Supporting Statement
Critical Access Hospital (CAH) Conditions of Participation
and Supporting Regulations (CMS-10239)

A. Background

This information collection package is being submitted as an extension of the current, OMB-approved collection. This package has been updated to reflect the current number of facilities and 2017 Bureau of Labor (BLS) salary information.

Additionally, CMS published revisions to certain CAH Conditions of Participation on September 30, 2019.

The Critical Access Hospital (CAH) Program, Distinct Part Units (DPUs)

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

CAHs represent a separate provider type with their own Medicare Conditions of Participation (CoPs) as well as a separate payment method. Unlike traditional hospitals that are paid based on a prospective payment system, CAHs are currently paid 101 percent of their reasonable costs. The CoPs for CAHs are listed in the Code of Federal Regulations (CFR) at 42 CFR 485.601 et seq.

The Act at Section 1820(c)(2)(B) requires a Medicare participating hospital to meet the following criteria in order be certified as a CAH status:

- Be located in a State that has established a State rural health plan for the State Flex Program;
- Be located in a rural area or be treated as rural pursuant to Section 1886(d)(8)(E);
- Makes available 24-hour emergency care services 7 days a week;
- Provide no more than 25 inpatient beds that can be used for either inpatient or swing bed services;
- Have an average annual length of stay of 96 hours or less per patient for acute care; and
- Be located either more than a 35-mile drive from any hospital or CAH or more than a 15-mile drive in areas with mountainous terrain or only secondary roads OR certified as a CAH prior to January 1, 2006, based on State designation as a "necessary provider" of health care services to residents in the area.

Section 1820(c)(2)(E)(i) of the Act provides that a CAH may establish and operate a psychiatric or rehabilitation distinct part units (DPU). Each DPU may maintain up to 10

beds and must comply with the hospital requirements specified in 42 CFR Subparts A, B, C, and D of part 482.

For purposes of Information Collection Request (ICR) compliance, CAHs which have DPUs are treated separately from CAHs without DPUs. For CAHs without DPUs, which make up the bulk of the CAH program, their associated ICR burden is addressed in the present package CMS-10239, (0938-1043).

At the outset of the CAH program, the information collection requirements for all CAHs were addressed together under CMS-R-48 (0938-0328). As the CAH program has grown in scope of services and in number of providers, for purposes of ICR compliance, the burden associated with CAHs with DPUs was separated from the CAHs without distinct part units (DPUs). CAHs with DPUs must meet additional requirements, including the CoPs for hospitals, as specified in Subparts A, B, C, and D of Part 482. Presently, 128 CAHs have rehabilitation or psychiatric DPUs. The burden associated with CAHs that have DPUs continues to be reported under CMS-R-48, along with the burden for all accredited and non-accredited hospitals.

Currently, there are 1,215 CAHs. This figure represents the 1,343 CAHs minus the 128 CAHs that have DPUs. Also, over the past three years there were 10 terminated providers and 10 new providers, with an overall net result of -0- increase.

Patient-Related Activities

The burden associated with most patient-related activities (such as healthcare plans, patient records, and clinical records) is not included in this ICR because these activities would take place in the absence of the Medicare and Medicaid programs. These activities are considered usual and customary business practices and, as stated in 5 CFR 1320.3(b)(2), are exempt from the Paperwork Reduction Act (PRA) requirements.

Salary Data

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2017 National Occupational Employment and Wage Estimates found at https://www.bls.gov/oes/2017/may/oes_nat.htm. Where we were able to identify positions linked to specific positions, we used that compensation information. However, in some instances, we have used a general position description or information for comparable positions, or we have generated the average wage of multiple positions. We calculated the estimated hourly rates based upon the national median salary for that particular position, including fringe benefits and overhead estimated at 100 percent of the base salary. Since CAHs are located in rural areas, where salaries tend to be lower, we have used the national “median” (rather than the higher “mean”) salary reported by BLS.

The salary estimates (including estimated fringe benefits and overhead at 100%) contained in this package are based on the following healthcare personnel:

"Administrator" refers to the BLS national estimates for Management Occupation, Chief Executives (11-1011). The median wage is $94.25 per hour. For purposes of this ICR, we use the figure $189 per hour, representing the median wage plus fringe benefits and overhead.

"Clerical person" refers to the BLS national estimates for Healthcare Support Workers, all healthcare workers not listed separately (31-9099). The median wage is $18.56 per hour. For purposes of this ICR, we use the figure $37 per hour, representing the median wage plus fringe benefits and overhead.

"Clinical Nurse Specialist" refers to the BLS national estimates for "Registered Nurses" (29-1141), which, the BLS explains, includes Clinical Nurse Specialists. The median wage is $35.36 per hour. For purposes of this ICR, we use the figure $71 per hour, representing the median wage plus fringe benefits and overhead.

"Clinician" refers to the BLS national estimates for a Registered Nurse (29-1141). The median wage is $35.36 per hour. For purposes of this ICR, we use the figure $71 per hour, representing the median wage plus fringe benefits and overhead.

"Coordinator" refers to the BLS national estimates for Medical and Health Service Managers (11-9111). The median wage is $53.69 per hour. For purposes of this ICR, we use the figure $107 per hour, representing the median wage plus fringe benefits and overhead.

"Nurse practitioner" refers to the BLS national estimates for Nurse Practitioners (29-1171). The median wage is $51.68 per hour. For purposes of this ICR, we use the figure $103 per hour, representing the median wage plus fringe benefits and overhead.

The "Physician" salary refers to the BLS national estimates for Internists, General (29-1063). The median wage is equal to or greater than $95.37 per hour. For purposes of this ICR, we use the figure $191 per hour, representing the median wage plus fringe benefits and overhead.

"Physician Assistant" refers to the BLS national estimates for Physician Assistants (29-1071). The median wage is $50.37 per hour. For purposes of this ICR, we use the figure $101 per hour, representing the median wage plus fringe benefits and overhead.

"Records technician" refers to the BLS national estimates for Medical Records and Health Information Technicians (29-2071). The median wage is $20.59 per hour. For purposes of this ICR, we use the figure $41 per hour, representing the median wage plus fringe benefits and overhead.

B. JUSTIFICATION

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR 485, Subpart F. These regulations implement sections 1102, 1138, 1814(a)(8), 1820(a-f), 1861(mm), 1864, and 1871 of the Act. Sections 1820 and 1861(mm) of the Act provide that CAHs participating in Medicare meet certain specified requirements. 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 or CAH. The Secretary may impose additional requirements if they are necessary in the interest of the health and safety of the individuals who are furnished services in the hospital or CAH.

Section 1864 of the Act provides for the use of State survey agencies to ascertain whether certain entities, including CAHs, comply with the applicable statutory definitions and implementing regulations for that provider or supplier type. Section 1865(a) of the Act permits providers and suppliers accredited by an approved Medicare accreditation program of a national accrediting body to be "deemed" to meet the applicable CoPs for that provider or supplier type. To receive approval, a national accrediting organization (AO) must demonstrate to CMS that its Medicare accreditation program requirements meet or exceed the applicable Medicare CoPs. To the extent that a program has higher standards than the Medicare CAH CoP, such "higher" requirements are not the result of the CoPs but rather of voluntary decisions by the AO.

Accreditation by an AO is voluntary on the part of a CAH and is not required for Medicare certification. There are currently 472 CAHs (out of a total of 1,343 certified CAHs) that have demonstrated compliance on the basis of their accreditation under a CMS-approved Medicare accreditation program.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 restrained the growth of the CAH program by terminating, as of January 1, 2006, a State's authority to designate a CAH as a necessary provider and thereby waive the CAH minimum distance requirement relative to other CAHs or hospitals. As a result, CMS has certified very few new CAHs since 2006 because most hospitals that meet the location and distance criteria and which are interested in CAH status have already converted to CAH status. Based on data from the past three years (10 new providers and 10 terminated providers), we anticipate a -0- net increase in CAH providers. As explained above, this information collection request addresses those CAHs which do not have DPUs. Therefore, this information collection request uses the figure 1,215 (1,343 CAHs minus the 128 CAHs that have DPUs.)

Statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating CAHs require the inclusion of these requirements in the CoPs for CAHs. We note that the ICRs contained within the regulations are comparable to those of the various AOs and are necessary safeguards against potential overpayments, excessive utilization, and poor health care that may occur in the absence of such requirements. Therefore, we believe many of the requirements

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

2. Information Users

The CAH CoPs and accompanying ICRs specified in the regulations are used by surveyors as a basis for determining whether a CAH is meeting the requirements to participate in the Medicare program.

3. Use of Information Technology

CAHs may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation does not specify how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate to meet their needs.

4. Duplication of Efforts

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

5. Small Businesses

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

6. Less Frequent Collection

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

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

This information collection request is associated with Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23) which was proposed on September 20, 2018 (83 FR 47686), and finalized on September 30, 2019 (84 FR 51732). There were no comments received specific to these ICRs.

9. Payment/Gift To Respondents

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

10. Confidentiality

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

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

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

Burden associated with this requirement is exempt from the PRA.

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

Prior to any relocation of a necessary provider CAH, the CAH may voluntarily send a letter of intent to the State Agency and to the CMS Regional Office (RO) if it seeks a preliminary determination from CMS as to whether it's proposed new location would meet CMS requirements. The RO provides notice of preliminary approval of the relocation if the proposed relocation complies with the regulatory standards at 42 CFR 485.610(b) and (d). The CAH's Administrator, or other appropriate person, would draft the attestation letter with the relocation proposal, stating that the facility meets the conditions to relocate and continue its necessary provider designation. We estimate that fewer than 5 facilities a year will relocate and that it would take one hour to draft the letter and 30 minutes for clerical personnel to put it into a final form.

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

485.616 Standard: Agreements with network hospitals

Burden associated with this requirement is exempt from the PRA.

Each CAH must have an agreement with respect to credentialing and quality assurance with at least one hospital that is a member of the network; one QIO or equivalent entity; or one other appropriate and qualified entity identified in the State rural health care plan. The agreement should include patient referral and transfer. The initial development of the agreement will take approximately two hours. We estimate that no more than six CAHs a year become certified under Medicare. As stated in 5 CFR 1320.3(c)(4), this information collection requirement is exempt from the PRA as it will impose burden on fewer than 10 entities on an annual basis.

485.618(c) – Standard: Blood and blood products

The chart below reflects the burden associated with this requirement.

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

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Coordinator @ $107/hr x 1hr/yr	1,215 hours	$130,005
1 Clerical person @ $37/hr x 1hr/yr	1,215 hours	$44,955
TOTAL	**2,430 hours**	**0**

485.618(d)(1)(ii)(C) - Emergency Services

No burden is attributed to this task.

The State must maintain documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency. This information is included in each State's rural healthcare plan and is maintained by the State.

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

Burden associated with this requirement is exempt from the PRA.

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine (MD) or osteopathy (DO) is immediately

available by telephone or radio contact on a 24-hour a day basis to receive emergency call, provide information on treatment of emergency patients and refer patients to the CAH or other appropriate locations for treatment.

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

485.623(d)(4) – Standard: Life Safety from fire

The chart below reflects the burden associated with this requirement.

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

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Clerical person @ $37/hr. x 0.5 hr	608	$22,496
TOTAL	**608**	**$22,496**

Section 485.631-Staffing and staff responsibilities

The chart below reflects the burden associated with this requirement.

The burden associated with this requirement is the time it takes to review the CAH's written policies and make appropriate changes or updates. In conjunction with a non-physician practitioner, the MD or DO develops, executes, and periodically reviews the CAH's written policies governing the services it furnishes. Such non–physician practitioner would either be a physician assistant, nurse practitioner, or clinical nurse specialist. For purposes of this ICR, we estimate the wages of the non-physician practitioner by taking an average of the median wages for the above-mentioned practitioners. We also estimate that a CAH will utilize the services of one clerical person for half an hour to process any changes or updates.

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Physician @ $191/hr x 1 hr/yr	1,215	$232,065
1 Non-physician practitioner @ *average wage** of $92/hr x 1 hr/yr * *Physician Assistant @ $101/hr, Nurse Practitioner @ $103/hr, or Clinical Nurse Specialist @ $71/hr*	1,215	$111,780
1 Clerical person @ $37/hr x 0.5 hr	608	$22,496
TOTAL	**0**	**0**

485.631(b)(2)- Responsibilities of the Doctor of Medicine or Osteopathy

No burden is attributed to this task.

A doctor of medicine or osteopathy must be present for sufficient periods of time to provide medical direction, medical care services, consultation, and supervision for the services provided in the CAH. We believe that this can be documented in patient records and in the monthly meeting notes of the board. No burden is being assessed for this requirement, as keeping patient records is standard and keeping minutes of meetings (board and staff level) are common and practical activities for the industry.

Section 485.635(a) – Patient care policies

Section 485.635(a)(4) requires CAHs to conduct an annual review of all its policies and procedures. We are reducing the frequency that is currently required for CAHs to perform a review of all their policies and procedures from an annual review to a biennial review. Accordingly, this would reduce the burden on CAHs by half in a given period of time. The burden associated with the annual review was previously considered a usual and customary business practice, and was therefore not accounted for in this package. Although that may still be the case, we have chosen to begin accounting for the remaining biennial review. We estimate that it would take a CAH approximately 16 hours for administrative and clinical staff to review and make changes to policies and procedures biennially, as detailed in the table below.

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Administrator @ $189/hr x 2 hr (4 hr biennially)	2,430	$459,270
1 Clerical staff @ $37/hr x 1.5 hr (3 hr biennially)	1,823	$67,451
1 Registered Nurse @ $71/hr x 1.5 hr (3 hr biennially)	1,823	$129,433
1 Nurse practitioner @ $103/hr x 1.5 hr (3 hr biennially)	1,823	$187,769

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Physician @ $191/hr x 1.5 hr (3 hr biennially)	1,823	$348,193
TOTAL	**0**	**0**

Section 485.635(c)(3) – Standard: Services provided through agreements or arrangements

The chart below reflects the burden associated with this requirement.

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

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Administrator @ $189/hr x 1 hr	1,215	$229,635
1 Clerical @ $37/hr x 1 hr	1,215	$44,955
TOTAL	**2,430**	**0**

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

The chart below reflects the burden associated with this requirement.

Section 485.635(f) requires a CAH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in §485.635(f) (1) through (f)(4). Such policies and procedures are vital to patient well-being and treatment. In their absence, physicians, nurses, and other staff caring for the patient often miss an opportunity to gain valuable patient information from individuals 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.

As stated under §485.635, the information requirements contained within these regulations are comparable to such industry standards related to the healthcare of inpatients. CAHs and other inpatient facilities have guidelines and protocol on patient visitation. We estimate that the ICR burden associated with this requirement is minimal as most CAHs have established policies and procedures regarding visitation rights of patients. The ICR burden associated with this requirement reflects the time and effort necessary the CAH administrator or other appropriate person to ensure that the information was distributed to the patients in his or her facility. The Administrator could accomplish this task in 15 minutes.

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Administrator @ $189/hr x 0.25 hrs/yr	304	$57,456
TOTAL	**304**	**$57,456**

485.638 – Clinical Records

No burden is attributed to this task.

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

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

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

Section 485.641 – Condition of participation: Quality assessment and performance improvement program

§ 485.641 requires CAHs to develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven QAPI program. The QAPI program must be appropriate for the complexity of the CAH's organization and the services it provides. In addition, CAHs must comply with all of the requirements set forth in § 485.641(b) through (e).

The 1,004 non TJC-accredited CAHs would need to review their current programs and then revise and develop new provisions of their programs to ensure compliance with the new requirements. We believe that the CAH QAPI leadership (consisting of a physician, and/or administrator, mid-level practitioner, and a nurse) would need to have at least two meetings to ensure that the current annual evaluation and quality assurance (QA) program is transitioned into the QAPI format. The first meeting would be to discuss the current quality assurance program and what needs to be included based on the new QAPI provision. The second meeting would be to discuss strategies to update the current policies, and then to discuss the process for incorporating those changes. We believe that these meetings would take approximately two hours each. We estimate that the physician would have a limited amount of time, approximately 1 hour to devote to the QAPI activities. Additionally, we estimate these activities would require 4 hours of an administrator's time, 4 hours of a mid-level practitioner's time, 8 hours of a nurse's time, and 2 hours of a clerical staff person's time for a total of 19 burden hours. We believe that the CAH's QAPI leadership (formerly the periodic evaluation and quality assurance leadership) would need to meet periodically to review and discuss the changes that would need to be made to their program. We also believe that a nurse would likely spend more time developing the program with the mid-level practitioner. The physician would likely review and approve the program. The clerical staff member would probably assist with the program's development and ensure that the program was disseminated to all of the necessary parties in the CAH.
Since a CAH is currently required to evaluate its total program and evaluate the quality and appropriateness of the services furnished, take appropriate action to address deficiencies and document such activities, we believe that the resources utilized on the current QA program would be utilized for the ongoing QAPI activities under § 485.641(b)-(e). Thus, we estimate that for each CAH to comply with the requirements in this section it would require 19 burden hours (1 for a physician + 4 for an administrator + 4 for a mid-level practitioner + 8 for a nurse + 2 for a clerical staff person) at a cost of $1,657 ($191 for a physician + $428 for an administrator (4 hours x $107) + $404 for a mid-level practitioner (4 hours x $101) + $568 (8 hours x $71 for a nurse) + $66 for a clerical staff person (2 hours x $33). Therefore, for all 1,004 non TJC-deemed CAHs to comply with these requirements, it would require 19,076 burden hours (19 x 1,004 non TJC-deemed CAHs) at a cost of approximately $1.7 million ($1,657 for each CAH x 1,004 non TJC-deemed CAHs). We note here the difference in hourly wage between a hospital CEO/administrator ($189) and a CAH CEO/administrator ($107). This is estimated to be an additional 15,431 hours and $1.3 million in cost compared to the existing QA burden.

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)

Updating policies: 1 Coordinator @ $107/hr. x 3 hrs/yr	3,645	$390,015
TOTAL	**3,645**	**$390,015**

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

CAHs are required to have and implement written protocols that:
(1) Incorporate an agreement with an 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 ensure that all usable tissues and eyes are obtained from potential donors.

We believe that prudent healthcare institutions would have written protocols for handling a death that occurs in its institution. Therefore, we have estimated that the burden associated with this requirement reflects the time necessary to notify the OPO of a death or an imminent death.

Based on the 2016 CMS Integrated Data Repository (IDR), 7,719 deaths occurred in all CAHs that year. Based on this data, if the average call to an OPO to report a death takes 5 minutes (0.0833 hours) and the total number of calls made for all CAHs equals 7,719, the annual burden for a single CAH would be approximately 0.49 hours (6 calls/CAH x 0.0833 hours). We therefore estimate 595 hours for the 1,215 CAHs without DPUs.

Personnel, Wages, and Hours (for 1,215 CAHs)	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Clinician @ $71/hr. x 0.0833 hours/call x 6 calls/yr/CAH	595	$42,245
TOTAL	**595**	**$42,245**

485.645(d) SNF Services

The chart below reflects the burden associated with this requirement.

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

The facility must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare. Before a facility can transfer or discharge a resident the facility must notify the resident of the actions to be taken in writing and in a language and manner they understand. The burden associated with this requirement is the time and effort necessary to disclose the notice requirement referenced above to each patient. The FY 2016 IDR data reported that 1,215 CAHs had a total of 302,010 live discharges. We estimate that on average, approximately a third of the discharges were from swing beds.

Therefore, using the IDR data, we estimate a total of 103,243 annual discharges from all CAHs.

We estimate that it will take a clerical staff at each CAH 5 minutes to notify each patient receiving SNF level care of the transfer or discharge. On average, we have estimated that a CAH that provides "swing-bed care" will transfer or discharge 110 residents annually (1,215 CAHs x 110 residents x .0833 minutes) with annual burden hours of 11,133.

Personnel, Wages, and Hours	Annual Burden Hours (for 1,215 CAHs)	Annual Cost Burden (for 1,215 CAHs)
1 Clerical person @ $37/hr. x .0833 hours x 110 notices	11,133	$411,921
TOTAL	**11,133**	**$411,921**

The table below provides a summary of the estimates within this package.

CFR SECTION	**Annual Burden Hours** for 1,215 CAHs	**Annual Cost Burden** for 1,215 CAHs
485.618(c)	2,430	$174,960
485.623(d)(4)	608	$22,496
485.631	3,038	$366,341
485.635(a)	9,722	$1,192,116
485.635(c)(3)	2,430	$274,590
485.635(f)	304	$57,456
485.641	3,645	$390,015
485.643(a) and (b)	595	$42,245
485.645(d)	11,133	$411,921
TOTAL	**0**	**0**

13. Capital Costs

There are no capital costs.

14. Cost To Federal Government

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

and if an initial determination to terminate a CAH for noncompliance is to be made, such decisions are made by the RO.

15. Adjustments/ Program Changes

This package has been updated to reflect changes related to patient care policies. Although we are changing that requirement from an annual review to a biennial review, resulting in real-world savings, the burden associated with that review was not previously accounted for in this package due to it being considered a usual and customary business practice. Introducing the remaining biennial review to this package results in an increase in burden from 24,183 hours to 33,905 hours.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number 0938-1043.