Supporting Statement

Hospital Conditions of Participation (CoPs) and Supporting Regulations

(OMB No. 0938-0328/CMS-R48)

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. 0938-0328, titled "***Hospital Conditions of Participation (CoPs) and Supporting Regulations***."

The information collection requirements described herein are needed to implement the Medicare and Medicaid Conditions of Participation (CoPs) for a total of 5,132 facilities that includes: 4,994 accredited and non-accredited hospitals and 138 Critical Access Hospitals (CAHs) with Distinct Part Units (DPUs); specifically, 119 CAHs with psychiatric DPUs and 19 CAHs with rehabilitation DPUs. The information collection requirements for the 1,245 CAHs without DPUs (1,383 total CAHs less 138 CAHs with DPUs) are covered under **OMB No. 0938-1043/CMS-10239**.

This is a reinstatement of the information collection request that expired on 11/30/2017. The previous iteration of this OMB No. 0938-0328 (approved November 14, 2014) had a burden of 14,424,655 annual hours. For this requested reinstatement, with changes, the adjusted annual hourly burden for industry is **3,566,521** hours at an annual cost of **$310,989,894**.

The decrease in burden hours is primarily due to the fact that many of the information collections that were previously required as CoPs by CMS are now customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. In addition, where possible, CMS reduced the burden of CoPs with prior information collections. For example, the burden for individuals hospitals that are part of a multi-hospital system was reduced by allowing a multi-hospital system, which represent approximately 70% of hospitals today, to develop a unified Quality Assessment and Performance Improvement (QAPI) program rather than requiring each hospital in the system to maintain separate programs and reporting requirements.

This reinstatement also reflects a change in how the annual burden costs for information collection requirements for Hospital CoPs are calculated. In prior submissions, the fully loaded wage estimates applied only an additional 33% to the hourly wage to account for fringe benefits. This reinstatement applies an additional 100% to the median hourly wage to reflect the costs more accurately to hospitals for compliance with the current CoPs.

Additional changes reflected in this reinstatement are some of the information collections were placed on participating hospitals as CoPs during the recent COVID-19 Public Health Emergency (PHE), specifically regarding collecting and reporting data on incidents and hospital management of infection diseases. The burden of many of these information collections were accounted for in other OMB submissions, such as the "*Unified Hospital Data Surveillance System (U.S. Healthcare COVID-19 Collection"*(OMB 0990-0478), and some of these collections ended or were revised after HHS declared the end of the COVID-19 PHE in April 2024. As a result, this reinstatement does not include information collection requirements that have expired, and only includes the annual burden and costs to participating hospitals and CAHs with DPUs for information collections that have remained as CoPs after the COVID-19 PHE ended. In addition, 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, 89 FR 68986) (August 28, 2024)(hereinafter "August 2024 Final Rule") - this package includes burden estimates for additional information collection requirements that CMS is adding as CoPs in the interest of public health and ensuring resiliency in the U.S. health care system.

Finally, this reinstatement incorporates additional information collection requirements associated with a number of new CoPs for hospitals and CAHs regarding obstetrical services which are outlined in detail in: 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 "July 2024 Proposed Rule").

For a summary of changes to the annual burden hours and costs for specific CoPs, see **Table 18** (**Appendix)** for more details.

1. Hospital CoPs Changes Post 2014:

Since the last ICR, some changes have been made to the CoPs for hospitals through the

following list of Proposed and Final Rules. In general, these rules revise the CoPs for both hospitals and a subset of critical access hospitals (CAHs) to: (1) conform the requirements to current standards of practice; (2) reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care; (3) encourage improvements in quality of care; (4) reduce barriers to care; (5) reduce issues that may exacerbate workforce shortage concerns; (6) encourage innovative approaches to patient-service delivery.

A) Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732 (September 30, 2019)

Incorporates the following:

- "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction," 83 FR 47686 (September 20, 2018);
- "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care," 81 FR 39448 (June 16, 2016);
- "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Dialysis Facilities," 81 FR 76899 (November 4, 2016)

B) Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 19230 (April 4, 2020)

C) Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers, 85 FR 25510 (May 1, 2020)

D) Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19), 85 FR 85866 (December 29, 2020)

Incorporates the following:

- Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 54820 (September 2, 2020)

E) Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 FR 61555 (November 5, 2021)

F) Medicare 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, 87 FR 48780 (August 10, 2022)

Incorporates the following:

- Proposed Rule: "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation," 87 FR 28108 (May 10, 2022)

- "Medicare 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation; Corrections," 87 FR 66558 (November 3, 2022)

G) Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements, 88 FR 36485 (June 5, 2023)

H) Medicare 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation; Corrections, 88 FR 49552 (July 31, 2023)

I) 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)

J) 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, 89 FR 68986 (August 28, 2024)

2. Related ICRs

The following Information Collection Requirements (ICRs) reference other Conditions of Participation for hospitals and CAHs, and as a result, are **not included** in this ICR (OMB 0938-0328):

- 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 5,132 (i.e., 4,994 hospitals and 138 CAHs which include 119 CAHs that have psychiatric DPUs and 19 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,245 CAHs are accounted for in **OMB No. 0938-1043** *"Conditions of Participation for Critical Access Hospitals and Supporting Regulations (CMS-10239)."*
  - **OMB 0938-1043** incorporates relevant changes under: Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates, 87 FR 40350 (July 6, 2022)
- The information collection requirements for Emergency Preparedness on hospitals and CAHs are accounted for in **OMB No. 0938-1325** Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (September 16, 2016)
- Information collection requirements for COVID-related CoPs for Hospitals are accounted for in:
  - **OMB No. 0990-0478** Unified Hospital Data Surveillance System (U.S. Healthcare COVID-19 Collection (August 10, 2022)
    - Hospitals (IC ID: 251157)
    - Psychiatric and Rehabilitation Units (IC ID: 251021)
  - **OMB No. 0920-1299** "*COVID-19 Pandemic Response, Laboratory Data Reporting*" which includes relevant changes under: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 FR 54820 (September 2, 2020)
  - **OMB No. 0938-1278** (CMS-10552) "*Implementation of Medicare and Medicaid Programs; - Promoting Interoperability Programs Stage 3*" which includes relevant changes under: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and

Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19), 85 FR 85866 (December 29, 2020)(stating "the burden associated with these reporting activities will be submitted under OMB control number 0938-NEW. For purposes of burden estimates, we do not differentiate among general acute care and CAHs, as they all complete the same data collection).

B. JUSTIFICATION

1. Need and Legal Basis

Hospitals and CAHs

Under sections 1866 and 1902 of the Social Security Act ("Act"), providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary of Health and Human Services ("Secretary") or the state Medicaid agency, as appropriate. The Secretary may impose additional requirements if necessary to protect the health and safety of patients.

Section 1861(e)(9) of the Act authorizes the Secretary to promulgate any regulations that are deemed necessary to protect the health and safety of patients at hospitals and Sections 1820(e)(3) and 1861(mm) of the Act authorizes regulations that are deemed necessary to protect the health and safety of patients at critical access hospitals (CAHs). These collective regulatory requirements, or Conditions of Participation (CoPs), establish standards designed to ensure that every hospital and CAH have trained staff to provide the appropriate type and level of care for the environment of patients. The CoPs apply to all hospitals and CAHs, including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals.

The relevant Conditions of Participation (CoPs) are codified in the implementing regulations at part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs. 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).

CoPs for hospitals and CAHs that contain information collection requirements include:

42 CFR 482.12(d)(1), 482.12(d)(2), 482.12(d)(4), 482.12(d)(5), 482.12(e)(2), 482.12(f)(2), 482.13(a)(1), 482.13(a)(2), 482.13(d), 482.13(e), 482.13(f), 482.13(g), 482.13(h), 482.21, 482.21(b)(4), 482.21(e), 482.21(g), 482.22(c)(5),482.23(b)(7), 482.24(c)(2), 482.24(c)(3), 482.24(c)(4), 482.24(d); 482.27(a)(2), 482.27(b)(2), 482.27(b)(3), 482.27(b)(5), 482.27(b)(6), 482.27(b)(9), 482.27(b)(10), 482.30(c)(1), 482.30(d)(3), 482.41(b), 482.42(a)(2), 482.43(c), 482.45(a)(1), 482.45(a)(2); 482.45(b)(3), 482.53(d)(3), 482.55(c); 482.56(b), 482.57(b)(1), 482.58; 482.59(a)(2); 482.59(b) and (c); 482.59(c); 482.60(c), 482.61(f), 482.62(a), 482.92(a), 485.616(c)(1) - (c)(4).

This document represents the majority of information collection requirements of CoPs currently in effect for hospitals and a subset of CAHs. Other ICRs related to hospitals and CAH's not included here are discussed in Section A.2. above.

2. Information Users

The ICRs contained in this regulation are designed to assure that hospitals have written policies and procedures regarding the requirements finalized. 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. There are 5,132 hospitals and CAHs with Distinct Part Units (DPUs), that must meet these CoPs in order to receive program payment for services provided to Medicare or Medicaid patients.

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.

4. Duplication of Similar Information

The ICRs 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 these requirements. The general nature of the ICRs makes variations in the substance and format of these records from one facility to another acceptable.

5. **Small Business**

The ICRs do affect small businesses. However, the general nature of the ICRs allows the flexibility for facilities to meet the requirements in a way consistent with their existing operations.

6. **Less Frequent Collection**

CMS does not collect information directly from hospitals 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. The information collection serves as a basis for determining whether a hospital qualifies for approval or re-approval under Medicare**.** Surveyors make an in-person visit to hospitals to conduct their survey.

The collection of information does not prescribe the manner, timing, or frequency of the records or information that must be available. Hospital 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 hospital patients and provision of quality healthcare.

7. **Special Circumstances**

There are no special circumstances.

8. **Federal Register/Outside Consultation**

The 60-day Federal Register published August 7, 2024 (89 FR 64463). There were no public comments.

The 30-day Federal Register published October 15, 2024 (89 FR 83015).

9. **Payment/Gifts to Respondents**

There is no payment/gift to respondent.

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 sensitive questions.

12. **Burden Estimates (Hours & Wages)**

Assumptions

Facilities Impacted

There are 5,132 hospitals, including 138 CAHs with Distinct Part Units (DPUs), that must meet CoPs in this ICR in order to receive program payment for services provided to Medicare or Medicaid patients. Specifically, for the Calendar Year 2023, there were 4,994 accredited and non-accredited hospitals and 1,383 CAHs certified

by CMS per CASPER. Of all CAHs, 138 have DPUs (119 have psychiatric DPUs and 19 have rehabilitation DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. Thus, this ICR (OMB No. 0938-0328) analyzes the burden for all 4,994 hospitals and 138 CAHs with DPUs, or a total of 5,132 facilities. The burden of the Medicare and Medicaid CoPs on the 1,245 CAHs without DPUs (1,383 total CAHs less 138 CAHs with DPUs) is analyzed under the ICR for OMB No. 0938-1043/CMS-10239.

Additional facilities-related assumptions for burden calculations in this ICR include:

- Two hospitals per year will become newly certified under Medicare and Medicaid.
- Of all existing hospitals, fifty do not offer emergency services.
- 20% of hospitals (4,994) are non-accredited, or 999.[1]
- 68% of hospitals (3,396) are part of multi-hospital systems.

Table 1: Facility Summary

Hospitals	
Accredited Hospitals (80% of total)	3,995
Non-Accredited Hospitals (20% of total)	999
Total # of Hospitals	**4,994**
# Newly Certified/Year	2
# in multi-hospital systems (68% of total)	3,396
CAHs	
# of CAHs covered in 0938-0328	**138**
# of CAHs w/rehab DPUs	19
# of CAHs w/psych DPUs	119
Total # of CAHs	1,383
# of CAHs covered in 0938-1043	**1,245**
Total facilities impacted by this ICR	**5,132**

Wages

To estimate labor wages, we used salary labor categories as defined in the U.S. Department of Labor Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates found at www.bls.gov. Because this ICR impacts hospitals, we used hourly median wage data specific to the *Hospital Industry Sector (NAICS 622100) for General Medical and Surgical Hospitals* (including privately and publicly owned). We applied a 100% increase to the estimated BLS median hourly wage rate to factor in the fully loaded wage costs, which includes benefits such as Paid leave, Supplemental Pay, Insurance, Retirement and Savings, and other legally required benefits.[2] We also rounded all amounts to the nearest dollar. The salary estimates contained in this package are based on the following healthcare personnel:

Table 2: May 2023 Bureau of Labor Statistics Wage Data[3]

Personnel	BLS Labor Code	Hourly Median Wage	Wages w/Benefits	BLS Labor Title
ADMINISTRATOR/ DIRECTOR	11-9111	$62.13	**$124**	Medical and Health Services Manager
PHYSICIAN	29-1210	$94.83	**$190**	Physician
CLINICIAN	29-1141	$42.45	**$85**	Registered Nurse
RECORDS TECHNICIAN	29-2072	$25.32	**$51**	Medical Records Specialist
COORDINATOR	31-1131	$18.66	**$37**	Nursing Assistant
CLERICAL PERSON	43-4000	$18.99	**$38**	Information and Record Clerk
CMS SURVEYOR	19-3022	**$31.40**	**$63**	Survey Researchers

1 See e.g., Hospital Accreditation Fact Sheet | The Joint Commission

2 Prior ICRs estimated fringe benefits to be an additional 33% of the hourly wage to calculate the loaded wage cost.

3 Note: This package also includes burden estimates from newly released and future proposed regulations and refers to the same wage assumptions that were used in the rule for consistency.

Source: General Medical and Surgical Hospitals - May 2023 OEWS Industry-Specific Occupational Employment and Wage Estimates (bls.gov)

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 in accordance with 5 CFR §1320.3(b)(2).

Section 482.12(d)(1),(d)(2), and (d)(4) - Condition of participation: Standard: Governing Body - Institutional Plan and Budget

On an annual basis, the governing body, administrative and medical staff of the hospital must prepare an operating budget and plan for future capital expenditures (e.g., land or facility improvements, expansion, or modernization) that identifies the sources of financing for costs over $600,000. We estimate 95% of all hospitals would have such expenditures to report.

For existing facilities already certified, we estimate the following staff hours to review and update the annual budget and capital expenditures plan on behalf of the hospital's governing body. For newly certified facilities (2 per year), we estimate it will take 3 times the hours required of existing hospitals to comply with this CoC and 100% of the facilities would have expenditures over $600,000 to report.

Prepare/Update report

- Clerical staff will spend 3 hours to gather the most current budget and expenditure information from the hospital's financial office and update the forms required for the governing body to approve.
- The hospital administrator will spend 2 hours to review the updated budget and plan and to present the plan to the governing body to approve.
- For 95% of existing facilities, the hospital administrator will need an additional hour to prepare details for the capital expenditures over $600K.

Governing Body review

- The Governing body, which consists of 3 Administrator level staff, will spend .5 hours each to review/approve plan.

Table 3: IC-1 CoP: ***Operating Budget & Capital Expenditures: 42 CFR 482.12(d)(1), (d)(2), (d)(4)***

Task Per Facility	Hours Required	Hourly Wage	Total Per Task
1) Prepare/Update/Finalize Plan (d)(1) and (d)(2)			
Clerical Person	3.0	$38	$114
Administrator	2.0	$124	$248
Sub-total	5.0		$362
2) Prepare 482.12(d)(4) - capital expenditures (95% of facilities)			
Administrator	1.0	$124	$124
3) Governing Body Review			
3 Administrators @ ½ hr. each	1.5	$124	$186
Total per Facility	**7.5**		**$672**

Task All Facilities	# Facilities	Hours Per Task	Cost Per Task	Annual Total Hours	Annual Total Cost
Existing Facilities					
Prepare/Update	5,132	5.0	$362	25,660	$9,288,920
482.12(d)(4) (95% Of Facilities)	4,875	1.0	$124	4,875	$604,500
Governing Body Review	5,132	1.5	$186	7,698	$1,431,828
New Facilities - 3x Existing					
Prepare/Update	2	15.0	$362	30	$10,860
482.12(d)(4) (100% Of Facilities)	2	3.0	$124	6	$744

Governing Body Review	2	4.5	$186	9	$1,674
IC-1: Total Annual Burden & Costs				**38,278**	**$11,338,526**

Section 482.12(d)(5) – Planning Agency Review

The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. The "Section 1122" review does not apply if 75% of the hospital's patients enrolled in an HMO or competitive medical plan are expected to use the service or facility that is related to the capital expenditure. As a significant portion of Medicare and Medicaid beneficiaries are enrolled in an HMO, this requirement impacts less than 10 hospitals on an annual basis and is exempt from the PRA per 5 CFR §1320.3(c)(4).[4]

Section 482.12(e)(2) - Condition of participation: Standard: Governing Body-Contracted Services

The regulation requires 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 CMS 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.

Table 4: IC- 2: ***CoP: Contracted Services - 482.12(e)(2)***

Task	Hourly Wage	Hours/Task	Cost/Task
Administrator	$124	0.25	$31
Clerical Person	$38	0.25	$10
Task Total		**0.50**	**$41**
# Facilities Impacted	5,132		
Annual Burden/Costs		**2,566**	**$207,846**

Section 482.12(f)(2): Condition of participation: Standard: Governing Body- Emergency Services

We previously calculated a burden for this CoP. However, this requirement – to maintain written policies for "appraisal of emergencies, initial treatment, and referral when appropriate" - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2). For example, written policies for how medical staff must handle emergencies must exist in order for hospitals to be able to comply with Emergency Medical Treatment & Labor Act (EMTALA) (Section 1867 of the Social Security Act).

Section 482.13(a)(1) - (a)(2): Condition of participation: Standard: Notice of Rights

We previously calculated a burden for this CoP. However, this requirement should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

Section 482.13(d) - Condition of participation: Standard: Confidentiality of Patient Records

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 Health Insurance Portability and Accountability Act of 1996 (HIPAA), state or local law. Prior ICRs did not make this exemption explicit but did not include burden hours or cost for this CoP.

Section 482.13(e) - Condition of participation: Standard: Restraint or seclusion

Similar to previous ICRs, 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.

Section 482.13(f) - Condition of participation: Standard: Staff training requirements

We previously calculated a burden for this CoP, but only for non-JCAHO accredited hospitals. However, this requirement should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

Section 482.13(g) - Condition of participation: Standard: Death reporting requirements

We previously calculated a burden for this CoP. However, this requirement should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

Section 482.13(h)- Condition of participation: Standard: Patient Visitation Rights

We previously calculated a burden for this CoP. However, this requirement should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

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[4] See e.g., ManagedCareEnrollmentTrendsDataBrief2012-2021_0.pdf (cms.gov), EXHIBIT 30. Percentage of Medicaid Enrollees in Managed Care by State and Eligibility Group - MACPAC

Quality Assessment and Performance Improvement (QAPI)

Per 42 CFR § 482.21, hospitals must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program (QAPI).

When the QAPI programs were first required as a CoP, we identified and 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, hospitals that fail to monitor quality and make improvements would inevitably lead to poor patient outcomes, higher costs, and potentially legal liability for any hospital, whether or not certified by CMS. As a result, the majority of the information collection requirements associated with a hospital's QAPI program should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

There are three exceptions to the customary and usual PRA exemptions. First, we calculate below the additional burden created by the CoP that requires hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS. Second, we calculate the burden associated with an optional CoP that was implemented in 2019 (and thus not included in the last PRA package) for multi-system hospitals to develop a new QAPI program. Finally, we calculate the additional burden created by a new CoP for hospitals under the July 2024 Proposed Rule provide obstetrical services to develop and maintain a QAPI program to improve maternal health outcomes.

Section 482.21 - Condition of participation: CMS Review of QAPI program

Because hospitals must "maintain and demonstrate evidence" of their QAPI program to CMS Surveyors – which they otherwise would not need to do but for the CoP – we estimate the burden associated with this information collection requirement. We estimate a QAPI Coordinator would 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 Director 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 5: IC- 3: ***CoP: QAPI Program Review - 482.21***

Task	Hourly Wage	Hours/ Task	Cost/ Task
Per Facility/Year			
QAPI Coordinator	$37	2.0	$74
QAPI Director	$124	3.0	$372
Task Total/Year		**5.0**	**$446**
# Facilities Impacted	5,132		
Total Annual Burden/Costs		**25,660**	**$2,288,872**

NEW CoPs: Condition of participation: QAPI for Hospitals with Obstetrical Services - Sections 482.21(b)(4) and (e)

Per 482.21(b)(4), hospitals that provide obstetrical services (hereinafter "OB services") must collect and analyze data to help improve maternal child health outcomes.[5] Specifically, hospitals must:

1) "Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients."
2) "Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients."
3) "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."
4) 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.

Because this a newly proposed CoP, we calculate below the burden only for the 4,994 participating hospitals and will calculate the burden of the new CoP for all 1,383 CAHs (including the 19 CAHs with rehabilitation DPUs and the 119 CAHs with psychiatric DPUs) in the upcoming ***Critical Access Hospitals (CAHs)(0938-1043/CMS-10239)*** PRA submission.

New CoP: One-time IT update for OB Services Data Collection – Section 482.21(b)(4)

Applying the assumptions regarding the information collection requirements of the new CoP in the July 2024 Proposed Rule to implement the new CoPs, hospitals 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. 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 6: IC- 4 - ***CoP: Initial IT Update for OB services Data Collection - 482.21(b)(4)***

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task

[5] July 2024 Proposed Rule

IT Staff (BLS Code: 15-0000)	$108.78		
Per Facility/Year			
Year 1 - IT System Changes		8.0	$870
Ongoing IT maintenance		4.0	$435
# Facilities Impacted	4,994		
Year 1 Burden Hours/Costs		**39,952**	**$4,345,979**
Ongoing Annual Burden Hours/Costs		**19,976**	**$2,172,989**
Annualized Burden Hours/Costs Over 3 Years		**26,635**	**$2,897,319**

New CoP: Ongoing Data Analysis for OB services – Section 482.21(b)(4)

We estimate every hospital 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 on an ongoing basis in order to comply with the CoP at Section 482.21(b)(4).

Table 7: IC- 5 - ***CoP: Ongoing Data Analysis for OB services - 482.21(b)(4)***

Task	Hourly Mean Wage	Hours/ Task	Cost/ Task
Per Facility/Year			
Data Scientist (BLS Code: 15-2051)	$114.46	8.0	$916
# Facilities Impacted	4,994		
Total Annual Burden/Costs		**39,952**	**$4,574,504**

New CoP: Ongoing Maternal Death Reporting to MMRC – Section 482.21(e)

Per the July 2024 Proposed Rule, hospitals must report maternal deaths to the local maternal mortality review committee (MMRC). We estimate hospitals will report 663 maternal deaths per year, which would require 4 hours of Physician's and Medical Records Specialist's time.

Table 8: IC- 6 - ***CoP: Ongoing Maternal Death Reporting to MMRC - 482.21(e)***

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	**$152.63**
# of Tasks	**Factors**	**Hospitals**	**CAHs**
Total Annual Maternal Deaths	850		
Total Facilities	6,377	4,994	1,383
% of Total		78%	22%
# of Maternal Deaths to report/year		663	187
Total Annual Burden/Costs			
Hospitals	**663**	**5,304**	**$809,550**

New CoP: Condition of participation: Standard: Unified and integrated QAPI program for multi-hospital systems - Section 482.21(g)

In 2019, a new, optional CoP for multi-hospital systems was added which allows a multi-hospital system to create one unified and integrated QAPI program for all its participating hospitals rather than creating and maintaining separate QAPI programs for each hospital.[6]

We estimate below the one-time burden of creating a new, unified QAPI program under this new CoP. Although a unified QAPI program is an optional CoP, we assume all multi-hospital systems would consolidate existing QAPI programs into a single, unified QAPI because of the increased efficiencies, consistent policies and metrics, and reduced burden of implementing a unified QAPI.

Based on the 2022 American Hospital Association's Annual Survey, 68% of all U.S. hospitals (68% of 4,994 or 3,396) are part of a multi-hospital system.

[6] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732 (September 30, 2019). Note: As of July 2024, Section 482.21(f) was redesignated as 482.21(g) under the proposed rule at 89 FR 59186, 59578.

Applying the assumptions used in the 2019 final rule (84 FR 51732), we estimate a physician, the QAPI Director, the QAPI Coordinator, and a clerical staff member would each require 8 hours to develop a new unified QAPI program for each multi-hospital system.[7] Because not every hospital in a multi-hospital system would be required to dedicate 4 staff members to this effort, we estimate on the high range that 50% of all hospitals that are part of a multi-hospital system (50% of 3,996 or 1,698) would have their staff assist with the development of a unified QAPI program for the other 50%. In reality, the actual number of staff involved, and hence the actual burden hours and cost, is likely to be much lower.

Table 9: IC- 7: ***CoP: Unified QAPI Program Review - 482.21(g)***

Task	Hourly Wage	Hours/Task	Cost/Task
One-time development of unified QAPI program			
Physician	$190	8.0	$1,520
QAPI Director	$124	8.0	$992
QAPI Coordinator	$37	8.0	$296
Clerical	$38	8.0	$304
Total Task/Facility		**32.0**	**$3,112**
# Facilities Impacted	1,698		
Total Annual Burden/Costs		**54,336**	**$5,284,176**

Section 482.22(c)(5)- Condition of participation: Standard: Medical Staff By-Laws

Similar to prior ICRs, the burden associated with this requirement – that medical staff adopt by laws that include requirements around patient care - is exempt from the PRA, as defined in 5 CFR §1320.3(b)(2) because this requirement is considered customary and usual industry practice.

In 2019, there was a technical correction made to Sections 482.22(c)(5)(i) – (c)(5)(iii) to revise "oromaxillofacial surgeons" to "oral and maxillofacial surgeons.[8]" In addition, a new, optional requirement was added for outpatient surgeries at Section 482.22(c)(5)(v) for medical staff that choose to develop and maintain a policy for pre-surgical patient assessments per Sections 482.22(c)(5)(iii) and (c)(5)(iv). The policy to identify specific patients must include evidence of the patient's need for surgical services in a manner that is consistent with the current standards of both anesthesia care and surgical care. Because the CoP requires evidence based on nationally recognized guidelines and standards of practice for the assessment of specific types of patients prior to specific outpatient surgeries and procedures, Section 482.22(c)(5)(v) should also be considered customary and usual industry practice and is exempt from the PRA, as defined in 5 CFR §1320.3(b)(2).

Section 482.23(b)(4) - Condition of participation: Nursing services: Standard: Staffing and delivery of care – Nursing Care Plan

We previously calculated a burden for this CoP. However, this requirement - that the nursing staff of a hospital develop and keep a nursing plan for each patient - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

Section 482.23(b)(7) - Condition of participation: Nursing services: Nursing plan

In 2019, a new CoP was added at Section 482.23(b)(7) for hospitals with outpatient departments to have policies and procedures that clarify when a hospital does not need to have a registered nurse present."[9] Per the final rule, this CoP is already required by accredited hospitals and therefore is exempt from the PRA under 5 CFR §1320.3(b)(2) as customary and usual industry practice.

However, non- accredited hospitals have a one-time burden to review and update their existing policies in order to comply with this CoP.[10] The current number of non-accredited hospitals to comply with this CoP is 999.[11] For the initial policy development, we estimate that this would require a physician, a nurse, and one administrator and each person would spend three hours on this activity for a total of nine hours. We estimate that review of the policies and procedures once every 3 years would take one hour each.

Table 10: IC-8: ***CoP: Non-Accredited Hospitals Nursing Plan - 482.23(b)(7)***

Task	Hourly Wage	Hours/Task	Cost/Task
# Non-Accredited Hospitals	999		
1) One-time development of outpatient nursing plan			

[7] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732, 51761 (September 30, 2019)

[8] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732, (September 30, 2019), 51742

[9] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732, (September 30, 2019), 51787

[10] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732, (September 30, 2019), 51787

[11] See e.g., Hospital Accreditation Fact Sheet | The Joint Commission

Physician	$190	3.0	$570
Administrator	$124	3.0	$372
Registered Nurse	$85	3.0	$255
Total Task/Facility		9.0	$1,197
Total Facilities Impacted	**999**	**8,991**	**$1,195,803**
2) Ongoing review of outpatient nursing plan (every 3 yrs.)			
Physician	$190	1.0	$190
Administrator	$124	1.0	$124
Registered Nurse	$85	1.0	$85
Total Task/Facility		3.0	$399
Total Facilities Impacted	**999**	2,997	$398,601
Total Burden Hours/Cost		**11,988**	**$1,594,404**

Sections 482.24(c)(2) and (c)(3) Condition of participation: Medical record services – Standard: Content of record

We previously calculated a burden for this CoP. The burden associated with these requirements – that practitioners authenticate verbal orders (Section 482.24(c)(2)) and that hospitals are allowed to use pre-printed and electronic standing orders (Section 482.24(c)(3)) - are exempt from the PRA, as defined in 5 CFR §1320.3(b)(2) because both requirements should be considered customary and usual industry practice.

Section 482.24(c)(4) Condition of participation: Medical record services – Standard: Content of record

In 2019, Section 482.24(c)(4) was added as a CoP to allow hospitals to determine what pre-surgery/pre-procedure assessment for outpatient surgeries needed to be documented in the medical record "after registration, but prior to surgery or a procedure requiring anesthesia services, for specific outpatient surgical or procedural services rather than requiring a comprehensive medical history and physical examination."[12] This change in the CoP would have reduced the burden on hospital staff for outpatient surgeries and may have required hospitals to amend their patient care policies. Nevertheless, having a policy that requires hospital staff to adequately document the need for surgery - whether inpatient or outpatient – in a patient's medical record prior to the procedure should be considered customary and usual industry practice. Therefore, any burden created from the new CoP at Section 482.24(c)(4) is exempt from the PRA, as defined in 5 CFR §1320.3(b)(2).

Section 482.24(d) and 482.61(f) - Condition of participation: Medical record services – Standard: Electronic notifications

In 2020, Section 482.24(d) was added to "require hospitals, psychiatric hospitals, and CAHs [with existing electronic health record (EHR) systems] to make electronic patient event notifications available to applicable post-acute care services providers and suppliers, and to community practitioners such as the patient's established primary care practitioner, established primary care practice group or entity, or other practitioner or practice group or entity identified by the patient as primarily responsible for his or her care."[13] Such notifications "are one type of health information exchange intervention that has been increasingly recognized as an effective and scalable tool for improving care coordination across settings.[14]" In the May 2020 final rule, CMS estimated that more than 70% of hospitals had implemented a certified EHR (with electronic patient notifications) by 2018; as of 2021, 96% of hospitals had adopted a certified EHR.[15] Due to numerous mandates on interoperability in the U.S. health care system over the past decade, electronic patient notifications from hospitals and CAHs to other providers – as required by this CoP - should be considered customary and usual industry practice.[16] Therefore, any burden created from the new CoP at Section 482.24(d) is exempt from the PRA, as defined in 5 CFR §1320.3(b)(2).

Note: The "electronic notifications" CoP for hospitals discussed above was added at the same time for CAHs with psychiatric DPUs at **42 CFR § 482.61(f)** and other CAHs at **42 CFR § 485.638(d)**.[17] For all the same reasons stated above, any burden created on CAHs by this CoP is exempt from the PRA per 5 CFR § 1320.3(b)(2). We include the CoP at 42 CFR § 482.61(f) in this ICR because it applies to CAHs with psychiatric DPUs. However, the information collection requirements for CoPs for other CAHs, such as 42 CFR § 485.638(d), are included under OMB No. 0938-1043 (CMS 10239).

Section 482.27(a)(2) - Condition of participation: Standard: Adequacy of Laboratory Services

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12 Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 84 FR 51732 (September 30, 2019)

13 Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers, 85 FR 25510, 25608 (May 1, 2020)

14 Id. at 25609

15 National Trends in Hospital and Physician Adoption of Electronic Health Records | HealthIT.gov

16 See e.g., Health Information Technology for Economic and Clinical Health (HITECH) Act, the Trusted Exchange Framework and Common Agreement (TEFCA) (required by the 21st Century Cures Act) and CMS' Medicare Promoting Interoperability Program

17 Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers, 85 FR 25510 (May 1, 2020)

We previously calculated a burden for the CoP at Section 482.27(a)(2) – requiring written description of available laboratory services be provided medical staff - but incorrectly referenced it as Section 482.27(b)(2), which requires hospitals to have adequate laboratory services for patients with hepatitis C. Yet both of these requirements should be considered customary and usual industry practice for hospitals and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

Other CoPs for Laboratory Services

Note: The prior ICR referenced the CoPs related to laboratory services and policies and procedures for potentially infectious blood and blood products listed below and assigned "one token hour of burden to these requirements." Instead, these requirements should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).

- *Section 482.27(b)(3)- Condition of participation: Standard: Laboratory Services- Potentially Infectious Blood and Blood Products- Collection Services*
- *Section 482.27(b)(5)- Condition of participation: Standard- Potentially Infectious Blood and Blood Products - Record Keeping*
- *Section 482.27(b)(6)- Condition of participation: Standard: Laboratory Services- Potentially Infectious Blood and Blood Products- Patient Notification*
- *Section 482.27(b)(9) - Condition of participation: Standard- Potentially Infectious Blood and Blood Products-Policies and Procedures*
- *Section 482.27(b)(10)- Condition of participation: Standard- Potentially Infectious Blood and Blood Products-Notification to legal representative or relative*

Section 482.30(c)(1) and (d)(3) - Condition of participation: Utilization Review - Scope and Frequency of Review

Under these CoPs, hospitals must have a plan to conduct a utilization review for services provided to Medicare and Medicaid patients. The prior ICR indicated creating a utilization plan per this CoP would apply only to newly certified hospitals – estimated to be only two per year - and thus was exempt from the PRA under 5 CFR §1320.3(c)(4). These CoPs should instead be exempt from the PRA under 5 CFR §1320.3(b)(2) as customary and usual practices because all hospitals should have a utilization plan and conduct utilization reviews for all patients (rather than only newly certified hospitals or creating a plan for a subset of patients).

Section 482.41(b) - Condition of participation: Standard: Physical Environment- Life Safety from Fire

The burden associated with this requirement is exempt from the PRA, as defined in 5 CFR §1320.3(b)(2) because this requirement is considered customary and usual industry practice. This CoP was mentioned in the prior ICR without a burden calculated, but the exemption was not clearly stated.

Section 482.42(a)(2) - Condition of participation: Infection prevention and control and antibiotic stewardship programs.

We previously noted that monitoring of infections to be a customary and usual practice but calculated a burden with regards to the requirement that a hospital specifically keep a log for monitoring, instead of allowing the hospital to determine the best way to track incidents.

In order to effectively monitor infections, hospitals would be expected to document incidents in some manner. Because "¡nfection prevention and control is a primary goal of hospitals and CAHs in their normal day-to-day operations," the CoP that hospitals monitor infections – including maintaining a log - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).[18]

NEW CoP: Condition of participation - Ongoing Reporting of Acute Respiratory Illnesses -- Section 482.42(f)

Under new CoPs per *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* (CMS-1808)(RIN 0938-AV34), hospitals and 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.

As this is a new rule, we calculate below the burden on participating hospitals only and will calculate the burden of the new CoP for all CAHs (including the 19 CAHs with rehabilitation DPUs and the 119 CAHs with psychiatric DPUs) in the upcoming ***Critical Access Hospitals (CAHs)(0938-1043/CMS-10239)*** submission. We estimate that total annual burden hours for all participating hospitals to comply with the ongoing reporting of acute respiratory illnesses requirements would be 194,766 hours based on weekly reporting by approximately 4,994 hospitals × 52 weeks per year and at an average weekly response time of 0.75 hours. The estimate for total annual costs for 4,994 hospitals to comply with the weekly ongoing reporting requirements by a registered nurse with an average hourly salary of $78 would be $15,191,748 or approximately $3,042 per facility annually ($15,191,748/ 4,994 facilities).

Table 11: IC-9: ***CoP: Ongoing Reporting of Acute Respiratory Illnesses – 482.42(f)***

Task	Factors	Hours/ Task	Cost/ Task	Annual Burden Hours	Annual Burden Cost
Clinician - Registered Nurse	$78				
Reports/Year/Facility	52	0.75	$59	39	$3,042
# of Facilities	4,994				

[18] See e.g., Medicare 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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, 87 FR 48780, 49377 (August 10, 2022)

All Facilities	**259,688**			**194,766**	**$15,191,748**

NEW CoP: Condition of participation -Future Public Health Emergency (PHE) Reporting of Acute Respiratory Illnesses - Section 482.42

Per the new CoPs under the August 2024 Final Rule, hospitals and 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." 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 encapsule 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. Regardless of frequency, we estimate that future reporting of acute respiratory illnesses during a PHE would require 1.5 hours for a registered nurse to complete and submit. Note that burden estimates would significantly decrease as reporting becomes more automated over time. As stated earlier, because this is a new rule, we calculate below the burden of future reporting of acute respiratory illnesses during a PHE on participating hospitals only and will calculate the burden of the new rule for all CAHs (including the 19 CAHs with rehabilitation DPUs and the 119 CAHs with psychiatric DPUs) in the upcoming ***Critical Access Hospitals (CAHs) (0938-1043/CMS-10239)*** submission.

Based on ***twice weekly reporting*** (low range), we estimate that total annual burden hours for all participating hospitals to comply with future reporting requirements would be 779,064 hours (4,994 hospitals × 52 weeks x 2 times per week x 1.5 hours). The estimate for total annual costs for all hospitals for ***twice weekly reporting*** (low range) by a registered nurse with an average hourly salary of $78 would be $60,766,992 or approximately $12,168 per facility annually ($60,766,992/ 4,994 hospitals). Based on ***daily reporting*** (high range), we estimate that total annual burden hours for hospitals to comply with future reporting requirements would be 2,734,215 hours (4,994 hospitals × 365 days x 1.5 hours). The estimate for total annual costs for all participating hospitals for ***daily reporting*** (high range) by a registered nurse with an average hourly salary of $78 would be $213,268,770 or approximately $42,705 per facility annually ($213,268,770/ 4,994 hospitals).

Table 12: IC-10: ***CoP: Future PHE Reporting of Acute Respiratory Illnesses – 482.42***

Task	Factors	Hours/ Task	Cost/ Task	Annual Burden Hours	Annual Burden Cost
Clinician - 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	4,994				
Low Range (2 x week)				**779,064**	**$60,766,992**
High Range (Daily)				**2,734,215**	**$213,268,770**

New CoP: Condition of participation: Staff Vaccinations - Section 482.42(g)

In 2021, CMS added Section 482.42(g) as a CoP requiring hospitals to "develop and implement policies and procedures to ensure all hospital staff were fully vaccinated for COVID-19."[19] This CoP was removed by CMS in 2023 because "in lieu of regulatory requirements…CMS intends to continue supporting and encouraging for health care staff vaccinations through other mechanisms, including its quality programs."[20]

New CoP: Condition of participation: Standard: Written Transfer Protocol - Section 482.43(c)

Under 482.43(c), hospitals must have written protocols for transferring patients to the appropriate level of care and must ensure staff are trained on these protocols.[21] 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 CoP. We do not include an estimate for updating standards since reviewing and updating policies and procedures is a customary business practice. For each hospital, we estimate that an Administrator at the loaded hourly mean rate of $129.28 and a medical secretary at $41.70 per hour would each require 2 hours to ensure an existing transfer protocol meets the new requirements. We determine the burden cost using a blended wage rate per the table below.

Table 13: IC-11: ***CoP: Written Transfer Protocol – 482.43(c)***

Task	Hourly Mean Wage	Hours/Task	Cost/Task

[19] Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 FR 61555, 61619 (November 5, 2021)

[20] Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements, 88 FR 36485 (June 5, 2023)

[21] July 2024 Proposed Rule

One-time development of Transfer Protocol			
Administrator	$129.28	2.0	$258.56
Medical Secretary	$41.70	2.0	$83.40
Total Task/Facility		4.0	$341.96
		Aggregate Staff Cost/Task	**$85.49**
# Facilities Impacted	4,994		
Total Annual Burden/Costs		**19,976**	**$1,707,748**

Section 482.45(a)(1) and (a)(2) - Condition of participation: Standard: Organ procurement responsibilities - Notification to OPO and agreement with eye and tissue banks

We previously calculated a burden for these CoPs. However, these requirements – that hospitals 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).

Section 482.45(b)(3) - Condition of participation: Standard: Organ transplantation responsibilities

We previously calculated a burden for this CoP. However, this requirement – that hospitals which perform transplants should provide data to Organ Procurement and Transplantation Network (OPTN), Organ Procurement Organization (OPO), or CMS when requested - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2). In addition, CoPs related to transplant centers are captured under OMB 0938-1069 (CMS -10266).

New CoP: Condition of participation: Standard: Emergency services readiness - Section 482.55(c)

Under Section 482.55(c)(1), hospitals 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." Hospital staff would be required to be trained in these protocols and provisions. Per Section 482.55(c)(2), hospitals must ensure the necessary equipment, supplies, and medications are readily available for providing emergency services and the treatment area for every emergency room patient is equipped with a "call-in-system."

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. We estimate that it would take 4 hours for each staff member involved because this CoP requires adding to an existing protocol rather than creating a new protocol for emergency services, which would require more time. For each hospital, we estimate that the following staff will be involved in writing the new protocol – a physician at the loaded hourly mean rate of $253.70, a lawyer at $169.68 per hour, a registered nurse at $90.84 per hour, a medical secretary at $41.70 per hour, and an Administrator at $129.28 per hour. We determine the burden cost using a blended wage rate per the table below.

Table 14: IC-12: ***CoP: Written protocols for Emergency services readiness – 482.55(c)***

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	4,994		
Total Annual Burden/Costs		**99,880**	**$13,687,555**

New CoP: Condition of participation: Obstetrical Services - Section 482.59

After extensive research and stakeholder feedback as detailed under "Section XXI: Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals" in 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)." [22] We estimate below the burden of information collection requirements associated with new CoPs for Obstetrical Services proposed by CMS in July 2024 Proposed Rule.

New CoP: Condition of participation: Practitioners' Roster – Section 482.59(a)(2)

The CoP requires hospitals have a list of their medical staff indicating their specific competencies and privileges. We estimate the burden on every hospital to ensure this list is updated annually requires a medical secretary at a loaded hourly wage of $41.70 to spend 8 hours per year.

Table 15: IC-13: ***CoP: Practitioners' Roster – 482.59(a)(2)***

Task	Hourly Mean Wage	Hours/Task	Cost/Task
Per Facility/Year			
Medical Secretary	$41.70	8.0	$333.60
# Facilities Impacted	4,994		
Total Annual Burden/Costs		**39,952**	**$1,665,998**

New CoP: Condition of participation: Written policies for Obstetrical Services - Section 482.59(b) and (c)

Per Section 482.59(c), hospitals 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.

Per earlier, we estimate the one-time burden of creating the required written policies and protocols for OB services proposed in the July 2024 Proposed 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 mainly 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.[23] Thus, we estimate 999 (20% of 4,994 hospitals) non-accredited hospitals will be impacted by the information collection requirements associated with this new CoP for OB services.

For each non-accredited hospital, we estimate that it would take 8 hours for each staff member involved to develop the required protocols and that the following staff will be involved in writing the new protocol – a physician at the loaded hourly mean rate of $253.70, a lawyer at $169.68 per hour, a registered nurse at $90.84 per hour, a medical secretary at $41.70 per hour, and an Administrator at $129.28 per hour. We determine the burden cost using a blended wage rate per the table below.

Table 16: IC-14: ***CoP: Written protocols for Obstetrical Services – 482.59(b) and (c)***

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**
All Hospitals	4,994		
% that are not accredited	20.0%		
# Facilities Impacted	999		
Total Annual Burden/Costs		**39,960**	**$5,476,118**

New CoP: Condition of participation: Written policies on staff training - Section 482.59(c)

Hospitals 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. The requirement to document staff have completed the required training is considered customary and usual practice and thus any related information collection is exempt from the PRA per 5 CFR §1320.3(b)(2). As before, we estimate the one-time burden of developing the appropriate policies assuming 8 hours of time for the staff and hourly wage listed below. We assume only one policy per facility is required to meet this CoP.

[22] July 2024 Proposed Rule at 59488-59500.

[23] See e.g., Hospital Accreditation Fact Sheet | The Joint Commission

Table 17: IC-15: ***CoP: Written policies for staff training – 482.59(c)***

Task	Hourly Mean Wage	Hours/Task	Cost/Task
One-time development of ER protocols			
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	4,994		
Total Annual Burden/Costs		**199,760**	**$27,375,110**

Other CoPs exempt from the PRA

The burdens of information collection requests associated with the following CoPs are exempt from the PRA, as defined in 5 CFR §1320.3(b)(2) because they are considered customary and usual industry practice.

- *Section 482.52 - Condition of participation: Anesthesia services -Standard: Delivery of services.*
- *Section 482.53(d)(1) - Condition of participation: Standard: Nuclear Medicine Service - Standard: Records*
- *Section 482.53(d)(3) - Condition of participation: Standard: Nuclear Medicine Service – Standard: Records*
- *Section 482.56(b) - Condition of participation: Standard: Rehabilitation Services-Delivery of Rehabilitation Services*
- *Section 482.57(b)(1) - Condition of participation: Standard: Respiratory Care Services- Delivery of Services*

Psychiatric Hospitals

- *Section 482.60(c) - Condition of participation: Special Provisions Applying to Psychiatric Hospitals - Clinical Records*
- *Section 482.62(a) - Condition of participation: Standard: Personnel Staff Requirements for Psychiatric Hospitals - Individualized treatment plans*

Section 482.92(a) - Condition of participation: Organ recovery and receipt - Standard: Organ receipt

We previously calculated a burden for this CoP. However, this requirement – that medical staff ensure compatibility between living donors prior to the transplant - 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).

CoP's for Critical Access Hospitals (CAHs)

Section 485.616(c)(1) – (c)(4) - Condition of participation: Agreements. Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners

We previously calculated burdens for the CoPs at 42 CFR § 485.616. However, the ICR for Conditions of Participation for CAHs are documented under OMB No. 0938-1043 (CMS 10239). This ICR includes a subset of all CAHs (1,383) that have psychiatric (119) and rehabilitative DPUs (19) or a total of 138 CAHs that must comply with the CoPs for hospitals.

In addition, the prior burden calculations - for the subset of CAHs for the CoP under 42 CFR § 485.616 - should be considered customary and usual industry practice and thus exempt from the PRA under 5 CFR §1320.3(b)(2).[24]

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

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 hospitals and a subset of 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 wage of $63 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 $252 per facility (4 hours x $63). Based on the estimate that two facilities are newly certified each year, the total burden to the Federal government per year is estimated to be $504 ($252 x 2 facilities) and 8 hours (4 hours x 2 facilities).

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 $63 per facility (1 hour x $63). For each ICR related to all facilities, the total burden to the Federal government is estimated to be $323,316 ($63 x 5,132 facilities) and 5,132 hours (1 hour x 5,132 facilities). 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.

Table 18: Total Burden and Costs for Federal Government

Information Collection No.	# of Facilities	Hourly Wage	Hours/ Task	Total Burden Hours	Total Burden Costs
IC-1: 42 CFR 482.12(d)(1), (d)(2), (d)(4)					
Initial Review	2	$63	4	8	$504
Existing Facilities	5,132	$63	1	5,132	$323,316
IC-2: 42 CFR 482.12(e)(2)	5,132	$63	1	5,132	$323,316
IC-3: 42 CFR 482.21	5,132	$63	1	5,132	$323,316
IC-4: 482.21(b)(4) - Yr. 1- IT System Changes/Initial Review	4,994	$63	4	19,976	$1,258,488
IC-4: 482.21(b)(4) - Ongoing IT System Maintenance	4,994	$63	1	4,994	$314,622
IC-5: 482.21(b)(4) - Data Analysis	4,994	$63	1	4,994	$314,622

[24] Note: The burden calculations from the prior ICR for the CAHs with DPUs should have only applied to 101 CAHs, but instead was incorrectly based on 1,314 CAHs.

IC-6: 482.21(e)	4,994	$63	1	4,994	$314,622
IC-7: 482.21(g) - Initial Review	1,698	$63	4	6,792	$427,896
IC-8: 42 CFR 482.23(b)(7)					
Initial Review	999	$63	4	3,996	$251,748
Existing Facilities	999	$63	1	999	$62,937
IC-9: 482.42(f) (New) - Initial Review	4,994	$63	4	19,976	$1,258,488
IC-10: 482.42 (New) - Initial Review	4,994	$63	4	19,976	$1,258,488
IC-11: 482.43(c) - Initial Review	4,994	$63	4	19,976	$1,258,488
IC-12: 482.55(c) - Initial Review	4,994	$63	4	19,976	$1,258,488
IC-13: 482.59(a)(2)	4,994	$63	1	4,994	$314,622
IC-14: 482.59(b) and (c) - Initial Review	999	$63	4	3,996	$251,748
IC-15: 482.59(c) - Initial Review	4,994	$63	4	19,976	$1,258,488
			Total	**171,019**	**$10,774,197**

The annual burden hours to the federal government is **171,019** with an annual cost of **$10,774,197.**

15. Changes to Burden

The annual burden hours to industry decreased from 14,424,655 to **3,566,521**. For details regarding this change in annual burden hours, see the **Background** section above.

Table 19: Total Burden and Costs for Industry

Information Collection (IC) for Industry	Industry Burden Hours	Industry Burden Costs
IC-1: 42 CFR 482.12(d)(1), (d)(2), (d)(4)	38,278	$11,338,526
IC-2: 482.12(e)(2)	2,566	$207,846
IC-3: 482.21	25,660	$2,288,872
IC-4: 482.21(b)(4) - Yr. 1 - IT System Changes	39,952	$4,345,979
IC-4: 482.21(b)(4) - Ongoing IT System Maintenance	19,976	$2,172,989
IC-5: 482.21(b)(4) - Data Analysis	39,952	$4,574,504
IC-6: 482.21(e)	5,304	$809,550
IC-7: 482.21(g)	54,336	$5,284,176
IC-8: 482.23(b)(7)	11,988	$1,594,404
IC-9: 482.42(f) (New)	194,766	$15,191,748
IC-10: 482.42 (New)(High range)	2,734,215	$213,268,770
IC-11: 482.43(c)	19,976	$1,707,748
IC-12: 482.55(c)	99,880	$13,687,555
IC-13: 482.59(a)(2)	39,952	$1,665,998
IC-14: 482.59(b) and (c)	39,960	$5,476,118
IC-15: 482.59(c)	199,760	$27,375,110
Total	**3,566,521**	**$310,989,894**

All other CoPs for hospitals and CAHs with psychiatric and rehabilitative DPUs are exempt from the PRA. See **Appendix** for more details.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

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.

18. Certification

There is no exception to the certification.

19. Appendix

Table 18: Summary of Changes

		Current ICR		Prior ICR	
Title 42 CFR CoP	**Current Status**	**Burden Hours**	**Burden Costs**	**Burden Hours**	**Burden Costs**
482.12(d)(1), (d)(2), (d)(4)	**IC -1**	**38,278**	**$11,338,526**	31,194	$1,898,976

482.12(d)(5)	Exempt: 5 CFR § 1320.3(c)(4)	n/a	n/a		
482.12(e)(2)	**IC-2**	**2,566**	**$207,846**	2,496	$103,538
482.12(f)(2)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	76	$4,537
482.13(a)(1), (a)(2)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	3,190,927	$43,674,926
482.13(d)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.13(e)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.13(f)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	4,550,880	$2,308,733
482.13(g)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	114,793	$5,116,500
482.13(h)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	1,215	$71,746
482.21	**IC-3 Revised**	**25,660**	**$2,288,872**		
482.21(a)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	244,559	$9,218,676
482.21(b) and (c)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	504,091	$17,427,472
482.21(b)(4) – Yr. 1	**IC-4 New ICR**	**39,952**	**$4,345,979**		
482.21(b)(4) – Yr. 2+1	**IC-4 New ICR**	**19,976**	**$2,172,989**		
482.21(b)(4) –	**IC-5 New ICR**	**39,952**	**$4,574,504**		
482.21(d)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	159,712	$5,631,445
482.21(e)	**IC-6 New ICR**	**5,304**	**$809,550**		
482.21(g)	**IC-7 New ICR**	**54,336**	**$5,284,176**	n/a	n/a
482.22(c)(5)	New/Exempt: 5 CFR §1320.3(b)(2)	n/a	n/a	n/a	n/a
482.23(b)(4)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	2,400,000	$108,000,000
482.23(b)(7)	**IC-8 New ICR**	**11,988**	**$1,594,404**	n/a	n/a
482.24(c)(2), (c)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	2,488,500	$167,282,500
482.24(c)(4)	New/Exempt: 5 CFR §1320.3(b)(2)	n/a	n/a	n/a	n/a
482.24(d)	New/Exempt: 5 CFR §1320.3(b)(2)	n/a	n/a	n/a	n/a
482.27(a)(2), (b)(2)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	8,735	$540,251
482.27(b)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	1	
482.27(b)(5)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.27(b)(6)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.27(b)(9)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.27(b)(10)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.30(c)(1) and (d)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.41(b)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.42(a)(2)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	147,000	$6,615,000
482.42(f)	**IC-9 New ICR**	**194,766**	**$15,191,748**	n/a	n/a
482.42	**IC-10 New ICR** (High range)	**2,734,215**	**$213,268,770**	n/a	n/a
482.42(g)	New ICR - Repealed	n/a	n/a	n/a	n/a
482.43	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	274,907	$7,570,927
482.43(c)	**IC-11 New ICR**	**19,976**	**$1,707,748**	n/a	n/a
482.45(a)(1), (a)(2)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	67,633	$1,789,933
482.45(b)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	115,743	$3,187,562
482.53(d)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.55(c)	**IC-12 New ICR**	**99,880**	**$13,687,555**	n/a	n/a
482.56(b)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.57(b)(1)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.58	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.59(a)(2)	**IC-13 New ICR**	**39,952**	**$1,665,998**		

482.59(b) and (c)	**IC-14 New ICR**	**39,960**	**$5,476,118**		
482.59(c)	**IC-15 New ICR**	**199,760**	**$27,375,110**	n/a	n/a
482.60(c)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.61(f)	New/Exempt: 5 CFR §1320.3(b)(2)	n/a	n/a		
482.62(a)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a		
482.92(a)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	1,305	$161,820
485.616(c)(1)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	31,536	$2,512
485.616(c)(1)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	7,884	
485.616(c)(2), (c)(4)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	42,048	$1,088
485.616(c)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	31,536	$2,512
485.616(c)(3)	Exempt: 5 CFR § 1320.3(b)(2)	n/a	n/a	7,884	
		3,566,521	**$310,989,894**	14,424,655	$380,610,654