirements would have a significant economic impact on hospitals.

Total	**4,550,880.00**	**2,308,733.40**

d. Section 482.13(g) Standard: Death reporting requirements.

This requirement, previously an element in the interim final rule with comment period, has been revised to be a separate standard. In revising this to form a separate standard, we have made it applicable to all deaths associated with the use of restraint or seclusion throughout the hospital instead of just pertaining to behavioral health settings only. We have added the requirements at §482.13(g)(1)(i) that a hospital must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospital, at §482.13(g)(1)(ii) each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, and at §482.13(g)(1)(iii) that the hospital must report each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint seclusion contributed directly or indirectly to a patient's death.

At §482.13(g)(2) and §481.13(g)(3), we require that each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. We said in the final rule we believed the number of deaths related to restraint or seclusion use to be under-reported. In October 1998, the Hartford Courant cited the results of a study that identified 142 deaths from seclusion and restraint use in behavioral health treatment facilities over the past 10 years. Since the Patient's Rights CoP became effective in 1999, the annual total

of patient deaths related to restraint and seclusion use has been reported to CMS as follows: 1999 (14), 2000 (34), 2001 (22), 2002 (19), 2003 (17), 2004 (22), 2005 (33), and 2006 (20). We expected that once the Patient's Rights CoP was finalized, there would be more deaths reported. However, we did not expect the increased volume of deaths from restraint and seclusion that have been reported as a result of this regulatory change.
Since finalization of the Patient's Rights CoP on December 8, 2006 (effective January 8, 2007) until June 30, 2007, over 1,000 deaths from seclusion and restraint have been reported to CMS. Although our goal is to reduce the utilization of restraint or seclusion and associated deaths, we are aware that the actual number of deaths from seclusion and restraint use could increase due to the increased reporting requirements in all treatment settings in the hospital. Thus, we anticipate that there will be burden associated with this requirement due to the increased number of deaths that will be reported by the various units within the hospital. For the purposes of calculating burden, we are assuming the number of deaths based on current levels and are not considering the reduction in the number of deaths we expect to result from this regulation.

Given this historical data, we believe the number of reports will average .2 per hospital per year, that is, the total number of deaths in 2007 (approximately 1,000) divided by the total number of hospitals (4,991) (i.e., 1,000 deaths per year ÷ 4,991 hospitals). Thus, we believe the impact associated with this provision (that is, making a telephone call and filling in a written form to report a death to the CMS) is as follows:

We estimate that one clerical person would report the death to CMS and document the death in the patient's medical record. The burden associated with the completion of this task would be .25 (15 minutes divided by 60 minutes in one hour) x an average of 1,000 occurrences per year throughout the 4,991 hospitals, .25 x 1,000 = 250 hours. The estimated cost associated would be 250 hours x $.22 (that is, $12.98 hour divided by 60 minutes per hour x 15 minutes = 3.24 x 1,000 occurrences per year = $3,244.99 annually).

Hours/Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Costs Estimate
Reporting death to CMS and documenting in medical record		
1 clerical person @ $12.98 hr. x 15min. x average of 1,000 occurrences in hospital annually	250.00	$3,244.99
Total	250.00	$3,244.99

Section 482.13(h) Condition of participation: Patient's rights

Section 482.13(h) requires a hospital to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable

restriction or limitation that the hospital 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 §482.13(h)(1) through (h)(4).

The ICR burden associated with this §482.13(h) with this requirement is the time and effort necessary for a hospital to develop written policies and procedures with respect to visitation rights for patients and to distribute that information to the patients. The hospital 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 Hospitals (4,860)	Annual Burden Hours	Annual Cost Estimate
1 Administrator @ $59.05/hr X .25 hrs X 1 a yr. X 4,860	1,215	$71,746
SUB-TOTAL	**1,215**	**$71,746**

2. Effect on Beneficiaries

The implementation of the Patient's Rights CoP will serve to protect not only Medicare and Medicaid beneficiaries but also all patients receiving care in any of the 4,991 Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. Our goal is to safeguard against the mistreatment of all patients in these facilities including, but not limited to, deaths due to inappropriate seclusion and restraint use, violation of patients' privacy and confidentiality in various aspects of the healthcare delivery process, and systematic frustration of the patient's efforts to acquire his or her medical record. The patient will benefit from the hospital's focus on patients' rights. Through these protections, patient care can be delivered in an atmosphere of respect for an individual patient's comfort, dignity, and privacy. We also believe that implementation of the Patients' Rights CoP should lead to a reduction in the numbers of restraint-related injuries and deaths in hospitals.

Section 482.21 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

This revised section requires the hospital to develop, implement, and maintain an ongoing effective hospital-wide, data driven, QAPI program. This condition further requires the hospital to examine its methods and practices of providing care, identify opportunities to improve its performance, and then take actions that result in higher quality of care and improved safety for hospital patients.

Section 482.21(a) Standard: Program Scope

(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

We have not prescribed the structures and methods for implementing this requirement and have focused the condition on the expected results of the program. This provides flexibility to the hospital, as it is free to develop a creative program that meets the needs of the hospital and reflects the scope of its services. Thus, some hospitals may need to revise their existing programs to conform to this regulation. We believe the writing of internal policies governing the hospital's approach to the development, implementation, maintenance, and evaluation of the QAPI program will impose minimal burden, depending somewhat on the level of compliance with the previous quality assurance requirements. Flexibility is provided to the hospitals to ensure that each program reflects the scope of its services and operations. We believe this requirement provides a performance expectation for hospitals to set their own goals and use their own information to continuously strive to improve their performance over time. Given the one time burden that is necessary in the initial stage to develop and implement the QAPI program, the variability across the hospitals in size and experience, flexibility provided by the regulation, and the provisions of the previous requirements, we believe the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the QAPI program will reflect that diversity, making it difficult to predict an exact burden. However, for the sake of quantitative analysis, we have based our figures on all hospitals having to either develop or update their QAPI program.

The projected training time for staff is expected to cost an average hospital allocating a group of 3 clinicians with various duties and responsibilities, approximately $247.86 based on an average hourly rate of $27.54 per hour (3 hours x $27.54 per hour x 3 clinicians = $247.86). We estimate 12 hours of training for the QAPI coordinator, which is projected to cost $423.12, based on an average salary of $35.26 per hour (12 hours x $35.26 per hour x 1 coordinator). The total hourly burden for each hospital is projected to be 21 hours (3 hours x 3 staff) and (12 hours x 1 coordinator).

Hours/Estimated Salary/Number of Hospitals	Annual Burden Hours	Annual Cost Estimate
Training: 3 clinicians @ $27.54 per hr. x 4,991 hospitals x 3 hours per hospital	44,919.00	$1,237,069.20
1 coordinator @ $35.26 per hr. x 12 hrs per hospital x 4,991 hospitals	59,892.00	$2,111,791.90
SUBTOTAL	**104,811.00**	**$3,348,861.10**

We estimate that the burden associated with updating and in some instances, writing the internal policies would be an average of 8 hours annually (although this figure may be much lower, since many hospitals have existing internal quality improvement programs).

If the nurse coordinator does the updating or writing of the internal policies, we estimate the cost at $282.08 per year (8 hours x $35.26 per hour).

Hours/Estimated Salary/Number of Hospitals	Annual Burden Hours	Annual Cost Estimate
Updating policies: 1 coordinator @ $35.26 per hr. x 8 hrs annually x 4,991 hospitals	39,928.00	$1,407,861.20
SUBTOTAL	**39,928.00**	**$1,407,861.20**

We also note that the following factors may also affect the costs of updating and writing of the internal policies:

- *Additional Staff Costs.* Examples of these costs include- (1) physician or other professional staff reviewing the internal policies; and (2) clerical staff providing typing, printing, or copying support.
- *Staff Training Costs.* Staff may need additional training to write, update or review the hospital's internal policies.
- *Printing and Copying Costs.* These costs are dependent upon the magnitude of the hospital's changes to its internal policies and the number of copies of the policies and the number of copies of the policy that are made available to staff.

Policy development is necessary to patient health and safety because the by-laws provide the framework within which all-patient care services are furnished. Thus, we have included the involvement of a physician at approximately $560 annually (8 hrs. x $70.00 per hr.), a coordinator at $282.08 annually (8 hrs. x $35.26 per hr.), and a clerical person at $103.84 annually (4 hrs. x $12.98 per hr.).

Hours/Estimated Salary/Number of Hospitals	Annual Burden Hours	Annual Cost Estimate
Policy development: 1 physician @ $70.00/hr. x 8 hrs. x 4,991 hospitals	39,928.00	$2,794,960.00
1 coordinator @ $35.26/hr. x 8 hrs. x 4,991 hospitals	39,928.00	$1,407,861.20
1 clerical person @ $12.98/hr. x 4 hrs. x 4,991 hospitals per yr.	19,964.00	$259,132.72
SUBTOTAL	**99,820.00**	**$4,461,953.90**

The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under

Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA (5 CFR 1320.3(c)(4)).

TOTAL ANNUAL BURDEN HOURS	**244,559.00**	
TOTAL ANNUAL COST ESTIMATE		**$9,218,676.20**

Section 482.21(b) Standard: Program Data

This regulation would require data collection and analysis and necessitates staff training on data collection. Again, we estimate the burden associated with this requirement will vary, depending on the sophistication of the hospital's quality assurance programs currently in place. Given the variability associated with this requirement it is difficult to estimate the exact burden. Included in this estimate is the training required for the data collection. It is included to add emphasis on data accuracy that ensures the production of meaningful outcome reports. Other procedures to be used by the hospital to monitor data accuracy (including interdisciplinary comparisons and external resources) require training as they are implemented. Once hospital staff are familiar with data collection tools and methods, the quality improvement data collection imposes minimal burden. The projected training time for staff is expected to cost an average hospital allocating a group of 3 clinicians with various duties and responsibilities, approximately $247.86 based on an average hourly rate of $27.54 per hour (3 hours x $27.54 per hour x 3 clinicians = $247.86). We have proposed 12 hours of training for the QAPI coordinator, which is projected to cost $423.12, based on an average salary of $35.26 per hour (12 hours x $35.26 per hour x 1 coordinator). The total hourly burden for each hospital is projected to be 21 hours (3 hours x 3 staff) and (12 hours x 1 coordinator). Additionally, we estimate the associated burden for data collection and analysis to be approximately $2,820.80 based on an average salary of $35.26 per hour (80 hours x $35.26 per hour x 1 coordinator).

Hours/ Estimated Salary/Number of Hospitals	**Annual Burden Hours**	**Annual Cost Estimate**
Training: 3 clinicians @ $27.54 per hour x 3 hours x 4,991 hospitals	44,919.00	$1,237,069.20
Training cont'd: 1 coordinator @ $35.26 per hr. x 4,991 hospitals x 12 hours per yr.	59,892.00	$2,111,791.90
Data Collection and Analysis: 1 coordinator @ $35.26 per hr. x 4,991 hospitals x 80 hrs. per yr.	399,280.00	$14,078,612.00

TOTAL	**504,091.00**	**$17,427,473.00**

Section 482.21(c) Standard: Program Activities

The QAPI CoP focuses on the continuous improvement of the hospital as an organization requiring hospitals to track incidents, analyze their causes, and share and implement preventive actions and mechanisms of feedback and learning throughout the facility. We realize it is neither practical nor economically feasible to collect data and analyze all areas, processes, and systems of the hospital. Therefore, we are requiring the hospital's governing body to ensure the priorities set by the QAPI program are reflective of the hospitals services, ensure quality of care, and protect the safety of the patients. The burden associated with these requirements are captured above in sections 482.21 (a) and (b).

Section 482.21(d) Standard: Performance Improvement Projects

This requirement reflects an interdisciplinary, coordinated approach to performance improvement. The performance improvement projects requirement sets forth the requirement that each hospital must establish a mechanism that further explores the specific needs identified in the organization's assessment. This mechanism of action is a performance improvement project. These projects demonstrate the hospital's ability to: identify problems; evaluate and track quality indicators, or other aspects of performance; and implement actions or adopt changes that reflect processes of care and hospital operations. The hospital must be able to document and demonstrate to the SA what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

We are estimating that the QAPI coordinators document the projects being conducted, the reason for the projects, and the measurable progress on these projects. We estimate the coordinator will do this 4 times a year, approximately 8 hours per quarter or 32 hours yearly.

Hours/ Estimated Salary/Number of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 coordinator X 4,991 hospitals X 32 hours X $35.26 per hour	159,712.00	$5,631,445.10
TOTAL	**159,712.00**	**$5,631,445.10**

Section 482.21(e) Standard: Executive Responsibilities

The participating hospitals must have in writing by-laws governing the medical staff and the governing body. This incorporation of executive responsibilities pertaining to QAPI would be a one-time development by an administrative team consisting of medical staff or an appointed committee of approximately five physicians and one clerical person. We are not associating burden with this requirement, as by-laws should be updated regularly as a normal function of the hospital. This requirement is necessary to patient

health and safety because the by-laws provide the framework within which all-patient care services are furnished.

Not more than 2 hospitals a year become certified under Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA (5 CFR 1320.3(c)(4)).

482.22(c)- Standard: Medical Staff By-Laws

The participating hospitals must adopt and enforce bylaws to carry out their responsibilities. The bylaws must be approved by the governing body; include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.); describe the organization of the medical staff; describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body; include a requirement that a medical history and physical examination be done no more than 30 days before or 24 hours after an admission for each patient by a physician (as defined in §1861(r) of the Act), an oromaxillofacial surgeon, or other qualified individual in accordance with State law and hospital policy, and must be placed in the patient's medical record within 24 hours after admission; must include a requirement that when the medical history and physical examination are completed within 30 days before admission, an updated medical record entry documenting an examination for any changes in a patient's condition must be completed and documented in the medical record within 24 hours after admission; and, must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

Hospitals need to revise the medical staff bylaws to reflect the new requirements regarding the medical history and physical examination that were finalized in the November 27, 2006 final rule (effective January 26, 2007). Existing requirements were revised specifically to update this CoP to reflect current practice. Therefore, because we believe these requirements reflect customary and usual business and medical practice, burden is not subject to the PRA in accordance with §1320.3(b)(2).

Additionally, not more than 2 hospitals a year become certified under Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA (5 CFR 1320.3(c)(4)).

482.23(c) – Standard: Preparation and Administration of Drugs

482.23(c)(2) –

This requirement clarifies that, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contradictions, orders for drugs and biologicals must be documented and signed by a practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy and in accordance with State law. This standard has not been revised and, therefore, was finalized without change.

482.23(c)(2)(i) and (ii) –
These provisions reinforce current requirements that when verbal orders are used, they are to be used infrequently, and be accepted only by persons authorized by hospital policy and procedures consistent with Federal and State law. This standard has not been revised and, therefore, has been finalized without change.

The burden associated with these requirements is the time spent by the practitioner in documenting and signing orders. We believe that these requirements reflect customary and usual business and medical practice. Thus, burden is not subject to the PRA in accordance with §1320.3(b)(2).

482.24(c) - Standard: Content of Record
482.24(c) -
This requirement maintains and reinforces the current regulation for authentication of all medical record entries. It requires that all patient medial record entries be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided. This standard was not revised and, therefore, was finalized without change.

482.24(c)(1)(i) -
This provision requires that all orders, including verbal orders, be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in subsection (ii). One minor revision was made in the final rule based on public comment. The word "prescribing" has been replaced by the word "ordering."

482.24(c)(1)(ii) -
This provision permits a temporary exception to the requirement that all orders, including verbal orders, be dated, timed, and authenticated by the ordering practitioner. For a period of 5 years beginning with the effective date of this final rule, verbal orders will not need to be signed by the ordering practitioner, but could be authenticated by another practitioner responsible for the care of the patient. One minor revision was made based on public comment by replacing the word "prescribing" with the word "ordering."

482.24(c)(2)(i) (A) and 482.24(c)(2(i)(B)
These requirements were revised to be consistent with the changes in the Medical staff CoP. These regulations specify documentation requirements for history and physical examinations. The two provisions require evidence of: (1) A medical history and physical examination completed within 30 days before or 24 hours after admission, and placed in the patient's medical record within 24 hours after admission; and (2) an updated medical record entry documenting an examination for any changes in the patient's condition when the medical history and physical examination were completed within 30 days before admission. This updated examination will need to be completed and documented in the patient's medical record within 24 hours of admission. These

standards were not revised from the proposed rule and, thus, were finalized without change.

The burden associated with these requirements is the time spent in signing and dating medical record entries and in placing evidence of a history and physical examination in the patient's records. We believe that these requirements reflect customary and usual business and medical practice. Thus, the burden is not subject to the PRA in accordance with §1320.3(b)(2).

482.27 Laboratory Services
482.27(b)(2) - Standard: Adequacy of Laboratory Services
The hospital must make available to the medical staff a written description of services provided. This is necessary to prevent the loss of treatment time that would occur if a practitioner ordered services that were unavailable from the hospital's lab, and then had to search for a lab to provide the needed services. We estimate that hospitals will employ at least two physicians and one clerical personnel to prepare or update the service description within 45 minutes.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
2 physicians @ $70.00/hr X .75 X 4,991 hospitals =	7,486.50	$524,055.00
1 clerical person @ $12.98/hr X .25 X 1 a yr. X 4,991 hospitals	1,247.75	$16,195.80
TOTAL	**8,734.25**	**$540,250.80**

482.27 Condition of participation: Laboratory services.
The interim final rule with comment period, CMS-3014-IFC, published in the Federal Register, Volume 72, No. 164 on August 24, 2007, requires hospitals that transfuse blood and blood components to: prepare and follow written procedures for appropriate action when it is determined that blood and blood components the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period for transfusion-related data to 10 years.

These changes are based on recommendations by the Secretary's Advisory Committee on Blood Safety and Availability and were being published in conjunction with the Food and Drug Administration's (FDA) Final Rule, "Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection" ("lookback"). The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention that, in most cases, can occur many years after recipient exposure to a donor.

Section 482.27(b)(3) requires a hospital that regularly uses the services of an outside "blood collecting establishment" (BCE) to establish and maintain a written agreement with the BCE that governs the procurement, transfer, and availability of blood and blood components. We are using the FDA's term for a "blood collecting establishment." This section also requires the BCE to notify the hospital within 3 calendar days after the date on which the donor tested reactive for evidence of HCV infection or after the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, as outlined in (b)(3)(i) through (iii).

Section 482.27(b)(5) requires a hospital to maintain, in a manner that permits prompt retrieval, adequate records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition. In addition, this section requires a hospital to maintain a fully funded and documented plan that will allow the hospital to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

Section 482.27(b)(6) requires a hospital that has administered potentially HIV or HCV infectious blood or blood components (either directly through its own BCE or under an agreement), or released the blood or blood components to another entity or individual, to make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood components were transfused to the patient. Time frame and notification requirements are outlined in §482.27(b)(6), (b)(7), and (b)(8).

Section 482.27(b)(9) requires a hospital to maintain policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records.

Section 482.27(b)(10) requires a physician or hospital, if the patient has been adjudged incompetent by a State court, to notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process for HIV or HCV infection

and inform the deceased patient's legal representative or relative. If the patient is a minor, the legal guardian must be notified.

While all of the information collection requirements referenced above are subject to the Paperwork Reduction Act, the burden associated with these requirements is captured and discussed in the FDA's final regulation titled "Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection" published in the **Federal Register** dated August 24, 2007. It is important to note that, although this interim final rule with comment period presents the costs that would be imposed on all payers of hospital services, including the Medicare and Medicaid programs, it merely conforms to the FDA's final rule and has no additional economic impact. We have simply restated the analysis performed in the FDA companion rule; both rules present the same total costs to hospitals. Therefore, we are assigning one token hour of burden to these requirements.

482.27(b)(5)- Standard- Potentially Infectious Blood and Blood Products - Record Keeping

The hospital must update policy agreements with blood banks to ensure prompt notifications about potentially infected blood and blood products. We estimate that hospitals will employ one coordinator for one hour and one clerical person for ½ hour to update the policy agreements.

482.27(b)(6)- Standard: Laboratory Services- Potentially Infectious Blood and Blood Products- Patient Notification

The hospital must notify the physicians of patients who received potentially infectious blood or blood product, the patient themselves, a legal representative or surviving relative to alert them of the need for testing and counseling. The hospital must document notification efforts in the patient's medical record.

482.27(b)(9) Standard- Potentially Infectious Blood and Blood Products-Policies and Procedures

The hospital must update policies and procedures for notification and documentation, including requirements for confidentiality and medical records.

482.30(c)(1) and (d)(3) - Utilization Review - Scope and Frequency of Review

Hospitals wishing to participate under the Medicare or Medicaid programs shall submit a written description of their utilization review plan. The purpose of the utilization review plan is two fold. It ensures the maintenance of high quality patient care and effective utilization of available health facilities and services. The initial development of the written descriptions will take approximately 1 hour. No more than 2 hospitals a year become certified under Medicare/Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA (5 CFR 1320.3(c)(4)).

482.41(b) - Standard: Physical Environment- Life Safety From Fire
Except as otherwise provided in this section, the hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association.

482.43 Standard: Discharge Planning
This section states that the hospital must include in the discharge plan, a list of home health agencies (HHAs) or skilled nursing facilities (SNFs) that are available to the patient, that participate in the Medicare program, that serve the geographic area, and that request to be listed by the hospital as available. Hospitals are also required to maintain such documentation. Additionally, hospitals must identify disclosable financial interests in an HHA or SNF in which the beneficiary is referred. This section also specifies other information that the discharge plan must contain.

The burden associated with these requirements is the time and effort for the hospital to provide a list to beneficiaries, for whom home health care or post hospital extended care services are necessary, and document the patient's medical record. CMS provides this information at www.medicare.gov. Since the information is easily obtainable, the burden associated with these requirements is estimated to be 5 minutes per hospital per discharge.

To illustrate how the burden estimate will be calculated, we determine the percentage of persons referred by hospitals to SNFs and HHAs by using 2007 data for the total number of hospitals (i.e., 4,991) and preliminary data for calendar year 2004 for the total number of persons discharged from hospitals (i.e., 13.0 million), and the total number of persons served in SNFs (i.e., 1.7 million). We assume persons served in SNFs were discharged from a hospital to a SNF. We used the 2003 data for number of persons who were served by HHAs that were discharged from hospitals (i.e., 1.7 million).

Thus, we estimate 13.1% of persons discharged from hospitals were served in SNFs
(i.e., 1.7 million ÷ 13.0 million = 13.1%). This resulted in the calculated total number of patients discharged from hospitals sent to SNFs and HHAs, respectively, is 3,400,000 patients.

For the year 2004, the average total discharges per hospital would be 661.23
(i.e., 3,400,000 ÷ 4,991 = 661.23 discharges per hospital).
Thus, .0833 hours per hospital per discharge X 661.23 discharges per hospital X 4,991 hospitals = 274,906.57 annual burden hours. Finally, the associated annual cost estimate would be 6,882,223.60
(i.e., 1 clinician @ $27.54 X .0833 hours per hospital per discharge X 601.08 discharges per hospital X 4,991 hospitals).

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 clinician @ $27.54/hr. x .0833 hours x 661.23 discharges per hospital X 4,991 hospitals	274,906.57	$7,570,926.90
TOTAL	**274,906.57**	**$7,570,926.90**

482.45(a) Standard: Organ procurement responsibilities

Hospitals are required to have and implement written protocols that:

(1) incorporate an agreement with an Organ Procurement Organization (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 cooperate to assure that all usable tissues and eyes are obtained from potential donors;

There were approximately 752,000 deaths in U.S. hospitals in 2005 (the most recent year for which figures are available). There are approximately 4,991 Medicare hospitals in the U.S. If the average call to an OPO to report a death takes 5 minutes and the total number of calls made equals 752,000, the annual burden is approximately 62,641.60 hours. If each call is made by a clinician who is paid $27.54 per hour, the cost burden would be $1,725,149.60.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 clinician @ $27.54/hr. x .0833 hours per call x 752,000 calls	62,641.60	$1,725,149.60
TOTAL	**62,641.60 (454,400)**	**$1,725,149.60**

Hospitals may, in addition to reporting every death to the OPO, contact the tissue bank and eye bank about tissue and eye donors. Since the regulation went into effect, we have found that hospitals do not contact tissue and eye banks in addition to their OPOs. Therefore, we have not factored calls to tissue banks and eye banks into our burden estimate.

The requirement to maintain protocol documentation is estimated at one hour per year per hospital. If the individual who is required to maintain the protocol documentation is a clerk who is paid $12.98 per hour, the annual cost burden would be $64,783.18.

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate
1 clerical person @ $12.98/hr. X 1 hr. each for documentation X 4,991 hospitals	4,991.00	$64,783.18
TOTAL	**4,991.00 (454,400)**	**$64,783.18**

Thus, the total associated burden hours found in meeting the reporting and documentation requirements for this requirement are 67,632.60 (62,641.60 + 4,991). Additionally, the associated annual cost burden for these same requirements is $1,789,932.70 (1,788,621.80 + 64,783.18).

TOTAL ANNUAL BURDEN HOURS	**62,641.60**	
TOTAL ANNUAL COST ESTIMATE		**$1,789,932.70**

482.45(b)(3) Standard: Organ transplantation responsibilities

If a hospital performs transplants, it must provide organ-transplant-related data as requested by the Organ Procurement and Transplantation Network, the Scientific Registry, and the OPOs. These hospitals must also provide such data directly to the Department when requested by the Secretary.

As of May 2007, there were 258 hospitals with transplant programs. Every hospital with a transplant program is required by the regulation to provide data to the OPOs. These data are currently provided by the hospitals to OPOs, which use the data to track the disposition of the organs they recover. As a condition of their membership in the OPTN, hospitals with transplant programs are required to report data to the OPTN and the Scientific Registry. The remaining requirement (that hospitals with transplant programs must report data as requested by the Secretary) would be collected on an individual basis and/or during the pursuit of an administrative action, audit, or investigation and is, therefore, not subject to the requirements of the Paperwork Reduction Act.

Transplant hospitals currently supply data to their OPOs. Therefore, we have assigned one token hour for each of the 258 transplant hospitals to provide data to their OPOs. The burden for transplant hospitals to provide data to the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) is currently imposed by the Health Resources and Services Administration (HRSA). These data are provided by the transplant hospitals by completing a number of different forms, depending upon the type of donor (living or cadaveric) and the organ type. HRSA has calculated a burden estimate for transplant hospitals to provide these data by determining the amount of time needed to complete each separate form (ranging from .060 hours to .530 hours annually per form), multiplying the product of the amount of time required per form by the number of times the form is submitted annually, and then adding the total burden for each form to arrive at the total annual burden hours for all transplant hospitals to supply data to the OPTN and SRTR. On an annual basis, the total number of submissions for all forms is estimated by HRSA to be 334,344, and the total burden is estimated to be 115,485 hours. If a clinician making $27.54 per hour reports these data, the cost of reporting data to the OPTN and SRTR is estimated to be $3,180,456.90 (115,485 hours x $27.54). The total cost for 258 hospitals with transplant programs to report data to their OPOs is $7,105.32 (258 hours x $27.54). Thus, the total cost to transplant hospitals is $3,187,562.20 ($3,180,456.90 + $7,105.32).

Hours /Est. Salary/ # of Hospitals	Annual Burden Hours	Annual Cost Estimate

1 clinician per hospital x 258 hospitals to report data to the OPOs annually	258.00	
334,344 annual submissions (HRSA estimate)	115,485.00 (HRSA estimated)	
1 clinician @ $27.54 hr. x 258 hrs. to report data to the OPOs		$7,105.32
1 clinician @ $27.54 hr. x 115,485 hrs. to report data to the OPTN and SRTR		$3,180,456.90
TOTAL	**115,743.00**	**$3,187,562.20**

Our intent was not to require hospitals routinely to report identical data to more than one entity, but rather to authorize direct requests by each of these entities. Thus, we have not determined the type of organ transplant data that might be requested by the Department.

This provision is included to give the Department the flexibility to request data from transplant hospitals in the event that needed data could not be obtained expeditiously from the OPOs, the OPTN, or the Scientific Registry. In accordance with 42 CFR 121.11(a)(2) (record maintenance requirements for OPOs and transplant programs) and 121.11(b)(2) (reporting requirements for OPOs and transplant hospitals) these programs are required to maintain and report to the OPTN, the Scientific Registry, and the Secretary data concerning, among other things, each potential donor identified. Therefore, this paperwork requirement, when considered with the requirements in the OPTN rule, will enable the Department to obtain information routinely from all transplant hospitals and OPOs in support of donation programs.

Confidentiality of the death data provided by hospitals is assured by both hospital and OPO regulations, which require hospitals and OPOs to have procedures for ensuring the confidentiality of patient records. Hospitals and OPOs must ensure that unauthorized individuals cannot gain access to or alter patient records. Hospitals must also ensure that original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas. [See 42 CFR 482.24(b)(3)]. OPOs must ensure the confidentiality and security of personally identifiable information [See 42 CFR 486.330]. There are costs for some OPOs to improve computer systems to process and maintain the information on deaths they receive from hospitals. However, the regulation applies only to hospitals and does not require OPOs to process, maintain, or report the information they receive.

CMS most likely will use transplant data internally to assess whether a transplant hospital is qualified to participate (or continue to participate) in the Medicare program and to monitor organ donation. It is unlikely CMS will need to collect patient identifiable data.

Some sensitive information needed to assess a potential donor's suitability for organ donation (e.g., information regarding the donor's sexual behavior or illicit drug use as it relates to HIV status) may be required.

<u>482.52: Anesthesia Services</u>

There are no information collection requirements imposed.

482.53(d): Standard: Nuclear Medicine Service
The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures for at least 5 years. This is necessary to prevent duplication of services if the copies entered in the patient's record are lost. We estimate that maintaining these records require 15 minutes per patient and that only 5 percent of the patients would receive such services. Thus, for this report, the number of patients will be represented by the annual number of hospital admissions (39,006,027) per the American Hospital Association at www.aha.org. However, we believe these efforts are performed on a usual and customary basis by hospitals thereby are exempt from the PRA (5 CFR 1320.3(b)(2)).

482.53(d)(3) Standard: Nuclear Medicine- Records
The hospital must maintain records of the receipt and disposition of radiopharmaceuticals. This is necessary to minimize the risk of environmental contamination, or loss of these materials, either of which would pose a health and safety risk to patients, staff or the public. We estimate that only 10 percent of the hospital's patients (169) will receive the services. We estimate that maintaining these records will take a record technician 12 hours per year. However, we believe these efforts are performed on a usual and customary basis by hospitals thereby are exempt from the PRA (5 CFR 1320.3(b)(2)).

482.56(b) - Standard: Rehabilitation Services-Delivery of Rehabilitation Services
Rehabilitation services must be furnished in accordance with a written plan of treatment. We are attributing no burden to this requirement, as this is also an industry standard.

482.57(b)(1) - Standard: Respiratory Care Services- Delivery of Services
Personnel qualified to perform specific services in this area must be designated in writing. No burden is being assessed to this requirement because the industry requires the same,e.g., in the JCAHO standard for respiratory care services.

482.60(c) - Special Provisions Applying to Psychiatric Hospitals
Psychiatric hospitals must maintain clinical records on all patients. We have assessed no burden for this information requirement, as this is a standard practice in the hospital industry.

482.61 - Special Medical Record Requirements for Psychiatric Hospitals
The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution. No burden is being attributed to maintenance of medical records because this recordkeeping is standard practice.

482.62(a) Standard: Personnel Staff Requirements for Psychiatric Hospitals
The hospital must have qualified professionals and support staff to formulate written individualized treatment plans. Although individualized treatment plans are required, no

burden is being assessed, for this too, is an industry requirement and standard for providing quality care.

482.66(a)(7) Standard: Special requirements for hospital providers of long-term care services ("swing-beds") *
The hospital must provide written assurance to CMS that it will not operate over 99 beds, except in connection with a catastrophic event. This requirement is necessary to ensure proper care is rendered to all patients of the hospital. It should take ½ hour of preparation by the hospital administrator and 30 minutes for one clerical person to prepare and mail in the written assurance to CMS.

* Note: This requirement was removed from the CFR per the Balanced Budget Refinement Act of 1999 (BBA). Thus, we no longer require hospitals to meet this requirement.

13. Capital Costs

14. There are no capital costs. 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 are responsible for acting on the information collection requirements discussed in this package as they relate to hospital compliance. Once state survey agencies have completed their surveys and if a final decision to terminate a hospital for noncompliance is to be made, such decisions are made by the RO.

15. Program/Burden Changes or Adjustements

We are revising the currently approved information collection request to include the burden associated with the requirements in §482.13(h). 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.