

**Emergency Preparedness Requirements for Medicare and Medicaid Participating
Providers and Suppliers (OMB No. 0938-1325/CMS-10578)
Supporting Statement – Part A**

A. BACKGROUND

Introduction

This is a **reinstatement of the information collection request** (“ICR”) that expired on January 31, 2023. The previous iteration of this OMB No. 0938-1325 (ICR Reference No. 202001-0938-006, approved January 27, 2020) had a burden of 1,260,474 annual hours. For this requested reinstatement, with changes, the total annual burden hours for industry is 1,251,158 hours and the annual burden costs are \$401,106,506. The reasons for the decrease is discussed in section 15, Changes to Burden.

Emergency Preparedness information collections were established as a result of omnibus final rule “[Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers](#),” 81 FR 63860 (September 16, 2016)(hereinafter “[2016 Final Rule](#)”). This information collection request captures the burden necessary for existing providers and suppliers to maintain their emergency preparedness collection of information requirements. This request also captures the burden to develop and implement the emergency preparedness requirements for newly approved Medicare and Medicaid providers and suppliers, also referred to as facilities.

This information collection (“IC”) is an “Omnibus” request. The emergency preparedness Conditions of Participation (CoPs) apply to the 19 Medicare and Medicaid providers that are listed in the next section. However, for reasons discussed in the Background section below, this information collection request captures the burden for 17 of the affected Medicare and Medicaid providers and suppliers.

This is a departure, as we normally submit information collection requests (“ICRs”) by provider and supplier type. For example, the collection of information(s) stemming from the Conditions of Participation for the “Hospital” provider type are under OMB No. 0938-0328 (CMS-R-48). The collection of information(s) stemming from the Conditions of Participations for the “Hospice” provider type are under OMB No. 0938-1067 (CMS-10277), etc. We make this exception for continuity and simplicity. We continue to cross reference this emergency preparedness IC in each provider type’s individual information collection request.

Background

In response to past terrorist attacks, natural disasters, and the subsequent national need to refine the nation’s strategy to handle emergency situations, there continues to be a coordinated effort across Federal agencies to establish a foundation for development and expansion of emergency preparedness systems.

The Emergency Preparedness CoPs affect the following 19 Medicare and Medicaid providers:

- Religious Nonmedical Health Care Institutions (RNHCIs) – § 403.748

- Ambulatory Surgical Centers (ASCs) – § 416.54
- Hospices – § 418.113
- Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs) – § 441.184
- Programs of All-Inclusive Care for the Elderly (PACE) – § 460.84
- Hospitals – § 482.15
- Transplant Programs – § 482.78
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) – § 483.475
- Home Health Agencies (HHAs) – § 484.102
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) – § 485.68
- Critical Access Hospitals (CAHs) – § 485.625
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) – § 485.727
- Community Mental Health Centers (CMHCs) – § 485.920
- Organ Procurement Organizations (OPOs) – § 486.360
- Rural Health Clinics (RHCs) – § 491.12
- Federally Qualified Health Centers (FQHCs) – § 491.12
- End-Stage Renal Disease (ESRD) Facilities – § 494.62
- Rural Emergency Hospitals (REHs) – § 485.542
- Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) (also referred to as Long Term Care (LTC) Facilities) – § 483.73

This reinstatement includes a new facility type, Rural Emergency Hospitals (REHs), which was created in 2021, after the prior reinstatement for this package had been approved in 2020. Congress introduced the designation Rural Emergency Hospitals (REHs) as part of the Consolidated Appropriations Act of 2021 (Public Law 116-260), which is codified at 42 United States Code § 1395x(kkk)(1) or Section 1861(kkk)(1) of the Social Security Act. REHs are subject to the Emergency Preparedness CoPs per 42 CFR § 485.542 and are similar to the Critical Access Hospital (CAH’s) Emergency Preparedness CoPs.¹

As stated in the [2016 Final Rule](#), we identified four core elements central to an effective and comprehensive framework of emergency preparedness requirements for the various Medicare and Medicaid participating providers and suppliers. The four elements are as follows:

- **Risk assessment and Emergency Plan:** An emergency preparedness plan must be developed, maintained, and reviewed and updated at least every two years. Prior to establishing an emergency plan, a risk assessment must be performed based on utilizing an “all hazards” approach. An all-hazards approach is an integrated

¹ See implementing regulations for REHs EP CoPs at: “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19,” 87 FR 71748, 72202-04 (November 23, 2022) at: <https://www.federalregister.gov/documents/2022/11/23/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment#h-553>

approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters.

- **Policies and procedures:** Policies and procedures based on the emergency plan and risk assessment must be developed, implemented, and reviewed and updated at least every two years.
- **Communication plan:** An emergency preparedness communication plan that complies with both Federal and State law must be developed, maintained, and reviewed and updated at least every two years. Patient care must be well-coordinated within the facility, across health care providers, and with State and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.
- **Training:** An emergency preparedness training and testing program must be developed, implemented, and reviewed and updated at least every two years. Facilities must conduct an initial training of their emergency preparedness policies and procedures to new and existing staff, and thereafter, provide training at least every 2 years or after the emergency preparedness policies and procedures are significantly updated.. Staff must demonstrate knowledge of emergency procedures and documentation of the training must be maintained..
- **Testing:** Providers must conduct testing exercises annually to test their emergency plan and will vary whether they provide inpatient or outpatient services. Inpatient providers must conduct two of any of the following types of exercises per year: community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, a tabletop exercise or a workshop that includes a group discussion led by a facilitator. Outpatient providers must conduct one testing exercise each year, which could include a drill, a tabletop exercise or workshop. At least every two years, they must conduct a community-based, full-scale exercise (if available) or an individual facility-based functional exercise.

For existing providers and suppliers, these information collections would have been drafted and implemented in 2016/2017. Therefore, this information collection consists primarily of the annual update of these information collections for existing provider and supplier types. In addition, these information collections consist of any new providers and/or suppliers that would have to initially develop the required program, plan, or policies.

B. Justification

1. Need and Legal Basis

Various sections of the Social Security Act (the Act) define the terms Medicare uses for each provider and supplier type and list the requirements that each provider and supplier must meet to be eligible for Medicare participation. Each statutory provision also specifies that the Secretary may establish other requirements as the Secretary finds necessary in the interest of the health and safety of patients, although the exact wording of such authority may differ slightly between different provider and supplier types. Further, the Public Health

Service (PHS) Act sets forth additional requirements that certain Medicare providers and suppliers must meet to participate.

Emergency Preparedness CoPs were initially implemented per “[Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers](#),” 81 FR 63860 (September 16, 2016)(hereinafter “[2016 Final Rule](#)”). The CoPs were subsequently revised per:

- “[Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction](#),” 83 FR 47686 (September 20, 2018)(hereinafter “[2018 Proposed Rule](#)”)
- “[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)(hereinafter “[2019 Final Rule](#)”).

This reinstatement incorporates the assumptions in all three of these final rules related to the Emergency Preparedness CoPs. The following are the statutory and regulatory citations for the Medicare certified providers and suppliers that are subject to the Conditions of Participation (CoPs) related to Emergency Preparedness:

- [Religious Nonmedical Health Care Institutions \(RNHCIs\)](#) – section 1821 of the Act and 42 CFR 403.700 through 403.756.
- [Ambulatory Surgical Centers \(ASCs\)](#) – section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.40 through 416.49.
- [Hospices](#) – section 1861(dd)(1) of the Act and 42 CFR 418.52 through 418.116.
- [Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Residential Treatment Facilities \(PRTFs\)](#) – sections 1905 (a) and 1905 (h) of the Act and 42 CFR 441.150 through 441.182 and 42 CFR 483.350 through 483.376.
- [Programs of All-Inclusive Care for the Elderly \(PACE\)](#) - sections 1894, 1905(a), and 1934 of the Act and 42 CFR 460.2 through 460.210.
- [Hospitals](#) - section 1861(e)(9) of the Act and 42 CFR 482.1 through 482.66.
- [Transplant Programs](#) – sections 1861(e)(9) and 1881(b)(1) of the Act and 42 CFR 482.68 through 482.104.
- [Long Term Care \(LTC\) Facilities](#) –Skilled Nursing Facilities (SNFs) –under section 1819 of the Act, Nursing Facilities (NFs) – under section 1919 of the Act, and 42 CFR 483.1 through 483.180.
- [Intermediate Care Facilities for Individuals with Intellectual Disabilities \(ICF/IID\)](#) - section 1905(d) of the Act and 42 CFR 483.400 through 483.480.
- [Home Health Agencies \(HHAs\)](#) - sections 1861(o), 1891 of the Act and 42 CFR 484.1 through 484.55.
- [Comprehensive Outpatient Rehabilitation Facilities \(CORFs\)](#) - section 1861(cc)(2) of the Act and 42 CFR 485.50 through 485.74.
- [Critical Access Hospitals \(CAHs\)](#) - sections 1820 and 1861(mm)of the Act and 42 CFR 485.601 through 485.647.

- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) – section 1861(p) of the Act and 42 CFR 485.701 through 485.729.
- Community Mental Health Centers (CMHCs) – section 1861(ff)(3)(B)(i)(ii) of the Act, §1913(c)(1) of the PHS Act, and 42 CFR §410.110.
- Organ Procurement Organizations (OPOs) - section 1138 of the Act and section 371 of the PHS Act and 42 CFR 486.301 through 486.348.
- Rural Health Clinics (RHCs) - section 1861(aa) of the Act and 42 CFR 491.1 through 491.11; Federally Qualified Health Centers (FQHCs) - section 1861(aa) of the Act and 42 CFR 491.1 through 491.11, except 491.3.
- End-Stage Renal Disease (ESRD) Facilities – sections 1881(b), 1881(c), 1881(f)(7) of the Act and 42 CFR 494.1 through 494.180. Rural Emergency Hospitals (REHs) - section 1861(kkk)(1) of the Act and 42 CFR 485.500 through 485.546

Although all 19 providers must meet the emergency preparedness CoPs, this information collection captures the burden necessary to support the development and implementation of emergency preparedness requirements for 17 affected Medicare and Medicaid providers and suppliers.

First, we are not including the burden associated with the information collection requirements (ICRs) for skilled nursing facilities (SNFs) and nursing facilities (NFs) at 42 CFR §483.73 because the Paperwork Reduction Act (PRA) requirements are waived for regulations pertaining to SNFs and NFs per Sections 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87).²

Second, similar to the prior supporting statement, we are not including the burden associated with information collection requirements (ICRs) for transplant programs at section 482.78 in order to avoid duplication. Hospitals in which a transplant program is located (“transplant hospitals”) must account for the transplant program in the hospitals’ emergency preparedness requirements set forth in §482.15. Thus, the burden for hospitals to meet the emergency preparedness CoPs at §482.15 includes the burden for transplant programs to meet their CoPs at §482.78.

2. Information Users

This regulation requires Medicare and Medicaid participating providers and suppliers to establish emergency preparedness policies and procedures to adequately plan for both natural and man-made disasters. The healthcare industry, along with CMS, primarily uses the information collected to ensure the well-being and safety of patients and residents, including staff, while also preventing violations under their programs. CMS will also use this information for regulatory and other enforcement purposes, as well as for emergency planning and program development.

² Sections 4204(b) and 4214(d) of The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) provide a waiver of Paperwork Reduction Act (PRA) requirements for regulations pertaining to SNFs and NFs (Sections 4201-4206 and 4211-4218, respectively.) Thus, regulations related to CoPs for SNFs and NFs are not subject to the PRA. See also notes in 42 U.S. Code § 1395i-3 (SNFs) and 42 U.S. Code § 1396r (NFs).

3. Improved Information Technology

Providers and suppliers may use various information technologies to comply with the requirements of this regulation. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Similar Information

There are no other information collections that duplicate the ICRs in the final rule.

5. Small Businesses

These requirements do affect small businesses. However, the general nature of the requirements allows the flexibility for facilities to meet the requirement in a way consistent with their existing operations. In an effort to minimize burden, we have also evaluated existing Federal, state and local laws that are currently imposed on the providers affected by these requirements. In addition, we considered the emergency preparedness accreditation standards of those accrediting organizations (AOs) that have deeming authority for Medicare providers and suppliers.

6. Less Frequent Collection

CMS does not collect information directly from impacted providers 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 required plans, programs, policies & 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 patients and residents, as well as others, including staff and visitors, and the provision of quality healthcare.

7. Special Circumstances

There are no special circumstances.

8. Federal Register

The 60-day Federal Register package published XXXXXXXXXXXX.

9. Payments/Gifts to Respondents

There will not be any payment or gifts provided to respondents for the collection of this information.

10. Confidentiality

Standard medical confidentiality practices, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), assure the confidentiality of this information. The requirements of this regulation must be in compliance with HIPAA Privacy Rules at 45 CFR 160 and 164, which protect the privacy and security of an individual's protected health information.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

a. Background Information

As stated in the introduction section, the burden for existing providers and suppliers for these information collections would have been drafted and implemented in 2016/2017. Therefore, the burden for this information collection request consists primarily of the annual update of these information collections for existing provider and supplier types. In addition, to annual updates, these information collections consist of any burden imposed on new providers and/or suppliers that would have to initially develop the required program, plan, or policies as they seek to be an approved Medicare and Medicaid provider.

With regard to burden estimates for new provider types and as stated in the previous iteration of this information collection, the burden calculation for each provider or supplier type will vary based on factors such as the provider or supplier type (i.e., hospital, CAH, ASC) or whether they provide inpatient or outpatient services as each provider and supplier type has requirement nuances. Moreover, even where the regulatory requirements are the same, certain factors will greatly affect the burden for different facilities, such as their size and location, whether or not they participate in any type of network or health care system, and whether they already have an emergency preparedness program due to related CoPs.

Finally, as specified in the [2016 Final Rule](#), certain provider types are not included in the burden analysis for specific information collections because the specific CoP was seen as usual and customary practice, and therefore exempt from the PRA under CFR §1320.3(b)(2). For example, providers who had to comply with certain requirements in order to receive accreditation by The Joint Commission (TJC) – such as TJC-accredited hospitals, may have already developed an emergency preparedness program, plan or policies that would meet the CoP. Therefore, the burden analysis for a specific information collection may exclude accredited providers (as exempt from the PRA) and only include non-accredited providers in a certain provider type, or the analysis may include all providers (accredited and non-accredited) in a certain provider type. The basis for which provider types are exempt from the PRA and thus excluded from the burden analysis for each information collection is detailed in the [2016 Final Rule](#), the [2018 Proposed Rule](#), and the [2019 Final Rule](#).

Wage Summary

For purposes of estimating burden hours and cost for this reinstatement, we are assuming the same staffing across provider types would be involved in complying with the emergency preparedness CoPs and that the wages for those positions would be consistent across provider types.

We obtained all salary information for the different positions identified in the following assessments from the United States by the Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates (Cross-Industry) found at https://www.bls.gov/oes/current/oes_nat.htm#00-0000. To ensure that fringe benefits and overhead are included in the estimated hourly mean wage for each position, we calculated and added in the amount that would ensure that 100 percent of the total compensation was for overhead and fringe benefits. We also rounded all amounts to the nearest dollar.

Provider and Supplier Summary

We obtained the number of the various Medicare and Medicaid providers and suppliers below from Medicare’s Certification and Survey Provider Enhanced Reporting (CASPER) for Calendar Year 2023 (unless otherwise noted), per the Quality, Certification & Oversight Reports (QCOR) at qcor.cms.gov, as of January 5, 2025. We have not included data for health care facilities that are not Medicare and/or Medicaid certified.

Table 1 – Number of Providers/Suppliers based on Type

Provider or Supplier Type	CY 2023	
	Existing	New
Ambulatory Surgical Centers (ASCs) - (CY 2021)	6,170	254
TJC Accredited	581	63
Non-TJC Accredited	5,589	191
Community Mental Health Centers (CMHCs)	117	9
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	149	3
Critical Access Hospitals (CAHs)	1,341	18
TJC Accredited	325	4
Non-TJC Accredited	1,016	14
End-Stage Renal Disease (ESRD) Facilities	7,844	102
Federally Qualified Health Centers (FQHCs)	11,850	771
Home Health Agencies (HHAs) - (CY 2020)	8,925	361
TJC-Accredited	831	27
Non-TJC Accredited	8,094	334
Hospices - (CY 2021)	6,266	912
Inpatient Hospices (hospital, SNF, and NF based hospices)	301	0
Outpatient Hospices (home health based and freestanding)	5,732	685
Hospitals	4,417	94
TJC Accredited	3,296	49
Non-TJC Accredited	1,121	45

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	5,520	24
Organ Procurement Organizations (OPOs)	57	0
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”)	1,996	60
Programs of All-Inclusive Care for the Elderly (PACE)	148	1
Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs)	345	9
Religious Nonmedical Health Care Institutions (RNHCIs)	3	0
Rural Emergency Hospitals (REHs)	19	19
TJC Accredited	0	0
Non-TJC Accredited	19	19
Rural Health Clinics (RHCs)	5,545	339
Transplant Hospitals	239	1

For purposes of determining the annual burden and costs in this reinstatement, we assume the number of newly certified facilities by provider or supplier type remains consistent over the 3-year period.

b. Condition of Participation: Emergency Preparedness

Applicable information collections stemming from the Emergency Preparedness, Condition of Participations, are provided below. We organize these as IC-1a, Risk Assessment. IC-1b Emergency Preparedness plan, IC-1c: Biennial Review of Plan, IC-2: Policies and Procedures, IC-3: Communication Plan; IC-4a: Training Program, IC-4b: Conduct Biennial Training, IC-4c: Conduct Annual Testing, IC-5: OPO Agreement

IC-1a: Risk Assessment

Risk assessments are applicable to the following providers: RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at §484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a).

Each newly certified facility must conduct a facility-based and community-based risk assessment that utilizes an all-hazards approach. Facilities must consider its location and geographical area; patient population, including those with special needs; and the type of services they have the ability to provide in an emergency. Risk assessments are components of the providers’ or suppliers’ emergency preparedness plans.

Per the [2016 Final Rule](#), risk assessments completed by TJC-accredited ASCs, CAHs, HHAs, and hospitals meet the required standards of this CoP, and thus the burden for this CoP is seen as usual and customary practice for these providers.³ These providers are not included in the burden analysis below because they are exempt from the PRA under CFR §1320.3(b)(2). In addition, the burden for completing risk assessment is different for inpatient v. outpatient hospices.⁴

For every new Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for conducting the initial risk assessment.

Table 2 below lays out the one-time burden hours and cost for newly certified providers to conduct the initial risk assessment. We estimate the total collection of information burden impacting the 2,606 newly certified, non-exempt providers and suppliers is 24,848 burden hours at an annual cost of \$7,976,208, see Table 2.

³ [2016 Final Rule](#) at 63936 (ASCs); 63978 (CAHs); 63969 (HHAs); 63953 (hospitals)

⁴ [2016 Final Rule](#) at 63941-42.

Table 2 - IC-1a - Burden Hours and Cost Estimates for Newly Certified Facilities to Conduct Initial Risk Assessment

No.	Provider or Supplier Type	42 CFR	Newly Certified Facilities/ # of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response* (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs - Non-TJC Accredited	§ 416.54(a)	191	191	8	1,528	**	\$490,488
2	CAHs - Non-TJC Accredited	§ 485.625(a)	14	14	15	210	**	\$67,410
3	CMHCs	§ 485.920(a)	9	9	10	90	**	\$28,890
4	CORFs	§ 485.68(a)	3	3	8	24	**	\$7,704
5	ESRD Facilities	§ 494.62(a)	102	102	12	1,224	**	\$392,904
6	FQHCs	§ 491.12(a)	771	771	5	3,855	**	\$1,237,455
7	HHAs - Non-TJC Accredited	§ 484.102(a)	334	334	11	3,674	**	\$1,179,354
8	Hospices - Inpatient	§ 418.113(a)	0	0	10	0	**	\$0
9	Hospices - Outpatient	§ 418.113(a)	685	685	12	8,220	**	\$2,638,620
10	Hospitals - Non-TJC Accredited	§ 482.15(a)	45	45	34	1,530	**	\$491,130
11	ICF/IIDs	§ 483.475(a)	24	24	8	192	**	\$61,632
12	OPOs	§ 486.360(a)	0	0	10	0	**	\$0
13	“Organizations”	§ 485.727(a)	60	60	9	540	**	\$173,340
14	PACE organizations	§ 460.84(a)	1	1	14	14	**	\$4,494
15	PRTFs	§ 441.184(a)	9	9	8	72	**	\$23,112
16	REHs	§ 485.542(a)	19	19	15	285	**	\$91,485
17	RHCs	§ 491.12(a)	339	339	10	3,390	**	\$1,088,190
18	RNHCIIs	§ 403.748(a)	0	0	9	0	**	\$0
Total Annual Burden/Costs			2,606	2,606	208	24,848	n/a	\$7,976,208

* Based on [2016 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

IC-1b: Develop Emergency Preparedness Plan

The requirement to develop an Emergency Preparedness plan is applicable to the following providers: RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at §484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a).

After conducting the risk assessment, newly certified facilities must develop an emergency preparedness plan or update their existing preparedness plan to be in compliance with the Emergency Preparedness CoP. The development of an emergency preparedness plan requires individual expertise, identifying mitigation options to problems, and documenting policies and procedures to mitigate potential challenges that may arise depending on the identified hazards in their risk assessment. We continue to anticipate that completing an emergency preparedness plan will take more time than conducting a risk assessment as the plan must be tailored to each facility’s specific, identified hazards.

Per the [2016 Final Rule](#), the emergency preparedness plan initially developed by TJC-accredited ASCs, CAHs, and hospitals meet the required standards of this CoP, and thus the burden for this CoP is seen as usual and customary practice for these providers. These providers are not included in the burden analysis below because they are exempt from the PRA under CFR §1320.3(b)(2). However, the TJC-accredited HHAs are not exempt from the PRA and are included in the burden analysis below. In addition, the burden for the initial development of the emergency preparedness plan is different for inpatient v. outpatient hospices.⁵

For every new Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for the initial development of the emergency preparedness plan.

Table 3 below lays out the one-time burden hours and cost for newly certified providers – who are not already subject to this requirement due to their accreditation - to develop of the required emergency preparedness plan. We estimate the total collection of information burden impacting the 2,633 newly certified, non-exempt providers and suppliers is 37,898 burden hours at an annual cost of \$12,165,258, see Table 3.

⁵ [2016 Final Rule](#) at 63942-43.

Table 3 - IC-1b - Burden Hours and Cost Estimates for Newly Certified Facilities to Develop Emergency Preparedness Plan

No.	Provider or Supplier Type	42 CFR	Newly Certified Facilities/ # of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs - Non-TJC Accredited	§ 416.54(a)	191	191	11	2,101	**	\$674,421
2	CAHs - Non-TJC Accredited	§ 485.625(a)	14	14	26	364	**	\$116,844
3	CMHCs	§ 485.920(a)	9	9	15	135	**	\$43,335
4	CORFs	§ 485.68(a)	3	3	11	33	**	\$10,593
5	ESRD Facilities	§ 494.62(a)	102	102	10	1,020	**	\$327,420
6	FQHCs	§ 491.12(a)	771	771	8	6,168	**	\$1,979,928
7	HHAs - Non-TJC Accredited	§ 484.102(a)	334	334	15	5,010	**	\$1,608,210
8	HHAs - TJC-Accredited	§ 484.102(a)	27	27	10	270	**	\$86,670
9	Hospices - Inpatient	§ 418.113(a)	0	0	14	0	**	\$0
10	Hospices - Outpatient	§ 418.113(a)	685	685	20	13,700	**	\$4,397,700
11	Hospitals - Non-TJC Accredited	§ 482.15(a)	45	45	62	2,790	**	\$895,590
12	ICF/IIDs	§ 483.475(a)	24	24	9	216	**	\$69,336
13	OPOs	§ 486.360(a)	0	0	22	0	**	\$0
14	“Organizations”	§ 485.727(a)	60	60	12	720	**	\$231,120
15	PACE organizations	§ 460.84(a)	1	1	23	23	**	\$7,383
16	PRTFs	§ 441.184(a)	9	9	12	108	**	\$34,668
17	REHs	§ 485.542(a)	19	19	26	494	**	\$158,574
18	RHCs	§ 491.12(a)	339	339	14	4,746	**	\$1,523,466
19	RNHCIIs	§ 403.748(a)	0	0	12	0	**	\$0
Total Annual Burden/Costs			2,633	2,633	332	37,898	n/a	\$12,165,258

* Based on [2016 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

IC-1c: Biennial Review of Emergency Preparedness Plan

The requirement to conduct biennial reviews of their Emergency Preparedness plan is applicable to the following providers: RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at §484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a).

Currently certified facilities must review and update their emergency preparedness plan at least biennially.⁶ However, CMS expects that facilities will update their emergency preparedness program more frequently, especially after a facility experiences an emergency so that their plan incorporates lessons learned or areas for improvement.

This CoP was originally identified in the [2016 Final Rule](#) as a usual and customary business practice for facilities with existing emergency preparedness requirements, and thus the burden from this ICR was exempt from the PRA per 5 CFR §1320.3(b)(2) for most facilities.⁷ However, per the [2018 Proposed Rule](#) and the [2019 Final Rule](#), CMS reassessed the burden hours and costs for an annual review of the plan for all providers based on stakeholder feedback before reducing the hours by 50% to account for the change from an annual to biennial review of the emergency preparedness plan.⁸ In addition, the burden for biennial review applies to all providers, regardless of accreditation and does not vary between inpatient v. outpatient hospices. We update this collection of information request to reflect this change.

For every existing Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for the ongoing review of and updates to the emergency preparedness plan.

Table 4 below lays out the burden hours and cost for existing providers to review the emergency preparedness plan every two years. We estimate the total collection of information burden impacting the 60,712 existing, non-exempt providers and suppliers is 675,696 burden hours at an annual cost of \$216,898,256, see Table 4.

⁶ The requirement for facilities to review their emergency preparedness plan was changed from annually to biennially for all facilities except LTC facilities which must continue to review their plans annually. See [2018 Proposed Rule](#) at 47713; [2019 Final Rule](#) at 51735.

⁷ See [2016 Final Rule](#) at 63931. Burden hours and costs for annual review of the emergency preparedness plan in the 2016 Final Rule were only calculated for the following facilities: CMHCs, OPOs, PRTFs and outpatient hospices.

⁸ See [2018 Proposed Rule](#) at 47725; [2019 Final Rule](#) at 51767-68.

Table 4 - IC-1c- Burden Hours and Cost Estimates for Existing Certified Facilities to Biennial Review of Emergency Preparedness Plan

No.	Provider or Supplier Type	42 CFR	Existing Certified Facilities/# of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASC	§ 416.54(a)	6,170	6,170	10	61,700	**	\$19,805,700
2	CAHs	§ 485.625(a)	1,341	1,341	12	16,092	**	\$5,165,532
3	CMHCs	§ 485.920(a)	117	117	12	1,404	**	\$450,684
4	CORFs	§ 485.68(a)	149	149	8	1,192	**	\$382,632
5	ESRD Facilities	§ 494.62(a)	7,844	7,844	12	94,128	**	\$30,215,088
6	FQHCs	§ 491.12(a)	11,850	11,850	8	94,800	**	\$30,430,800
7	HHAs	§ 484.102(a)	8,925	8,925	14	124,950	**	\$40,108,950
8	Hospices	§ 418.113(a)	6,266	6,266	14	87,724	**	\$28,159,404
9	Hospitals	§ 482.15(a)	4,417	4,417	22	97,174	**	\$31,192,854
10	ICF/IIDs	§ 483.475(a)	5,520	5,520	6	33,120	**	\$10,631,520
11	OPOs	§ 486.360(a)	57	57	16	912	**	\$292,752
12	“Organizations”	§ 485.727(a)	1,996	1,996	6	11,976	**	\$3,844,296
13	PACE Organizations	§ 460.84(a)	148	148	12	1,776	**	\$570,096
14	PRTFs	§ 441.184(a)	345	345	12	4,140	**	\$1,328,940
15	REHs	§ 485.542(a)	19	19	12	228	**	\$73,188
16	RHCs	§ 491.12(a)	5,545	5,545	8	44,360	**	\$14,239,560
17	RNHCIIs	§ 403.748(a)	3	3	6.5	20***	**	\$6,260
Total Annual Burden/Costs			60,712	60,712	190.5	675,696	n/a	\$216,898,256

* Based on [2019 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

*** Rounded to nearest zero

IC-2: Develop EP Policies and procedures

The requirement to develop emergency preparedness policies and procedures are applicable to the following providers: RNHCIs at §403.748(b); ASCs at §416.54(b); Hospices at §418.113(b); PRTFs at §441.184(b); PACE at §460.84(b); Hospitals at §482.15(b); Transplant Programs §482.78(b); ICF/IIDs at §483.475(b); HHAs at §484.102(b); REHs at §485.542(b); CAHs at §485.625(b); CORFs at §485.68(b); “Organizations” at §485.727(b); CMHCs at §485.920(b); OPOs at §486.360(b); RHCs/FQHCs at §491.12(b); ESRD facilities at §494.62(b).

Newly certified facilities must develop emergency preparedness policies and procedures in accordance with their emergency preparedness plan, risk assessment, and communication plan. Facilities who are not already subject to this requirement due to their accreditation must develop new policies and procedures that would ensure that the emergency preparedness plans address the specific requirements of the regulations.

Per the [2016 Final Rule](#), the emergency preparedness policies and procedures initially developed by TJC-accredited ASCs meet the required standards of this CoP, and thus the burden for ASCs for this CoP is seen as usual and customary practice and is exempt from the PRA under CFR §1320.3(b)(2).⁹ However, the policies and procedures developed by TJC-accredited CAHs, HHAs, and hospitals do not meet the standards required by this CoP and are included in the burden analysis below. In addition, the burden for the development of the policies and procedures varies for accredited and non-accredited CAHs and hospitals and is different for inpatient v. outpatient hospices.¹⁰

For every new Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for the initial development of the emergency preparedness policies and procedures.

Table 5 below lays out the one-time burden hours and cost for newly certified providers – who are not exempt - to develop the required emergency preparedness policies and procedures. We estimate the total collection of information burden impacting the 2,686 newly certified, non-exempt providers and suppliers is 29,386 burden hours at an annual cost of \$9,432,906, see Table 5.

⁹ [2016 Final Rule](#) at 63938.

¹⁰ [2016 Final Rule](#) at 63942-43 (hospices); 63957 (hospitals); 63981-82 (CAHs).

Table 5 – IC-2 - Burden Hours and Cost Estimates for Newly Certified Facilities to Develop Emergency Preparedness Policies and Procedures

No.	Provider or Supplier Type	42 CFR	Newly Certified Facilities/# of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs - Non-TJC Accredited	§ 416.54(b)	191	191	9	1,719	**	\$551,799
2	CAHs - Non-TJC Accredited	§ 485.625(b)	14	14	10	140	**	\$44,940
3	CAHs - TJC-Accredited	§ 485.625(b)	4	4	14	56	**	\$17,976
4	CMHCs	§ 485.920(b)	9	9	12	108	**	\$34,668
5	CORFs	§ 485.68(b)	3	3	9	27	**	\$8,667
6	ESRD Facilities	§ 494.62(b)	102	102	10	1,020	**	\$327,420
7	FQHCs	§ 491.12(b)	771	771	8	6,168	**	\$1,979,928
8	HHAs	§ 484.102(b)	361	361	18	6,498	**	\$2,085,858
9	Hospices - Inpatient	§ 418.113(b)	0	0	8	0	**	\$0
10	Hospices - Outpatient	§ 418.113(b)	685	685	9	6,165	**	\$1,978,965
11	Hospitals - Non-TJC Accredited	§ 482.15(b)	45	45	33	1,485	**	\$476,685
12	Hospitals - TJC Accredited	§ 482.15(b)	49	49	17	833	**	\$267,393
13	ICF/IIDs	§ 483.475(b)	24	24	9	216	**	\$69,336
14	OPOs	§ 486.360(b)	0	0	20	0	**	\$0
15	“Organizations”	§ 485.727(b)	60	60	10	600	**	\$192,600
16	PACE Organizations	§ 460.84(b)	1	1	12	12	**	\$3,852
17	PRTFs	§ 441.184(b)	9	9	9	81	**	\$26,001
18	REHs	§ 485.542(b)	19	19	10	190	**	\$60,990
19	RHCs	§ 491.12(b)	339	339	12	4,068	**	\$1,305,828
20	RNHCIIs	§ 403.748(b)	0	0	6	0	**	\$0
Total Annual Burden/Costs			2,686	2,686	245	29,386	n/a	\$9,432,906

* Based on [2016 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

Biennial Review of EP Policies and Procedures

We believe that the requirement for providers to review and update their policies and procedures every two years (biennially) constitutes a usual and customary business practice.¹¹ Thus this IC is not subject to the PRA in accordance with 5 CFR §1320.3(b)(2).

IC-3: Develop Communication plan

The requirement to develop an emergency preparedness communication plan is applicable to the following providers: RNHCIs at §403.748(c); ASCs at §416.54(c); Hospices at §418.113(c); PRTFs at §441.184(c); PACE at §460.84(c); Hospitals at §482.15(c); Transplant Programs §482.78(c); ICF/IIDs at §483.475(c); HHAs at §484.102(c); REHs at §485.542(c); CAHs at §485.625(c); CORFs at §485.68(c); “Organizations” at §485.727(c); CMHCs at §485.920(c); OPOs at §486.360(c); RHCs/FQHCs at §491.12(c); ESRD facilities at §494.62(c).

Newly certified facilities must develop an emergency preparedness communication plan that complies with both federal and state law. Per the [2016 Final Rule](#), the emergency preparedness communication plan initially developed by TJC-accredited ASCs and hospitals meet the required standards of this CoP, and thus the burden for this CoP is seen as usual and customary practice for these providers and is exempt from the PRA under CFR §1320.3(b)(2). However, the communication plan developed by TJC-accredited CAHs and HHAs do not meet the standards required by this CoP and are included in the burden analysis below.¹²

For every new Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for the initial development of the emergency preparedness communication plan.

Table 6 below lays out the one-time burden hours and cost for the newly certified providers – who are not exempt - to develop the initial emergency preparedness communication plan. We estimate the total collection of information burden impacting the 2,864 newly certified, non-exempt providers and suppliers is 16,318 burden hours at an annual cost of \$5,238,078, see Table 6.

¹¹ [2019 Final Rule](#) at 51767-68.

¹² [2016 Final Rule](#) at 63972 (HHAs); 63982 (CAHs).

**Table 6 - IC-3 - Burden Hours and Cost Estimates for Newly Certified Facilities to Develop
Emergency Preparedness Communication Plan**

No.	Provider or Supplier Type	42 CFR	Newly Certified Facilities/ # of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs - Non-TJC Accredited	§ 416.54(c)	191	191	4	764	**	\$245,244
2	CAHs	§ 485.625(c)	18	18	9	162	**	\$52,002
3	CMHCs	§ 485.920(c)	9	9	8	72	**	\$23,112
4	CORFs	§ 485.68(c)	3	3	8	24	**	\$7,704
5	ESRD Facilities	§ 494.62(c)	102	102	4	408	**	\$130,968
6	FQHCs	§ 491.12(c)	771	771	5	3,855	**	\$1,237,455
7	HHAs	§ 484.102(c)	361	361	10	3,610	**	\$1,158,810
8	Hospices	§ 418.113(c)	912	912	3	2,736	**	\$878,256
9	Hospitals - Non-TJC Accredited	§ 482.15(c)	45	45	10	450	**	\$144,450
10	ICF/IIDs	§ 483.475(c)	24	24	6	144	**	\$46,224
11	OPOs	§ 486.360(c)	0	0	14	0	**	\$0
12	“Organizations”	§ 485.727(c)	60	60	8	480	**	\$154,080
13	PACE Organizations	§ 460.84(c)	1	1	7	7	**	\$2,247
14	PRTFs	§ 441.184(c)	9	9	5	45	**	\$14,445
15	REHs	§ 485.542(c)	19	19	9	171	**	\$54,891
16	RHCs	§ 491.12(c)	339	339	10	3,390	**	\$1,088,190
17	RNHCIIs	§ 403.748(c)	0	0	4	0	**	\$0
Total Annual Burden/Costs			2,864	2,864	124	16,318	n/a	\$5,238,078

* Based on [2016 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

Biennial Review and Update of Communication Plan

Consistent with the [2016 Final Rule](#) and [2019 Final Rule](#), the CoP for accredited and non-accredited providers to biennially review and update their emergency preparedness communication plans constitutes a usual and customary business practice and is not subject to the PRA in accordance with 5 CFR §1320.3(b)(2).¹³

¹³ See e.g., [2016 Final Rule](#) at 63959 (hospitals); 63982 (CAHs); 63973 (HHAs).

IC-4a: Develop Training Program

The requirement to develop an emergency preparedness training program is applicable to the following providers: RNHCIs at §403.748(d); ASCs at §416.54(d); Hospices at §418.113(d); PRTFs at §441.184(d); PACE at §460.84(d); Hospitals at §482.15(d); Transplant Programs §482.78(d); ICF/IIDs at §483.475(d); HHAs at §484.102(d); REHs at §485.542(d); CAHs at §485.625(d); CORFs at §485.68(d); “Organizations” at §485.727(d); CMHCs at §485.920(d); OPOs at §486.360(d); RHCs/FQHCs at §491.12(d); ESRD facilities at §494.62(d).

Providers and suppliers are required to develop an emergency preparedness training and testing program. The training program must include initial training in emergency preparedness policies and procedures for all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles and must be documented.

Per the [2016 Final Rule](#), the emergency preparedness training program initially developed by TJC-accredited hospitals meet the required standards of this CoP, and thus the burden for this CoP is seen as usual and customary practice and is exempt from the PRA under CFR §1320.3(b)(2).¹⁴ However, the training program developed by TJC-accredited ASCs, CAHs and HHAs do not meet the standards required by this CoP and are included in the burden analysis below.¹⁵

For every new Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for the initial development of an emergency preparedness training program communication plan.

Table 7 below lays out the one-time burden hours and cost for newly certified providers – who are not exempt - to develop the initial emergency preparedness training program. We estimate the total collection of information burden impacting the 2,927 newly certified, non-exempt providers and suppliers is 27,768 burden hours at an annual cost of \$8,913,528, see Table 7.

¹⁴ [2016 Final Rule](#) at 63959 (stating any additional burden for TJC accredited hospitals would be negligible).

¹⁵ [2016 Final Rule](#) at 63939 (ASCs); 63983 (CAHs); 63973 (HHAs).

Table 7 – IC-4a - Burden Hours and Cost Estimates for Newly Certified Facilities to Develop Emergency Preparedness Training Program

No.	Provider or Supplier Type	42 CFR	Newly Certified Facilities/ # of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs	§ 416.54(d)	254	254	6	1,524	**	\$489,204
2	CAHs	§ 485.625(d)	18	18	14	252	**	\$80,892
3	CMHCs	§ 485.920(d)	9	9	10	90	**	\$28,890
4	CORFs	§ 485.68(d)	3	3	8	24	**	\$7,704
5	ESRD Facilities	§ 494.62(d)	102	102	7	714	**	\$229,194
6	FQHCs/ RHCs	§ 491.12(d)	1,110	1,110	10	11,100	**	\$3,563,100
7	HHAs	§ 484.102(d)	361	361	16	5,776	**	\$1,854,096
8	Hospices	§ 418.113(d)	912	912	6	5,472	**	\$1,756,512
9	Hospitals - Non-TJC Accredited	§ 482.15(d)	45	45	40	1,800	**	\$577,800
10	ICF/IIDs	§ 483.475(d)	24	24	7	168	**	\$53,928
11	OPOs	§ 486.360(d)	0	0	40	0	**	\$0
12	“Organizations”	§ 485.727(d)	60	60	8	480	**	\$154,080
13	PACE Organizations	§ 460.84(d)	1	1	12	12	**	\$3,852
14	PRTFs	§ 441.184(d)	9	9	10	90	**	\$28,890
15	REHs	§ 485.542(d)	19	19	14	266	**	\$85,386
16	RNHCIIs	§ 403.748(d)	0	0	7	0	**	\$0
Total Annual Burden/Costs			2,927	2,927	215	27,768	n/a	\$8,913,528

* Based on [2016 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

Biennial Review of Training Program

Existing, certified facilities must biennially review their current training programs, document the training was completed, and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. Where necessary, facilities will need to revise or develop new sections or materials. This constitutes a usual and customary business practice and thus is exempt from the PRA per 5 CFR §1320.3(b)(2).

IC-4b: Conduct Trainings

The requirement to conduct emergency preparedness trainings is applicable to the following providers: RNHCIs at §403.748(d)(1); ASCs at §416.54(d)(1); Hospices at §418.113(d)(1); PRTFs at §441.184(d)(1); PACE at §460.84(d)(1); Hospitals at §482.15(d)(1); Transplant Programs §482.78(d)(1); ICF/IIDs at §483.475(d)(1); HHAs at §484.102(d)(1); REHs at §485.542(d)(1); CAHs at §485.625(d)(1); CORFs at §485.68(d)(1); “Organizations” at §485.727(d)(1); CMHCs at §485.920(d)(1); OPOs at §486.360(d)(1); RHCs/FQHCs at §491.12(d)(1); ESRD facilities at §494.62(d)(1).

Except for LTC facilities, existing, certified facilities must conduct EP training biennially.¹⁶ Facilities must provide an initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, and must maintain documentation of the training.

Per the [2016 Final Rule](#), TJC-accredited hospitals meet the required standards of this CoP, and thus the burden for this CoP is seen as usual and customary practice and is exempt from the PRA under CFR §1320.3(b)(2).¹⁷ However, the training program developed by TJC-accredited ASCs, CAHs and HHAs do not meet the standards required by this CoP and are included in the burden analysis below.¹⁸

For existing Medicare certified providers that are not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101, would all be responsible for conducting emergency preparedness training every two years.

Table 8 below lays out the burden hours and cost for existing providers - who are not exempt - to conduct the required emergency preparedness training every two years. We estimate the total collection of information burden impacting the 57,416 existing, non-exempt providers and suppliers is 287,326 burden hours at an annual cost of \$92,231,486, see Table 8.

¹⁶ See [2018 Proposed Rule](#) at 47726-27 and [2019 Final Rule](#) at 51756-57. Note that LTC facilities must conduct their emergency preparedness training programs annually.

¹⁷ [2016 Final Rule](#) at 63960.

¹⁸ [2016 Final Rule](#) at 63940 (ASCs); 63983 (CAHs); 63973 (HHAs).

**Table 8 – IC-4b - Burden Hours and Cost Estimates for Existing Facilities to Biennially Conduct
Emergency Preparedness Training**

No.	Provider or Supplier Type	42 CFR	Existing Certified Facilities/# of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
1	ASCs	§ 416.54(d)(1)	6,170	6,170	3	18,510	**	\$5,941,710
2	CAHs	§ 485.625(d)(1)	1,341	1,341	7	9,387	**	\$3,013,227
3	CMHCs	§ 485.920(d)(1)	117	117	5	585	**	\$187,785
4	CORFs	§ 485.68(d)(1)	149	149	4	596	**	\$191,316
5	ESRD Facilities	§ 494.62(d)(1)	7,844	7,844	3.5	27,454	**	\$8,812,734
6	FQHCs	§ 491.12(d)(1)	11,850	11,850	5	59,250	**	\$19,019,250
7	HHAs	§ 484.102(d)(1)	8,925	8,925	8	71,400	**	\$22,919,400
8	Hospices	§ 418.113(d)(1)	6,266	6,266	3	18,798	**	\$6,034,158
9	Hospitals - Non-TJC Accredited	§ 482.15(d)(1)	1,121	1,121	20	22,420	**	\$7,196,820
10	ICF/IIDs	§ 483.475(d)(1)	5,520	5,520	3.5	19,320	**	\$6,201,720
11	OPOs	§ 486.360(d)(1)	57	57	20	1,140	**	\$365,940
12	“Organizations”	§ 485.727(d)(1)	1,996	1,996	4	7,984	**	\$2,562,864
13	PACE Organizations	§ 460.84(d)(1)	148	148	6	888	**	\$285,048
14	PRTFs	§ 441.184(d)(1)	345	345	5	1,725	**	\$553,725
15	REHs	§ 485.542(d)(1)	19	19	7	133	**	\$42,693
16	RHCs	§ 491.12(d)(1)	5,545	5,545	5	27,725	**	\$8,899,725
17	RNHCIIs	§ 403.748(d)(1)	3	3	3.5 ***	11 ***	**	\$3,371
Total Annual Burden/Costs			57,416	57,416	113***	287,326***	n/a	\$92,231,486

* Based on [2019 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

*** Rounded to nearest zero

IC-4c: Annual Testing Exercises

The requirement to annually conduct emergency preparedness testing exercises is applicable to the following providers: RNHCIs at §403.748(d)(2); ASCs at §416.54(d)(2); Hospices at §418.113(d)(2); PRTFs at §441.184(d)(2); PACE at §460.84(d)(2); Hospitals at §482.15(d)(2); Transplant Programs §482.78(d)(2); ICF/IIDs at §483.475(d)(2); HHAs at §484.102(d)(2); REHs at §485.542(d)(2); CAHs at §485.625(d)(2); CORFs at §485.68(d)(2); “Organizations” at §485.727(d)(2); CMHCs at §485.920(d)(2); OPOs at §486.360(d)(2); RHCs/FQHCs at §491.12(d)(2); ESRD facilities at §494.62(d)(2).

Per the [2019 Final Rule](#), facilities that provide inpatient services, must conduct two testing exercises annually (as described in the [2016 Final Rule](#)) while facilities that provide outpatient services are required to conduct only one testing exercise each year.¹⁹ Annual testing may be a community-based full-scale exercise, an individual, facility-based functional exercise, a drill, a tabletop exercise or a workshop that includes a group discussion by a facilitator. The burden of this CoP includes developing scenarios for their drills and exercises, analyzing their responses to the testing exercises and actual emergency events, and maintaining documentation. If an actual natural or man-made emergency that requires activation of the emergency plan is experienced, then the required testing that year can be deferred until the following year.

Per the [2016 Final Rule](#), TJC-accredited CAHs and hospitals meet the required standards of this CoP – to annually conduct emergency preparedness training/testing exercises - and thus the burden for this CoP is seen as usual and customary practice for these providers.²⁰ These providers are not included in the burden analysis below because they are exempt from the PRA under CFR §1320.3(b)(2). However, TJC-accredited ASCs and HHAs are not exempt from the PRA and are included in the burden analysis below.²¹

For each existing Medicare certified provider that is not exempt from this information collection, we estimate that an Administrator (Medical and Health Services Manager - BLS Occupation Code 11-9111) at a loaded hourly rate of \$129, a Registered Nurse (BLS Occupation Code 29-1141) at a loaded hourly rate of \$91 and a Facility Director (Administrative Services & Facilities Manager – BLS Occupation Code 11-3010) at a loaded hourly rate of \$101 at each facility, would all be responsible for running the required testing exercises.

Table 9 below lays out the annual burden hours and cost for existing providers – who are not exempt - to complete emergency preparedness testing exercises. We estimate the total collection of information burden impacting the 49,014 existing, non-exempt providers and suppliers is 148,499 burden hours at an annual cost of \$47,668,019, see Table 9.

¹⁹ [2019 Final Rule](#), 51801-02. Inpatient services are provided by the following: inpatient Hospices, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care facilities (LTCFs), ICFs/IIDs, and CAHs. [2019 Final Rule](#) at 51757. Although RNHCIs provide inpatient services, they are only required to conduct a paper-based, tabletop exercise annually. See [2016 Final Rule](#) at 63935; [2019 Final Rule](#) at 51757.

²⁰ [2016 Final Rule](#) at 63983 (CAHs); 63960 (hospitals). There are no accredited REHs, but if their accreditation is similar to CAHs, they may also be exempt from this information collection. In addition, ESRD facilities are also exempt per 5 CFR §1320.3(b)(2) because they must conduct regular testing under other CoPs, See [2016 Final Rule](#) at 64006. Finally, the additional burden of this CoP for CORF and PT OT organizations is minimal because they must conduct ongoing drills and exercises to test their disaster plans. [2019 Final Rule](#) at 51802.

²¹ [2016 Final Rule](#) at 63940 (ASCs); 63973 (HHAs).

Table 9- IC-4c - Burden Hours and Cost Estimates for Existing Facilities for Performing Testing Exercises

No.	Provider or Supplier Type	42 CFR	Existing Certified Facilities/# of Respondents (a)	# of Responses (b = a x 1)	Burden Hrs Per Response * (c)	Total Burden Hours *** (d = b x c)	Hourly Wage ** (e)	Total Cost Estimate (f = d x e)
Inpatient								
1	CAHs - Non-TJC Accredited	§ 485.625(d)(2)	1,016	1,016	8	8,128	**	\$2,609,088
2	Hospices - Inpatient	§ 418.113(d)(2)	301	301	4	1,204	**	\$386,484
3	Hospitals - Non-TJC Accredited	§ 482.15(d)(2)	1,121	1,121	9	10,089	**	\$3,238,569
4	ICF/IIDs	§ 483.475(d)(2)	5,520	5,520	4	22,080	**	\$7,087,680
5	PRTF	§ 441.184(d)(2)	345	345	3	1,035	**	\$332,235
6	REHs - Non-TJC Accredited	§ 485.542(d)(2)	19	19	8	152	**	\$48,792
7	RNHCIIs	§ 403.748(d)(2)	3	3	3	9	**	\$2,889
Outpatient								
8	ASCs	§ 416.54(d)(2)	6,170	6,170	2	15,425	**	\$4,951,425
9	CMHCs	§ 485.920(d)(2)	117	117	2	234	**	\$75,114
10	CORFs	§ 485.68(d)(2)	149	149	3	447	**	\$143,487
11	FQHCs	§ 491.12(d)(2)	11,850	11,850	2	29,625	**	\$9,509,625
12	HHAs	§ 484.102(d)(2)	8,925	8,925	3	31,238	**	\$10,027,238
13	Hospices - Outpatient	§ 418.113(d)(2)	5,732	5,732	2	11,464	**	\$3,679,944
14	OPOs	§ 486.360(d)(2)	57	57	2.5	143	**	\$45,743
15	“Organizations”	§ 485.727(d)(2)	1,996	1,996	1.5	2,994	**	\$961,074
16	PACE Organizations	§ 460.84(d)(2)	148	148	2.5	370	**	\$118,770
17	RHCs	§ 491.12(d)(2)	5,545	5,545	2.5	13,863	**	\$4,449,863
Total Annual Burden/Costs			49,014	49,014	64	148,499	n/a	\$47,668,019

* Based on [2019 Final Rule](#)

** The hourly labor cost is blended between the wages for multiple staffing levels.

*** Rounded to nearest zero

IC-5: §486.360(e) - Emergency Agreements with Other OPOs

Section 486.360(e) requires OPOs to develop and maintain mutually agreed upon protocols as required in §486.344(d) that cover the duties and responsibilities of the transplant program, only in the hospital in which the transplant program operates.

Table 10 below estimates the number of protocols each OPO would need to develop and maintain. Since the number of transplant hospitals varies between the donation services areas (DSAs) and the number of transplant programs in each of those hospitals also varies, we have estimated the burden based on the average number of transplant hospitals for each DSA and the number of transplant programs in those hospitals.

There are about 770 transplant programs and 239 transplant hospitals. For each OPO's DSA, there is an average of 4 transplant hospitals (239 transplant hospitals /57 OPOs) with 3 transplant programs (770 transplant programs/239 transplant hospitals). Thus, we estimate that each OPO would need to develop protocols for 12 transplant programs (4 transplant hospitals for each DSA x 3 transplant programs in each transplant hospital). See Table 10.

Table 10- Number of Mutually Agreed upon Protocols each OPO must develop and maintain

(a)	# of Transplant Programs	770
(b)	# of Transplant Hospitals	239
(c)	# of OPO Organizations	57
(d)	# of Transplant Programs/Transplant Hospitals ($d = a \div b$)	3
(e)	# of Transplant Hospitals/OPO DSA ($e = b \div c$)	4
(f)	Total # of Protocols per OPO ($f = d \times e$)	12

Table 11 below lays out the annual burden hours and cost to develop a mutually agreed upon protocol. The burden associated with this requirement will be the time and effort necessary to negotiate with each hospital and transplant program and then draft the protocols that address each one's duties and responsibilities during an emergency. Based on our experience with OPOs, transplant centers, and the hospitals in which they operate, we believe that they have already had to deal with some type of emergency and have a basis for those protocols, especially the types of services that are needed by the waiting list patients and the transplant recipients and the services that each of them can provide during an emergency.

Per Table 11, we believe that conducting these negotiations would require the involvement of: the OPO's Director (BLS Occupation Code 11-1011), the Medical Director (Physician - BLS Occupation Code 29-1210), QAPI Director (BLS Occupation Code 11-9111), and an Organ Procurement Coordinator (OPC)(Registered Nurse – 29-1141). We expect that these individuals would attend an initial meeting and then the QAPI director, would draft the protocols and ensure they are reviewed by all required parties and agreed to. This would require an hour of everyone's time, except for the QAPI director who would require 2 hours for each transplant program. Thus, for each transplant program, the OPO would need 5 burden hours. See Table 11.

Table 11-Burden Hours and Cost Estimates to Develop Protocol

Burden Hours/Cost per Protocol			
Position	Hourly Wage (a)	Burden Hours/Task (b)	Cost/Task (c= a x b)
Director (11-1011)	\$249	1	\$249
Medical Director (29-1210)	\$254	1	\$254
Quality Assessment and Performance Improvement (QAPI) Director (11-9011)	\$129	2	\$258
Organ Procurement Coordinator (OPC) (29-1141)	\$91	1	\$91
Total Burden Hours/Cost per Protocol	n/a	5	\$852

Table 12 below lays out the annual burden hours and cost for all OPOs to comply with §486.360(e). Per Table 10 above, each OPO would need to develop protocols for 12 transplant programs. Thus, to comply with this requirement, each OPO would require 60 burden hours (5 burden hours x 12 transplant programs) at a cost of \$10,224 (\$852 for each transplant program x 12 transplant programs). For all 57 OPOs, we estimate that the total burden to develop these protocols would be 3,420 burden hours (60 burden hours for each OPO x 57 OPOs) at a cost of \$582,768 (\$10,224 for each OPO x 57 OPOs). See Table 12.

Table 12 - IC-5 - Burden Hours and Cost Estimates for all OPOs to Develop Mutually Agreed upon Protocols

Item	Number	Burden Hours	Cost
# of Protocols per OPO (Table 10)	12		
Burden Hours/Cost per Protocol (Table 11)		5	\$852
Burden Hours/Cost per OPO		60	\$10,224
# of Total OPOs	57		
Burden Hours/Cost for all OPOs		3,420	\$582,768

Agreement for Policies and Procedures with Other Hospitals - §482.15(b)(7)

Per the implementing regulations at 81 FR 63860, hospitals with written Agreements with other hospitals or providers must develop policies and procedures to be able to transfer and receive patients during emergencies that may impact the hospital's operations and ability to maintain continuity of services to hospital patients.²²

This CoP was initially identified as an IC with burden hours and costs for hospitals in the [2016 Final Rule](#) but should be considered a usual and customary business practice and thus exempt from the PRA per 5 CFR §1320.3(b)(2).

²² [2016 Final Rule](#) at 63958.

Burden Summary

Table 13 below provides a summary of the information collections burden hours and costs for the industry within this package. Based on the analysis above, we estimate that for all providers and suppliers to comply with the ICRs would require 1,251,158 burden hours at a cost of \$401,106,506 per Table 13.

Table 13 - Total Burden Hours and Cost Estimates for Industry

Information Collection No.	# of Respondents	# of Responses	Total Annual Burden Hours	Total Cost Estimate
IC-1a: Conduct Risk Assessment	2,606	2,606	24,848	\$7,976,208
IC-1b: Develop Emergency Preparedness Plan	2,633	2,633	37,898	\$12,165,258
IC-1c: Biennial Review of Emergency Preparedness Plan	60,712	60,712	675,696	\$216,898,256
IC-2: Develop Policies & Procedures	2,686	2,686	29,386	\$9,432,906
IC-3: Develop Communication Plan	2,864	2,864	16,318	\$5,238,078
IC-4a: Develop Training Program	2,927	2,927	27,768	\$8,913,528
IC-4b: Conduct Trainings	57,416	57,416	287,326	\$92,231,486
IC-4c: Conduct Annual Testing	49,014	49,014	148,499	\$47,668,019
IC-5: Emergency Agreements with Other OPOs	57	57	3,420	\$582,768
Total	180,915	180,915	1,251,158	\$401,106,506

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The Federal government will sustain a burden from implementing and enforcing this final rule. Specifically, Section 1864 of the Act provides for the use of State survey agencies to ascertain whether facilities subject to the Conditions of Participation (CoPs) comply with the applicable statutory definitions and implementing regulations for that provider or supplier type. The burden and costs to the federal government for this IC are estimated to include the time spent by CMS surveyors to complete CoP compliance evaluations for all impacted facilities.

The burden for completing these responsibilities was calculated using a loaded hourly mean wage of \$64 per hour for a State Survey Agency reviewer (BLS Occupation Code 19-3022), including benefits and overhead. For the initial compliance review, we estimate the cost to the Federal government to ensure each *newly certified* facility's compliance to be 4 hours, with a net cost of \$256 per facility (4 hours x \$64). For ongoing compliance, we estimate the cost to the Federal government to ensure each *existing* facility's compliance to be 1 hour, with a net cost of \$64 per facility (1 hour x \$64). 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.

Per Table 14 below, the total annual burden hours to the federal government is 222,063 with an annual cost of \$14,212,032 for this reinstatement.

Table 14: Total Burden Hours and Cost Estimates for Federal Government

Information Collection No.	# of Facilities (a)	Hourly Wage (b)	Hours/ Task (c)	Total Burden Hours (d = a x c)	Total Burden Costs (e = b x d)
IC-1a: Conduct Risk Assessment	2,606	\$64	4	10,424	\$667,136
IC-1b: Develop Emergency Preparedness Plan	2,633	\$64	4	10,532	\$674,048
IC-1c: Biennial Review Emergency Preparedness Plan	60,712	\$64	1	60,712	\$3,885,568
IC-2: Develop Policies and Procedures	2,686	\$64	4	10,744	\$687,616
IC-3: Develop Communication Plan	2,864	\$64	4	11,456	\$733,184
IC-4a: Develop Training Program	2,927	\$64	4	11,708	\$749,312
IC-4b: Conduct Trainings	57,416	\$64	1	57,416	\$3,674,624
IC-4c: Conduct Annual Testing	49,014	\$64	1	49,014	\$3,136,896
IC-5: OPO Agreements 42 CFR §483.60(e)	57	\$64	1	57	\$3,648
Total	180,915	n/a	n/a	222,063	\$14,212,032

IC-1a: Conduct Risk Assessment

- RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at §484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a). State Survey Agency reviewers are responsible for reviewing *new* facilities’ risk assessment. We estimate the cost to the Federal government to ensure each facility’s compliance to be 4 hours, with a net cost of \$256 per facility (4 hours x \$64). The total burden to the Federal government is estimated to be 10,424 hours (4 hours x 2,606 facilities) and \$667,136 (\$256 x 2,606 facilities).

IC-1b: Develop Emergency Preparedness Plan

- RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at §484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a). State Survey Agency reviewers are responsible for reviewing *new* facilities’ emergency preparedness plan. We estimate the cost to the Federal government to ensure each facility’s compliance to be approximately 4 hours, with a net cost of \$256 per facility (4 hours x \$64). The total burden to the Federal government is estimated to be 10,532 hours (4 hours x 2,633 facilities) and \$674,048 (\$256 x 2,633 facilities).

IC-1c: Biennial Review of Emergency Preparedness Plan

- RNHCIs at §403.748(a); ASCs at §416.54(a); Hospices at §418.113(a); PRTFs at §441.184(a); PACE at §460.84(a); Hospitals at §482.15(a); Transplant Programs §482.78(a); ICF/IIDs at §483.475(a); HHAs at

§484.102(a); REHs at §485.542(a); CAHs at §485.625(a); CORFs at §485.68(a); “Organizations” at §485.727(a); CMHCs at §485.920(a); OPOs at §486.360(a); RHCs/FQHCs at §491.12(a); ESRD facilities at §494.62(a).

State Survey Agency reviewers are responsible for ensuring **existing** facilities are conducting biennial reviews of their emergency preparedness plan. We estimate the cost to the Federal government to ensure each facility’s compliance to be approximately 1 hour, with a net cost of \$64 per facility (1 hour x \$64). The total burden to the Federal government is estimated to be 60,712 hours (1 hour x 60,712 facilities) and \$3,885,568 (\$64 x 60,712 facilities).

IC-2: Develop Policies and Procedures

- RNHCIs at §403.748(b); ASCs at §416.54(b); Hospices at §418.113(b); PRTFs at §441.184(b); PACE at §460.84(b); Hospitals at §482.15(b); Transplant Programs §482.78(b); ICF/IIDs at §483.475(b); HHAs at §484.102(b); REHs at §485.542(b); CAHs at §485.625(b); CORFs at §485.68(b); “Organizations” at §485.727(b); CMHCs at §485.920(b); OPOs at §486.360(b); RHCs/FQHCs at §491.12(b); ESRD facilities at §494.62(b). State Survey Agency reviewers are responsible for reviewing **new** facilities’ policies and procedures. We estimate the cost to the Federal government to ensure each facility’s compliance to be approximately 4 hours, with a net cost of \$256 per facility (4 hours x \$64). The total burden to the Federal government is estimated to be 10,744 hours (4 hours x 2,686 facilities) and \$687,616 (\$256 x 2,686 facilities).

IC-3: Develop Communication plan

- RNHCIs at §403.748(c); ASCs at §416.54(c); Hospices at §418.113(c); PRTFs at §441.184(c); PACE at §460.84(c); Hospitals at §482.15(c); Transplant Programs §482.78(c); ICF/IIDs at §483.475(c); HHAs at §484.102(c); REHs at §485.542(c); CAHs at §485.625(c); CORFs at §485.68(c); “Organizations” at §485.727(c); CMHCs at §485.920(c); OPOs at §486.360(c); RHCs/FQHCs at §491.12(c); ESRD facilities at §494.62(c). State Survey Agency reviewers are responsible for reviewing **new** facilities’ communication plan. We estimate the cost to the Federal government to ensure each facility’s compliance to be approximately 4 hours, with a net cost of \$256 per facility (4 hours x \$64). The total burden to the Federal government is estimated to be 11,456 hours (4 hours x 2,864 facilities) and \$733,184 (\$256 x 2,864 facilities).

IC-4a: Develop Training Program

- RNHCIs at §403.748(d); ASCs at §416.54(d); Hospices at §418.113(d); PRTFs at §441.184(d); PACE at §460.84(d); Hospitals at §482.15(d); Transplant Programs §482.78(d); ICF/IIDs at §483.475(d); HHAs at §484.102(d); REHs at §485.542(d); CAHs at §485.625(d); CORFs at §485.68(d); “Organizations” at §485.727(d); CMHCs at §485.920(d); OPOs at §486.360(d); RHCs/FQHCs at §491.12(d); ESRD facilities at §494.62(d). State Survey Agency reviewers are responsible for reviewing **new** facilities’ emergency preparedness training program. We estimate the cost to the Federal government to ensure each facility’s compliance to be approximately 4 hours, with a net cost of \$256 per facility (4 hours x \$64). The total burden to the Federal government is estimated to be 11,708 hours (4 hours x 2,927 facilities) and \$749,312 (\$256 x 2,927 facilities).

IC-4b: Conduct Trainings

— RNHCIs at §403.748(d)(1); ASCs at §416.54(d)(1); Hospices at §418.113(d)(1); PRTFs at §441.184(d)(1); PACE at §460.84(d)(1); Hospitals at §482.15(d)(1); Transplant Programs §482.78(d)(1); ICF/IIDs at §483.475(d)(1); HHAs at §484.102(d)(1); REHs at §485.542(d)(1); CAHs at §485.625(d)(1); CORFs at §485.68(d)(1); “Organizations” at §485.727(d)(1); CMHCs at §485.920(d)(1); OPOs at §486.360(d)(1); RHCs/FQHCs at §491.12(d)(1); ESRD facilities at §494.62(d)(1).

State Survey Agency reviewers are responsible for ensuring **existing** facilities are conducting the required emergency preparedness training and testing program. We estimate the cost to the

Federal government to ensure each facility compliance to be approximately 1 hour, with a net cost of \$64 per facility (1 hour x \$64). The total burden to the Federal government is estimated to be 57,416 hours (1 hour x 57,416 facilities) and \$3,674,624 (\$64 x 57,416 facilities).

IC-4c: Conduct Annual Testing

— RNHCIs at §403.748(d)(2); ASCs at §416.54(d)(2); Hospices at §418.113(d)(2); PRTFs at §441.184(d)(2); PACE at §460.84(d)(2); Hospitals at §482.15(d)(2); Transplant Programs §482.78(d)(2); ICF/IIDs at §483.475(d)(2); HHAs at §484.102(d)(2); REHs at §485.542(d)(2); CAHs at §485.625(d)(2); CORFs at §485.68(d)(2); “Organizations” at §485.727(d)(2); CMHCs at §485.920(d)(2); OPOs at §486.360(d)(2); RHCs/FQHCs at §491.12(d)(2); ESRD facilities at §494.62(d)(2)

State Survey Agency reviewers are responsible for ensuring *existing* facilities are conducting the required emergency preparedness training and testing program. We estimate the cost to the Federal government to ensure each facility compliance to be approximately 1 hour, with a net cost of \$64 per facility (1 hour x \$64). The total burden to the Federal government is estimated to be 49,014 hours (1 hour x 49,014 facilities) and \$3,136,896 (\$64 x 49,014 facilities)

IC-5: Emergency Agreements with Other OPOs - §486.360(e)

State Survey Agency reviewers are responsible for reviewing the emergency preparedness protocols for *new* organ procurement programs (OPOs). We estimate the cost to the Federal government to ensure each facility compliance to be approximately 1 hour, with a net cost of \$64 per facility (1 hour x \$64). The total burden to the Federal government is estimated to be 57 hours (1 hour x 57 facilities) and \$3,648 (\$64 x 57 facilities).

15. Changes to Burden

This package has been updated to reflect changes in information collection requirements related to new or revised Conditions of Participation. For this reinstatement, the total annual burden hours for industry are **1,251,158** hours and the annual burden costs are **\$401,106,506**. See Table 13.

The annual burden to industry decreased from 1,260,474 burden hours to 1,251,158 for the following reasons:

- Exclusion of LTC facilities
- Addition of new facility type, Rural Emergency Hospitals
- Differentiation between which CoPs that are ongoing requirements vs. the one-time development at the time a facility is newly certified.
- Reduction in frequency of required ongoing training of staff for IC-7 from annual to biennial for all facilities per the [2019 Final Rule](#).
- Reduction in quantity of required testing exercises per year for facilities that provide outpatient services from 2 testing exercises to 1 per year with no change to facilities that provide inpatient services per the [2019 Final Rule](#).

The burden costs to industry increased from \$122,698,058 to \$401,106,506 for the following reasons:

- Increase in hourly wages

- One of the Information Collection Requests (IC-3 Development of Communication Plan) was identified as exempt from the PRA in the prior submission contrary to the [2016 Final Rule](#).
- Differentiation between which CoPs that are ongoing requirements vs. the one-time development at the time a facility is newly certified.
- The specific staff and wage cost/task for all but one of the information collection requests was standardized across all facility types rather than accounting for differences in the number, type of position, and wage differentials of staff that may be involved in each information collection request. As a result, the burden cost estimated may be higher for some facilities than in prior submission but also underestimated for some facility types such as hospitals.

16. Publication/Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of the expiration date. We are requesting a three-year approval, the maximum allowed under the PRA. Please note that the information collection does not contain a collection instrument but educational materials and websites that discuss these requirements will include the OMB control number and the expiration date.

18. Certification Statement

There is no exception to the certification.