Supporting Statement – Part A

Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

A. INTRODUCTION

This information collection package is a collection request for a new OMB control number.

We are not including the burden associated with requirements for LTC facilities. Sections 4204(b) and 4214(d), which cover skilled nursing facilities (SNFs) and nursing facilities (NFs), respectively, of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for the regulations that implement the OBRA '87 requirements. Thus, the information collection requirements (ICRs) for the requirements in §483.73 are not subject to the PRA. In addition, we have not included burden associated with requirements for transplant centers. Section 482.78 will require that transplant programs be included in the emergency preparedness planning and the emergency preparedness program for the hospital in which it is located. We note that a transplant center is not individually responsible for the emergency preparedness requirements set forth in §482.15.

B. 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. This information collection captures the burden necessary to support the development and implementation of emergency preparedness requirements that will be consistent and enforceable across 17 affected Medicare and Medicaid providers and suppliers.

We obtained the data used in this discussion on the number of the various Medicare and Medicaid providers and suppliers from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of June 1, 2016. We have not included data for health care facilities that are not Medicare and/or Medicaid certified. The 17 Medicare and Medicaid providers that this regulation affects include:

- Religious Nonmedical Health Care Institutions (RNHCIs)
- Ambulatory Surgical Centers (ASCs)
- Hospices
- Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)

- Hospitals
- Transplant Centers
- Long Term Care (LTC) Facilities
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers (CMHCs)
- Organ Procurement Organizations (OPOs)
- Rural Health Clinics (RHCs)
- Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities.

We have identified four core elements that are 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/updated at least annually. 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 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 and implemented.

● Communication plan: An emergency preparedness communication plan that complies with both Federal and State law must be developed and maintained. 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 and testing: An emergency preparedness training and testing program must be developed and implemented. A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. Staff must demonstrate knowledge of emergency procedures and provide this training at least annually. Facilities must also conduct testing exercises to test the emergency plan.

Therefore, this information collection consists primarily of the review, revision, and/or development of emergency plans, policies and procedures, and training and testing materials to ensure on-going compliance with the requirements contained in the regulation, discussed above.

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.

The following are the statutory and regulatory citations for the providers and suppliers for which we intend to implement emergency preparedness requirements:

● 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) – sections1905 (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 Centers – 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 – 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.

2. Information Users

This regulation requires Medicare and Medicaid participating providers and suppliers to establish emergency preparedness policies and procedures in order 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.

3. Use of Information Technology

Providers and suppliers may use various information technologies to comply with the requirements of this regulation. We believe that most, if not all, providers/suppliers have online access and can use technologically advanced software (i.e. Word, Excel, etc.). Some may develop electronic tools for purposes of documenting and maintaining their emergency plans, policies and procedures, communication plans, training documents, and any documentation related to their testing exercises. These requirements in no way prescribe how the facility should prepare or maintain these records. In addition, there are various online resources and tools that are free or low cost that providers and suppliers can use to satisfy developing emergency preparedness programs, policies and procedures, and plans. Each facility is free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

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

5. Small Businesses

These requirements will not have a significant impact on most hospitals and other providers that are small entities. 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

The information required by these providers and suppliers should not be collected less

frequently than annually. Inadequate review and updating could lead to outdated or obsolete emergency plans and a lack of preparedness, which would threaten the safety of patients and residents, as well as others, including staff and visitors.

7. Special Circumstances

This collection of information does not require any special circumstances.

8. Federal Register

The 60-day Federal Register notice was published on December 27, 2013 (78 FR 79082). The 30-day Federal Register notice was published on September 16, 2016 (81 FR 63859).

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

We obtained all salary information for the different positions identified in the following assessments from the May 2014 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at http://www.bls.gov/oes/current/oes_nat.htm. To ensure that fringe benefits and overhead are included in the estimated hourly 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.

Where we were able to identify positions linked to specific providers or suppliers, we used that compensation information. However, in some instances, we used a general position description, such as director of nursing, or we used information for comparable positions.

For example, we were not able to locate specific information for physicians who practice in hospices. However, since hospices provide palliative care, we used the compensation information for physicians who work in specialty hospitals. Based on our experience, certain providers and suppliers typically pay less than the median salary, in which case, we used a salary from a lower percentile. Salary may also be affected by the rural versus urban locations.

Table 1 below lays out the positions used in this information collection request and the corresponding salaries based on the provider type.

Table 1—Positions and Corresponding Salaries Based on Provider Type

	RNHCI	ASC	Hospice	PRTF	PACE	Hospital	ICF/IID	HHA	CORF	CAH	OP PT ORGS	CMHC	OPO	RHC/FQHC	ESRD
Administrator	$72	$110	$80	$93		$172	$93	$97	$97	$97	$94	$94		$97	$106
Program Director					$110								$106		
Medical Director					$182					$181			$207		$207
Nurse Manager															$94
Director of Nursing	$34					$104		$97		$97					
Social Worker			$45		$55							$41			$51
Physician														$181	
Nurse Practitioner or Physician Assistant														$94	
Registered Nurse			$60	$64			$64					$71		$71	
Attorney						$127									
Facilities Director						$104				$83					
Food Services Director						$70				$54					
Director of Training															
Director of Rehabilitation								$88							
Office Manager								$52							
Counselor			$34												
Physical Therapist									$79		$79				
QAPI Director													$94		
Registered Nurse-Quality Improvement Nurse		$71			$64										
Organ Procurement Coordinator													$94		
Education Coordinator													$63		
Head of Maintenance	$26														
Patient Care Dialysis Technician															$39
Home Care Coordinator					$64										
Chief Medical Officer						$199									
Chief of Surgery						$231									
Pharmacy Director						$142									

	RNHCI	ASC	Hospice	PRTF	PACE	Hospital	ICF/IID	HHA	CORF	CAH	OP PT ORGS	CMHC	OPO	RHC/FQHC	ESRD
Health Information Services Director						$104									
Health Care Trainer						$68									
Security Manager						$104									
Medical Secretary						$32									
Community Relations Manager						$107									
Risk Management Director						$104									

Given the range of providers and suppliers covered in this regulation, even where the proposed regulatory requirements are the same, certain factors would greatly affect the burden for different providers and suppliers. A significant factor in the burden for each provider or supplier type would be their accreditation status. Some accrediting organization (AOs) that have deeming authority for Medicare providers and suppliers have emergency preparedness standards similar or virtually identical to the requirements in this regulation. Those organizations are: The Joint Commission (TJC), the American Osteopathic Association/Healthcare Facilities Accreditation (AOA/HFAP), the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the American Association for Accreditation for Ambulatory Surgery Facilities, Inc. (AAAASF), and Det Norske Veritas (DNV) GL - Healthcare (DNV GL). Accreditation can substantially affect the burden a provider would sustain under this regulation; therefore, when appropriate we have assessed the burden for accredited facilities separately from non-accredited facilities.

b. Condition of Participation: Emergency Preparedness

Risk Assessment and Planning—§403.748(a), §416.54(a), §418.80(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §482.78(a), §483.475(a), §484.22(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §491.12(a), §494.62(a)

This regulation requires providers and suppliers to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We expect that each provider and supplier would conduct a thorough risk assessment that will 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. They each would also need to identify the measures needed to ensure continuity of its operation, including delegations and succession plans.

For the purposes of determining the burden for this ICR, we expect that TJC-accredited providers and suppliers already conduct a risk assessment that complies with these requirements. If there are any tasks needed for completion to satisfy the requirement for a risk assessment, we expect that the burden imposed by this proposed requirement would be negligible.

We also expect that the TJC accredited HHAs already have an emergency plan that will satisfy most of our requirements. However, TJC standards for HHAs do not completely address our requirements for the development of an emergency plan. Therefore, we believe the TJC accredited HHAs will incur some burden, but expect that their burden will be substantially less than the non-TJC accredited HHAs, so we have analyzed the burden on HHAs based on their accreditation status (TJC accredited vs. non-TJC accredited).

In addition, while subject to the PRA, for the TJC-accredited ASCs, and hospitals, the burden associated with the risk assessment requirement would constitute a usual and customary business practice as defined in the implementing regulations of the PRA at 5 CFR §1320.3(b)(2). Therefore, we have not estimated the amount of regulatory burden for those providers and suppliers.

Table 2 below lays out the burden hours and cost for each provider to develop an emergency plan and conduct a risk assessment.

Table 2--Burden Hours and Cost Estimates for Providers to Develop an Emergency Plan and Perform a Risk Assessment

Provider Type	Number of Providers	Responses Per Provider	Burden Hours Per Response	Total Annual Burden Hours	Total Cost Estimate
RNHCIs	18	1	21	378	$15,552
Non-TJC Accredited ASCs	4,994	1	19	94,886	$8,489,800
Inpatient Hospices	412	1	24	9,888	$790,216
Home Based Hospices	3,989	1	40	159,560	$12,433,713
PRTFs	377	1	24	9,048	$658,842
PACE organizations	119	1	37	4,403	$345,457
Non-TJC Accredited Hospitals	1,345	1	98	129,120	$15,655,800
ICF/IIDs	6,237	1	17	106,029	$8,775,459
Non-TJC Accredited HHAs	8,005	1	26	208,130	$18,027,260
TJC-Accredited HHAs	4,330	1	10	43,300	$3,732,460
CORFs	205	1	19	3,895	$355,6754$
Non-TJC Accredited CAHs	999	1	41	40,959	$4,051,944
PT OT Organizations	2,135	1	21	44,835	$4,022,340
CMHCs	198	1	25	5,940	$449,856
OPOs		1	32	2,204	$257,926
RHCs	4,200	1	24	100,800	$10,327,800
FQHCs	7,300	1	13	94,900	$9,358,600
ESRD Facilities	6,648	1	22	146,256	$15,436,656
Totals	**51,569**		**524**	**1,204,531**	**$113,185,356**

Policies and procedures—§403.748(b), §416.54(b), §418.80(b), §441.184(b), §460.84(b), §482.15(b), §482.78(b), §483.73(b), §483.475(b), §484.22(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §491.12(b), §494.62(b)

This regulation requires providers and suppliers to develop and maintain emergency preparedness policies and procedures in accordance with their emergency plan, risk assessment, and communication plan. Each would need to thoroughly review their emergency preparedness policies and procedures and revise, or in some cases, develop new policies and procedures that would ensure that the emergency preparedness plans address the specific requirements of this regulation.

For the purposes of determining the burden associated with this ICR, we expect that the requirement for emergency preparedness policies and procedures would constitute a usual and customary business practice in accordance with the implementing regulations of the PRA at 5 CFR §1320.3(b)(2) for TJC-accredited ASCs; therefore, we did not include them in this burden assessment.

Many of the requirements related to policies and procedures have a corresponding requirement in the TJC and AOA accreditation standards for hospitals and CAHs. Subsequently, for the TJC and AOA accredited hospitals and CAHs the burden for this requirement is negligible or lower than the non-accredited hospitals and CAHs. Therefore, we assessed the burden for them separately.

Table 3 lays out the burden hours and cost estimates for each provider to develop emergency preparedness policies and procedures.

Table 3--Burden Hours and Cost Estimates for Providers to Develop Policies and Procedures

Provider Type	Number of Providers	Responses Per Provider	Burden Hours Per Response	Total Annual Burden Hours	Total Cost Estimate ($)
RNHCIs	18	1	6	108	$4,212
Non-TJC Accredited ASCs	4,994	1	9	44,946	$3,580,698
Inpatient Hospices	412	1	8	3,296	$255,028
Outpatient Hospices	3,989	1	9	35,901	$2,788,311
PRTFs	377	1	9	3,393	$249,951
PACE organizations	119	1	12	1,428	$102,340
Non-TJC Accredited Hospitals	1,345	1	33	44,385	$5,152,695
TJC Accredited Hospitals	3,448	1	17	58,616	$7,106,328
All Hospitals	4,793	1	8	38,344	$4,970,341
ICF/IIDs	6,237	1	9	56,133	$4,677,750
HHAs	112,335	1	18	222,030	$19,538,640
CORFs	205	1	9	1,845	$167,895
TJC and AOA Accredited CAHs	369	1	10	3,690	$362,727
Non- Accredited CAHs	892	1	14	12,488	$1,210,444
PT OT Organizations	2,135	1	10	21,350	$1,910,825
CMHCs	198	1	12	2,376	$186,912
OPOs	58	1	20	1,160	$124,932
RHCs	4,200	1	12	50,400	$6,224,400
FQHCs	7,300	1	8	58,400	$6,803,600
ESRD Facilities	6,648	1	10	66,480	$7,419,168
Totals	**60,072**			**726,769**	**$72,837,197**

Communication plan—§403.748(c), §416.54(c), §418.80(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.22(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §491.12(c), §494.62(c)

This regulation requires providers and suppliers to develop and maintain an emergency preparedness communication plan that complies with both federal and state law and must be reviewed and updated at least annually. The burden associated with this requirement would be the time and effort necessary to review, revise, and if necessary, develop a new

communications plan to ensure that it complies with the requirements of this regulation. However, we believe that most providers have some type of emergency preparedness communication plan. It is standard practice in the health care industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients.

The TJC has communication plan requirements for accredited ASCs and hospitals that satisfy the emergency preparedness requirements of this regulation. If any revisions or additions are necessary to satisfy the requirements, we expect the revisions or additions would be those incurred during the course of normal business and thereby impose no additional burden. Thus, for the TJC-accredited ASCs and hospitals, the ICRs related to the communication plan would constitute a usual and customary business practice as stated in the implementing regulations of the PRA at 5 CFR §1320.3(b)(2). Thus, we did not include this activity in the burden analysis.

Table 4 below lays out the annual burden hours and cost for each provider to develop an emergency preparedness communication plan.

Table 4--Burden Hours and Cost Estimates for Providers to Develop a Communication Plan

Provider Type	Number of Providers	Responses Per Provider	Burden Hours Per Response	Total Annual Burden Hours	Total Cost Estimate
RNHCIs	18	1	4	72	$2,988
Non-TJC Accredited ASCs	4,994	1	4	19,976	$1,613,062
Hospices	4,401	1	3	13,203	$1,056,240
PRTFs	377	1	5	1,885	$142,506
PACE organizations	119	1	7	833	$53,312
Non-TJC Accredited Hospitals	1,345	1	10	13,450	$1,494,295
ICF/IIDs	6,237	1	6	37,422	$3,118,500
HHAs	12,335	1	10	123,350	$10,188,710
CORFs	205	1	8	1,640	$148,010
CAHs	1,337	1	9	12,033	$1,111,047
PT OT Organizations	2,135	1	8	17,080	$1,541,470
CMHCs	198	1	8	1,584	$126,126
OPOs	58	1	14	812	$90,828
RHCs	4,200	1	10	42,000	$4,729,200
FQHCs	7,300	1	5	36,500	$4,109,900
ESRD Facilities	6,648	1	4	26,592	$3,410,424
Totals	**51,907**			**348,432**	**$32,936,618**

Training and testing—§403.748(d), §416.54(d), §418.80(d), §441.184(d), §460.84(d), §482.15(d), §483.73(d), §483.475(d), §484.22(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §491.12(d), §494.62(d)

This regulation requires providers and suppliers to develop and maintain 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. The testing program must include participation in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If an actual natural or man-made emergency that requires activation of the emergency plan is experienced, then this requirement is exempt for 1 year following the onset of the actual event. In addition, the testing program must include one additional testing exercise, which may be determined by the provider or supplier.

For CAHs, we assess the burden associated with the testing requirements for non-accredited CAHs only. The TJC and the AOA accredited CAHs both have required standards for testing their emergency operations plan (EOP) that satisfy the testing requirement. Therefore, the burden associated with compliance for this requirement would constitute a usual and customary business practice for TJC and AOA accredited CAHs and would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR §1320.3(b)(2). However, all CAHs would be subject to the requirements for training.

For hospitals, TJC has standards that satisfy both the training and testing requirements of this regulation. Thus, for the TJC-accredited hospitals, the burden associated with all of the all the requirements would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR §1320.3(b)(2). Therefore, we have assessed the burden associated with complying with the communications plan requirements for non TJC-accredited hospitals only.

Table 5 below lays out the annual burden hours and cost for each provider to maintain an emergency preparedness training and testing program.

Table 5--Burden Hours and Cost Estimates for Providers for Training and Testing

Provider Type	Number of Providers	Responses Per Provider	Burden Hours Per Response	Total Annual Burden Hours	Total Cost Estimate
RNHCIs	18	1	10	180	$7,488
ASCs	3,485	1	11	60,335	$4,711,615
Hospices	4,401	1	10	44,010	$2,640,600
PRTFs	377	1	13	4,901	$313,664
PACE organizations	119	1	17	2,023	$129,472
Non-TJC Accredited Hospitals	1,345	1	49	65,905	$5,046,440
ICF/IIDs	6,237	1	11	68,607	$4,752,594
HHAs	12,335	1	24	283,705	$21,191,530
CORFs	205	1	14	2,870	$259,940
CAHs	1,337	1	14	18,718	$1,759,492
Non- Accredited CAHs	892	1	8	7,136	$679,704
PT OT Organizations*	2,135	1	11	23,485	$2,111,515
CMHCs	198	1	14	2,772	$196,812
OPOs	58	1	45	2,610	$227,476
RHCs/FQHCs	11,500	1	15	172,500	$10,913,500

ESRD Facilities	6,648	1	7	46,536	$5,364,936
Totals	**53,290**			**806,293**	**$60,306,778**

Proposed §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, the hospital in which the transplant program is operated and the OPO during an emergency. Section 486.344(d) does not currently require that emergency preparedness be addressed in those protocols. Thus, we believe that most OPOs do not currently address emergency preparedness in their protocols. OPOs will only be required to address emergency preparedness with the transplant centers and the hospitals in which they operate.

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 240 transplant hospitals. For each OPO's DSA, there is an average of 4 transplant hospitals (240 transplant hospitals / 58 OPOs) with 3 transplant programs (770 transplant programs/240 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).

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. Based on our experience with OPOs, we believe that conducting these negotiations would require the involvement of the OPO's director, medical director, QAPI director, and an organ procurement coordinator (OPC). We expect that these individuals would attend an initial meeting and then one individual, probably 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 each individual'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 at a cost of $595.

Table 6 below lays out the annual burden hours and cost for each OPO to comply with §486.360(e).

Table 6--Burden Hours and Cost Estimates for an OPO to Develop Mutually Agreed upon Protocols

Position	Hourly Wage	Burden Hours	Cost Estimates
Director	$106	1	$106
Medical Director	$207	1	$207
Quality Assessment and Performance Improvement (QAPI) Director	$94	2	$94
Organ Procurement Coordinator (OPC)	$94	1	$94
Totals		**5**	**$595**

As described previously, 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 $7,140 ($595 for each transplant program x 12 transplant programs). For all 58 OPOs, we estimate that the total burden to develop these protocols would be 3,480 burden hours (60 burden hours for each OPO x 58 OPOs) at a cost of $414,120 ($7,140 for each OPO x 58 OPOs).

Based on the analysis above, we estimate that for all providers and suppliers to comply with the ICRs in this final rule would require 3,089,505; burden hours (1,204,531 emergency plan and risk assessment burden hours + 726,769 policies and procedures burden hours + 348,432 communication plan burden hours + 806,293 training and testing burden hours + 3,480 protocols for OPOs burden hours) at a cost of $279,680,069 ($113,185,356 cost of emergency plan and risk assessment + $72,837,197 cost of policies and procedures + $32,936,618 cost of communication plan + $60,306,778 cost of training and testing + $414,120 cost of protocols for OPOs).

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, CMS will need to prepare guidance documents, including interpretative guidelines and will provide training for surveyors on these new requirements and subsequent interpretative guidelines. In addition, CMS will update the survey process and make IT systems changes. We anticipate that the burden to implement these new requirements and conduct surveys following implementation will be minimal beyond the normal labor costs for staff and standard business practices.

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

CMS has no objections to displaying the expiration date for this information collection request. We are requesting a three-year approval, the maximum allowed under the PRA. Please note that this information collection request does not utilize information collection instruments, but educational materials and CMS websites that discuss these requirements

will include information about the OMB control number and the expiration date of the collection. Should CMS develop any supplemental instructions or guidance documents, the documents will contain the OMB control number and the expiration date.

18. Certification Statement

We have not identified any exceptions.