**Supporting Statement**

**Hospital Conditions of Participation (CoPs) and Supporting Regulations**

**(OMB No. 0938-0328/CMS-R-48)**

## A. BACKGROUND

The purpose of this package is to revise the information collection request, associated with OMB No. 0938-0328, titled "Hospital Conditions of Participation (CoPs) and Supporting Regulations."

The existing information collection under OMB No. 0938-0328 currently includes 13 information collections (ICs)(IC-1 through IC-13) that document the collection of information burdens applicable to hospitals and Critical Access Hospitals (CAHs) with Distinct Part Units (DPUs) for Medicare certification under their Conditions of Participation. This includes a total of 5,132 facilities, which includes 4,994 accredited and non-accredited hospitals and 138 CAHs with DPUs (specifically, 119 CAHs with psychiatric DPUs and 19 CAHs with rehabilitation DPUs). The burden totals for IC-1 to IC-13 from the existing collection is 3,578,684 annual hours and $316,543,106 in annual costs.[1]

This revision adds two new ICs related to the proposed new CoP at Title 42 Code for Federal Regulations Section 482.46, which prohibits hospitals from performing sex-rejecting procedures on children.[2] The two new ICs are: (1) hospital notifications to patients or legal guardians (IC-14: 8,570 hours, $1,938,363), and (2) updating hospital policies and procedures (IC-15: 32,616 hours, $5,334,890). The revised information collection request totals **3,619,870 hours and $323,816,359**, an increase of 41,186 hours (1.15% increase) and $7,272,253 (2.3% increase). See **Section 15** for more details regarding the change.

## B. JUSTIFICATION

### 1. Need and Legal Basis

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).

This revision adds two new ICs related to proposed requirements at 42 CFR § 482.46, which would prohibit Medicare-participating hospitals from performing sex-rejecting procedures on children.[3] These requirements are proposed in compliance with Executive Order 14187, "Protecting Children from Chemical and Surgical Mutilation" (signed January 28, 2025), and are grounded in CMS' existing statutory authority to protect the health and safety of individuals

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1 Note: The total burden costs for the industry for IC-1 to IC-13 has been updated from the previous $312,497,786 to $316,543,106 which is the correct sum for the costs for IC-1 to IC-13.

2 Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children [CMS-3481-P], 90 FR 59463 (December 19, 2025)

3 90 FR 59463, 59472-74 (December 19, 2025). Although the proposed regulatory text for the new CoP at § 482.46 does not explicitly require patient notification, CMS expects hospitals currently performing these procedures will need to inform affected patients and families. CMS estimates this burden as a reasonably foreseeable operational consequence of the prohibition.

furnished services in hospitals.

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), **482.46 (New)**, 482.53(d)(3), 482.55(c); 482.56(b), 482.57(b)(1), 482.58; 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).

**2. Information Users**

CMS as well as the hospitals and CAHs with Distinct Part Units (DPUs) use the ICs to ensure they comply with Medicare and Medicaid CoPs in order to protect patient health and safety and to receive payment for services provided to Medicare or Medicaid patients. The ICs are collected and used by surveyors, employed by state agencies under agreements with CMS, to determine whether hospitals and CAHs with DPUs meet certification requirements as Medicare providers. The state surveyors conduct in-person on-site visits and use the ICs to complete the surveys.[4]

**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. These regulations in no way prescribe 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 ICs 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 complying with these requirements. The general nature of the ICs makes variations in the substance and format of these records from one facility to another acceptable.

**5. Small Business**

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

**6. Less Frequent Collection**

Less frequent information collection could limit CMS's ability to ensure compliance with Medicare Conditions of Participation (CoPs), which could potentially compromise patient health and safety. CMS does not collect the ICs directly from hospitals and instead relies on surveyors to review the ICs during their on-site a surveys for initial or continued participation in the Medicare program. These surveys help ensure that hospitals and CAHs with DPUs maintain a high level of quality and adhere to established standards for patient care and outcomes.

**7. Special Circumstances**

There are no special circumstances applicable to this information collection.

**8. Federal Register/Outside Consultation**

4 See e.g., State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidance for Hospitals, Revised 4/19/2024, Centers for Medicare and Medicaid Services, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_a_hospitals.pdf.

The proposed rule, titled "*Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children"[CMS-3481-P]*, published on December 19, 2025 (90 FR 59463), is associated with IC-14 and IC-15 (see below for details).

**9. Payment/Gifts to Respondents**

No payments or gifts are provided to respondents.

**10. Confidentiality**

Any information collected will be used only for stated purposes and disclosed only as permitted by law. Protected Health Information ("PHI") will be kept confidential as required by the Privacy Act of 1974 (5 U.S.C. § 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (at 45 CFR §§ 160 and 164). Hospitals and CAHs must also follow standard medical confidentiality practices, such as protecting medical records per 42 CFR § 482.24(d).

Surveyors must also follow these confidentiality rules and must display their identification badges during on-site surveys, ensuring accountability in the handling of sensitive information.

**11. Sensitive Questions**

There are no sensitive questions.

**12. Burden**

This section consists of the following three parts: Part 12-A, Part 12-B, and Part 12-C. Part 12-A summarizes the total annual burden hours and costs for the industry. Part 12-B explains the general assumptions used to estimate annual burden hours and burden costs. Part 12-C explains the CoPs in detail and describes the methodology used to estimate the annual burden hours and cost.

**Part 12-A: Summary**

This information collection includes 15 distinct ICs (IC-1 through IC-15) affecting on average 5,132 facilities. See Table 1. The ICs are organized into the following 4 categories:

- **Category A:** Information Collections related to Hospital Administration (IC-1, IC-2)
- **Category B:** Information Collections related to Basic Hospital Functions (IC-3 to IC-10)
- **Category C:** Information Collections related to Optional Hospital Services (IC-11 to IC-13)
  - **Category C-1:** Information Collections Related to Proposed § 482.46 **(NEW** -IC-14 and IC-15)
- **Category D:** Exemptions from Paperwork Burden

Per Table 1 below, the total annual burden for all 15 ICs is **3,619,870 hours** at a cost of **$323,816,359**. This represents an increase of 41,186 hours and $7,272,253 from the currently approved burden, due to the addition of two new one-time information collections (IC-14 and IC-15) related to proposed § 482.46.

Note: These one-time burdens will be removed in subsequent renewal cycles after initial implementation. For additional details on the requirements of § 482.46, see the proposed rule (CMS-3481-P) published at 90 FR 59463 (December 19, 2025).

**Table 1. Summary of Information Collections for Industry**

| Category | Table # | Information Collection (IC) | Responses | Respondents | Burden Hours | Burden Costs |
|---|---|---|---|---|---|---|
| A | 3b | IC-1: 42 CFR 482.12(d)(1), (d)(2), (d)(4) | 5,134 | 5,134 | 38,278 | $11,338,526 |

| | | | | | | |
|---|---|---|---|---|---|---|
| A | 4 | IC-2: 482.12(e)(2) | 5,132 | 5,132 | 2,566 | $207,846 |
| B | 5 | IC-3: 482.21 | 5,132 | 5,132 | 25,660 | $2,288,872 |
| B | 6 | IC-4a: 482.21(b)(4) - Yr. 1 - IT System Changes | 4,415 | 4,415 | 35,320 | $3,842,110 |
| B | 6 | IC-4b: 482.21(b)(4) - Ongoing IT System Maintenance | 4,415 | 4,415 | 17,660 | $$1,929,507 |
| B | 7 | IC-5: 482.21(b)(4) - Data Analysis | 4,415 | 4,415 | 35,320 | $4,060,515 |
| B | 8 | IC-6: 482.21(g) | 1,698 | 1,698 | 54,336 | $5,284,176 |
| B | 9 | IC-7: 482.23(b)(7) | 999 | 999 | 11,988 | $1,594,404 |
| B | 10 | IC-8: 482.42(e)(1) | 259,688 | 4,994 | 194,766 | $15,191,748 |
| B | 11 | IC-9: 482.42(e)(2) | 1,822,810 | 4,994 | 2,734,215 | $213,268,770 |
| B | 12 | IC-10: 482.43(c) | 5,797 | 5,797 | 23,188 | $1,982,342 |
| C | 13 | IC-11: 482.55(c) | 5,797 | 5,797 | 115,940 | $15,888,418 |
| C | 14 | IC-12: 482.59(b) | 2,821 | 2,821 | 112,847 | $15,464,608 |
| C | 15 | IC-13: 482.59(c) | 4,415 | 4,415 | 176,600 | $24,201,264 |
| C-1 | 16 | **New** IC-14: 482.46 - Hospital Notifications | 8,570 | 3,624 | **8,570** | **$1,938,363** |
| C-2 | 17 | **New** IC-15: 482.46 - Policy Updates | 3,624 | 3,624 | **32,616** | **$5,334,890** |
| | | **Total** | **2,144,862** | **67,406** | **3,619,870** | **$323,816,359** |

**Part 12-B: Assumptions**

Below are the global assumptions for facilities impacted and hourly wages used to estimate the associated burden hours and costs for IC-1 to IC-13.[5] However, IC-14 and IC-15 use facility data and May 2024 BLS wage data (rather than May 2023) as specified in the proposed rule published December 19, 2025.[6] See Table 16 and 17 for more details.

Facilities Impacted

As indicated above, for purposes of estimating the total burden to the industry in this information collection request, we assume there is a total of 5,132 facilities that must comply with the Hospital CoPs in order to receive program payment for services provided to Medicare or Medicaid patients. This includes 4,994 hospitals (consisting of 80% that are accredited (3,995) with the remainder non-accredited (999)) and 138 CAHs with Distinct Part Units (DPUs)(out of 1,383 total CAHs).[7] We also apply the following assumptions to the relevant ICs: a) 2 hospitals per year newly certified; b) 50% of hospitals do not offer emergency services.

Wage Data

Per Table 2, 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 the ICs impact 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. 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**

5 Note: Assumptions for burden estimates for IC-1 to IC-13 may vary as they were updated to ensure consistency with the assumptions used in the relevant proposed or final rule that implemented or revised the specific IC.

6 General Medical and Surgical Hospitals (622100) - May 2024 OEWS Industry-Specific Occupational Employment and Wage Estimates (bls.gov)

7 Based on data for Calendar Year 2023 from CMS' CASPER (Certification and Survey Provider Enhanced Reports Quality, Certification & Oversight Reports (QCOR), https://qcor.cms.gov/. (Accessed April 15, 2024). We assume 80% of all hospitals are accredited based on Hospital Accreditation Fact Sheet | The Joint Commission. Of the 138 CAHs with DPUs, 119 are psychiatric DPUs and 19 are rehabilitation DPUs. Note: The burden estimates for CAHs without DPUs (1,383- 138 = 1,245 CAHs) are in a separate information collection request (OMB No. 0938-1043/CMS-10239).

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

**Part 12-C: Details of ICs**

**Category A: Information Collections related to Hospital Administration**

**IC-1: Operating Budget & Capital Expenditures (§ 482.12(d)(1), (d)(2), (d)(4))**

On an annual basis, the governing body 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 existing 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. See Table 3a below.

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

| 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** |

For newly certified facilities (2 per year), we estimate it will take 3 times the hours required for each activity by existing hospitals (per Table 3a) to comply with this CoP and 100% of the facilities would have expenditures over $600,000 to report. See Table 3b below.

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

| Task All Facilities | # Facilities | Hours Per Task | Cost Per Task | Annual Total Hours | Annual Total Cost |
|---|---|---|---|---|---|
| **IC-1a: 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 |
| **Total for IC-1a** | 5,132 | n/a | n/a | 38,233 | $11,325,248 |
| **IC-1b: Newly Certified 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 |
| **Total for IC-1b** | 2 | n/a | n/a | 45 | $13,278 |
| **IC-1: Total Annual Burden & Costs** | **5,134** | n/a | n/a | **38,278** | **$11,338,526** |

**IC-2: Contracted Services (§ 482.12(e)(2))**

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. Per Table 4 below, we believe that the creation and maintenance of this list by the administrator and one clerical person will take 0.25 hours (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 | | |
| **IC-2: Total Annual Burden/Costs** | | **2,566** | **$207,846** |

**Category B: Information Collections related to Basic Hospital Functions**

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 for QAPI related ICs at § 482.21. First, we calculate below the burden associated with the CoP that requires hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS (IC-3). Second, we calculate the burden associated with the CoP that requires hospitals that provide obstetrical services to develop and maintain a QAPI program to improve maternal health outcomes (IC-4 and IC-5). Finally, we calculate the burden associated with an optional CoP for multi-system hospitals to develop a new QAPI program (IC-6).

**IC-3: CMS Review of QAPI Program (§ 482.21)**

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. Per Table 5,
we estimate a QAPI Coordinator would spend 2 hours per year gathering 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 | | |
| **IC-3: Total Annual Burden/Costs** | | **25,660** | **$2,288,872** |

**IC-4: Initial & Ongoing IT Update for OB services Data Collection (§482.21(b)(4))**

Section 482.21(b)(4) placed an initial one-time burden on hospitals to update their IT systems in Year 1 to capture data to better measure health disparities of their OB patients and ensure the system captures this data on an ongoing basis (IC-4a). Per Table 6 below, 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.[8] For ongoing IT maintenance for year 2 and beyond (IC-4b), we include a 0.44 percent annual increase in the real loaded wage rate.

**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 |
|---|---|---|---|

8 This CoP was added in 2024. The burden assumptions for this IC, including the number of facilities impacted, were those used in this rule. 89 FR 93912, 94544 (November 27, 2024).

| | | | |
|---|---|---|---|
| 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 | 4,415 | | |
| **IC-4a: Year 1 Burden Hours/Costs** | | **35,320** | **$3,842,110** |
| **IC-4b: Ongoing Annual Burden Hours/Costs** | | **17,660** | **$1,929,507** |
| **Annualized Burden Hours/Costs Over 3 Years**[9] | | **23,547** | **$2,569,871** |

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

Per Table 7 below, 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 Section 482.21(b)(4).[10] Since the requirements do not go into effect until year 2, we estimate no burden for year 1. For year 2 and beyond (IC-5), we include a 0.44 percent annual increase in the loaded wage rate.

**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 | 4,415 | | |
| **Year 1 Burden Hours/Costs** | | **0** | **$0** |
| **IC-5: Ongoing Annual Burden Hours/Costs** | | **35,320** | **$4,060,515** |
| **Annualized Burden Hours/Costs over 3 Years**[11] | | **23,547** | **$2,712,966** |

**IC-6: Unified QAPI Program for multi-hospital systems (§ 482.21(g))**

Section 482.21(g) is an optional CoP that 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.[12] 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.

We estimate below the one-time burden of creating a new, unified QAPI program under this CoP. Per Table 8 below, 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.[13] 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%.[14] In reality, the actual number of staff involved, and hence the actual burden hours and cost, is likely to be much lower.

**Table 8: IC-6: CoP: Unified QAPI Program - 482.21(g)**

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9 The annualized total is a sum of the Year 1, Year 2 & Year 3 (Year 2 with 0.44% growth) divided by 3.

10 See FN 8.

11 See FN 9.

12 This CoP was created in 2019 (84 FR 51732, 51761 (September 30, 2019)) at §482.21(f) and redesignated to §482.21(g) in 2024 (89 FR 93912, 94591 (November 27, 2024)). The one-time burden for this IC was included in the 2024 collection as it was not included in the previous collection and thus was applied to all hospitals here. However, the burden for this IC should only be applied to newly certified multi-system hospitals in future collections.

13 84 FR 51732, 51761 (September 30, 2019)

14 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.

| 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** |

**IC-7: Non-Accredited Hospitals Nursing Plan (§ 482.23(b)(7))**

Section 482.23(b)(7) requires hospitals with outpatient departments to have policies and procedures that clarify when a hospital does not need to have a registered nurse present."[15] Because this CoP is already required by accredited hospitals, this IC is exempt from the PRA under 5 CFR §1320.3(b)(2) for accredited hospitals 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.[16] Per our global assumptions above, the 999 non-accredited hospitals will need to comply with this CoP.[17] Per Table 9 below, 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 9: IC-7: 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** | | | |
| 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 |
| **IC-7: Total Burden Hours/Cost** | | **11,988** | **$1,594,404** |

**IC-8: Ongoing Reporting of Acute Respiratory Illnesses (§ 482.42(e)(1))**

Section 482.42(e)(1) requires hospitals and CAHs to continue to "electronically report information on acute respiratory illnesses, including influenza,

15 This CoP was created in 2019 (84 FR 51732, 51787 (September 30, 2019).

16 Id.

17 Note: Due to timing of this collection, the 999 facilities impacted is based on 20% of all hospitals are non-accredited (per Hospital Accreditation Fact Sheet | The Joint Commission) applied to the total number of hospitals found in the November 2024 rule (4,415) rather than the 4,994 (CY 2023) listed in the global assumptions.

SARS-CoV-2/COVID-19, and RSV, in a standardized format and frequency specified by the Secretary.[18]" 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."

Per Table 10 below, 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.[19] 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 10: IC-8: CoP: Ongoing Reporting of Acute Respiratory Illnesses – 482.42(e)(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 | $3,042 |
| # of Facilities | 4,994 | | | | |
| **All Facilities** | **259,688** | | | **194,766** | **$15,191,748** |

**IC-9: Future PHE Reporting of Acute Respiratory Illnesses (§ 482.42(e)(2))**

Section 482.42(e)(2) requires hospitals and CAHs 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 has been declared by the HHS Secretary in the future.[20] Specifically, the hospital must submit electronic reports "in a standardized format and frequency specified by the Secretary with the following data: 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.[21] Note that burden estimates would significantly decrease as reporting becomes more automated over time. We calculated the burden of future reporting of acute respiratory illnesses during a PHE on participating hospitals only and will calculate the burden 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.

Per Table 11 below, 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) (IC-9), 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).

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18 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-F), 89 FR 68986, 69886 (August 28, 2024). This new CoP was redesignated from 482.42(f) in CMS-1808-P to 482.42(e) in CMS-1808-F. 89 FR 89 FR 68986, 69913.

19 89 FR 68986, 69906-07 (August 28, 2024). Note: The burden estimates for IC-8 and IC-9 apply only to hospitals per the assumptions used in CMS-1808-F. The burden for all CAHs (including the 19 CAHs with rehabilitation DPUs and the 119 CAHs with psychiatric DPUs) to comply with §§ 482.42(e)(1) and (e)(2) will be included in the Critical Access Hospitals (CAHs)(0938-1043/CMS-10239) submission.

20 89 FR 68986, 69890 (August 28, 2024). This new CoP was redesignated from 482.42(f) in CMS-1808-P to 482.42(e) in CMS-1808-F. 89 FR 89 FR 68986, 69913.

21 89 FR 68986, 69908-09 (August 28, 2024)

**Table 11: IC-9: CoP: Future PHE Reporting of Acute Respiratory Illnesses – 482.4(e)(2)**

| 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 |
| **IC-9: High Range (Daily)** | | | | **2,734,215** | **$213,268,770** |

**IC-10: Written Transfer Protocol (§ 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.[22] There is a one-time burden associated with this CoP to develop the written protocols. However, we do not estimate a burden for updating transfer protocols since reviewing and updating policies and procedures is a customary business practice.[23] Per Table 12 below, 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 revised requirements.[24] We determine the burden cost using a blended wage rate per the table below.

**Table 12: IC-10: CoP: Written Transfer Protocol – 482.43(c)**

| Task | Hourly Mean Wage | Hours/Task | Cost/Task |
|---|---|---|---|
| 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 | 5,797 | | |
| **Total Annual Burden/Costs** | | **23,188** | **$1,982,342** |

**Category C: Information Collections related to Optional Hospital Services**

**IC-11: Emergency Services Readiness (§ 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."[25] 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."

We estimate the one-time burden of developing written protocols that meet the emergency services readiness requirements.[26] We do not include an estimate for updating standards since reviewing and updating policies and procedures is a customary business practice. Per Table 13 below, 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.[27] For each hospital, we estimate that the following staff will be involved in writing the revised protocol –

22 This CoP was added in 2024. 89 FR 93912, 94493-94 (November 27, 2024). See also, 89 FR 94592.

23 89 FR 93912, 94546 (November 27, 2024)

24 89 FR 93912, 94546-47 (November 27, 2024)

25 This CoP was added in 2024. 89 FR 93912, 94545 (November 27, 2024). See also, 89 FR 94592.

26 89 FR 93912, 94546 (November 27, 2024)

27 Id.

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 13: IC-11: 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 | 5,797 | | |
| **Total Annual Burden/Costs** | | **115,940** | **$15,888,418** |

**IC-12: Written Protocols for Obstetrical Services (§ 482.59(b))**

Section 482.59(b) requires hospitals to develop written policies for the delivery of obstetrical services that are "designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety."[28] As a result, there is a one-time burden for hospitals that provide OB services to develop and document written policies and protocols for delivery of these services.[29] There is no estimate for ongoing updates to the policies since that is a customary business practice.

For purposes of estimating the burden for IC-12, we assume not all currently certified hospitals will need the full 40 hours to meet this requirement. Because hospitals who are accredited by The Joint Commission (TJC) must satisfy extensive requirements to be certified, we assume 50% of all TJC-accredited hospitals will have already completed the work needed to meet the requirements under § 482.59(b).[30] Based on this assumption, we estimate that the total number of hospitals (including 100% of all non-accredited hospitals and 50% of the TJC-accredited hospitals) that will incur this one-time burden to develop and document protocols is 2,821(rounded).[31] See Table 14a below.

**Table 14a: # of Impacted Hospitals by § 482.59(b)**

| Facilities Impacted | % | Total # |
|---|---|---|
| *(a)* Total # of Hospitals Providing OB Services | 100% | 4,415 |
| *(b)* TJC-accredited Hospitals *(b) = (a) x 72.2%* | 72.2% | 3,187.63 |
| *(c)* 50% of the TJC-accredited hospitals *(c) = (b) x 50%* | 36.1% | 1,593.82 |
| *(d)* 100% of non-TJC accredited hospitals *(d) = (a) – (b)* | 27.8% | 1,227.37 |
| ***(e)*** **Total Hospitals Impacted** (TJC-accredited & non-accredited) ***(e) = (c) + (d)*** | **63.9%** | **2,821.19** |

Per Table 14b below, we estimate that it would take 8 hours for the following staff members to develop and document the required protocols – 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.[32] As a result, the one-time annual burden per hospital is 40 hours at a cost of $5,481.60. For all 2,821 hospitals im-

28 This CoP was added in 2024. 89 FR 93912, 94539 (November 27, 2024). See also, 89 FR 94592. CMS added Section 482.59 for hospitals that offer obstetrical services and created standards governing the following areas: a) organization and staffing, b) delivery of OB services; and c) staff training

29 89 FR 93912, 94541 (November 27, 2024). Although most hospitals that offer OB services likely have existing standards and protocols to ensure that OB services are well organized, provide high-quality care appropriate to the level of services provided, and comply with nationally accepted guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events, we assume all hospitals will need time to ensure these existing standards (and sources) are well-documented.

30 Id.; see also, Hospital Accreditation Fact Sheet | The Joint Commission

31 The facilities impacted for this IC reflects the assumptions used in 89 FR 93912, 94541 (November 27, 2024).

32 89 FR 93912, 94541 (November 27, 2024).

pacted, the one-time burden is 112,847 hours (40 hours/hospitals x 2,821.21 hospitals) at a one-time cost of $15,464,608 ($5,481.60 x 2,821.21 hospitals). See Table 14b below.

**Table 14b: IC-12: CoP: Written protocols for Obstetrical Services – 482.59(b)**

| One-time development of policies for delivery of OB services | Hourly Mean Wage | Burden Hours | Burden Cost |
|---|---|---|---|
| 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 |
| *(a)* Total Hours & Cost per Hospital | n/a | **40.0** | **$5,481.60** |
| | | | |
| *(b)* Total # of Hospitals impacted (Table 14a) | 2,821 | | |
| ***(c)* IC-12: Total Annual Burden/Costs *(c) = (a) x (b)*** | | **112,847** | **$15,464,608** |

**IC-13: Written Policies for Staff Training (§ 482.59(c))**

Section 482.59(c) requires hospitals that provide OB services to 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.[33] New staff must receive initial training, and the governing body must identify which staff must complete initial training and subsequent biennial training.[34] Per Table 15 below, we estimate the one-time burden to develop the OB staff training policies and procedures and assume this activity will take 8 hours for the staff and hourly wage listed below.[35]

**Table 15: IC-13: CoP: Written policies for staff training – 482.59(c)**

| One-time development of policies for staff training | Hourly Mean Wage | Hours/Task | Cost/Task |
|---|---|---|---|
| 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[36] | 4,415 | | |
| **Total Annual Burden/Costs** | | **176,600** | **$24,201,264** |

**Category C-1: Information Collections Related to Proposed § 482.46**

****NEW** IC-14: Hospital Notifications to Patients (§ 482.46)**

The proposed rule "Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children" which published on December 19, 2025 (90 FR 59463) establishes § 482.46, which prohibits Medicare-participating hospitals from performing sex-rejecting procedures (SRPs) on children under 18 years of age. In order to comply with the new requirement, we expect that hospitals that are currently performing these procedures on children would need to inform the child and their parents or legal guardians who are seeking such procedures that they no longer perform

33 89 FR 93912, 94542-43 (November 27, 2024)

34 The staff training requirement is effective after January 1, 2027. 89 FR 94543.

35 89 FR 93912, 94543 (November 27, 2024). The facilities impacted for this IC reflects the assumptions used in the November 27, 2024 rule. Note: 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). We also assume that documentation will consist of one comprehensive policy per facility.

36 89 FR 93912, 94543-44 (November 27, 2024). The total facilities impacted for ICs related to §482.59 reflects the assumptions included in this rule.

such procedures.

Estimated Notifications Required

In order to estimate the total number of notifications required by this policy change, we developed estimates for the number of parents or legal guardians of children under 18 years of age who are currently receiving or seeking SRPs using the following assumptions:

A. Estimated number of children receiving SRPs by state:

- Currently there are twenty-five states with state laws that restrict SRPs. Since these procedures are already prohibited, we assume that physicians or licensed practitioners in these States would not need to send a significant number of notifications. In addition, because of geographic distance and because children enrolled in these state's Medicaid or CHIP programs would not be able to use their coverage for out of state care, we do not expect there will be a significant number of children who have traveled outside of the state for SRPs and whose parents will need to be notified of the policy change.[37]
- Using Census Bureau population estimates, we then estimated there are 17.8 million children under between the ages of 10 to 17 living in states that do not have state laws restricting SRPs. We then evaluated publicly available research data to determine what % of children under 18 may already be receiving SRPs (including surgical and non-surgical procedures such as puberty blockers and hormone therapy) and thus would need to be notified of the policy change. Based on the percentage from various studies and assuming this rate would be lower for children with Medicaid coverage, we estimate there are 9,851 children under the age of 18 currently receiving SRP services who may need to be notified of the policy change.

B. Estimated number of children receiving SRPs in hospitals:

- Although puberty blockers and hormone replacement therapy are often prescribed by hospitals as part of sex-rejecting procedures, there may be children who receive SRPs from primary care providers (PCP) and endocrinologists outside of hospitals who provide SRPs and thus would not be affected by the policy change. If we assume 25% of the 9,851 children currently receiving SRPs are treated by PCPs or endocrinologists (25% x 9,851= 2,463) and 52% of those providers are outside the hospital system (52% x 2,463 = 1,281), then we assume there are a total of 8,570 (9,851-1,281 = 8,570) children currently receiving treatment whose parents or guardians would need to be notified by hospitals of the policy change.

Based on the above assumptions, this IC captures the one-time burden for Medicare and Medicaid participating hospitals who previously performed SRP procedures to send 8,570 notifications to the parents or legal guardians of children under 18 who are seeking such procedures that they no longer perform such procedures as a result of the new CoP at § 482.46.[38]

One-time Burden Hours and Cost for IC-14[39]

We estimate each notification will take 1 hour for a physician which includes 0.5 hours (30 minutes) to prepare written notification materials and 0.5 hours (30 minutes) to discuss the notification with the patient and parent/legal guardian and answer questions. Based on May 2024 BLS wage data for a physician (BLS occupation code 29-1210) in hospital settings (NAICS 622100) and applying a 100% increase to account for overhead and fringe benefits, the loaded hourly rate for each notification required under §482.26 is $226.18. Per Table 16 below, the one-time burden for IC-14 for all impacted hospitals is 8,570 hours (1 hour x 8,570 notifications) at an annual cost of $1,938,363 (8,570 hours x $226.18).

**Table 16: IC-14: Hospital Notifications to Patients (§ 482.46)**

| Per Notification | Hourly Mean Wage | Hours/ Notification | Cost/ Notification |
|---|---|---|---|
| Physician (29-1210) | $226.18 | 1.0 | $226.18 |
| # of Notifications Required | 8,570 | | |
| **IC-14: Total One-time Burden Hours/Cost** | | **8,570** | **$ 1,938,363** |

Source: General Medical and Surgical Hospitals (622100) - May 2024 OEWS Industry-Specific Occupational Employment and Wage Estimates (bls.gov)

37 45% of children in restrictive States are enrolled in their state's Medicaid/CHIP which excludes coverage for out-of-state SRPs. In addition, because the average drive time to a provider from a restrictive state to a non-restrictive State is on average more than 5 hours, this would likely limit the number of patients seeking SRPs across state lines.

38 See 90 FR 59463, 59472-73 (December 19, 2025) for all assumptions used for burden estimates.

39 Note: This is a one-time burden that will be removed in subsequent PRA renewal cycles after initial implementation.

****NEW** IC-15: Updating Hospital Policies and Procedures (§ 482.46)**

Hospitals will also need to update their policies and procedures to ensure compliance with the prohibition on performing SRPs on children proposed under § 482.46. This IC captures the one-time burden associated with hospitals reviewing, revising, and implementing updated policies to align with the new regulatory requirements.

Estimated number of hospitals affected

We first estimate the number of hospitals that would need to update their policies and procedures as a result of this policy change. Based on CMS' Q2 2025 Provider of Services File, there are currently 4,832 Medicare/Medicaid certified hospitals.[40] However, not all hospitals offer SRPs for children, and increasingly more hospitals nationwide are ending these services. We also assume there may be hospitals in states that have already restricted SRPs that may still need to update their policies and procedures because those laws may not have banned all SRP procedures per the new requirement at 482.46. Therefore, for purposes of estimating the one-time burden for this information collection, we estimate that 3,624 hospitals (which is 75% of the 4,832 currently certified hospitals) will need to update their policies and procedures to comply with proposed § 482.46.

One-time Burden Hours and Cost for IC-15[41]

For each hospital to update their policy and procedures to comply with § 482.46, we estimate this will require the following staff and time and average loaded hourly wage (per May 2024 BLS wage data for hospitals (NAICS 621000)) to complete this task:

- 3 hours for a Physician (BLS occupation code 29-1210) at $226.18/hour to review clinical implications and ensure medical accuracy of policy language;
- 3 hours for Legal counsel (BLS occupation code 23-1010) at $216.72/hour to review policy for legal compliance and risk management;
- 3 hours for Clerical staff (BLS occupation code 43-6010) $47.80/hour to document, format, and distribute updated policies

Per Table 17 below, the one-time burden for each impacted hospital to update policies and procedures to comply with 482.46 (IC-15) is 9 hours at a cost of $1,472.10. For all 3,624 impacted hospitals based on the assumptions above, the total one-time burden to the industry for IC-15 is 32,616 hours (9 hours x 3,624 facilities) at a cost of $5,334,890 ($1,472.10 x 3,624 facilities).[42]

**Table 17: IC-15: Updating Hospital Policies and Procedures (§ 482.46)**

| Per Hospital | Hourly Mean Wage | Hours/Task | Cost/Task |
|---|---|---|---|
| Physician (29-1210) | $226.18 | 3.0 | $678.54 |
| Lawyer (23-1010) | $216.72 | 3.0 | $650.16 |
| Clerical staff (43-6010) | $47.80 | 3.0 | $143.40 |
| Total Task/Facility | | 9.0 | $1,472.10 |
| # Hospitals Impacted | 3,624 | | |
| **Total One-time Burden/Costs** | | **32,616** | **$5,334,890** |
| Source: General Medical and Surgical Hospitals (622100) - May 2024 OEWS Industry-Specific Occupational Employment and Wage Estimates (bls.gov) | | | |

40 Centers for Medicare and Medicaid Services. "Provider of Services File—Hospital & Non-Hospital Facilities, Q2 2025." Data.CMS.gov, https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data

41 See 90 FR 59463, 59472-73 (December 19, 2025) for all assumptions used for burden estimates. Note: This is a one-time burden that will be removed in subsequent PRA renewal cycles after initial implementation. Ongoing policy reviews and updates are considered customary business practice and are not included in this burden estimate.

42 90 FR 59463, 59473 (December 19, 2025).

**Category D: Exemptions from Paperwork Burden**

The following hospital requirements are exempt from the Paperwork Reduction Act (PRA) because they are either: Standard industry practice that hospitals would do part of their normal business operations or are required by other laws (like HIPAA or state laws) or affect very few hospitals (fewer than 10 per year).

**Hospital Administration**

Planning Agency Review (§ 482.12(d)(5))

- What it requires: Hospitals must submit capital expenditure plans over $600,000 to state planning agencies.
- Why it's exempt: This affects fewer than 10 hospitals annually because most Medicare/Medicaid patients are in HMOs, which are excluded from this requirement
- PRA exemption: 5 CFR §1320.3(c)(4) - minimal impact

Emergency Services Policies (§ 482.12(f)(2))

- What it requires: Written policies for handling emergencies
- Why it's exempt: Hospitals must already have these policies to comply with EMTALA (Emergency Medical Treatment & Labor Act)
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Patient Rights Notices (§ 482.13(a)(1)-(a)(2))

- What it requires: Informing patients of their rights
- Why it's exempt: Standard practice in all healthcare settings
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Patient Record Confidentiality (§ 482.13(d))

- What it requires: Keeping patient records confidential
- Why it's exempt: Already required by HIPAA and state laws
- PRA exemption: 5 CFR §§1320.3(b)(2) and (b)(3) - required by other laws

Restraint and Seclusion Policies (§ 482.13(e))

- What it requires: Policies on using restraints or seclusion
- Why it's exempt: Required by state laws and standard medical practice
- PRA exemption: 5 CFR §§1320.3(b)(2) and (b)(3) - required by other laws

Staff Training (§ 482.13(f))

- What it requires: Training staff on patient rights and safety
- Why it's exempt: Standard practice for all hospitals, including accredited facilities
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Death Reporting (§ 482.13(g))

- What it requires: Reporting certain patient deaths
- Why it's exempt: Standard medical and legal practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Patient Visitation Rights (§ 482.13(h))

- What it requires: Policies on patient visitors
- Why it's exempt: Standard hospital practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

**Basic Hospital Functions Exemptions**

Medical Staff Bylaws (§ 482.22(c)(5))

- What it requires: Medical staff must adopt bylaws governing patient care
- Why it's exempt: All hospitals have medical staff bylaws as standard practice
- Note: The 2019 update allowing optional pre-surgical assessment policies for outpatient procedures is also exempt because it follows nationally recognized guidelines
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Nursing Care Plans (§ 482.23(b)(4))

- What it requires: Nurses must develop care plans for each patient
- Why it's exempt: Fundamental nursing practice in all hospitals
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Medical Record Authentication (§ 482.24(c)(2) and (c)(3))

- What it requires: Doctors must sign verbal orders; hospitals may use electronic standing orders
- Why it's exempt: Standard medical record-keeping practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Pre-Surgery Documentation (§ 482.24(c)(4))

- What it requires: Documenting medical need for surgery before the procedure
- Why it's exempt: Standard medical practice for patient safety
- Note: The 2019 update allows flexibility for outpatient surgery documentation
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Electronic Patient Notifications (§ 482.24(d) and § 482.61(f))

- What it requires: Hospitals with electronic health records (EHRs) must send notifications to other providers when patients are admitted or discharged
- Why it's exempt: 96% of hospitals already have certified EHRs with this capability; required by interoperability mandates
- Note: This also applies to Critical Access Hospitals (CAHs) with psychiatric units
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Laboratory Services (§ 482.27(a)(2) and related sections)

- What it requires: Written descriptions of lab services; policies for handling infectious blood products
- Why it's exempt: Standard laboratory practice and safety protocols
- Related exempt sections:
    - § 482.27(b)(3) - Collection services
    - § 482.27(b)(5) - Record keeping
    - § 482.27(b)(6) - Patient notification
    - § 482.27(b)(9) - Policies and procedures
    - § 482.27(b)(10) - Notification to family
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Utilization Review (§ 482.30(c)(1) and (d)(3))

- What it requires: Plans to review whether hospital services are medically necessary
- Why it's exempt: All hospitals conduct utilization reviews for quality and cost management
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Fire Safety (§ 482.41(b))

- What it requires: Life safety from fire standards
- Why it's exempt: Required by building codes and standard safety practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Infection Control Logs (§ 482.42(a)(2))

- What it requires: Monitoring and documenting infections
- Why it's exempt: Fundamental infection control practice in all hospitals
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Organ Procurement Notifications (§ 482.45(a)(1) and (a)(2))

- What it requires: Protocols for notifying organ procurement organizations; agreements with eye and tissue banks
- Why it's exempt: Standard practice for all hospitals; also covered under separate transplant program requirements (OMB 0938-1069)
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Organ Transplant Data Reporting (§ 482.45(b)(3))

- What it requires: Providing data to organ transplant networks when requested
- Why it's exempt: Standard practice; covered under separate transplant program requirements (OMB 0938-1069)
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

**Optional Hospital Services Exemptions**

The following requirements are exempt because they represent standard medical practice:

- Anesthesia Services (§ 482.52) - Standard delivery of anesthesia care
- Nuclear Medicine Records (§ 482.53(d)(1) and (d)(3)) - Standard record-keeping for nuclear medicine
- Rehabilitation Services (§ 482.56(b)) - Standard delivery of rehabilitation care
- Respiratory Care Services (§ 482.57(b)(1)) - Standard delivery of respiratory care
    - PRA exemption for all: 5 CFR §1320.3(b)(2) - standard practice

**Specialty Hospital Exemptions**

Psychiatric Hospital Records (§ 482.60(c))

- What it requires: Clinical records for psychiatric patients
- Why it's exempt: Standard psychiatric care practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Psychiatric Treatment Plans (§ 482.62(a))

- What it requires: Individualized treatment plans for psychiatric patients
- Why it's exempt: Standard psychiatric care practice
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

Organ Transplant Compatibility Testing (§ 482.92(a))

- What it requires: Ensuring donor-recipient compatibility before transplant

- Why it's exempt: Standard medical practice; covered under separate transplant program requirements (OMB 0938-1069)
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

**Critical Access Hospital (CAH) Exemptions**

Telemedicine Credentialing (§ 485.616(c)(1)-(c)(4))

- What it requires: Agreements for credentialing telemedicine physicians
- Why it's exempt: Standard practice; CAH requirements are documented under separate OMB package (0938-1043/CMS-10239)
- Note: This package only covers 138 CAHs with psychiatric (119) or rehabilitation (19) distinct part units
- PRA exemption: 5 CFR §1320.3(b)(2) - standard practice

**13. Capital Costs**

There are no capital costs.

**14. Cost to Federal Government**

The burden and costs to the federal government for these ICs 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 (May 2023 BLS wage data for 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).
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). The burden to the Federal government for each applicable 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 | May 2023 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 | 4,415 | $63 | 4 | 17,660 | $1,12,580 |
| IC-4: 482.21(b)(4) - Ongoing IT System Maintenance | 4,415 | $63 | 1 | 4,415 | $278,145 |
| IC-5: 482.21(b)(4) - Data Analysis | 4,415 | $63 | 1 | 4,415 | $278,415 |
| IC-6: 482.21(g) - Initial Review | 1,698 | $63 | 4 | 6,792 | $427,896 |
| IC-7: 42 CFR 482.23(b)(7) – Initial Review | 999 | $63 | 4 | 3,996 | $251,748 |
| IC-8: 482.42(e)(1) - Initial Review | 4,994 | $63 | 4 | 19,976 | $1,258,488 |
| IC-9: 482.42(e)(2) - Initial Review | 4,994 | $63 | 4 | 19,976 | $1,258,488 |
| IC-10: 482.43(c) - Initial Review | 5,797 | $63 | 4 | 23,188 | $1,460,844 |
| IC-11: 482.55(c) - Initial Review | 5,797 | $63 | 4 | 23,188 | $1,460,844 |
| IC-12: 482.59(b) - Initial Review | 2,821 | $63 | 4 | 11,284 | $710,892 |

| | | | | | |
|---|---|---|---|---|---|
| IC-13: 482.59(c) - Initial Review | 4,415 | $63 | 4 | 17,660 | $1,112,580 |
| **Subtotal for IC-1 thru IC-13** | n/a | n/a | n/a | 167,954 | $10,581,102 |
| **NEW:** IC-14: 482.46 – Hospital Notifications | 3,624 | $63 | 4 | 14,496 | $913,248 |
| **NEW:** IC-15: 482.46 – Policy Updates | 3,624 | $63 | 4 | 14,496 | $913,248 |
| **Revised Total** | n/a | n/a | n/a | **196,946** | **$12,407,598** |

Per Table 18 above, the annual burden hours to the federal government is revised to 196,946 with an annual cost of with an annual cost of $12,407,598. This includes surveyor time to verify compliance with all 15 information collections, including the new requirements under proposed § 482.46 (IC-14 and IC-15).

Note: IC-14 and IC-15 represent estimated downstream implementation costs associated with proposed § 482.46 rather than explicit information collection requirements subject to surveyor verification. These burden estimates are included conservatively to account for potential hospital activities related to the policy change and will be removed in subsequent PRA renewal cycles.

**15. Changes to Burden**

Per Table 19 below, for all existing information collections (IC-1 through IC-13) the annual burden hours to industry remain unchanged: total burden hours of 3,578,684 hours and burden costs of $316,543,106. For details for burden hours and costs for IC-1 through IC-13, see Table 1 above.[43]

This revision adds two new information collections related to proposed § 482.46, which prohibits hospitals from performing sex-rejecting procedures on children:

- IC-14: Hospital Notifications to Patients or Legal Guardians – 8,570 hours and $1,938,363 (one-time burden)
- IC-15: Updating Hospital Policies and Procedures – 32,616 hours and $5,334,890 (one-time burden)

The revised total burden is **3,619,870** hours and **$323,816,359** representing an increase of 41,186 hours (1.15%) and $7,272,253 (2.3%) from the previously approved total burden of 3,578,684 hours and $316,543,106. See Table 19.

**Table 19. Changes to Total Burden Hours and Cost to Industry**

| Information Collection (IC) for Industry | Responses | Respondents | Industry Burden Hours | Industry Burden Costs |
|---|---|---|---|---|
| ***(a)*** Total Burden Hours and Cost for Existing ICs - IC-1 to IC-13 (per Table 1) | 2,132,668 | 60,158 | 3,578,684 | $316,543,106 |
| | | | | |
| ***(b)*** **New** IC-14: 482.46 - Hospital Notifications | 8,570 | 3,624 | 8,570 | $1,938,363 |
| ***(c)*** **New** IC-15: 482.46 - Policy Updates | 3,624 | 3,624 | 32,616 | $5,334,890 |
| ***(d)*** Subtotal for IC-14 and IC-15 *(d) = (b) + (c)* | 12,194 | 7,248 | 41,186 | $7,272,253 |
| | | | | |
| **(e) Revised Total Burden Hours and Costs with IC-14 and IC-15** ***(e) = (a) + (d)*** | **2,144,862** | **67,406** | **3,619,870** | **$323,816,359** |

Note: IC-14 and IC-15 represent one-time, downstream implementation costs associated with proposed § 482.46. While included conservatively in this PRA package, these burdens are expected to be removed in subsequent renewal cycles as they reflect transitional activities rather than ongoing information collection requirements.

43 Note: The total burden costs in the previously approved submission of $312,497,786 was an inaccurate sum of all the costs reflected in the individual ICs. The correct total for the previously approved collection is $316,543,106.

**16. Publication and Tabulation Dates**

This information collection does not involve statistical surveys or studies requiring publication of results. Therefore, there are no publication and tabulation dates associated with this information collection request.

**17. Expiration Date**

CMS will display the OMB approval and expiration date in the Federal Register notice announcing approval of this information collection. The expiration date will also be available on OMB's website (www.reginfo.gov) under OMB Control Number 0938-0328.

**18. Certification**

There is no exception to the certification.