

Supporting Statement
Critical Access Hospital (CAH) Conditions of Participation
(CoPs) and Supporting Regulations
OMB No. 0938-1043/(CMS-10239)

A. Background

The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with changes, the information collection request, associated with OMB No. 0938-1043, titled “Critical Access Hospital (CAH) Conditions of Participation (CoPs) and Supporting Regulations.”

Sections 1820 and 1861(mm) of the Social Security Act provide that CAHs participating Medicare meet certain specified requirements. The regulations containing the 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.

This is a reinstatement of the information collection request that expired on March 31, 2024. The previous iteration of this OMB No. 0938-1043 (approved March 25, 2021) had a burden of 33,905 annual hours. For this requested reinstatement, with changes, the total annual burden hours for industry is 898,332 hours and the annual burden costs are \$74,020,673.

The increase in burden hours from the prior package is primarily due to new information collections associated with new CoPs for CAHs outlined in the two CMS rules referenced below. The new CoPs include multiple information collection requirements that are one-time burdens for developing new policies and protocols and ongoing reporting requirements, such as daily or biweekly reporting of respiratory illnesses as well as maternal deaths. The reasons for the increased information collections are discussed in more detail in the rules and are summarized later in this package.

Obstetrical services included in the proposed rule, Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities, 89 FR 59186 (July 22, 2024) (hereinafter referred to as the “July 2024 Proposed Rule”).

Reporting of acute respiratory illnesses in the interest of public health and ensuring resiliency in the U.S. health care system included in the Final rule: Medicare and Medicaid Programs and the Children’s Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment

System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes. The aforementioned final rule, CMS-1808-F (RIN 0938-AV34), is currently on display at the Office of the Federal Register and scheduled for publication on August 28, 2024 (hereinafter referred to as the “August 2024 Final Rule”).

The change in total burden hours is also due to prior information collection requests are exempt from the PRA because the requirements are customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs.

For a summary of the annual burden hours and costs for specific CoPs in this reinstatement see Table 14.

B. Justification

1. Need and Legal Basis

Section 1820 of the Social Security 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 Critical Access Hospital (CAHs). Unlike traditional hospitals that are paid based on a prospective payment system, CAHs are currently paid 101 percent of their reasonable costs. In addition, CAHs have their own Medicare Conditions of Participation (CoPs), which are codified in the implementing regulations at 42 CFR part 485, subpart F. 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).

Per Section 1820(c)(2)(B), CAHs must meet the following criteria in order to be certified as a Medicare participating hospital:

- 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 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 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. Presently, there are 119 CAHs with psychiatric DPUs and 19 CAHs with rehabilitation DPUs, for a total of 138. The ICR burdens associated with the 138 CAHs that have DPUs is included in the Hospital CoPs package at OMB No. 0938-0328/CMS-R48, along with the burden for all accredited and non-accredited hospitals.

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 138 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 designed to assure that CAHs have written policies and procedures regarding the requirements finalized. The requirements are used by surveyors as a basis for determining whether a CAH is meeting the requirements to participate in the Medicare program. The ICRs contained in this regulation 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.

3. Improved Information Technology

CAHs may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation 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 Similar Information

These requirements are specified in a way that does not require a CAH to duplicate its efforts. If a facility already maintains these general records, regardless of format, they are in

compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records, from one facility to another, acceptable.

5. Small 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 information directly from CAHs and instead relies on State surveyors (employed by State survey agencies) to review the collection of information at the time of their certification and at the time of their facility visit. Nor does the rule prescribe the manner, timing, or frequency of the records or information that must be available. CAH records, 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 Conditions for Participation (CoPs), which in turn, would jeopardize the health and safety of CAH patients and provision of quality healthcare.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register package published XXXXXXXXXXXX.

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

Confidentiality will be maintained to the extent provided by law. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Requirements of HIPAA's Privacy Rules (at 45 CFR 160 and 164) protect the privacy and security of an individual's protected health information

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

Assumptions

Facilities Impacted

For the Calendar Year 2023, 1,245 of the total number of CAHs (1,383) are subject to the CoPs listed in this reinstatement. The ICRs for the 138 CAHs that have Distinct Part Units (DPUs)(119 with psychiatric DPUs and 19 with rehabilitation DPUs) are included in Hospital package at OMB No. 0938-0328 because these CAHs must comply with the Hospital CoPs. Furthermore, as it relates to specific CoPs discussed in detail below, there are 513 CAHs that provide obstetric services and 25% of CAHs are accredited by The Joint Commission.¹

Table 1: Facility Summary

CAHs	
Total # of CAHs	1,383
# of CAHs covered in 0938-1043	1,245
# of CAHs covered in 0938-0328	138
# of CAHs w/rehab DPUs	19
# of CAHs w/psych DPUs	119
# of CAHs providing obstetric services	513
% Accredited by The Joint Commission	25%
Total facilities impacted by this ICR	1,245

Salary Data

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates (Cross-Industry) found at https://www.bls.gov/oes/current/oes_nat.htm#00-0000

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. 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, and rounded the numbers up to the next dollar amount where appropriate.² The salary estimates (including estimated fringe benefits and overhead at 100%) contained in this package are based on the following healthcare personnel:

¹ CASPER (Certification and Survey Provider Enhanced Reports) Data for Calendar Year 2023 per Provider of Services File—Hospital & Non-Hospital Facilities. Available at <https://data.cms.gov/provider-characteristics/hospitalsand-other-facilities/provider-of-services-filehospital-non-hospital-facilities/data>. Accessed April 10, 2024.

² If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar.

“Coordinator” refers to the BLS national estimates for Medical and Health Service Managers (11-9111). The median wage is \$53.21 per hour. For purposes of this ICR, we use the figure \$106 per hour, representing the median wage plus fringe benefits and overhead.

The “Physician” salary refers to the BLS national estimates for Physicians, Other (29-1229) as the medical staff at CAHs include physicians that are general Internists, surgeons, and other specialists. The median wage is equal to or greater than \$113.46 per hour. For purposes of this ICR, we use the figure \$227 per hour, representing the median wage plus fringe benefits and overhead.

“Clinician or Clinical Nurse Specialist” refers to the BLS national estimates for a Registered Nurse (29-1141). The median wage is \$41.38 per hour. For purposes of this ICR, we use the figure \$83 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 (29-2072). The median wage is \$23.45 per hour. For purposes of this ICR, we use the figure \$47 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 \$21.39 per hour. For purposes of this ICR, we use the figure \$43 per hour, representing the median wage plus fringe benefits and overhead.

Table 2: May 2023 Bureau of Labor Statistics Wage Data³

Personnel	Labor Code	Median Hourly Wage	Hourly Wages w/Benefits	BLS Labor Title
COORDINATOR	11-9111	\$53.21	\$106	Medical and Health Services Manager
PHYSICIAN	29-1229	\$113.46	\$227	Physicians, Other
CLINICIAN/CLINICIAN NURSE SPECIALIST	29-1141	\$41.38	\$83	Registered Nurse
RECORDS TECHNICIAN	29-2072	\$23.45	\$47	Medical Records Specialists
MEDICAL SECRETARY/CLERICAL	31-9099	\$21.39	\$43	Healthcare Support Workers, Other
CMS SURVEYOR	19-3022	\$29.31	\$59	Survey Researcher

Source: [May 2023 OEWS National Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/ocwage2.pdf)

Patient-Related Activities

We are not including burdens associated with most patient-related activities (such as healthcare plans, patient records, and clinical records) in this package because these activities constitute customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. CoP’s related to patient activities are not assigned a burden and are exempt from the Paperwork Reduction Act (PRA) requirements in accordance with 5 CFR §1320.3(b)(2).

³ Note: This package also includes burden estimates from newly released CMS rules and applies the specific wage assumptions that were used in the respective rules for consistency.

485.616(a)and (b)- CoP: Agreements with network hospitals

CAHs that are part of a rural health network, must have agreements with other providers in the network for communication, referrals, transportation of patients, and quality assurance between providers as a CoP. The burden associated with this CoPs is exempt from the PRA per 5 CFR 1320.3(b)(2) because it is usual and customary for facilities such as hospitals and CAHs to be able to receive and transfer patients from other acute facilities or providers (e.g., a local Federally Qualified Health Center) depending on the level of care patients need. For example, if a pregnant patient presents at a CAH, but that particular CAH does not offer obstetric services, the CAH should have standing agreements with the nearest hospital that does provide those services in order to be able to transfer the patient to a facility where she can obtain the services needed as seamlessly as possible.

485.616(c)(4)(iv) - CoP: Agreements for credentialing and privileging of telemedicine physicians and practitioners

CAHs that offer telemedicine services through an agreement with a distant-site telemedicine entity can rely on that entity's credentialing and privileging process and standards but must ensure it has "evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in the periodic appraisal of the distant-site physician or practitioner."

Because the use of telemedicine services has grown especially for patients in rural areas, CAHs should ensure these CoPs are met as a way to provide oversight when using a distant-site telemedicine entity. We estimate that obtaining and documenting the appraisal of distant-site practitioners periodically would require 2 hours of a medical secretary's time each year.

Table 3: IC-1: CoP: Telemedicine Agreements – 485.616(c)(4)(iv)

Task	Hourly Median Wage	Hours/Task	Cost/Task
Medical Secretary	\$43	2.0	\$86.00
# Facilities Impacted	1,245		
Total Annual Burden/Costs		2,490	\$107,070

485.618 – CoP: Emergency Services

A CAH must ensure it has the necessary staffing, equipment, supplies, and medication to provide emergency services. This includes coordinating with the local emergency response systems and being able to refer or transfer patients to other providers once a patient has been stabilized under EMTALA requirements. The burden associated with these CoPs is exempt from the PRA per 5 CFR 1320.3(b)(2) because it is usual and customary practice for facilities that provide emergency services and is also patient related.

We previously calculated a burden related to Section 485.618(c) requiring CAHs to update policy agreements with blood collection establishments to ensure prompt notification about

potentially infected blood and blood products. This burden is also exempt from the PRA per 5 CFR 1320.3(b)(2) because it should be usual and customary practice.

485.623(c)(4) – CoP: Life Safety from fire

We previously calculated a burden for the requirement that CAHs must maintain written evidence of regular fire inspections by local or state fire control agencies.⁴ However, the burden associated with this requirement is exempt from the PRA per 5 CFR 1320.3(b)(2) because maintaining documentation of safety inspections is usual and customary practice. Maintaining this evidence is also required by local and state agencies and thus this burden is also exempt per 5 CFR 1320.3(b)(3).

485.631(c)(1)(i) – CoP: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities for development and review of policies.

We previously calculated a burden for the “periodic review of the written policies governing the services the CAH furnishes” by medical staff. However, staffing requirements and responsibilities – including administrative functions that provide oversight and quality assurance – should be considered customary and usual practice. As a result, the burden associated with this staffing requirement is exempt from the PRA per 5 CFR 1320.3(b)(2).

485.635(a)(4) – CoP: Patient care policies

Per Section 485.635(a)(4), CAHs are required to conduct biennial review of policies and procedures related to patient care. This requirement previously was an annual review and we considered it usual and customary business practice and thus exempt from the PRA. Because the review is now every two years, it is related to patient care, and should be considered usual and customary practice, the burden associated with this staffing requirement is exempt from the PRA per 5 CFR 1320.3(b)(2).

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

We previously calculated a burden for the requirement that CAHs must maintain a list of all services furnished under arrangements or agreement. However, the burden associated with this requirement is exempt from the PRA per 5 CFR 1320.3(b)(2) because ensuring written agreements for providing services exist should be considered usual and customary practice.

485.635(f) - CoP: Provision of services

We previously calculated a burden for the requirement that CAHs 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. However, the burden associated with this requirement is exempt from the PRA per 5 CFR 1320.3(b)(2) because it is related to patient care and should also be considered usual and customary practice.

⁴ The requirement is at 42 CFR § 485.623(c)(4) but was incorrectly referenced as § 485.623(d)(4) in the prior package.

485.638 – CoP: Clinical Records

The CoP to maintain health records is patient related and usual and customary business practice. Thus, the burden associated with this requirement is exempt from the PRA per 5 CFR 1320.3(b)(2).

485.641 – CoP: Quality assessment and performance improvement program (QAPI)

When the QAPI programs were first required as a CoP, we identified and previously calculated the burden associated with information collection requirements for the creation of a QAPI program, implementing and tracking quality data, and making improvements based on the findings. Since then, however, CAHs that fail to monitor quality and make improvements would inevitably lead to poor patient outcomes, higher costs, and potentially legal liability, whether or not certified by CMS. As a result, the majority of the information collection requirements associated with a CAH's QAPI program should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR 1320.3(b)(2).

However, as a CoP under Section 485.641, CAHs must “maintain and demonstrate evidence of the effectiveness of its QAPI program” for CMS to review, which is a task CAHs would otherwise not need to do, but for the CoP. Thus, we estimate the burden associated with this requirement would require a QAPI clerical staff member to spend 2 hours per year to gather the relevant data and documents (e.g., quality metrics, progress reports) in preparation for review by a CMS Surveyor and a QAPI Coordinator would spend a total of 3 hours to present the information to a CMS Surveyor and conduct any follow up that may be required.

Table 4: IC- 2: CoP: QAPI Program Review – 485.641

Task	Hourly Wage	Hours/ Task	Cost/ Task
QAPI Clerical Staff	\$43	2.0	\$86
QAPI Coordinator	\$106	3.0	\$318
Task Total/Year		5.0	\$404
# Facilities Impacted	1,245		
Total Annual Burden/Costs		6,225	\$502,980

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

We previously calculated a burden for these CoPs. However, these requirements – that CAHs have and implement written protocols for notifying the Organ Procurement Organization (OPO) of a potential donor and to have agreements with at least one eye and tissue bank - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR 1320.3(b)(2). In addition, CoPs that are related to transplant centers are captured under OMB 0938-1069 (CMS -10266) which will be reinstated.

485.645(d) - CoP: SNF Services

CAHs that provide long term care (swing bed) services (SNF level care) must comply with numerous CoPs. We previously calculated a burden specifically related to the requirement that a CAH must notify a patient in writing before the patient is transferred or discharged. However, the burden associated with this requirement is exempt from the PRA per 5 CFR 1320.3(b)(2) because notifying patients prior to transfer or discharge should be usual and customary practice and because the requirement is patient related.

New Conditions of Participation for Reporting of Respiratory Illnesses

IC-3: New CoP: Ongoing Reporting of Acute Respiratory Illnesses - Section 485.640(d)

Under new CoPs detailed in the [August 2024 Final Rule](#), all participating CAHs will be required to continue to “electronically report information on acute respiratory illnesses, including influenza, SARS-CoV-2/COVID-19, and RSV, in a standardized format and frequency specified by the Secretary.” Ongoing reporting of acute respiratory illnesses must include the following data elements: (a) Confirmed infections for a limited set of respiratory illnesses, including but not limited to influenza, SARS-CoV-2/COVID-19, and RSV, among newly admitted and hospitalized patients; (b) Total bed census and capacity, including for critical hospital units and age groups; (c) Limited patient demographic information, including but not limited to age.

Based on the assumptions in the [August 2024 Final Rule](#), we estimate ongoing reporting would require 0.75 hours per week for a Registered Nurse with a loaded hourly rate of \$78 and that this requirement would apply to all participating CAHs (including CAHs with DPU). Based on weekly reporting, the annual burden hours would be 53,937 hours (1,383 CAHs × 52 weeks × 0.75 hours) and the annual burden costs would be \$4,243,044 or approximately \$3,068 per facility annually (\$4,243,044/1,383 CAHs).

Table 5: IC-3: CoP: Ongoing Reporting of Acute Respiratory Illnesses – 485.640(d)(1)

Task	Factors	Hours/ Task	Cost/ Task	Annual Burden Hours	Annual Burden Cost
Clinician - Registered Nurse	\$78				
Reports/Year/Facility	52	0.75	\$59	39.0	\$3,068
# of Facilities	1,383				
All Facilities	71,916			53,937	\$4,243,044

IC-4: New CoP: Future Public Health Emergency (PHE) Reporting of Acute Respiratory Illnesses - Section 485.640(d)(2)

Under the new CoPs, all participating CAHs will be required to report specific data elements to the CDC’s National Health Safety Network (NHSN), or other CDC-supported surveillance systems when an applicable Public Health Emergency for an acute respiratory illness (or threat of) has been declared by the HHS Secretary in the future.” As detailed in the [August 2024 Final Rule](#), the report will need to be in a standardized format, submitted at a frequency specified by the Secretary, and include the following data elements: a) Supply inventory shortages; b) staffing shortages; c) relevant medical countermeasures and therapeutic inventories, usage, or both; d) facility structure and operating status, including hospital/ED diversion status. During the COVID-19 PHE, reporting was required on a daily basis. However, future reporting may be required less frequently. Thus, we include two burden estimates to encapsulate a range in frequency of future reporting for acute respiratory illnesses during a PHE with a lower range based on twice a week reporting and a higher range based on daily reporting.

Based on the assumptions in the [August 2024 Final Rule](#), we estimate that future reporting of acute respiratory illnesses during a PHE for all participating CAHs (including CAHs with DPU) would require 1.5 hours for a Registered Nurse with a loaded hourly rate of \$78 to complete and submit, regardless of reporting frequency. Note that burden estimates would significantly decrease as reporting becomes more automated over time. Assuming CAHs report *twice a week* (low range), we estimate the annual burden hours would be 215,748 hours (1,383 CAHs × 52 weeks x 2 times per week x 1.5 hours) and the annual burden costs would be \$16,828,344 or approximately \$12,168 per facility annually (\$16,828,344/1,383 CAHs). Based on *daily reporting* (high range), we estimate that the annual burden hours would be 757,193 hours (1,383 CAHs× 365 days x 1.5 hours) and the annual burden costs would be \$59,061,015 or approximately \$42,705 per facility annually (\$59,061,015/1,383 CAHs).

Table 6: IC-4:CoP: Future PHE Reporting of Acute Respiratory Illnesses – 485.640(d)(2)

Task	Factors	Hours/ Task	Cost/ Task	Annual Burden Hours	Annual Burden Cost
Registered Nurse	\$78				
Reports/Year/Facility					
Low Range (2 x week)	104	1.5	\$117	156	\$12,168
High Range (Daily)	365	1.5	\$117	548	\$42,705
All Facilities	1,383				
Low Range (2 x week)				215,748	\$16,828,344
High Range (Daily)				757,193	\$59,061,015

New Conditions of Participation for CAHs that provide Obstetrical Services

After extensive research and stakeholder feedback as detailed under “Section XXI: Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals” of the [July 2024 Proposed Rule](#), CMS proposed new CoPs governing the organization, staffing, and delivery of OB services and staff training in order to establish “baseline care requirements for hospitals and CAHs that are specific to maternal-child services (that is, labor and delivery, prenatal and post-partum care, and care for newborn infants, alternately referred to in this discussion as obstetrical services, obstetrics, maternal health, or maternity care).”⁵

We estimate below the burden of information collection requirements associated with these new CoPs for Obstetrical Services based on the assumptions included in the [July 2024 Proposed Rule](#), including the estimate that 513 of all participating CAHs provide obstetric services.⁶

IC-5: New CoP: Emergency services readiness - Section 485.618(e)(1)

Under Section 485.618(e)(1), CAHs must have nationally recognized and evidence-based protocols to provide emergency services to all patients, including those with “obstetrical emergencies, complications, and immediate post-delivery care.” Applying the assumptions regarding the information collection requirements of the new CoP in the July 2024 proposed rule to implement the new CoPs, we estimate the one-time burden of developing written protocols that meet the new emergency services readiness requirements. We do not include an estimate for updating standards since reviewing and updating policies and procedures is a customary business practice.

Based on the assumptions in the [July 2024 Proposed Rule](#), we estimate this requirement would apply to all participating CAHs that provide emergency services (including CAHs with DPUs) and would take 4 hours for each staff member involved to add to an existing protocol rather than creating a new protocol for emergency services. We estimate the following staff (applying a loaded hourly mean rate from the BLS National Occupational Employment and Wage Estimates) will be involved in writing the new protocol: a Physician (BLS Code: 29-1229) at \$253.70 per hour, a lawyer (BLS Code: 23-1011) at \$169.68 per hour, a Registered Nurse (BLS Code: 29-1141) at \$90.84 per hour, a Medical Secretary (BLS Code: 43-6013) at \$41.70 per hour, and an Administrator (BLS Code: 11-1011) at \$129.28 per hour. We determine the burden cost using a blended wage rate per the table below.

⁵ [Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities](#), 89 FR 59186, 59488-59500, (July 22, 2024)

⁶ See 89 FR 59186, 59533. CMS’ CASPER (Certification and Survey Provider Enhanced Reports) Provider of Services File—Hospital & Non-Hospital Facilities. Available at <https://data.cms.gov/provider-characteristics/hospitalsand-other-facilities/provider-of-services-file/hospital-non-hospital-facilities/data>. Accessed April 10, 2024.

Table 7: IC-5: Written protocols for Emergency services readiness – 485.618(e)(1)

Task	Hourly Mean Wage	Hours/Task	Cost/Task
One-time development of ER protocols			
Physician	\$253.70	4.0	\$1,014.80
Lawyer	\$169.68	4.0	\$678.72
Administrator	\$129.28	4.0	\$517.12
Registered Nurse	\$90.84	4.0	\$363.36
Medical Secretary	\$41.70	4.0	\$166.80
Total Task/Facility		20.0	\$2,740.80
Aggregate Staff Cost/Task			\$137.04
# Facilities Impacted	1,383		
Total Annual Burden/Costs		27,660	\$3,790,526

New CoPs: Condition of participation: QAPI for Hospitals with Obstetrical Services
- Sections 485.641(d)(4) and (e)

Under the new CoP in [July 2024 Proposed Rule](#) at Section 485.641(d)(4), CAHs that provide obstetrical services (hereinafter “OB services”) must collect and analyze data to help improve maternal child health outcomes. Specifically, CAHs must:

“Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients.”

“Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients.”

“Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.”

Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital’s population(s) of obstetrical patients annually.

IC-6: New CoP: One-time IT update for OB Services Data Collection – Section 485.641(d)(4)

To comply with the new CoP, the 513 CAHs that provide OB services would need to update their IT systems in Year 1 to capture the data required and ensure the system continues to accurately capture the correct data on an ongoing basis. Based on the assumptions in the [July 2024 Proposed Rule](#), we estimate an IT staff member (BLS Occupation Code 15-0000 for all Computer and Mathematical Occupations) who earns a loaded mean wage of \$108.78 per

hour would need 8 hours in the first year and 4 hours per year on an ongoing basis to complete this task.

Table 8: IC-6 CoP: Initial IT Update for OB services Data Collection – 485.641(d)(4)

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task
IT Staff (BLS Code: 15-0000)	\$108.78		
<u>Per Facility/Year</u>			
Year 1 - IT System Changes		8.0	\$870
Ongoing IT maintenance		4.0	\$435
# Facilities Impacted	513		
Year 1 Burden Hours/Costs		4,104	\$446,310
Ongoing Annual Burden Hours/Costs		2,052	\$223,155
Annualized Burden Hours/Costs Over 3 Years		2,736	\$297,540

IC-7: New CoP: Ongoing Data Analysis for OB services – Section 485.641(d)(4)

Once the required maternal health data is collected, each facility must conduct ongoing data analysis of maternal health quality metrics and make improvements based on the findings. Per the assumptions in the [July 2024 Proposed Rule](#), we estimate that each of the 513 CAHs that provides OB services would need a Data Scientist (BLS Occupation Code 15-2051) who earns a loaded mean wage of \$114.46 per hour to spend 8 hours every year an ongoing basis to complete this task.

Table 9: IC- 7 CoP: Ongoing Data Analysis for OB services – 485.641(d)(4)

	Hourly Mean Wage	Hours/ Task	Cost/ Task
Data Scientist (BLS Code:15-2051)	\$114.46	8.0	\$916
# Facilities Impacted	513		
Total Annual Burden/Costs		4,104	\$469,908

IC-8: New CoP: Ongoing Maternal Death Reporting to MMRC – Section 485.641(d)(4)(ii)

Under Section 485.641(d)(4)(ii), every CAH that provides OB services must report maternal deaths to the local maternal mortality review committee (MMRC). Based on the assumptions in the July 2024 Proposed Rule, we estimate CAHs will report 69 maternal deaths per year (8% of 850 maternal deaths for both hospitals and CAHs) and each report would require a Physician (BLS Code: 29-1229) who earns a loaded hourly mean rate of \$253.70 and a Medical Records Specialist (BLS Code: 29-2072) who earns \$51.62 per hour to spend 4 hours each.

Table 10: IC- 8: CoP: Ongoing Maternal Death Reporting to MMRC – 485.641

Task	Hourly Mean Wage	Hours/Task	Cost/Task
Physician	\$253.70	4.0	\$1,015
Medical Records Specialist	\$51.62	4.0	\$206
		8.0	\$1,221
Aggregate Staff Cost/Task			\$152.66
# of Tasks	Factors	Hospitals	CAHs
Total Annual Maternal Deaths	850		
Total Facilities that provide OB services	6,310	5,797	513
% of Total		92%	8%
# of Maternal Deaths to report/year		781	69
Total Annual Burden/Costs			
	CAHs	69	553
			\$84,421

IC-9: New CoP: Practitioners’ Roster – Section 485.649(a)(2)

The new CoP at 485.649(a)(2) requires the 513 CAHs that provide OB services to annually update a list of their OB staff’s specific competencies and privileges. We estimate that each of the 513 CAHs that provides OB services would need a Medical Secretary (BLS Code 43-6013) who earns a loaded hourly mean rate of \$41.70 to spend 8 hours per year to annually update this “practioners’ roster.”

Table 11: IC-9 CoP: Practitioners’ Roster – 485.649(a)(2)

Task	Hourly Mean Wage	Hours/Task	Cost/Task
Medical Secretary	\$41.70	8.0	\$333.60
# Facilities Impacted	513		
Total Annual Burden/Costs		4,104	\$171,137

IC-10: New CoP: Written policies for Obstetrical Services - Section 485.649(b) and (c)

Per 485.649(b)(2), CAHs must develop written policies and procedures that are “consistent with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility’s QAPI program” and must train staff on these policies.

We estimate the one-time burden of creating the required written policies and protocols for OB services proposed in the July 2024 rule and do not include the burden hours and costs for ongoing updates to the policies since that is a customary business practice. Furthermore, we estimate that this CoP will impact non-accredited hospitals because accredited hospitals must already meet extensive requirements if they provide OB services in order to get certified by The Joint Commission. Per the assumptions in [July 2024 Proposed Rule](#), 25% of CAHs are accredited by The Joint Commission (TJC).⁷ Thus, we estimate 385 (75% of 513 CAHs that provide OB services) will be impacted by the information collection requirements associated with this new CoP for the one-time creation of written policies for OB services.

For each of the 385 impacted CAHs, we estimate the one time burden to develop written policies, which would require 8 hours for each staff member involved: a Physician (BLS Code: 29-1229) at \$253.70 per hour, a lawyer (BLS Code: 23-1011) at \$169.68 per hour, a Registered Nurse (BLS Code: 29-1141) at \$90.84 per hour, a Medical Secretary (BLS Code: 43-6013) at \$41.70 per hour, and an Administrator (BLS Code: 11-1011) at \$129.28 per hour. We determine the burden cost using a blended wage rate per the table below.

Table 12: IC-10: CoP: Written policies for Obstetrical Services – 485.649(b)(2)

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task
One-time development of policies			
Physician	\$253.70	8.0	\$2,029.60
Lawyer	\$169.68	8.0	\$1,357.44
Administrator	\$129.28	8.0	\$1,034.24
Registered Nurse	\$90.84	8.0	\$726.72
Medical Secretary	\$41.70	8.0	\$333.60
Total Task/Facility		40.0	\$5,481.60
Aggregate Staff Cost/Task			\$137.04
CAH providing OB services	513		
% that are not accredited	75%		
# Facilities Impacted	385		
Total Annual Burden/Costs		15,400	\$2,110,416

⁷ See 89 FR 59186, 59533. CMS’ CASPER (Certification and Survey Provider Enhanced Reports) Provider of Services File—Hospital & Non-Hospital Facilities. Available at <https://data.cms.gov/provider-characteristics/hospitalsand-other-facilities/provider-of-services-file/hospital-non-hospital-facilities/data>. Accessed April 10, 2024.

IC-11: New CoP: Written policies on staff training - Section 485.649(c)

The 513 CAHs that provide OB services must develop policies and procedures to ensure that staff are trained on select topics related to improving the delivery of maternal care and that the training is updated to reflect findings from the QAPI program. We assume only one policy per facility is required to meet this CoP. The additional requirement to document that staff have completed the required training is considered customary and usual practice and thus the ongoing information collection is exempt from the PRA per 5 CFR 1320.3(b)(2).

As before, we estimate the one-time burden of developing staff training policies, which would require 8 hours for each staff member involved: a Physician (BLS Code: 29-1229) at \$253.70 per hour, a lawyer (BLS Code: 23-1011) at \$169.68 per hour, a Registered Nurse (BLS Code: 29-1141) at \$90.84 per hour, a Medical Secretary (BLS Code: 43-6013) at \$41.70 per hour, and an Administrator (BLS Code: 11-1011) at \$129.28 per hour. We determine the burden cost using a blended wage rate per the table below.

Table 13: IC-11: CoP: Written policies for staff training – 485.649(c)

Task	Hourly Median Wage	Hours/Task	Cost/Task
One-time development of policies			
Physician	\$253.70	8.0	\$2,029.60
Lawyer	\$169.68	8.0	\$1,357.44
Administrator	\$129.28	8.0	\$1,034.24
Registered Nurse	\$90.84	8.0	\$726.72
Medical Secretary	\$41.70	8.0	\$333.60
Total Task/Facility		40.0	\$5,481.60
Aggregate Staff Cost/Task			\$137.04
# Facilities Impacted	513		
Total Annual Burden/Costs		20,520	\$2,812,061

13.Capital Costs

There are no capital costs.

14.Cost To Federal Government

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. The burden and costs to the federal government for this ICR are estimated to include the time spent by CMS surveyors to complete CoP compliance evaluations for Critical Access Hospitals (CAHs). There are

multiple points in time when CMS conducts evaluations of hospitals for compliance with CoPs. First, each hospital undergoes a CMS compliance review at the time of initial application for Medicare approval. Subsequent surveys for every hospital are conducted an average of every 4.5 years, but it varies between 3 and 6 years.

The burden for completing these responsibilities was calculated using a loaded hourly median wage of \$59 per hour for a State Survey Agency reviewer (BLS Occupation Code 19-3022) which includes benefits and overhead. For the initial compliance review, we estimate the cost to the Federal government to ensure each facility's compliance to be 4 hours, with a net cost of \$236 per facility (4 hours x \$59). For ongoing compliance, we estimate the cost to the Federal government to ensure each facility's compliance to be 1 hour, with a net cost of \$59 per facility (1 hour x \$59). The burden to the Federal government for each applicable information collection (IC) is calculated below with only those facilities that are impacted by each IC.

For this reinstatement, the total annual burden hours to the federal government is 27, 294 with an annual cost of \$1,610,346.

Table 15: Total Burden and Costs for Federal Government

Information Collection No.	# of Facilities	Hourly Wage	Hours/ Task	Total Burden Hours	Total Burden Costs
IC-1: 485.616(c)(4)(iv)	1,245	\$59	1	1,245	\$73,455
IC-2: 485.641	1,245	\$59	1	1,245	\$73,455
IC-3: 485.640(d)(1) - Initial Review	1,383	\$59	4	5,532	\$326,388
IC-4: 485.640(d)(2) (High range) - Initial Review	1,383	\$59	4	5,532	\$326,388
IC-5: 485.618(e)(1) - Initial Review	1,383	\$59	4	5,532	\$326,388
IC-6: 485.641(d)(4) - Yr. 1- IT System Changes/Initial Review	513	\$59	4	2,052	\$121,068
IC-6: 485.641(d)(4) - Ongoing IT System Maintenance	513	\$59	1	513	\$30,267
IC-7: 485.641(d)(4) - Data Analysis	513	\$59	1	513	\$30,267
IC-8: 485.641(e)	513	\$59	1	513	\$30,267
IC-9: 485.649(a)(2)	513	\$59	1	513	\$30,267
IC-10: 485.649(b)(2) - Initial Review	513	\$59	4	2,052	\$121,068
IC-11: 485.649(c) - Initial Review	513	\$59	4	2,052	\$121,068
Total				27,294	\$1,610,346

15.Changes to Burden

This package has been updated to reflect changes in information collection requirements related to new or revised Conditions of Participation for CAHs. For this reinstatement, the total annual burden hours for industry is **898,332** hours and the annual burden costs are

\$74,020,673. The table below provides a summary of the information collections burden hours and costs within this package.

The annual burden to industry increased from 33,905 hours to 898,332 hours. For details regarding this change in annual burden hours, see the **Background** section above.

Table 14: Total Burden and Costs for Industry

Information Collection No.	Annual Burden Hours	Annual Burden Costs
IC-1: 485.616(c)(4)(iv)	2,490	\$107,070
IC-2: 485.641	6,225	\$502,980
IC-3: 485.640(d)(1)	53,937	\$4,243,044
IC-4: 485.640(d)(2)(High range)	757,193	\$59,061,015
IC-5: 485.618(e)(1)	27,660	\$3,790,526
IC-6: 485.641(d)(4)	4,104	\$446,310
IC-6: 485.641(d)(4)	2,052	\$223,155
IC-7: 485.641(d)(4)	4,104	\$469,908
IC-8: 485.641(e)	553	\$84,421
IC-9: 485.649(a)(2)	4,104	\$171,137
IC-10: 485.649(b)(2)	15,390	\$2,109,046
IC-11: 485.649(c)	20,520	\$2,812,061
Total	898,332	\$74,020,673

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.

18.Certification

There is no exception to the certification.