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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, and 494

[CMS-3178-P]

RIN 0938-AO91

Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

We are proposing emergency preparedness requirements that 17 provider and supplier types must meet to participate in the Medicare and Medicaid programs. Since existing Medicare and Medicaid requirements vary across the types of providers and suppliers, we are also proposing variations in these requirements. These variations are based on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services. Despite these variations, our proposed regulations would provide generally consistent emergency preparedness requirements, enhance patient safety

during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-3178-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3178-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

AAAHC	Accreditation Association for Ambulatory Health Care, Inc.
AAAASF	American Association for Accreditation for Ambulatory Surgery Facilities, Inc.
AAR/IP	After Action Report/Improvement Plan
ACHC	Accreditation Commission for Health Care, Inc.
ACHE	American College of Healthcare Executives
AHA	American Hospital Association
AO	Accrediting Organization
AOA	American Osteopathic Association
ASC	Ambulatory Surgical Center
ARCAH	Accreditation Requirements for Critical Access Hospitals
ASPR	Assistant Secretary for Preparedness and Response
BLS	Bureau of Labor Statistics
BTCDP	Bioterrorism Training and Curriculum Development Program
CAH	Critical Access Hospital
CAMCAH	Comprehensive Accreditation Manual for Critical Access Hospitals
CAMH	Comprehensive Accreditation Manual for Hospitals
CASPER	Certification and the Survey Provider Enhanced Reporting
CDC	Centers for Disease Control and Prevention
CFC	Conditions for Coverage
CHAP	Community Health Accreditation Program
CMHC	Community Mental Health Center
COI	Collection of Information

COP	Conditions of Participation
CORF	Comprehensive Outpatient Rehabilitation Facilities
CPHP	Centers for Public Health Preparedness
CRI	Cities Readiness Initiative
DHS	Department of Homeland Security
DHHS	Department of Health and Human Services
DOL	Department of Labor
DPU	Distinct Part Units
DSA	Donation Service Area
EOP	Emergency Operations Plans
EC	Environment of Care
EMP	Emergency Management Plan
EP	Emergency Preparedness
ESF	Emergency Support Function
ESRD	End-Stage Renal Disease
FEMA	Federal Emergency Management Agency
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Clinic
GAO	Government Accountability Office
HFAP	Healthcare Facilities Accreditation Program
HHA	Home Health Agencies
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
HSC	Homeland Security Council

HSEEP	Homeland Security Exercise and Evaluation Program
HSPD	Homeland Security Presidential Directive
HVA	Hazard Vulnerability Analysis
ICFs/IID	Intermediate Care Facilities for Individuals with Intellectual Disabilities
ICR	information Collection Requirements
IDG	Interdisciplinary Group
IOM	Institute of Medicine
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
JPATS	Joint Patient Assessment and Tracking System
LD	Leadership
LPHA	Local Public Health Agencies
LSC	Life Safety Code
LTC	Long Term Care
MMRS	Metropolitan Medical Response System
MS	Medical Staff
NDMS	National Disaster Medical System
NF	Nursing Facilities
NFPA	National Fire Protection Association
NIMS	National Incident Management System
NIOSH	National Institute for Occupational Safety and Health
NLTN	National Laboratory Training Network
NRP	National Response Plan
NRF	National Response Framework

NSS	National Security Staff
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of the Inspector General
OPHPR	Office of Public Health Preparedness and Response
OPO	Organ Procurement Organization
OPT	Outpatient Physical Therapy
OPTN	Organ Procurement and Transplantation Network
OSHA	Occupational Safety and Health Administration
ORHP	Office of Rural Health Policy
PACE	Program for the All-Inclusive Care for the Elderly
PAHPA	Pandemic and All-Hazards Preparedness Act
PHEP	Public Health Emergency Preparedness
PIN	Policy Information Notice
PPD	Presidential Policy Directive
PRTF	Psychiatric Residential Treatment Facilities
QAPI	Quality Assessment and Performance Improvement
QIES	Quality Improvement and Evaluation System
RFA	Regulatory Flexibility Act
RNHCI	Religious Nonmedical Health Care Institutions
RHC	Rural Health Clinic
SAMHSA	Substance Abuse and Mental Health Services Administration
SLP	Speech Language Pathology
SNF	Skilled Nursing Facility

SNS	Strategic National Stockpile
TEFRA	Tax Equity and Fiscal Responsibility Act
TFAH	Trust for America's Health
TJC	The Joint Commission
TTX	Tabletop Exercise
UMRA	Unfunded Mandates Reform Act
UPMC	University of Pittsburgh Medical Center
WHO	World Health Organization

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I. Overview

A. Executive Summary

1. Purpose

Over the past several years, the United States has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornadoes and floods in the spring of 2011, the 2009 H1N1 influenza pandemic, and Hurricane Sandy in 2012, readiness for public health emergencies has been put on the national agenda. For the purpose of this proposed regulation, "emergency" or "disaster" can be defined as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of the Department of Health and Human Services (HHS), or the President of the United States. (See Health Resources and Services Administration (HRSA) Policy Information notice entitled, "Health Center Emergency

Management Program Expectations," (Document No. 2007-15, dated August 22, 2007, found at http://www.hsdl.org/?view&did=478559). Disasters can disrupt the environment of health care and change the demand for health care services. This makes it essential that health care providers and suppliers ensure that emergency management is integrated into their daily functions and values.

In preparing this proposed rule, we reviewed the guidance, developed by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Office of the Assistant Secretary for Preparedness and Response (ASPR). Additionally, we held regular meetings with these agencies and ASPR to collaborate on federal emergency preparedness requirements. To guide us in the development of this rule, we also reviewed several other sources to find the most current best practices in the health care industry. These sources included other federal agencies; The Joint Commission (TJC) standards for emergency preparedness; the American Osteopathic Association (AOA) standards for disaster preparedness (currently written for Critical Access Hospitals (CAHs) only); the National Fire Protection Association (NFPA) standards in NFPA 101 Life Safety Code and NFPA 1600: "Standard on Disaster/Emergency Management and Business Continuity Programs," 2007 Edition; state-level requirements for some states, including those for California and Maryland; and policy guidance from the American College of Healthcare Executives (ACHE), entitled the "Healthcare Executives' Role in Emergency Preparedness," which reinforces our position regarding the necessity of this proposed rule. Many of the resources we reviewed in the development of this proposed rule are listed in the APPENDIX—"Emergency Preparedness Resource Documents and Sites." We encourage

providers and suppliers to use these resources to develop and maintain their emergency preparedness plans.

We also reviewed existing Medicare emergency preparedness requirements for both providers and suppliers. We concluded that current emergency preparedness regulatory requirements are not comprehensive enough to address the complexities of actual emergencies. Specifically, the requirements do not address the need for: (1) communication to coordinate with other systems of care within local jurisdictions (for example. cities, counties) or states; (2) contingency planning; and (3) training of personnel.

Based on our analysis of the written reports, articles, and studies, as well as on our ongoing dialogue with representatives from the federal, state, and local levels and with various stakeholders, we believe that, currently, in the event of a disaster, health care providers and suppliers across the nation would not have the necessary emergency planning and preparation in place to adequately protect the health and safety of their patients. Underlying this problem is the pressing need for a more consistent regulatory approach that would ensure that providers and suppliers nationwide are required to plan for and respond to emergencies and disasters that directly impact patients, residents, clients, participants, and their communities. As we have learned from past events and disasters, the current regulatory patchwork of federal, state, and local laws and guidelines, combined with the various accrediting organization emergency preparedness standards, falls far short of what is needed to require that health care providers and suppliers be adequately prepared for a disaster. Thus, we are proposing these emergency preparedness requirements to establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness and response that incorporates the lessons learned from the past, combined with the proven best practices of the present. We recognize that

central to this approach is to develop and guide emergency preparedness and response within the framework of our national health care system. To this end, these proposed regulations would also encourage providers and suppliers to coordinate their preparedness efforts within their own communities and states as well as across state lines, as necessary to achieve their goals. We are soliciting comments on whether certain requirements should be implemented on a staggered basis.

2. Summary of the Major Provisions

We are proposing emergency preparedness requirements that will be consistent and enforceable for all affected Medicare and Medicaid providers and suppliers. This proposed rule addresses the three key essentials needed to ensure that health care is available during emergencies: safeguarding human resources, ensuring business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

Based on our research and consultation with stakeholders, 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 of the emergency preparedness program are as follows:

- Risk assessment and planning: This proposed rule would propose that prior to establishing an emergency plan, a risk assessment would 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. This approach is specific to the location of the

provider and supplier considering the particular types of hazards which may most likely occur in their area.

- Policies and procedures: We are proposing that facilities be required to develop and implement policies and procedures based on the emergency plan and risk assessment.

- Communication plan: This proposed rule would require a facility to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. 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: We are proposing that a facility develop and maintain an emergency preparedness training and testing program. A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. We propose that the facility ensure that staff can demonstrate knowledge of emergency procedures and provide this training at least annually. We would require that facilities conduct drills and exercises to test the emergency plan.

We are seeking public comments on when these CoPs should be implemented.

B. Current State of Emergency Preparedness

1. Federal Emergency Preparedness

In response to the September 11, 2001 terrorist attacks and the subsequent national need to refine the nation's strategy to handle emergency situations, there have been numerous efforts across federal agencies to establish a foundation for development and expansion of emergency preparedness systems. The following is a brief overview of some emergency preparedness

activities at the federal level. Additional information is included in the appendix to this proposed rule.

a. Presidential Directives

Three Presidential Directives HSPD-5, HSPD-21 and PPD-8, require agencies to coordinate their emergency preparedness activities with each other and across federal, state, local, tribal, and territorial governments. Although these directives do not specifically require Medicare providers and suppliers to adopt such measures, they have set the stage for what we expect from our providers and suppliers in regard to their roles in a more unified emergency preparedness system. The Homeland Security Presidential Directive (HSPD-5), "Management of Domestic Incidents," was issued on February 28, 2003. This directive authorizes the Department of Homeland Security to develop and administer the National Incident Management System (NIMS). The NIMS provides a consistent national template that enables federal, state, local, and tribal governments, as well as private-sector and nongovernmental organizations, to work together effectively and efficiently to prepare for, prevent, respond to, and recover from domestic incidents, regardless of cause, size, or complexity, including acts of catastrophic terrorism. The Presidential Policy Directive (PPD-8 focuses on strengthening the security and resilience of the nation through systematic preparation for the full range of 21st century hazards that threaten the security of the nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters. The directive is founded by 3 key principles which include: (1) employ an all-of-nation/whole community approach, integrate efforts across federal, state, local, tribal and territorial governments; (2) build key capabilities to confront any challenge; and (3) utilize an assessment system focused on outcomes to measure and track progress. Finally, the Presidential directive published on October 18, 2007, entitled, "Homeland Security Presidential

Directive/HSPD-21," addresses public health and medical preparedness. The directive, found at http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm, establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which aims to transform our national approach to protecting the health of the American people against all disasters. HSPD-21 summarizes implementation actions that are the four most critical components of public health and medical preparedness: biosurveillance, countermeasure stockpiling and distribution, mass casualty care, and community resilience. The directive states that these components will receive the highest priority in public health and medical preparedness efforts.

b. Assistant Secretary for Preparedness and Response

In December 2006, the President signed the Pandemic and All-Hazards Preparedness Act (PAHPA) (Pub. L. 109-417). The purpose of the Pandemic and All-Hazards Preparedness Act is "to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural." The Office of the Assistant Secretary for Preparedness and Response (ASPR) was created under the PAHPA Act in the wake of Katrina to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. The Secretary of HHS delegates to ASPR the leadership role for all health and medical services support functions in a health emergency or public health event. ASPR also serves as the senior advisor to the HHS Secretary on public health and medical preparedness and provides, at a minimum, support for; building federal emergency medical operational response and recovery capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of healthcare preparedness at the state, regional, local and healthcare coalition levels for public health emergencies and medical disasters. The office provides federal support, including medical

professionals through ASPR's National Disaster Medical System (NDMS), to augment state and local capabilities during an emergency or disaster. The purpose of the NDMS is to establish a single, integrated, and national medical response capability to assist state and local authorities in dealing with the medical impacts of major peacetime disasters and to provide support to the military and the Department of Veterans Affairs medical systems in caring for casualties evacuated back to the U.S. from overseas conflicts. The NDMS, as part of the HHS, led by ASPR, supports federal agencies in the management and coordination of the federal medical response to major emergencies and federally declared disasters including natural disasters, technological disasters, major transportation accidents, and acts of terrorism, including weapons of mass destruction events. Additional information can be found at: http://www.phe.gov/preparedness/responders/ndms/Pages/default.aspx.

ASPR also administers the Hospital Preparedness Program (HPP), which provides leadership and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Through the work of its state partners, HPP has advanced the preparedness of hospitals and communities in numerous ways, including building healthcare coalitions, planning for all hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners.

The first response in a disaster is always local, and comprised of local government emergency services supplemented by state and volunteer organizations. This aspect of the "disaster response" is specifically coordinated by state and local authorities. When an incident overwhelms or is anticipated to overwhelm state resources, the Governor of a state or chief

executive of a tribe may request federal assistance. In such cases, the affected local jurisdiction, tribe, state, and the federal government will collaborate to provide that necessary assistance. When it is clear that state capabilities will be exceeded, the Governor or the tribal executive can request federal assistance, including assistance under the Robert Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). The Stafford Act authorizes the President to provide financial and other assistance to state and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or major disaster declarations.

The National Response Framework (NRF), a guide to how the nation should conduct all hazards responses, includes 15 Emergency Support Functions (ESFs), which are groupings of governmental and certain private sector capabilities into an organizational structure. The purpose of the ESFs is to provide support, resources, program implementation, and services that are most likely needed to save lives, protect property and the environment, restore essential services and critical infrastructure, and help victims and communities return to normal following domestic incidents. HHS is the primary agency responsible for ESF 8- Public Health and Medical Services.

The Secretary of HHS leads all federal public health and medical response to public health and medical emergencies and incidents that are covered by the Stafford Act, via NRF, or the Public Health Service Act. Under the NRF, ESF 8 is coordinated by the Secretary of HHS principally through the Assistant Secretary for Preparedness and Response (ASPR). ESF 8 – Public Health and Medical Services provides the mechanism for coordinated federal assistance to supplement state, tribal, and local jurisdictional resources in response to a public health and

medical disaster, potential or actual incidents requiring a coordinated federal response, or during a developing potential health and medical emergency.

c. Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) Office of Public Health Preparedness and Response (OPHPR) leads the agency's preparedness and response activities by providing strategic direction, support, and coordination for activities across CDC as well as with local, state, tribal, national, territorial, and international public health partners. CDC provides funding and technical assistance to states to build and strengthen public health capabilities. Ensuring that states can adequately respond to threats will result in greater health security; a critical component of overall U.S. national security. Additional information can be found at: http://www.cdc.gov/phpr/. The CDC Public Health Emergency Preparedness (PHEP) cooperative agreement, led by OPHPR, is a critical source of funding for state, local, tribal, and territorial public health departments. Since 2002, the PHEP cooperative agreement has provided nearly $9 billion to public health departments across the nation to upgrade their ability to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Preparedness activities funded by the PHEP cooperative agreement are targeted specifically for the development of emergency-ready public health departments that are flexible and adaptable. The Strategic National Stockpile (SNS), administered by the CDC, is a stockpile of pharmaceuticals and medical supplies. The SNS program was created to assist states and local communities in responding to public health emergencies, including those resulting from terrorist attacks and natural disasters. The SNS program ensures the availability of necessary medicines, antidotes, medical supplies, and medical equipment for states and local communities, to counter the effects

of biological pathogens and chemical and nerve agents. (http://www.cdc.gov/phpr/stockpile/stockpile.htm).

The Cities Readiness Initiative (CRI), led by CDC, is a federally funded pilot program to help cities increase their capacity to deliver medicines and medical supplies within 48 hours after recognition of a large-scale public health emergency such as a bioterrorism attack or a nuclear accident. More information on this effort can be found at: http://www.bt.cdc.gov/cri/. An evaluative report of this program since its inception, requested by the CDC, performed by the RAND Corporation, and published in 2009, entitled, "Initial Evaluation of the Cities Readiness Initiative" can be found at http://www.rand.org/pubs/technical_reports/2009/RAND_TR640.pdf.

Given the heightened concern regarding the impact of various influenza outbreaks in recent years, the federal government has created a website with "one-step access to U.S. Government H1N1, Avian, and Pandemic Flu Information" at www.flu.gov. The website provides links to influenza guidance and information from federal agencies, such as the CDC, as well as checklists for pandemic preparedness. The information and links are found at http://www.flu.gov/professional/index.html. This website includes information for hospitals, long term care facilities, outpatient facilities, home health agencies, other health care providers, and clinicians. For example, the "Hospital Pandemic Influenza Planning Checklist" provides guidance on structure for planning and decision making; development of a written pandemic influenza plan; and elements of an influenza pandemic plan. The checklist is comprehensive and lists everything a hospital should do to prepare for a pandemic, from planning for coordination with local and regional planning and response groups to infection control.

2. State and Local Preparedness

A review of studies and articles regarding readiness of state and local jurisdictions reveals that there is inconsistency in the level of emergency preparedness amongst states and need for improvement in certain areas. In a report by the Trust for America's Health (TFAH) (December 2012, http://www.healthyamericans.org/report/101/) entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism" the authors assessed state-by-state public health preparedness nearly 10 years after the September 11th and anthrax tragedies. Using 10 key indicators to rate levels of public health preparedness, some key findings included: (1) 29 states cut public health funding from fiscal years (FY) 2010 through 2012, with 2 of these states cutting funds for a second year in a row and 14 for 3 consecutive years, and that federal funds for state and local preparedness have decreased by 38 percent from FY 2005 through 2012 and (2) 35 states and Washington D.C. do not currently have complete climate change adaption plans, which include planning for health threats posed by extreme weather events.

An article entitled, "Public Health Response to Urgent Case Reports," published in Health Affairs (August 30, 2005), Dausey, D., Lurie, N., and Diamond, A.) evaluated the ability of local public health agencies (LPHAs) to adequately meet "a preparedness standard" set by the CDC. The standard was for the LPHAs "to receive and respond to urgent case reports of communicable diseases 24 hours a day, 7 days a week." Using 18 metropolitan area LPHAs that were roughly evenly distributed by agency size, structure, and region of the country, the goal of the test was to contact an "action officer" (that is, physician, nurse, epidemiologist, bioterrorism coordinator, or infection control practitioner) responsible for responding to urgent case reports.

During a 4-month period of time, each LPHA was contacted several times and asked questions regarding triage procedures, what questions would be asked in the event of an urgent case being filed, next steps taken after receiving such a report, and who would be contacted. Although the LPHAs had a substantial role in community public health through prevention and treatment efforts, the authors found significant variation in performance and the systems in place to respond to such reports.

We also reviewed an article published in June 2004 by Lurie, N., Wasserman, J., Stoto, M., Myers, S., Namkung, P., Fielding, J., and Valdez, R. B., entitled, "Local Variations in Public Health Preparedness: Lessons from California" found at http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.341/DC1. The authors stated that "evidence–based measures to assess public health preparedness are lacking in California." Using an "expert-panel process," the researchers developed performance measures based on ten identified essential public health services. They performed site visits and tabletop exercises to evaluate preparedness across the state in geographic locations identified as urban, rural, and border status to detect and respond to a hypothetical smallpox outbreak based on the different measures of preparedness. Overall, the researchers found that there was a lack of consensus regarding what "emergency preparedness" encompassed and a wide variation in what various governmental agencies deemed to be adequate emergency preparedness "readiness" in California. They noted that gaps in the infrastructure were common.

Throughout the jurisdictions investigated, there were similarities noted in the shortage of nurses, the number of essential workers nearing retirement age, and the lack of epidemiologists, lab personnel, and public health nurses to meet potential needs. Such gaps in personnel infrastructure were found in many jurisdictions. In some jurisdictions, there was incomplete

information regarding the demographics of persons who could be considered potentially vulnerable or part of an underserved population.

In one situation, there was also great variability in the length of time it took to bring three suspicious cases to public health officers' attention and for these officers to realize that these cases were related. There was great variation in the public health officers' ability to rapidly alert the physician and hospital community of an outbreak. There was a lack of consensus regarding when to report a potential outbreak to the public. There also was wide variation in knowledge of public health legal authority, specifically, in regard to quarantine and its enforcement. We believe these findings to be typical of most states.

3. Hospital Preparedness

Hospitals are the focal points for health care in their respective communities; thus, it is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Additionally, since Medicare-participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and to arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities. We would expect hospitals to be prepared to provide care to the greatest number of disaster victims for which they have the capacity, while meeting at least minimal obligations for care to all who are in need.

In 2007, ASPR contracted with the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) (the Center) to conduct an assessment of U.S. hospital preparedness and to develop recommendations for evaluating and improving future hospital preparedness efforts. The Center's assessment, entitled "Hospitals Rising to the Challenge: The First Five

Years of the U.S. Hospital Preparedness Program and Priorities Going Forward" describes the most important components of preparedness for mass casualty response at the local and regional hospital and healthcare system levels. This evaluation report was based on extensive analyses of the published literature, government reports, and HPP program assessments, as well as on detailed conversations with 133 health officials and hospital professionals representing every state, the largest cities, and major territories of the U.S.

The authors stated that major disasters can severely challenge the ability of healthcare systems to adequately care for large numbers of patients (surge capacity) or victims with unusual or highly specialized medical needs (surge capability) such as occurred with Hurricane Katrina. The authors further stated that addressing medical surge and medical system resilience requires implementing systems that can effectively manage medical and health responses, as well as developing and maintaining preparedness programs. There were numerous findings and conclusions in the 2007 report. The researchers found that since the start of the HPP in 2002, individual hospitals' disaster preparedness has improved significantly. The report found that hospital senior leadership is actively supporting and participating in preparedness activities, and disaster coordinators within hospitals have given sustained attention to preparedness and response planning efforts. Hospital emergency operations plans (EOPs) have become more comprehensive and, in many locations, are coordinated with community emergency plans and local hazards. Disaster training has become more rigorous and standardized; hospitals have stockpiled emergency supplies and medicines; situational awareness and communications are improving; and exercises are more frequent and of higher quality. The researchers also found improved collaboration and networking among and between hospitals, public health departments,

and emergency management and response agencies. These coalitions are believed to represent the beginning of a coordinated community-wide approach to medical disaster response.

However, ASPR Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness (2012) and CDC Public Health Preparedness Capabilities: National Standards for State and Local Planning (March 2011) notes numerous federal directives that recognize the need for a consistent approach to preparedness planning across the nation so as to ensure an effective response. The 2010 IOM report also notes that direction at the federal level is essential in order to ensure a coordinated, interoperable disaster response. (IOM Medical Surge Capacity. 2009 Forum on Medical and Public Health Preparedness for Catastrophic Events, 2010)"

4. OIG and GAO Reports

Since Katrina, several studies regarding the preparedness of health care providers have been published. In general, these reports and studies point to a need for improved requirements to ensure that providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

In response to a request from the U.S. Senate Special Committee on Aging calling for an examination of nursing home emergency preparedness, the Office of the Inspector General (OIG) conducted a study during 2004 through 2005 entitled, "Nursing Home Emergency Preparedness and Responses During Recent Hurricanes," (OEI-06-06-00020) http://oig.hhs.gov/oei/reports/oei-06-06-00020.pdf). The OIG reviewed state survey data for emergency preparedness measures both for the nation in general and for the Gulf States (Alabama, Florida, Louisiana, Mississippi, and Texas). The study indicated that in 2004 through 2005, 94 percent of nursing homes nationwide met the limited federal regulations for emergency

plans then in existence, while only 80 percent met the federal standards for emergency training. Similar compliance rates were noted in the Gulf states. However, the OIG found that nursing homes in the Gulf states experienced problems even though they were in compliance with federal interpretive guidelines. Further, they experienced problems whether they evacuated residents or sheltered them in place. The OIG listed the problems encountered by Gulf state nursing homes including, transportation contracts that were not honored; lengthy travel times for residents; insufficient food and water for residents and staff; complicated resident medication needs; host facilities that were unavailable or that were inadequately prepared, provisioned, or staffed for the transfer of residents; and difficulty re-entering their own facilities. As further detailed in the OIG report, the main reasons for these problems were lack of effective planning; failure to properly execute emergency plans; failure to anticipate the specific problems encountered; and failure to adjust decisions and actions to specific situations.

The OIG also found that some facility administrators deviated, many significantly, from their emergency plans or worked beyond the plans, either because the plans were not updated or plans did not include instructions for certain circumstances. The report goes on to note that many of the nursing home emergency preparedness plans did not consider the following factors: the need to evacuate residents to alternate sites as evidenced by a formal agreement with a host facility; criteria to determine whether to evacuate residents or shelter them in place; a means by which an individual resident's care needs would be identified and met; and re-entry into the facility following an evacuation.

Although some local communities were directly involved in the evacuation of their nursing home residents, other nursing homes received assistance with evacuation from resident and staff family members, parent corporations, and "sister facilities," according to the OIG

report. A few nursing homes reported that problems with state and local government coordination during the hurricanes contributed to the problems they encountered.

Based on this study, the OIG had two recommendations for CMS: (1) strengthen federal certification standards for nursing home emergency plans by including requirements for specific elements of emergency planning; and (2) encourage communication and collaboration between state and local emergency entities and nursing homes. As a result of the OIG's recommendations, the Secretary initiated an emergency preparedness improvement effort to be coordinated across all HHS agencies. Our development of this proposed rule is an important part of HHS-wide efforts to meet the Department's overall emergency preparedness goals and objectives by directly addressing the OIG recommendations. In April 2012, the OIG issued a subsequent report entitled, "Gaps Continue to Exist in Nursing Home Emergency Preparedness and response During Disaters: 2007-2010," (OEI-06-09-00270 http://oig.hhs.gov/oei/reports/oei-06-09-00270.pdf). This report notes that many of the gaps in nursing home preparedness and response identified in the 2006 report still exist.

We also reviewed several Government Accountability Office (GAO) reports on emergency preparedness. One such report is entitled, "Disaster Preparedness: Preliminary Observations on the Evacuation of Hospitals and Nursing Homes Due to Hurricanes" (GAO-06-443R), was published on February 16, 2006, and can be found at http://www.gao.gov/new.items/d06443r.pdf). This report discusses the GAO's findings regarding--(1) responsibility for the decision to evacuate hospitals and nursing homes; (2) the issues administrators consider when deciding to evacuate hospitals and nursing homes; and (3) the federal response capabilities that support evacuation of hospitals and nursing homes.

The GAO found that "hospital and nursing home administrators are often responsible for deciding whether to evacuate patients from their facilities due to disasters, including hurricanes or other natural disasters. State and local governments can order evacuations of the population or segments of the population during emergencies, but health care facilities may be exempt from these orders." The GAO found that hospitals and nursing home administrators evacuate only as a last resort and that these facilities' emergency plans are designed primarily to shelter in place. The GAO also found that administrators considered the availability of adequate resources to shelter in place, the risks to patients in deciding when to evacuate, the availability of transportation to move patients, the availability of receiving facilities to accept patients, and the destruction of the facility's or community's infrastructure.

The GAO noted that nursing home administrators also must consider the fact that nursing home residents cannot care for themselves and generally have no home and no place to live other than the nursing home. Therefore, in the event of an evacuation, nursing homes also need to consider the necessity of locating facilities that can accommodate their residents for a long period of time.

A second report from the GAO about the hurricanes' impact entitled, "Disaster Preparedness: Limitations in Federal Evacuation Assistance for Health Facilities Should be Addressed," (GAO-06-826) July, 2006, www.gao.gov/cgi-bin/getrpt?GAO-06-826), supports the findings noted in the first GAO report on the disasters. In addition, the GAO noted that the evacuation issues that facilities faced during and after the hurricanes occurred due to their inability to secure transportation when needed. Despite previously established contracts with transportation companies, demand for this assistance overwhelmed the supply of vehicles in the community.

A third report, an after-event analysis entitled, "Hurricane Katrina: Status of Hospital Inpatient and Emergency Departments in the Greater New Orleans Area," (GAO-06-1003) September 29, 2006, http://www.gao.gov/docdblite/details.php?rptno=GAO-06-1003) revealed that, as of April 2006: (1) emergency departments were experiencing overcrowding; but that (2) the number of staffed inpatient beds per 1,000 population was greater than that of the national average and expected to increase further. However, the study found that the number of staffed inpatient beds was not available in psychiatric care settings. In fact, some persons with mental health needs had to be transferred out of the area due to a lack of beds. Attracting and retaining nursing and support staff were two problems that were identified as hindering efforts to maintain an adequate supply of staffed beds for psychiatric patients.

While this study focused specifically on patient care issues in the New Orleans area, the same issues are common to hospitals in any major metropolitan area. Given the vulnerability of persons with mental illness and the tremendous stress a man-made or natural disaster can put on the entire general population, an increase in the number of persons who seek mental health services and require inpatient psychiatric care can be expected following any natural or man-made disaster.

In another report from the GAO, an after-event analysis entitled, "Disaster Recovery: Past Experiences Offer Recovery Lessons for Hurricane Ike and Gustav and Future Disasters," (GAO-09-437T March 3, 2009, http://www.gao.gov/products/GAO-09-437T) the GAO concluded that recovery from major disasters is a complex undertaking that involves the combined efforts of federal, state, and local government in order to succeed. The GAO stated that while the federal government provides a significant amount of financial and technical

assistance for recovery, state and local jurisdictions should work closely with federal agencies to secure and make use of those resources.

In a report from the GAO, entitled, "Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed," (GAO-09-909T July 29, 2009; http://www.gao.gov/new.items/d09909t.pdf), the GAO expressed its concern that, despite a number of actions having been taken to plan for a pandemic, including developing a National Strategy and Implementation Plan, many gaps in pandemic planning and preparedness still existed in the presence of a potential pandemic influenza outbreak.

In November 2009, the GAO published an additional report entitled, "Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement," (GAO-10-73) (http://www.gao.gov/new.items/d1073.pdf). In this report, the GAO assessed the progress of the responsible federal agencies (including HHS) in implementing the action items set forth in the "National Strategy for Pandemic Influenza: Implementation Plan" (the Plan) (http://georgewbush-whitehouse.archives.gov/homeland/pandemic-influenza-implementation.html). Specifically, the researchers were interested in determining how the Homeland Security Council (HSC) and the responsible federal agencies were monitoring the progress and completion of the Plan's 342 action items, and assessing the extent to which selected action items were completed, whether activity had continued on the selected action items reported as complete, and the nature of that work. Having conducted an in-depth analysis of a random sample of 60 action items, the GAO found the status of selected action items considered complete was difficult to determine. Specifically, the GAO found that: (1) measures of performance used to determine status did not always fully reflect the descriptions of the action items; (2) some selected action items were

designated as complete despite requiring actions outside the authority of the responsible entities; and (3) additional work was conducted on some selected action items designated as complete. Ultimately, the GAO recommended that, in order to improve how progress is monitored and completion is assessed under the Plan and subsequent updates of the Plan, the HSC should instruct the White House National Security Staff (NSS) to work with responsible federal agencies to: (1) develop a monitoring and reporting process for action items that are intended for nonfederal entities, such as state and local governments; (2) identify the types of information needed to decide whether to carry out the response-related action items; and (3) develop measures of performance that are more consistent with the descriptions of the action items.

C. Statutory and Regulatory Background

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 and Medicaid 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. These requirements are called the Conditions of Participation (CoPs) for providers and the Conditions for Coverage (CfCs) for suppliers. The CoPs and CfCs are intended to protect public health and safety and ensure that high quality care is provided to all persons. 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 propose emergency preparedness regulations:

- 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 Facilities or Programs (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, section 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.

We considered proposing these regulations for each provider and supplier type individually, as we updated their CoPs or CfCs over time. However, for the reasons we have already discussed, we believe the most prudent course of action is to publish emergency preparedness requirements for Medicare and Medicaid providers and suppliers in a single proposed rule. Thus, we are proposing regulatory language for 17 Medicare and Medicaid providers and suppliers to address the four main aspects of emergency preparedness:--(1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training.

II. Provisions of the Proposed Regulations

This proposed rule responds to concerns from the Congress, the health care community, and the public regarding the ability of health care providers and suppliers to plan and execute appropriate emergency response procedures for disasters. We developed this proposed rule taking into consideration the extent of regulatory oversight that is currently in existence.

We are proposing requirements for facilities to ensure the continued provision of necessary care at the facility or, if needed, the evacuation and transfer of patients to a location that can supply necessary care. Regulations that address these functions too specifically may become outdated over time as technology and the nature of threats change. However, as our analysis of existing regulations, and the OIG and GAO reports discussed in section I. of this proposed rule, indicate regulations that are too broad may be ineffective. Our challenge is to develop core components that can be used across provider and supplier types as diverse as hospitals, organ procurement organizations, and home health agencies, while tailoring requirements for individual provider and supplier types to their specific needs and circumstances, as well as the needs of their patients, residents, clients, and participants.

We have identified four core elements that we believe are central to an effective emergency preparedness system and must be addressed to offer a more comprehensive framework of emergency preparedness requirements for the various Medicare- and Medicaid-participating providers and suppliers. The four elements are--(1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing. We have also proposed an additional requirement for OPOs entitled "Agreements with other OPOs and hospitals."

We believe many of the proposed elements of an emergency preparedness plan need to be conducted at the level of an individual facility. However, other elements may be addressed as effectively, and more efficiently, at a broader organizational level, for example, a system for preserving medical documentation. Our regulatory requirements for each provider and supplier type are based on the comprehensive emergency preparedness requirements that we are proposing for hospitals. Since we are aware that the application of the proposed regulatory language for hospitals may be inappropriate or overly burdensome for some providers and suppliers, we have used the proposed hospital requirements as a template for our proposed emergency preparedness regulations for other providers and suppliers but have specific proposed requirements tailored to each providers' and suppliers' unique needs. Any contracted services furnished to patients must be in compliance with all the facilities' CoPs and standards of this rule, and all services must be provided in a safe and effective manner.

All providers and suppliers would be required to establish an emergency preparedness plan that addressed the four core elements noted previously. The proposed requirements vary based on the type of provider. We discuss the hospital requirements in detail at the beginning of this section. The subsequent discussion of the proposed requirements for all remaining providers and suppliers focuses on how the requirements differ from those proposed for hospitals and why.

For example, because they are inpatient facilities, religious nonmedical health care institutions (RNHCIs), psychiatric residential treatment facilities (PRTFs), skilled nursing facilities and nursing homes (referred to in this document as long term care (LTC) facilities), intermediate care facilities individuals with intellectual disabilities (ICFs/IID), and critical access hospitals (CAHs) may have greater responsibility than outpatient facilities during an emergency for ensuring the health and safety of persons for whom they provide care, their

employees, and volunteers. Thus, proposed requirements for RNHCIs, PRTFs, ICFs/IID, LTC facilities, and CAHs are similar to those proposed for hospitals.

In the event of a natural or man-made disaster, providers and suppliers of outpatient services, such as ambulatory surgical centers (ASCs), programs of all-inclusive care for the elderly (PACE) organizations, home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), rural health clinics (RHCs), federally qualified health centers (FQHCs), and end stage renal disease (ESRD) facilities, may not open their facilities or may close them, sending patients and staff home or to a place where they can safely shelter in place. However, we recognize that outpatient facilities may find it necessary to shelter their patients until they can be evacuated or may be called upon to provide some level of care for community residents in the event of an emergency. For example, a CORF that is housed in a large building may open its doors to persons in the community who would otherwise have no place to go. The CORF may provide only shelter from the elements or may provide water, food, and basic self-care items, if available.

Finally, given that some hospice facilities provide both inpatient and home based services, and that transplant centers and OPOs are unique in their provision of health care, our proposed requirements are tailored even more specifically to address the circumstances of these entities. We believe lessons learned following the 2005 hurricanes and subsequent disasters, such as the flooding in the Midwest in 2008, and the tornadoes and flooding in 2011and 2012, have provided us with an opportunity to work collaboratively with the health care community to ensure best practices in emergency preparedness across providers and suppliers.

It is important to point out that we expect that implementation of certain requirements that we propose for providers and suppliers would be different, based on the category of the

provider or supplier. For example, we propose that nearly all providers and suppliers would be required to have policies and procedures to provide subsistence needs to staff and patients during an emergency. However, a small RHC's implementation of this requirement would be quite different from a large metropolitan hospital's implementation. Specifically, with respect the proposed requirement that hospitals, CAHs, inpatient hospice facilities, PRTFs, LTC facilities, ICFs/IID, and RNHCIs would be required to maintain various subsistence needs, we are requesting public comment regarding whether this should be a requirement and in what quantities and for what time period these subsistence needs would be maintained. Nevertheless, we expect that each facility would determine how to implement a requirement considering similar variables such as whether the provider might have the option of notifying staff and patients not to come to the facility due to an emergency; the number of staff and patients likely to be in the facility at the time of an emergency; whether the provider would have the capability of providing shelter, provisions, and health care to members of the community; and the amount of space within the facility available for storing provisions. Although various providers and suppliers utilize different nomenclature to describe the individuals for whom they provide care (patient, resident, client, or participant), unless otherwise indicated, we will use the term "patients" to refer to the individuals for whom the provider or supplier under discussion provides care.

Data regarding the number of providers cited in this proposed rule were obtained from a variety of different CMS databases. The number of providers and suppliers deemed by accrediting organizations to meet the Medicare conditions of participation are from CMS's second quarter fiscal year 2010 Accrediting Organization System for Storing User Recorded

Experiences (ASSURE) database. Currently, there are accrediting organizations with Medicare deeming authority for hospitals, critical access hospitals, HHAs, hospices, and ASCs.

Data for CAHs that report having psychiatric and rehabilitation Distinct Part Units (DPUs) are from the Medicare Quality Improvement and Evaluation System (QIES)/Certification and the Survey Provider Enhanced Reporting (CASPER) system as of March 2013. Data for CAHs that do not have DPUs are from the Online Survey, Certification, and Reporting (OSCAR) data system as of March 2013. Data for the number of transplant centers are from the CMS website as of March 2013. Data for the total number of accredited and non-accredited hospitals, HHAs, ASCs, hospices, RHNCHIs, PRTFs, SNFs, ICFs/IID, CORFs, OPOs, and RHCs/FQHCs are from the OSCAR data system as of March 2013. We acquired the PACE data from CMS's Health Plan Management System (HPMS), which reports the number of PACE contracts. Given that PACE organizations may have more than one "center," we are using the number of PACE contracts as a reflection of the number of PACE centers under contract with the CMS.

Note that the CMS OSCAR data system is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited facilities shown may not equal the total number of facilities.

Discussion of the proposed regulatory provisions for each type of provider and supplier follows the discussion in this section of the hospital requirements in the order in which they would appear in the Code of Federal Regulations (CFR). However, our discussion of the hospital requirements includes a general discussion of the differences between our proposed requirements, based on whether providers and suppliers provide outpatient services or inpatient

services or both. Thus, we encourage all providers to read the discussion of the proposed hospital emergency preparedness requirements in section II.A. of this proposed rule.

This section also provides detailed discussion of each proposed hospital requirement, offers resources that providers and suppliers can use to meet these proposed requirements, offers a means to establish and maintain emergency preparedness for their facilities, and provides links to guidance materials and toolkits that can be used to help meet these requirements.

A. Emergency Preparedness Regulations for Hospitals (§ 482.15)

Section 1861(e) of the Act defines the term "hospital" and subsections (1) through (8) list requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. Under the authority of 1861(e) of the Act, the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare conditions of participation (CoPs) to qualify for participation in Medicaid. The hospital CoPs are found at § 482.1 through § 482.66.

As of September 2012, 4,928 hospitals participated in Medicare. CAHs that have distinct part units (DPUs) must comply with all of the hospital CoPs with respect to those units. There are 1,332 active CAHs. Of these CAHs, there are 95 CAHs with DPUs. The remainder of CAHs (the vast majority) are not subject to hospital CoPs, and must comply with CAH-specific CoPs. Proposed requirements for CAHs are laid out in §485.625.

Services provided by hospitals encompass inpatient and outpatient care for persons with various acute or chronic medical or psychiatric conditions, including patient care services provided in the emergency department. Hospitals are the focal points for health care in their respective communities; thus, it is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Additionally, since Medicare-participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and to arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities.

We are proposing a new requirement under 42 CFR 482.15 that would require that hospitals have both an emergency preparedness program and an emergency preparedness plan. Conceptually, an emergency preparedness program encompasses an approach to emergency preparedness that allows for continuous building of a comprehensive system of health care response to a natural or man-made emergency. We are also proposing that a hospital, and all other providers and suppliers, utilize an "all-hazards" approach in the preparation and delivery of emergency preparedness services in order to meet the health and safety needs of its patient population. The definition of "all hazards" is discussed later in this section under "Emergency Plan."

We would expect that during an emergency, injured and ill individuals would seek health care services at a hospital or CAH, rather than from another provider or supplier. For example, during a pandemic, individuals with influenza-like symptoms are more likely to visit a hospital or CAH emergency department than an ASC. Typically, in the event of a chemical spill,

affected individuals would not expect to receive emergency health care services at an LTC facility but would seek health care services at the hospital or CAH in their community. However, we believe it is imperative that each provider think in broader terms than their own facility, and plan for how they would serve similar and other healthcare facilities, as well as the whole community during and surrounding an emergency event. We believe the first step in emergency management is to develop an emergency plan. An emergency plan sets forth the actions for emergency response based on a risk assessment that addresses an "all-hazards approach" to medical and non-medical emergency events. In keeping with the emergency management industry and with strong recommendation from the Department's Assistant Secretary for Preparedness and Response (ASPR), we are proposing that all providers utilize an all-hazards approach to emergency response. We do not specify the quantity or the expected level of detail in which each hazard would be addressed by each provider; however, we do believe it would encourage the adoption of a well thought out, cohesive system of response both within and across provider types.

Analysis of anticipated outcomes to the facility-based and community-based risk assessments would drive revision to the emergency preparedness program, the plan for response, or both. A facility-based risk assessment is contained within the actual facility and carried out by the facility. A community based risk assessment is carried out outside the organization within their defined community.

1. Emergency Plan

a. Emergency Planning Resources

To stimulate and foster improved emergency preparedness continuity of operations, the federal interagency community has developed fifteen all-hazards planning scenarios, entitled the

"National Planning Scenarios" for use in federal, state, and local homeland security preparedness activities. These scenarios serve as planning tools for response to the range of man-made and natural disasters the nation could face. The scenarios are: nuclear detonation-improvised nuclear device; biological attack – aerosol anthrax; biological disease outbreak – pandemic influenza; biological attack – plague; chemical attack – blister agent; chemical attack – toxic industrial chemicals; chemical attack – nerve agent; chemical attack – chlorine tank explosion; natural disaster – major earthquake; and natural disaster – major hurricane; radiological attack – radiological dispersal devices; explosive attack - bombing using improvised explosive device; biological attack – food contamination; biological attack – foreign animal disease (foot and mouth disease); and cyber attack. Additional scenarios include volcano preparedness and severe winter weather (snow/ice). Additional information regarding the National Planning Scenarios and how they align to the National Preparedness Goal can be found at: http://www.fema.gov/preparedness-1/learn-about-presidential-policy-directive-8#MajorElements.

These planning tools along with other emergency management and business continuity information can be found on HRSA's website at: http://www.hrsa.gov/emergency/ and also in HRSA's, Policy Information Notice entitled, "Health Center Emergency Management Program Expectations," (No. 2007-15), dated August 22, 2007, at: http://bphc.hrsa.gov/policiesregulations/policies/pin200715expectations.html). While these materials were developed for health centers, the content is relevant to all health providers. According to the notice emergency management planning is to ensure predictable staff behavior during a crisis, provide specific guidelines and procedures to follow and define specific roles. Also, emergency planning should address the four phases of emergency management that

include: mitigation activities to lessen the severity and impact a potential disaster or emergency might have on a health center's operation; preparedness activities to build capacity and identify resources that may be used should a disaster or emergency occur; response to the actual emergency and controls the negative effects of emergency situations; and recovery that begin almost concurrently with response activities and are directed at restoring essential services and resuming normal operations to sustain the long-term viability of the health center. HRSA further states that for FQHCs, this means protecting staff and patients, as well as safeguarding the facility's ability to deliver health care. According to HRSA, the expectations outlined in their guidance are intended to be broad to ensure applicability to the diverse range of centers and to aid integration of the guidance into what centers already are doing related to emergency and risk management. While this guidance is targeted toward centers, we believe hospitals and all other providers and suppliers can use this guidance in the development of their emergency preparedness plans.

The Agency for Healthcare Research and Quality (AHRQ) released a web-based interactive tool entitled, "Surge Tool Kit and Facility Checklist" (located at: http://www.cdc.gov/phpr/healthcare/documents/shuttools.pdf or at: http://archive.ahrq.gov/research/shuttered/toolkitchecklist/), which will allow hospitals and emergency planners to estimate the resources needed to treat a surge of patients resulting from a major disaster, such as an influenza pandemic or a terrorist attack. Designed to dovetail with the Homeland Security Council's 15 all-hazards National Planning Scenarios, previously discussed, the AHRQ Hospital Surge Model allows users to select a disaster scenario and estimate the number of patients needing medical attention by arrival condition and day; the number of casualties in the hospital by unit and day; and the cumulative number of both dead or discharged

casualties by day. The tool also calculates the level of hospital resources, including personnel, equipment and supplies, needed to treat patients. The model estimates resources for biological, chemical, nuclear or radiological attacks. (For the development of emergency preparedness plans, providers and suppliers may also find the National Fire Protection Association's (NFPA) NFPA 1600: "Standard on Disaster/Emergency Management and Business Continuity Programs, 2013 Edition," particularly helpful. The NFPA document can be found at: http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=1600. The standard sets forth the basic criteria for a comprehensive program that addresses disaster recovery, emergency management, and business continuity. Under most definitions, the NFPA 1600 is an industry standard for disaster management.

Also of concern when developing an emergency plan is the issue of the allocation of scarce resources during a potentially devastating event. Disasters can create situations where such resources must be distributed in a manner that is different from usual circumstances, but still appropriate to the situation. As discussed in "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide, Publication No. 07-0001, Rockville, MD: Agency for Healthcare Research and Quality," (found at: http://archive.ahrq.gov/research/mce/), such resource considerations are part of the impact that natural or man-made disasters have on hospitals. This guide provides information on the circumstances that communities would likely face as a result of a mass casualty event (MCE); key constructs, principles, and structures to be incorporated into the planning for an MCE; approaches and strategies that could be used to provide the most appropriate standards of care possible under the circumstances; examples of tools and resources available to help states and communities in their planning processes; and illustrative examples of how some health systems, communities, or states have approached

certain issues as part of their MCE-related planning efforts. Building on the work from 2008, the Institute of Medicine (IOM) released in 2012 a guidance report entitled "The Crisis Standards of Care (CSC): A Systems Framework for Catastrophic Disaster Response" available at: http://www.iom.edu/Reports/2012/Crisis-Standards-of-Care-A-Systems-Framework-for-Catastrophic-Disaster-Response.aspx . The guidance report expanding upon prior scarce resources reports and defined crisis standards of care as "the optimal level of health care that can be delivered during a catastrophic event, requiring a substantial change in usual health care operations." The report stated that CSC; provides a mechanism for responding to situations in which the demand on needed resources far exceeds the resource availability (that is, scarce resources); implementation of CSC involves a substantial shift in normal health care activities and reallocation of staff, facilities, and resources; and that to transition quickly and effectively, each organization and agency has a responsibility to plan and identify in advance the core functions it must carry out in a crisis and who will be responsible for each task.

Another resource that would be useful in helping planners address the issues associated with preparing for and responding to an MCE in the context of broader emergency planning processes is the document entitled, "Standing Together: An Emergency Planning Guide for America's Communities" (published by The Joint Commission (TJC), formerly known as the Joint Commission on the Accreditation of Healthcare Organizations, 2006). The document by TJC is a comprehensive resource that offers step-by-step guidance for development of an emergency preparedness plan that is applicable to small, rural, and suburban communities. This document can be found at:

http://www.jointcommission.org/Standing_Together__An_Emergency_Planning_Guide_for_Am

ericas_Communities/. This document may be particularly useful for small or rural facilities and agencies.

Rural communities face challenges in the delivery of health care that are often very different from those faced by urban and suburban communities. While rural communities depend on public health departments, hospitals, and emergency medical services (EMS) providers just as urban and suburban communities do, rural communities tend to have fewer health care resources overall. A report entitled, "Rural Communities and Emergency Preparedness," (published by the Health Resources and Services Administration's (HRSA) Office of Rural Health Policy, April 2002, found at: ftp://ftp.hrsa.gov/ruralhealth/RuralPreparedness.pdf) addresses the issues faced by rural communities with respect to emergency preparedness.

The authors report that there are many factors that limit the ability of rural providers and suppliers to deliver optimal health care services in the event of a natural or man-made disaster. The authors found that geographic isolation is a significant barrier to providing a coordinated emergency response. Rural areas are also more affected by variations in weather conditions and by seasonal variations in populations (for instance, tourism). As reported by the authors, these areas have fewer human and technical resources (that is, health care professionals, medical equipment, and communication systems).

For example, the study found that in 2002, only 20 percent of the 3,000 local public health departments in the United States had developed a plan to deal with a bioterrorism event. The researchers also found that the majority of rural public health agencies are closed evenings and weekends, and are not equipped to respond to an emergency situation on a 24-hour basis. While these factors may not affect a rural hospital directly, as an integral part of the larger

system of health care delivery for its community, a hospital must be ready to manage the surge of persons who would seek care at the hospital during and after a disaster when many smaller health care entities may be non-operational.

b. Risk Assessment

To ensure that all hospitals operate as part of a coordinated emergency preparedness system, as outlined in the PPD-8, NIMS, NRF, HSPD-21, and PAHPA/PAHPRA, we are proposing at § 482.15 that all hospitals establish and maintain an emergency preparedness plan that complies with both federal and state requirements. Additionally, we propose that a hospital would develop and maintain a comprehensive emergency preparedness program, utilizing an "all-hazards" approach. The emergency preparedness plan would have to be reviewed and updated at least annually.

In keeping with the focus of the emergency management field, we propose that prior to establishing an emergency preparedness plan, the hospital and all other providers would first perform a risk assessment based on utilizing an "all-hazards" approach. An all-hazards approach is an integrated approach to emergency preparedness planning. In the abstract of a November 2007 paper entitled, "Universal Design: The All-Hazards Approach to Vulnerable Populations Planning" by Charles K.T. Ishikawa, MSPH, Garrett W. Simonsen, MSPS, Barbara Ceconi, MSW, and Kurt Kuss, MSW, the researchers described an all-hazards planning approach as "a more efficient and effective way to prepare for emergencies. Rather than managing planning initiatives for a multitude of threat scenarios, all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters." Thus, all-hazards planning does not specifically address every

possible threat but ensures that hospitals and all other providers will have the capacity to address a broad range of related emergencies.

It is imperative that hospitals perform all-hazards risk assessment consistent with the concepts outlined in the National Preparedness Guidelines, the "Guidelines" published by the U.S. Department of Homeland Security that we described in section I.A.3 of this proposed rule. Additional guidance and resources for assistance with designing and performing a hazard vulnerability assessment include: the Comprehensive Preparedness Guide 201: Threat and Hazard Identification and Risk Assessment Guide (available at: http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5823), the Use of Threat and Hazard Identification and Risk Assessment for Preparedness Grants (available at: http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5826), the Preparedness Guide 201 Supplement 1: Threat and Hazard Identification and Risk Assessment Guide Toolkit (available at: http://www.fema.gov/library/viewRecord.do?fromSearch=fromsearch&id=5825), the Hazard Risk Assessment Instrument Workbook (available at: http://www.cphd.ucla.edu/hrai.html) and the Understanding Your Risks: Identifying Hazards and Estimating Losses document (available at: http://www.fema.gov/library/viewRecord.do?id=1880).

Additionally, AHRQ published two additional guides to help hospital planners and administrators make important decisions about how to protect patients and health care workers and assess the physical components of a hospital when a natural or manmade disaster, terrorist attack, or other catastrophic event threatens the soundness of a facility. The guides examine how hospital personnel have coped under emergency situations in the past to better understand what

factors should be considered when making evacuation, shelter-in-place, and reoccupation decisions.

The guides entitled, "Hospital Evacuation Decision Guide" and "Hospital Assessment and Recovery Guide" are intended to supplement hospital emergency plans, augment guidance on determining how long a decision to evacuate may be safely deferred, and provide guidance on how to organize an initial assessment of a hospital to determine when it is safe to return after an evacuation.

The evacuation guide distinguishes between "pre-event evacuations" which are undertaken in advance of an impending disaster, such as a storm, when the hospital structure and surrounding environment are not yet significantly compromised and "post-event evacuations," which are carried out after a disaster has damaged a hospital or the surrounding community. It draws upon past events including: the Northridge, CA, earthquake of 1994; the Three Mile Island nuclear reactor incident of 1979; and Hurricanes Katrina and Rita in 2005. The guide offers advice regarding sequence of patient evacuation and factors to consider when a threat looms.

The assessment and recovery guide helps hospitals determine when to get back into a hospital after an evacuation. Comprised primarily of a 45-page checklist, the guide covers 11 separate areas of hospital infrastructure that should be evaluated before determining that it is safe to reoccupy a facility, such as security and fire safety, information technology and communication and biomedical engineering.

The "Hospital Evacuation Decision Guide" can be found at: http://archive.ahrq.gov/prep/hospevacguide/) (AHRQ Publication No.10-0009), and the "Hospital Assessment and Recovery Guide" can be found at (found at: http://archive.ahrq.gov/prep/hosprecovery/) (AHRQ Publication No. 10-0081).

Based on the guidance and information in these resources, we would expect a hospital's risk assessment, which we would require at § 482.15(a)(1), to be based on and include a documented, facility-based and community-based risk assessment, utilizing an all hazards approach. In order to meet this requirement, we would expect hospitals to consider, among other things, the following--(1) identification of all business functions essential to the hospitals operations that should be continued during an emergency; (2) identification of all risks or emergencies that the hospital may reasonably expect to confront; (3) identification of all contingencies for which the hospital should plan; (4) consideration of the hospital's location, including all locations where the hospital delivers patient care or services or has business operations; (5) assessment of the extent to which natural or man-made emergencies may cause the hospital to cease or limit operations; and (6) determination of whether arrangements with other hospitals, other health care providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency.

We propose at § 482.15(a)(2) that the emergency plan include strategies for addressing emergency events identified by the risk assessment. For example, a hospital in a large metropolitan city may plan to utilize the support of other large community hospitals as alternate placement sites for its patients if the hospital needs to be evacuated. However, we would expect the hospital to have back-up evacuation plans for circumstances in which nearby hospitals also were affected by the emergency and were unable to receive patients. We would expect these plans to include consideration for how the hospital would work in collaboration with hospitals and other providers and suppliers across state lines, if applicable. Individuals who live near the border with an adjoining state could use the services of a hospital located in the adjoining state if the hospital was closer or provided more services than the nearest hospital in the state in which

the individual resides. Therefore, we would encourage hospitals in adjoining states to work together to formulate plans to provide services across state lines in the event of a natural or man-made disaster to ensure continuity of care during a disaster.

c. Patient Population and Available Services

At § 482.15(a)(3), we propose that a hospital's emergency plan address its patient population, including, but not limited to, persons at-risk. As defined by the PAHPA, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision, and medical care. In addition to those individuals specifically recognized as at-risk in the statute (children, senior citizens, and pregnant women), we are proposing to define "at-risk populations" as individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. Also, as discussed in "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide," (http://archive.ahrq.gov/research/mce/), at-risk populations would include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities, and infants, and children. Hospitals may find this resource helpful in establishing emergency plans that address the needs of such patients.

We also propose at § 482.15(a)(3) that a hospital's emergency plan address the types of services that the hospital would be able to provide in an emergency. The hospital should base these determinations on factors such as the number of staffed beds, whether the hospital has an emergency department or trauma center, availability of staffing and medical supplies, the

hospital's location, and its ability to collaborate with other community resources during an emergency.

d. Succession Planning and Cooperative Efforts

In regard to emergency preparedness planning, we are also proposing at § 482.15(a)(3) that all hospitals include delegations and succession planning in their emergency plan to ensure that the lines of authority during an emergency are clear and that the plan is implemented promptly and appropriately.

Finally, at § 482.15(a)(4), we propose that a hospital have a process for ensuring cooperation and collaboration with local, tribal, regional, state, or federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. We believe that planning with officials in advance of an emergency to determine how such collaborative and cooperative efforts will be achieved will foster a smoother, more effective, and more efficient response in the event of a disaster.

While we are aware that the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the hospital would need to document its efforts to contact these officials and inform them of the hospital's participation in the coordinated emergency response. Although we propose to require the same efforts for all providers and suppliers as we propose for hospitals, we realize that federal, state, and local officials may not elect to collaborate with some providers and suppliers due to their size and role in the community. For example, a RNHCI, by the limited nature of its service within the community, may not be called upon to participate in such collaborative and

cooperative planning efforts. In this instance, we are proposing that such a provider or supplier would only need to provide documentation of its efforts to contact such officials and, when applicable, its participation.

Through the work of its state partners, the ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including building healthcare coalitions, planning for all hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. Many more community healthcare facilities have equipment to protect healthcare workers and decontaminate patients in chemical, biological, radiological, or nuclear emergencies.

While the HPP program continues to encourage preparedness at the hospital level, evidence and real-world events have illustrated that hospitals cannot be successful in response without robust community healthcare coalition preparedness--engaging critical partners. Critical partners include emergency management, public health, mental/behavioral health providers, as well as community and faith-based partners. Together these partners make up a community's Healthcare Coalition (HCC). A key goal of HPP moving forward is to strengthen the capabilities of the HCC, not just the individual hospital. HCCs are a cornerstone for the HPP and an integral component for community-wide planning for healthcare resiliency.

We are aware that, among some emergency management leaders, healthcare coalitions are viewed as a valued and essential component of a coordinated system of response and that many providers now participate in such coalitions. While we are not requiring that providers participate in coalitions, we do recognize and support their value in the well-coordinated emergency response system and encourage providers of all types and sizes to engage in such

collaborations, where possible, to ensure better coordination in planning, including the assessment of risk, surrounding an emergency event. The primary goal of health care coalitions is to foster collaboration amongst provider types in order to strengthen the overall health system by leveraging expertise, sharing resources, and increasing capacity to respond; thus reducing potential administrative burden for emergency preparedness, while similarly enabling easier emergency response integration and coordination during an emergency. Healthcare coalition activities provide, at a minimum, an optimal forum for: leveraging leadership and operational expertise (health, public health, emergency management, public works, public safety, etc.) within a community; conducting mutual hazard vulnerability/risk assessments to identify community health gaps and develop plans and strategies to address them; developing standardized tools, emergency plans, processes and protocols, training and exercises to support the community and support ease of integration; and facilitating timely and/or shared resource management and coordination of communications and information during an emergency

2. Policies and Procedures

We are proposing at § 482.15(b) that a hospital be required to develop and implement emergency preparedness policies and procedures based on the emergency plan proposed at § 482.15(a), the risk assessment proposed at § 482.15(a)(1), and the communication plan proposed at § 482.15(c). These policies and procedures would be reviewed and updated at least annually. We are soliciting public comment on the timing of the updates.

We propose at § 482.15(b)(1) that a hospital's policies and procedures would have to address the provision of subsistence needs for staff and patients, whether they evacuated or sheltered in place, including, but not limited to, at (b)(1)(i), food, water, and medical supplies. Analysis of the disaster caused by the hurricanes in the Gulf states in 2005 revealed that hospitals

were forced to meet basic subsistence needs for community evacuees, including visitors and volunteers who sheltered in place, resulting in the rapid depletion of subsistence items and considerable difficulty in meeting the subsistence needs of patients and staff. Therefore, we are proposing that a hospital's policies and procedures also address how the subsistence needs of patients and staff who were evacuated would be met during an emergency. For example, a hospital might arrange for storage of supplies outside the facility, have contracts with suppliers for the acquisition of supplies during an emergency, or address subsistence needs for evacuees in an agreement with a facility that was willing to accept the hospital's patients during an emergency.

Based on our experience with hospitals, most hospitals do maintain subsistence supplies in the event of an emergency. Thus, we believe it would be overly prescriptive to require hospitals to maintain a defined quantity of subsistence needs for a defined period of time. We believe hospitals and other inpatient providers should have the flexibility to determine what is adequate based on the location and individual characteristics of the facility. Although we propose requiring only that each hospital addresses subsistence needs for staff and patients, we recommend that hospitals keep in mind that volunteers, visitors, and individuals from the community may arrive at the hospital to offer assistance or seek shelter and consider whether the hospital needs to maintain a store of extra provisions. We are soliciting public comment on this proposed requirement.

As stated earlier, we also have learned from attendance in the Hurricane Katrina Sharing Information During Emergencies (SIDE) conference held in July of 2006, and from on-going participation in the CMS Survey & Certification (S&C) Emergency Preparedness Stakeholder Communication Forum, that many facilities placed back-up generators in basements that

subsequently became inoperable due to water damage. In turn, this led to possible unsafe conditions for their patients and other persons sheltered in the facility. We note that existing regulations at §482.41 require hospitals to have emergency power and lighting in certain areas (operating, recovery, intensive care, emergency rooms, and stairwells). Emergency lighting only in these areas will not assist staff if there is a requirement to continue operations for long periods of time with no power (for example, in the wards). Power outages lasted several days after Hurricane Sandy in some areas of the northeast. Similarly, should a large-scale evacuation be required, a lack of emergency lighting in general areas of the hospital such as wards and corridors would greatly hinder this process. This was of particular concern in impacted healthcare facilities during Hurricane Sandy (Redlener I, Reilly M, Lessons from Sandy—Preparing Health Systems for Future Disasters. N ENGL J MED. 367;24:2269-2271.) Thus, as previously stated, at § 482.15(b)(1)(ii) we also propose that the hospital have policies and procedures that address the provision of alternate sources of energy to maintain: (1) temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (2) emergency lighting; (3) fire detection, extinguishing, and alarm systems. We are also proposing at § 482.15(b)(1)(ii)(D) that the hospital develop policies and procedures to address provision of sewage and waste disposal. We are proposing to define the term "waste" as including all wastes including solid waste, recyclables, chemical, biomedical waste and wastewater, including sewage. These proposed requirements concern assuring the continuity of the power source for the fire detection, extinguishing and alarm systems and are an essential prerequisite for successful implementation of existing requirements during emergencies that result in loss of regular power. These proposed requirements are more in line with best practice rather than mere sufficiency.

We are proposing at § 482.15(b)(2) that the hospital develop policies and procedures regarding a system to track the location of staff and patients in the hospital's care both during and after an emergency. We believe it is imperative that the hospital be able to track a patient's whereabouts, to ensure adequate sharing of patient information with other providers and to inform a patient's relatives and friends of the patient's location within the hospital, whether the patient has been transferred to another facility, or what is planned in respect to such actions. Therefore, we believe that hospitals must develop a means to track patients, which would include evacuees in the hospital's care during and after an emergency event. ASPR has developed tools, programs and resources to facilitate disaster preparedness planning at the local healthcare facility-level. One of these tools, The Joint Patient Assessment and Tracking System (JPATS), was developed through an interagency association between HHS/ASPR and DoD, and is available for providers at: https://asprwebapps.hhs.gov/jpats/protected/home.do

Use of the JPATS is referenced in Health Preparedness Capabilities: National Guidance for Health System Preparedness (2012). This document provides guidance for healthcare systems, healthcare coalitions and healthcare organizations emergency preparedness efforts that is intended to serve as a planning resource. Broad guidance as to the requirement for bed and patient tracking is included.

Given the lessons learned, this requirement is being proposed for providers and suppliers who provide ongoing care to inpatients or outpatients. Such providers and suppliers would include RNHCIs, hospices, PRTFs, PACE organizations, LTC facilities, ICFs/IID, HHAs, CAHs, and ESRD facilities. Despite providing services on an outpatient basis, we would require hospices, HHAs, and ESRD facilities to assume this responsibility. These providers and suppliers maintain current patient census information and would be required to provide

continuing patient care during the emergency. In addition, we would require ASCs to maintain responsibility for their staff and patients if patients were in the facility. Other outpatient providers, such as CORFs, FQHCs and clinics maintain patient information but they have the flexibility of cancelling appointments during an emergency thereby not needing to assume responsibility of the patients.

This requirement is not being proposed for transplant centers; CORFs; OPOs; clinics, rehabilitation agencies as providers of outpatient physical therapy and speech-language pathology services; and RHCs/FQHCs. Transplant centers' patients and OPOs' potential donors would be in hospitals, and, thus, would be the hospital's responsibility. We believe it is likely that outpatient providers and suppliers would close their facilities prior to or immediately after an emergency, sending staff and patients home.

We are not proposing a requirement for a specific type of tracking system. A hospital would have the flexibility to determine how best to track patients and staff, whether it used an electronic database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response system as needed in the interest of the patient. A number of states already have such tracking systems in place or under development and the systems are available for use by health care providers and suppliers. Lessons learned from the hurricanes in the Gulf States revealed that some facilities, despite having patient-related information backed up to computer databases within or outside of the state in which the disaster occurred, could not access the information in a timely manner. Therefore, we would recommend that a hospital using an electronic database consider backing up its computer system with a secondary source.

Although we believe that it is important that a hospital, and other providers of critical care, be able to track a patient's whereabouts to ensure adequate sharing of patient information with other providers and to inform a patient's relatives of the patient's location after a disaster, we are specifically soliciting comments on the feasibility of this requirement for any outpatient facilities.

We propose at § 482.15(b)(3) that hospitals have policies and procedures in place to ensure the safe evacuation from the hospital, which would include standards addressing consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

We propose at § 482.15(b)(4) that a hospital must have policies and procedures to address a means to shelter in place for patients, staff, and volunteers who remain in the facility. We expect that hospitals would include in their policies and procedures both the criteria for selecting patients and staff that would be sheltered in place and a description of the means that they would use to ensure their safety.

During the Gulf Coast hurricanes, some hospitals were able to shelter their patients and staff in place. However, the physical structures of many other hospitals were so damaged that sheltering in place was impossible. Thus, when developing policies and procedures for sheltering in place, hospitals should consider the ability of their building(s) to survive a disaster and what proactive steps they could take prior to an emergency to facilitate sheltering in place or transferring of patients to alternate settings if their facilities were affected by the emergency.

We propose at § 482.15(b)(5) that a hospital have policies and procedures that would require a system of medical documentation that would preserve patient information, protect the

confidentiality of patient information, and ensure that patient records were secure and readily available during an emergency. In addition to the current hospital requirements for medical records located at § 482.24(b), we are proposing that hospitals be required to ensure that patient records are secure and readily available during an emergency.

Such policies and procedures would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Regulations at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information. Information on how HIPAA requirements can be met for purposes of emergency preparedness and response can be found at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/index.html. The tornadoes that occurred in Joplin, Missouri in 2011, presented an example of the value of electronic health records during a disaster. There were primary care clinics and other providers that had electronic health records and because their records were not destroyed, they were able to find new locations, contact their patients and re-establish operations very quickly.

We propose at § 482.15(b)(6) that facilities would have to have policies and procedures in place to address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

Facilities may find it helpful to utilize assistance from the Medical Reserve Corps (MRC), a national network of community-based volunteer units that focus on improving the health, safety and resiliency of their local communities. MRC units organize and utilize public health, medical and other volunteers to support existing local agencies with public health activities throughout the year and with preparedness and response activities for times of need.

One goal of the MRC is to ensure that members are identified, screened, trained and prepared prior to their participation in any activity. While MRC units are principally focused on their local communities, they have the potential to provide assistance in a statewide or national disaster as well.

Hospitals could use the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), found in section 107 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188), to verify the credentials of volunteer health care workers. The ESAR-VHP is a federal program to establish and implement guidelines and standards for the registration, credentialing, and deployment of medical professionals in the event of a large-scale national emergency. The program is administered by ASPR within the Department. All states must participate in ESAR-VHP.

The purpose of the program is to facilitate the use of volunteers at all tiers of response (local, regional, state, interstate, and federal). The ESAR-VHP program has been working to establish a national network of state-based programs that manage the information needed to effectively use health professional volunteers in an emergency. These state-based systems will provide up-to-date information regarding the volunteer's identity and credentials to hospitals and other health care facilities in need of the volunteer's services. Each state's ESAR-VHP system is built to standards that will allow quick and easy exchange of health professionals with other states. We propose at § 482.15(b)(7) that hospitals would have to have a process for the development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations at their facilities, to ensure the continuity of services to hospital patients.

We believe this requirement should apply only to providers and suppliers that provide continuous care and services for individual patients. Thus, we are not proposing this requirement for transplant centers; CORFs; OPOs; clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services; and RHCs/FQHCs.

We also propose at § 482.15(b)(8) that hospital policies and procedures would have to address the role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, for the provision of care and treatment at an alternate care site (ACS) identified by emergency management officials. We propose this requirement for inpatient providers only. We would expect that state or local emergency management officials might designate such alternate sites, and would plan jointly with local providers on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted. Under section 1135 of the Act, the Secretary is authorized to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements for health care providers to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in an emergency area (or portion of such an area) during any portion of an emergency period. Under an 1135 waiver, health care providers unable to comply with one or more waiver-eligible requirements may be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). Requirements to which an 1135 waiver may apply include Medicare conditions of participation or conditions for coverage and requirements under the Emergency Medical

Treatment and Labor Act (EMTALA). The 1135 waiver authority applies only to specific federal requirements and does not apply to any state requirements, including licensure.

In determining whether to invoke an 1135 waiver (once the conditions precedent to the authority's exercise have been met), the ASPR with input from relevant HHS operating divisions (OPDIVs) determines the need and scope for such modifications, considers information such as requests from Governor's offices, feedback from individual healthcare providers and associations, and requests from regional or field offices for assistance. Additional information regarding the 1135 waiver process is provided in the CMS Survey and Certification document entitled, "Requesting an 1135 Waiver", and located at: http://www.cms.gov/About-CMS/Agency-Information/H1N1/downloads/requestingawaiver101.pdf.

Providers must resume compliance with normal rules and regulations as soon as they are able to do so. Waivers or modifications permitted under an 1135 waiver are no longer available after the termination of the emergency period. Generally, federally certified or approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

When a waiver has been issued under section 1135(b)(3) of the Act, EMTALA sanctions do not apply to a hospital with a dedicated emergency department, providing the conditions at §489.24(a)(2)(i) are met. The EMTALA part of the 1135 waiver only applies for a 72-hour period, unless the emergency involves a pandemic infectious disease situation (see 42 CFR 489.24(a)(2)(ii)). Further information on the 1135 waiver process can be found at: http://www.cms.hhs.gov/H1N1/.

Once an 1135 waiver is authorized, health care providers and suppliers can submit requests to operate under that authority to the CMS Regional Office, with a copy to the State

Survey Agency. The Regional Office or State Survey Agency may also be able to help providers and suppliers identify other relief that may be possible and which does not require an 1135 waiver.

This proposed requirement would be consistent with the ASPR's expectation that hospital grant awardees will continue to develop and improve their `` (ACS) plans and concept of operations for providing supplemental surge capacity within the health care system in their state. Further discussion of ASPR's expectation for ACSs can be found in the annual grant guidance on the web at: http://www.phe.gov/Preparedness/planning/hpp/Pages/funding.aspx.

With respect to states, ASPR stresses that effective planning and implementation would depend on close collaboration among state and local health departments (for example, state public health agencies, state Medicaid agencies, and state survey agencies), provider associations, community partners, and neighboring and regional health-care facilities. ASPR recommends that using existing buildings and infrastructure as ACSs would be the most practical solution if a surge medical care facility were needed. When identifying sites, states should consider how ACSs will interface with other state and federal assets. Federal assets may require what ASPR describes as an "environment of opportunity" for set up and operation and might not be available for as long as 72 hours. Therefore, ASPR believes it is critical that healthcare facilities, public health systems and emergency management agencies work with other emergency response partners when choosing a facility to use as an ACS. Many of the partners (for example, the American Red Cross) may have already identified sites that would be used during an event.

While our discussion is geared toward the state level response, we expect that hospitals would operationalize these efforts by working closely with the federal, state, tribal, regional, and

local communities. According to AHRQ's "Providing Mass Medical Care with Scarce Resources: A Community Planning Guide," the impact of an MCE of any significant magnitude will likely overwhelm hospitals and other traditional venues for health care services. AHRQ believes an MCE may render such venues inoperable, necessitating the establishment of ACSs for the provision of care that normally would be provided in an inpatient facility. According to AHRQ, advance planning is critical to the establishment and operation of ACSs; this planning must be coordinated with existing health care facilities, as well as home care entities. Planners must delineate the specific medical functions and treatment objectives of the ACS. Finally, AHRQ asserts that the principle of managing patients under relatively austere conditions, with limited supplies, equipment, and access to pharmaceuticals and a minimal staffing arrangement, is the starting point for ACS planning.

Further discussion of the issues and challenges of establishing and operating ACSs during an MCE, as well as specific case study examples of ACSs in operation during the response to Hurricane Katrina, can be found in Chapter VI of the AHRQ publication. The chapter discusses issues surrounding non-federal, non-hospital-based ACSs. It describes different types of ACSs, including critical issues and decisions that will need to be made regarding these sites during an MCE; addresses potential barriers; and includes examples of case studies.

Subsequently, on October 1, 2009, AHRQ released two Disaster Alternate Care Facility Selection Tools, entitled the "Disaster Alternate Care Facility Selection Tool" and the "Alternate Care Facility Patient Selection Tool to help emergency planners and responders select and run alternate care facilities during disaster situations. These two tools can be found at: http://archive.ahrq.gov/prep/acfselection/pselectmatrix/(S(fidfow2u5az1o155srb0h1nb))/default.aspx and at:

http://archive.ahrq.gov/prep/acfselection/acftool/(S(o53i55e3v452tl550uxvm055))/default.aspx. Under contract to AHRQ, Denver Health developed these new tools for AHRQ as an update to a previous alternate care site selection tool, entitled the Rocky Mountain Regional Care Model for Bioterrorist Events, which it developed in 2004 and can be found at: http://archive.ahrq.gov/research/altsites.htm#down. AHRQ led development of the tools with funding from the ASPR National Hospital Preparedness Program (HPP), formerly the HRSA Bioterrorism Hospital Preparedness Program.

3. Communication Plan

For a hospital to operate effectively in an emergency situation, we propose at § 482.15(c) that the hospital be required to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. The hospital would be required to review and update the communication plan at least annually.

As part of its communication plan, the hospital would be required at § 482.15(c)(1) to include in its plan, names and contact information for staff; entities providing services under arrangement; patients' physicians; other hospitals; and volunteers. During an emergency, it is critical that hospitals have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner. We propose at § 482.15(c)(2) requiring hospitals to have contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance. Patient care must be well-coordinated within the hospital, 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. Again, we support hospitals and other

providers engaging in coalitions in their area for assistance in effectively meeting this requirement.

We propose to require at § 482.15(c)(3) that hospitals have primary and alternate means for communicating with the hospital's staff and federal, state, tribal, regional, or local emergency management agencies, because in an emergency, a hospital's landline telephone system may not be operable. While we do not propose specifying the type of alternate communication system that hospitals must have, we would expect that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. In areas where available, satellite telephone communication systems may be useful as well.

We recognize that some hospitals, especially in remote areas, have difficulty using some current communication systems, such as cellular phones, even in non-emergency situations. We would expect these hospitals to address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency.

The National Communication System (NCS) offers a wide range of National Security and Emergency Preparedness (NS-EP) communications services that support qualifying federal, state, local, and tribal governments, industry, and non-profit organizations in the performance of their missions during emergencies. Hospitals may seek further information on the NCS' programs for Government Emergency Telecommunications Services (GETS), Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and Shared Resources (SHARES) High Frequency Radio Program at: www.ncs.gov. (Click on "services").

Under this proposed rule, we would also require at § 482.15(c)(4) that hospitals have a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to ensure continuity of care. Sharing of patient information and documentation was found to be a significant problem during the 2005 hurricanes and flooding in the Gulf Coast States. In some hospitals, patient care information in hard copy and electronic format was destroyed by flooding while, in others, patient information that was backed up to alternate sites was not always readily available. As a result, some patients were discharged or evacuated from facilities without adequate accompanying medical documentation of their conditions for other providers and suppliers to utilize. Other patients who sheltered in place were also left without proper medical documentation of their care while in the hospital.

We would expect hospitals to have a system of communication that would ensure that comprehensive patient care information would be disseminated across providers and suppliers in a timely manner, as needed. Such a system would ensure that information was sent with an evacuated patient to the next care provider or supplier, information would be readily available for patients being sheltered in place, and electronic information would be backed up both within and outside the geographic area where the hospital was located.

Health care providers, who were in attendance during the Emergency Preparedness Summit in New Orleans, Louisiana in March 2007, discussed the possibility of storing patient care information on flash drives, thumb devices, compact discs, or other portable devices that a patient could carry on his or her person for ready accessibility. We would expect hospitals to consider the range of options that are available to them, but we are not proposing that certain specific devices would be required because of the associated burden and the potential obsolescence of such devices.

We propose at § 482.15(c)(5) that hospitals have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 of the HIPAA Privacy Regulations. Thus, hospitals would need to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted, to family members and others. Section 164.510 "Uses and disclosures requiring an opportunity for the individual to agree to or to object," is part of the "Standards for Privacy of Individually Identifiable Health Information," commonly known as "The Privacy Rule."

This proposed requirement would not be applied to transplant centers; CORFs; OPOs; clinics rehabilitation agencies and public health agencies as providers of outpatient physical therapy and speech-language pathology services; or RHCs/FQHCs. We believe this requirement would best be applied only to providers and suppliers who provide continuous care to patients, as well as to those providers and suppliers that have responsibilities and oversight for care of patients who are homebound or receiving services at home.

We propose at § 482.15(c)(6) requiring hospitals to have a means of providing information about the general condition and location of patients under the facility's care, as permitted under 45 CFR 164.510(b)(4) of the HIPAA Privacy Regulations. Section 164.510(b)(4), "Use and disclosures for disaster relief purposes," establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient's location or general condition. We are not proposing prescriptive requirements for how a hospital would comply with this requirement. Instead, we would allow hospitals the flexibility to develop and maintain their own system.

We propose at § 482.15(c)(7) that a hospital have a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. We support hospitals and other providers engaging in coalitions in their area for assistance in effectively meeting this requirement.

4. Training and Testing

We propose at § 482.15(d) that a hospital develop and maintain an emergency preparedness training and testing program. We would require the hospital to review and update the training and testing program at least annually.

We believe a well organized, effective training program must include providing initial training in emergency preparedness policies and procedures. Therefore, we propose at § 482.15(d)(1) that hospitals provide such training to all new and existing staff, including any individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of such training. We propose that the hospital ensure that staff can demonstrate knowledge of emergency procedures, and that the hospital provides this training at least annually.

While some large hospitals may have staff that could provide such training, smaller and rural hospitals may need to find resources outside of the hospital to provide such training. Many state and local governments can provide emergency preparedness training upon request. Thus, small hospitals and rural hospitals may find it helpful to utilize the resources of their state and local governments in meeting this requirement. Again, we support hospitals and other providers participating in coalitions in their area for assistance in effectively meeting this requirement. Conducting exercises at the healthcare coalition level could help to reduce the administrative

burden on individual healthcare facilities and demonstrate the value of connecting into the broader medical response community during disaster planning and response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities. Regional planning coalitions (multistate coalitions) meet and provide exercises on a regular basis to test protocols for state-to-state mutual aid. The members of the coalitions are often able to test command and control procedures and processes for sharing of assets that promote medical surge capacity.

Regarding testing, at § 482.15(d)(2), we would require hospitals to conduct drills and exercises to test the emergency plan. We propose at § 482.15(d)(2)(i) requiring hospitals to participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, we would require the hospital to conduct an individual, facility-based mock disaster drill at least annually. However, we propose at § 482.15(d)(2)(ii) that if a hospital experienced an actual natural or man-made emergency that required activation of the emergency plan, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the actual event.

We propose at § 482.15(d)(2)(iii) requiring a hospital to conduct a paper-based, tabletop exercise at least annually. The tabletop exercise could be based on the same or a different disaster scenario from the scenario used in the mock disaster drill or the actual emergency. In the proposed regulations text, we would define a tabletop exercise as a "group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan."

Comprehensive emergency preparedness includes anticipating and adequately addressing the various natural and man-made disasters that could impact a given facility. We expect that

hospitals would conduct both mock disaster drills and tabletop exercises, using various emergency scenarios, based on their risk analyses.

Generally, in a mock disaster drill, a hospital must consider how it will move persons within and outside of the building to designated "safe zones" to ensure the safety of both ambulatory patients and those who are wheelchair users, have mobility impairments or have other special needs. Moving patients or mock patients to "safe zones" in and outside of buildings during fire drills and other mock disaster drills is common industry practice. However, if it is not feasible to evacuate patients, hospitals could meet this requirement by moving its special needs patients to "safe zones" such as a foyer or other areas as designated by the hospital. To assist hospitals, other providers, and suppliers in conducting table-top exercises, we sought additional resources to further define the actions involved in a paper-based, tabletop exercise. One hospital system representative described a tabletop exercise as one where the staff conducts, on paper, a simulated public health emergency that would impact the hospital and surrounding health care facilities. For this hospital, the tabletop exercise is a half-day event for representatives of every critical response area in the hospital. It is designed to test the effectiveness of the response plan in guiding the leadership team's efforts to coordinate the response to an emergency event.

The hospital representative further explained that the exercise consists of a group discussion led by a facilitator, using a narrated, clinically-relevant scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. Exercise facilitators introduce the scenario, keep the exercise on schedule, and inject timed challenges to stress specific disaster response systems. Following the tabletop exercise, a

debriefing for hospital staff is held, and then the hospital staff provides written feedback and planning improvement suggestions to the hospital administration.

Some hospitals may be well-versed in performing mock drills and tabletop exercises. Other providers and suppliers, especially those that are small or remote, may not have any knowledge or hands-on experience in conducting such exercises. To this end, the Bureau of Communicable Disease in the New York City Department of Health and Mental Hygiene has produced a very detailed document entitled, "Bioevent Tabletop Exercise Toolkit for Hospitals and Primary Care Centers," (September 2005, found at: http://www.nyc.gov/html/doh/downloads/pdf/bhpp/bhpp-train-hospital-toolkit-01.pdf), which may help hospitals and other providers and suppliers that have limited or no emergency preparedness training experience. This document is designed to walk a facility through the process of performing a tabletop exercise and after-event analysis. The toolkit consists of things to consider before engaging in a tabletop exercise, the process of planning the exercise, running the exercise, evaluating the exercise and its impact, and public health emergency scenarios for tabletop exercises, including the plague, Sever Acute Respiratory Syndrome (SARS), anthrax, smallpox, and pandemic flu.

There are also other training resources that may prove useful for hospitals and other providers and suppliers to comply with as they attempt to meet this proposed emergency preparedness requirement. In 2005, the RAND Corporation produced a technical report for ASPR entitled, "Bioterrorism Preparedness Training and Assessment Exercises for Local Public Health Agencies," by Dausey, D. J., Lurie, N., Alexis, D., Meade, B., Molander, R. C., Ricci, K. A., Stoto, M. A., and Wasserman, J. (http://www.rand.org/pubs/technical_reports/2005/RAND_TR261.pdf).

The report was intended as a resource to train public health workers to detect and respond to bioterrorism events and to assess local public health agencies' (LPHAs) levels of preparedness over time. The exercises were beta tested and refined in 13 LPHAs across the United States over 10 months. However, the report would be a useful resource for hospitals and other healthcare facilities to train their own healthcare workers.

RAND also developed a 2006 technical report entitled, "Tabletop Exercise for Pandemic Influenza Preparedness in Local Public Health Agencies," by Dausey, D.J., Aledort, J. E., and Lurie, N. (http://www.rand.org/pubs/technical_reports/2006/RAND_TR319.pdf). The report was designed to provide state and local public health agencies and their healthcare and governmental partners with exercises in training, building relationships, and evaluation. These exercises were pilot-tested at three metropolitan-area local public health agencies in three separate states from August through November 2005.

Finally, the Centers for Medicare & Medicaid Services (CMS), Survey and Certification Group has developed a document entitled, the Health Care Provider After Action Report/Improvement Plan (AAR/IP) template with the assistance of the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response, the U.S. Department of Homeland Security (DHS), and the CMS Survey and Certification Emergency Preparedness Stakeholder Communication Forum. The template can be accessed at http://www.cms.gov/SurveyCertEmergPrep/03_HealthCareProviderGuidance.asp and then scrolling down to click on the download entitled, the "Health Care Provider Voluntary After Action Report/Improvement Plan Template and Instructions for Completion." The AAR/IP was intended to be a voluntary, user-friendly tool for health care providers to use to document their performance during emergency planning exercises and real emergency events to

make recommendations for improvements for future performance. We do not mandate use of this AAR/IP template; however thorough completion of the template complies with our requirements for provider exercise documentation.

The "Health Care Provider After Action Report/Improvement Plan" template also meets requirements for hospitals or other health care providers wishing to ensure their compliance with the Hospital Preparedness Program (HPP).

This AAR/IP template is based on the U.S. Department of Homeland and Security Exercise and Evaluation Program (HSEEP) Vol. III, issued in February 2007, which includes guidelines that are focused towards emergency management agencies and other governmental/non-governmental agencies. The HSEEP is a capabilities and performance-based exercise program that provides a standardized methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning. Health care providers may also use the AAR/IP to document real life emergency events and can customize or personalize the CMS "Health Care Provider AAR/IP" template to best meet their needs.

There are seven types of exercises defined within HSEEP, each of which is either discussions-based or operations-based.

Discussions-based exercises familiarize participants with current plans, policies, agreements and procedures, or may be used to develop new plans, policies, agreements, and procedures.

Types of discussion-based exercises include the following:

- Seminar: A seminar is an informal discussion, designed to orient participants to new or updated plans, policies, or procedures (for example, a seminar to review a new Evacuation Standard Operating Procedure).

- Workshop: A workshop resembles a seminar, but is employed to build specific products, such as a draft plan or policy (for example, a Training and Exercise Plan Workshop is used to develop a Multiyear Training and Exercise Plan).
- Tabletop Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures.
- Games: A game is a simulation of operations that often involves two or more teams, usually in a competitive environment, using rules, data, and procedure designed to depict an actual or assumed real-life situation.

Operations-based exercises validate plans, policies, agreements and procedures, clarify roles and responsibilities, and identify resource gaps in an operational environment. Types of operations-based exercises include the following:

- Drill: A drill is a coordinated, supervised activity usually employed to test a single, specific operation or function within a single entity (for example, a nursing home conducts an evacuation drill).
- Functional exercise (FE): A functional exercise examines or validates the coordination, command, and control between various multi-agency coordination centers (for example, emergency operation center, joint field office, etc.). A functional exercise does not involve any "boots on the ground" (that is, first responders or emergency officials responding to an incident in real time).
- Full-Scale Exercise (FSE): A full-scale exercise is a multi-agency, multi-jurisdictional, multi-discipline exercise involving functional (for example, joint field office, emergency operation centers, etc.) and "boots on the ground" response (for example,

firefighters decontaminating mock victims). We expect hospitals to engage in such tabletop exercises to the extent possible in their communities. For example, we would expect a large hospital in a major metropolitan area to perform a comprehensive exercise with coordination, if possible, across the public health system and local geographic area.

We propose at § 482.15(d)(2)(iv) that hospitals analyze their response to and maintain documentation on all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan as needed. Resources discussed previously can be used to guide hospitals in this process.

Finally, we propose at §482.15(e)(1)(i) that hospitals must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). We intend to require compliance with future LSC updates as may be adopted by CMS. The current LSC states that the hospital's alternate source of power (for example, generator) and all connected distribution systems and ancillary equipment, must be designed to ensure continuity of electrical power to designated areas and functions of a health care facility. Also, the LSC (NFPA 110) states that the rooms, shelters, or separate buildings housing the emergency power supply shall be located to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures.

In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the hospital anticipates it will require during an emergency. As a result of lessons learned from hurricane Sandy, we believe that this annual 4 hour test will more closely reflect

the actual conditions that would be experienced during a disaster of the magnitude of hurricane Sandy.

We have also proposed the same emergency and standby power requirements for CAHs and LTC facilities. As such, we request information on this proposal and in particular on how we might better estimate costs in light of the existing LSC and other state and federal requirements.

We have included a table of requirements based on the 5 standards in the regulation text for each of the 17 providers and suppliers. The table includes both additional requirements and exemptions. This table can be used to provide guidance to the facilities in planning their emergency preparedness program and disaster planning.

TABLE 1--EMERGENCY PREPAREDNESS REQUIREMENTS BY PROVIDER TYPE

Provider Type	Emergency Plan	Policies and Procedures	Communication Plan	Training and Testing	Additional Requirements
Inpatient Providers					
Hospital	*Develop a plan based on a risk assessment using an "all hazards" approach, which is an integrated approach focusing on capacities and capabilities critical to preparedness for a full spectrum of emergencies and disasters. The plan must be updated annually.	*Develop and implement policies and procedures based on the emergency plan and risk assessment, which must be reviewed and updated at least annually.	*Develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across health care providers and with state and local public health departments and emergency systems.	*Develop and maintain training and testing programs, including initial training in policies and procedures and demonstrate knowledge of emergency procedures and provide training at least annually. Conduct drills and exercises to test the emergency plan.	Generators--Develop policies and procedures that address the provision of alternate sources of energy to maintain: (1) temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (2) emergency lighting; (3) fire detection, extinguishing, and alarm systems.
Critical Access Hospital	*	*	*	*	Generators.
Long Term Care Facility	Must account for missing residents (existing requirement).	*	Share with resident/family/representative appropriate information from emergency plan (additional requirement).	*	Generators.
PRTF	*	*	*	*	

Provider Type	Emergency Plan	Policies and Procedures	Communication Plan	Training and Testing	Additional Requirements
ICF/IID	Must account for missing clients (existing requirement).	*	Share with client/family/representative appropriate information from emergency plan (additional requirement).	*	
RNHCI	*	*	*	No drills.	
Transplant Center	*	*	*	*	Maintain agreement with transplant center & OPO.
Outpatient Providers--Outpatient providers are not required to provide subsistence needs for staff and patients.					
Hospice	*	In home services—inform officials of patients in need of evacuation (additional requirement).	In home services--will not need to provide occupancy information.	*	
Ambulatory Surgical Center	*	*	Will not need to provide occupancy information.	*	
PACE	*	Inform officials of patients in need of evacuation (additional requirement).	Will not need to provide occupancy information.	*	
Home Health Agency	*	Will not require shelter in place, provision of care at alternate care sites. Inform officials of patients in need of evacuation (additional requirement).	Will not need to provide occupancy information.	*	

Provider Type	Emergency Plan	Policies and Procedures	Communication Plan	Training and Testing	Additional Requirements
CORF	Must develop emergency plan with assistance from fire, safety experts (existing requirement).	Will not need to provide transportation to evacuation locations, or have arrangements with other CORFs to receive patients.	Will not need to provide occupancy information.	Assign specific emergency preparedness tasks to new personnel. Provide instruction in location, use of alarm systems, signals & firefighting equip (existing requirements).	
CMHC	*	*	*	*	
OPO	Address type of hospitals OPO has agreement (additional requirement).	Needs to have system to track staff during & after emergency and maintain medical documentation (additional requirement).	Does not need to provide occupancy info, method of sharing pt. info, providing info on general condition & location of patients.	Only tabletop exercise	Must maintain agreement with other OPOs & hospitals.
Clinics, Rehabilitation, and Therapy	Must develop emergency plan with assistance from fire, safety experts. Address location, use of alarm systems and signals & methods of containing fire (existing requirements).	*	Does not need to provide occupancy information.	*	
RHC/FQHC	*	Appropriate placement of exit signs (existing requirement). Does not have to track patients, or have arrangements with other RHCs to receive patients or have alternate care sites	Does not need to provide occupancy information.	*	

Provider Type	Emergency Plan	Policies and Procedures	Communication Plan	Training and Testing	Additional Requirements
ESRD	Must contact local emergency preparedness agency annually to ensure dialysis facility's needs in an emergency (existing requirement).	Policies and procedures must include emergencies regarding fire equipment, power failures, care related emergencies, water supply interruption & natural disasters (existing requirement).	Does not need to provide occupancy information.	Ensure staff demonstrate knowledge of emergency procedures, informing patients what to do, where to go, whom to contact if emergency occurs while patient is not in facility (alternate emergency phone number), how to disconnect themselves from dialysis machine. Staff maintain current CPR certification, nursing staff trained in use of emergency equipment & emergency drugs, patient orientation (existing requirements).	

*Indicates that the requirements are the same as those proposed for hospitals.

B. Emergency Preparedness Regulations for Religious Nonmedical Health Care Institutions (RNHCIs) (§ 403.748)

Section 1861(ss)(1) of the Act defines the term "Religious Nonmedical Health Care Institution" (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation.

We have implemented these provisions in 42 CFR part 403, Subpart G, "Religious Nonmedical Health Care Institutions" Benefits, Conditions of Participation, and Payment." As of March 2012, there were 16 Medicare-certified RNHCIs that were subject to the RNHCI regulations and were receiving payment for services provided to Medicare or Medicaid patients.

A RNHCI is a facility that is operated under all applicable federal, state, and local laws and regulations, which furnishes only non-medical items and services on a 24-hour basis to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. The religious non-medical care or religious method of healing means care provided under the established religious tenets that prohibit conventional or unconventional medical care for the treatment of the patient and exclusive reliance on the religious activity to fulfill a patient's total health care needs.

Thus, Medicare would cover the nonmedical, non-religious health care items and services in a RNHCI for beneficiaries who would qualify for hospital or skilled nursing facility care but for whom medical care is inconsistent with their religious beliefs. Medicare does not cover the religious aspects of care. Nonmedical items and services are furnished to inpatients exclusively through nonmedical nursing personnel. Such Medicare coverage would include both nonmedical items that do not require a doctor's order or prescription (such as wound dressings or use of a

simple walker during a stay) and non-religious health care items and services (such as room and board).

The RNHCI does not furnish medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs or biologicals) to its patients. RNHCIs must not be owned by or under common ownership or affiliated with a provider of medical treatment or services.

This proposed rule would expand the current emergency preparedness requirements for RNHCIs, which are located within § 403.742, Condition of participation: Physical Environment, by requiring RNHCIs to meet the same proposed emergency preparedness requirements as we propose for hospitals, with several exceptions.

Our "Physical environment" CoP at § 403.742(a)(1) currently requires that the RNHCI provide emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems. Section 403.742(a)(4) requires that the RNHCI have a written disaster plan that addresses loss of water, sewage, power and other emergencies. Section 403.742(a)(5) requires that a RNHCI have facilities for emergency gas and water supply. We propose relocating the pertinent portions of the existing requirements at § 403.742(a)(1),(4),and (5) at proposed § 403.748(a) and § 403.748(b)(1). However, we believe these current requirements do not provide a sufficient framework for ensuring the health and safety of a RNHCI's patients in the event of a natural or man-made disaster.

Proposed § 403.748(a)(1) would require RNHCIs to consider loss of power, water, sewage and waste disposal in their risk analysis. The proposed policies and procedures at § 403.748(b)(1) would require that RNHCIs provide for subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, sewage and

waste disposal, non-medical supplies, alternate sources of energy for the provision of electrical power, the maintenance of temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions, gas, emergency lights, and fire detection, extinguishing, and alarm systems.

The proposed hospital requirement at § 482.15(a)(1) would be modified for RNHCIs. At proposed § 403.748(a)(1), unlike for other providers and suppliers whom we propose to have a community risk assessment that is based upon an all-hazards approach, including the loss of power, water, sewage and waste disposal. However, at proposed § 403.748(b)(1)(i) for RNHCIs, we have removed the terms "medical and nonmedical" to reflect typical RNHCI practice. RNHCIs do not provide most medical supplies. At § 482.15(b)(3), we would require hospitals to have policies and procedures for the safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. However, at § 403.748(b)(3), we propose to incorporate the hospital requirement but to remove the words "and treatment" from the hospital requirement, to more accurately reflect care provided in a RNHCI.

At proposed § 403.748(b)(5), we would remove the term "health" from the proposed hospital requirement for "health care documentation" to reflect the non-medical care provided by RNHCIs.

The proposed hospital requirements at § 482.15(b)(6) would require hospitals to have policies and procedures to address the use of volunteers in an emergency or other staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency. For RNHCIs, at proposed

§ 403.748(b)(6), we propose to use the hospital provision, but remove the language, "including the process and role for integration of state or federally designated health care professionals" since it is not within the religious framework of a RNHCI to integrate care issues for their patients with health care professionals outside of the RNHCI industry.

The proposed hospital requirements at § 482.15(b)(7) would require that hospitals develop arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients. For RNHCIs, at § 403.748(b)(7) we added the term "non-medical" to accommodate the uniqueness of the RNHCI non-medical care.

The proposed hospital requirement at § 482.15(c)(1) would require hospitals to include in their communication plan: names and contact information for: staff; entities providing services under agreement; patients' physicians; other hospitals; and volunteers. For RNHCIs, we propose substituting "next of kin, guardian or custodian" for "patients' physicians" because RNHCI patients do not have physicians.

Finally, unlike proposed regulations for hospitals at § 482.15(c)(4), at proposed § 403.748(c)(4), we propose to require RNHCIs to have a method for sharing information and care documentation for patients under the RNHCIs' care, as necessary, with health care providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative. Also, at proposed § 403.748(c)(4), we have removed the term "other" from the requirement for sharing information with "other health care providers" to more accurately reflect the care provided by RNHCIs.

At § 482.15(d)(2), "Testing," we propose that hospitals would conduct drills and exercises to test the emergency plan. Because RNHCIs have such a specific role and provide

such a specific service in the community, we believe RNHCIs would not participate in performing such drills. We propose the RNHCI would be required to only conduct a tabletop exercise annually. Likewise, unlike that which we have proposed for hospitals at § 482.15(d)(2)(i), we do not propose that the RNHCI conduct a community mock disaster drill at least annually or to conduct an individual, facility-based mock disaster drill. Although we proposed for hospitals at § 482.15(d)(2)(ii) that if the hospital experienced an actual natural or man-made emergency, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event, we are not proposing this requirement for RNHCIs.

At § 482.15(d)(2)(iv), we propose to require hospitals to maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. Again, at § 403.748(d)(2)(d)(ii), for RNHCIs, we propose to remove reference to drills.

Currently, at existing § 403.724(a), we require that an election form be made by the Medicare beneficiary or his or her legal representative and further requires that the election must be a written statement that the beneficiary: (1) is conscientiously opposed to accepting non-excepted medical treatment; (2) believes that non-excepted medical treatment is inconsistent with his or her sincere religious beliefs; (3) understands that acceptance of non-excepted medical treatment constitutes revocation of the election and possible limitation of receipt of further services in a RNHCI; (4) knows that he/she may revoke the election by submitting a written statement to CMS, and (5) knows that the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs. Thus, at § 403.748(c)(4), we are proposing that election documentation be shared with other care providers to preserve continuity of care.

C. Emergency Preparedness Requirements for Ambulatory Surgical Centers (ASCs) (§ 416.54)

Section 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an admission.

Section 1833(i)(1)(A) of the Act authorizes the Secretary to specify those surgical procedures that can be performed safely in an ASC. The surgical services performed in ASCs generally are scheduled, elective, non-life-threatening procedures that can be safely performed in either a hospital setting (inpatient or outpatient) or in a Medicare-certified ASC.

Patients are examined immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Patients also are evaluated just prior to discharge from the ASC to ensure proper anesthesia recovery.

Currently, there are 5,354 Medicare certified ASCs in the U.S. The ASC Conditions for Coverage (CfCs) at 42 CFR part 416, Subpart C are the minimum health and safety standards a facility must meet to obtain Medicare certification. The existing ASC CfCs do not contain requirements that address emergency situations. However, existing § 416.41(c), which was adopted in November 2008, requires ASCs to have a disaster preparedness plan. This existing requirement states the ASC must--(1) have a written disaster plan that provides for the emergency care of its patients, staff and others in the facility; (2) coordinate the plan with state and local authorities; and (3) conduct drills, annually and complete a written evaluation of each drill, promptly implementing any correction to the plan. Since these proposed requirements are similar to and would be redundant with existing rules, we propose to remove existing § 416.41(c). Existing § 416.41(c)(1) would be incorporated into proposed § 416.54(a), (a)(1),

(a)(2), and (a)(4). Existing § 416.41(c)(2) would be incorporated into proposed § 416.54(a)(4)and (c)(2). Existing § 416.41(c)(3) would be incorporated into proposed § 416.54(d)(2)(i) and § 416.54(d)(2)(iv).

This proposed regulation would require the ASC to meet most of the same proposed emergency preparedness requirements as those we propose for hospitals, with two exceptions. At § 416.54(c)(7), we propose that ASCs would be required to have policies and procedures that include a means of providing information about the ASCs' needs and its ability to provide assistance (such as physical space and medical supplies) to the authority having jurisdiction (local, state agencies) or the Incident Command Center, or designee. However, we are not proposing that these facilities provide information regarding their occupancy, as we have proposed for hospitals, since the term "occupancy" usually refers to bed occupancy in an inpatient facility. We are not proposing that these facilities provide for subsistence needs for their patients and staff.

While a large ASC in a metropolitan area may find it relatively easy to perform a risk analysis and develop an emergency plan, policies and procedures, a communications plan, and train staff, we understand a small or rural ASC may find it more challenging to meet our proposed requirements. However, we believe these requirements are important and small or rural ASCs would be able to develop an appropriate emergency preparedness plan and meet our proposed requirements with the assistance of resources in their state and local community guidance.

D. Emergency Preparedness Regulations for Hospices (§ 418.113)

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248, added section 1861(dd) to the Act to provide coverage for hospice care to

terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in Medicare and Medicaid. Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of patients under hospice care. To implement this requirement, state survey agencies conduct surveys of hospices to assess their compliance with the CoPs. The CoPs found at part 418, Subparts C and D apply to a hospice, as well as to the services furnished to each patient under hospice care.

Hospice care provides palliative care rather than traditional medical care and curative treatment to terminally ill patients. Palliative care improves the quality of life of patients and their families facing the problems associated with terminal illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. Hospices use an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers.

Hospices are unique health care providers because they serve patients and their families in a wide variety of settings. Hospice patients may be served in their place of residence, whether that residence is a private home, a nursing home, an assisted living facility, or even a recreational vehicle, as long as such locations are determined to be the patient's place of residence. Hospice patients may also be served in inpatient facilities operated by the hospice.

As of March 2013, there were 3,773 hospice facilities nationally. Under the existing hospice regulations, hospice inpatient facilities are required to have a written disaster preparedness plan that is periodically rehearsed with hospice employees, with procedures to be followed in the event of an internal or external disaster, and procedures for the care of casualties (patients and staff) arising from such disasters. This requirement, which is limited in scope, is found at § 418.110(c)(1)(ii) under "Standard: Physical environment."

We believe that all hospices, even those without inpatient facilities, should have an emergency plan. Also, we believe that, given the diverse nature of hospice patients and the variety of locations where they receive hospice services, simply having a written plan that is "periodically" rehearsed with staff does not provide sufficient protection for hospice patients and hospice employees.

For hospices, we propose to retain existing regulations at § 418.110(c)(1)(i), which states that a hospice must address real or potential threats to the health and safety of the patients, others, and property. However, we propose incorporating the existing requirements at § 418.110(c)(1)(ii) into proposed § 418.113(a)(2) and proposed § 418.113(d)(1). We would require at § 418.113(a)(2) that the hospice have in effect an emergency preparedness plan for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. In addition, we would require at § 418.113(d)(1) that the hospice must periodically review and rehearse its emergency preparedness plan with hospice employees with special emphasis placed on carrying out the procedures necessary to protect patients and others. Section 418.110(c)(1)(ii) and the designation for clause § 418.110(c)(1)(i) would be removed.

Otherwise, the proposed emergency preparedness requirements for hospice providers are very similar to those for hospitals. However, the average hospice (freestanding, not-for-profit, with far fewer annual admissions, and employees) is very different from an average hospital. Typically, hospice inpatient facilities are small buildings or a single unit in a larger medical complex, such as a hospital or long term care facility. Furthermore, hospice patients, given their terminally ill status, may be equally or more vulnerable in an emergency situation than their hospital counterparts. This may be due to the inherent severity of the hospice patient's illness or to the probability that the hospice patient's caregiver may not have the level of professional expertise, supplies, or equipment as that of the hospital-based clinician surrounding a natural or man-made emergency.

Despite these core differences, we believe the hospital emergency preparedness requirement, with some reorganization and revision, is appropriate for hospice providers. Thus, our discussion will focus on the requirements as they differ from the requirements for hospitals within the context of the hospice setting. Since hospices serve patients in both the community and within various types of facilities, we propose to re-organize the requirements for the hospice provider's policies and procedures differently from the proposed policies and procedures for hospitals. Specifically, we propose to group requirements that apply to all hospice providers at § 418.113(b)(1) through § 418.113(b)(5) followed by requirements at § 418.113(b)(6) that apply only to hospice inpatient care facilities.

Unlike our proposed hospital policies and procedures, we would require all hospices, regardless of whether or not they operate their own inpatient facilities, to have policies and procedures to inform state and local officials about hospice patients in need of evacuation from their respective residences at any time due to an emergency situation based on the patient's

medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate. This proposed requirement recognizes that many of the frail hospice patients may be unable to evacuate from their homes without assistance during an emergency. This additional proposed requirement recognizes the responsibility of the hospice to support the safety of its patients that reside in the community.

We expect that hospices would be able to identify patients most in need of evacuation assistance (for example, patients residing alone and patients using certain types of durable medical equipment), safe and appropriate evacuation methods, and the appropriate state or local authorities to assist in such evacuations. We believe this requirement is necessary to ensure the safety of vulnerable hospice patients, who are likely not capable of evacuating without assistance.

We note that the proposed requirements for communication at § 418.113(c) are the same as for hospitals, with the exception of proposed § 418.113(c)(7). At § 418.113(c)(7), for hospice facilities, we are proposing to limit to inpatients the proposed requirement that the hospice have policies and procedures that would include a means of providing information about the hospice's occupancy and needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. Since hospice facilities provide care to patients in the home or in an inpatient setting, we are proposing that only inpatient hospice facilities, including those under arrangement, be required to report the hospice facilities' inpatient occupancy. The proposed requirements for patients receiving care in their home would require only that hospices report their needs and ability to provide assistance. The proposed requirements for training and testing at §418.113(d) are similar to those proposed for hospitals.

E. Emergency Preparedness Regulation for Inpatient Psychiatric Residential Treatment Facilities (PRTFs) (§ 441.184)

Sections 1905(a)(16) and (h) of the Act define the term "Psychiatric Residential Treatment Facility" (PRTF) and list the requirements that a PRTF must meet to be eligible for Medicaid participation. To qualify for Medicaid participation, a PRTF must be certified and comply with conditions of payment and conditions of participation (CoPs), at § 441.150 through § 441.182 and § 483.350 through § 483.376 respectively. As of March 2013, there were 387 PRTFs.

A PRTF provides inpatient psychiatric services for patients under age 21; services must be provided under the direction of a physician. Inpatient psychiatric services must involve active treatment which means implementation of a professionally developed and supervised individual plan of care. The patient's plan of care includes an integrated program of therapies, activities, and experiences designed to meet individual treatment objectives that have been developed by a team of professionals along with the patient, his or her parents, legal guardians, or others into whose care the patient will be released after discharge. The plan must also include post-discharge plans and coordination with community resources to ensure continued services for the patient, his or her family, school, and community.

The current PRTF requirements do not include any requirements for emergency preparedness. We propose requiring that PRTF facilities meet the same requirements we are proposing for hospitals. Because these facilities vary widely in size, we expect their risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. Nevertheless, we believe each of these providers/suppliers has the capability to comply fully with the requirements so that

the health and safety of its patients are protected in the event of an emergency situation or disaster.

F. Emergency Preparedness Regulations for Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.84)

The Balanced Budget Act (BBA) of 1997 established the Program of All-Inclusive Care for the Elderly (PACE) as a permanent Medicare and Medicaid provider type. Under sections 1894 and 1934 of the Act, a state participating in PACE must have a program agreement with CMS and a PACE organization. Regulations at § 460.2 describe the statutory authority that permits entities to establish and operate PACE programs under section 1894 and 1934 of the Act and § 460.6 defines a PACE organization as an entity that has in effect a PACE program agreement. Sections 1894(a)(3) and 1934(a)(3) of the Act define a "PACE provider." The PACE model of care was adopted from On Lok Senior Health Services, an organization that continues to serve seniors in San Francisco and surrounding areas of California. It is a unique model of managed care service delivery for the frail community-dwelling elderly. The PACE model of care includes the provision of adult day health care and interdisciplinary team care management as core services. Medical, therapeutic, ancillary, and social support services are furnished in the patient's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract.

Generally, a PACE organization provides medical and other support services to patients predominately in a PACE adult day care center. Day center attendance is based on individual needs. The majority of PACE patients go to a PACE adult day health center on a regular basis. On average, a PACE patient attends the day center 3 times a week. As of March 2013,there are 91 PACE programs nationally.

Regulations for PACE organizations at part 460, subparts E through H, set out the minimum health and safety standards a facility must meet in order to obtain Medicare certification. The current CoPs for PACE organizations include some requirements for emergency preparedness. We propose to remove the current PACE organization requirements at § 460.72(c)(1) through (5) and incorporate these existing requirements into proposed § 460.84, Emergency preparedness requirements for Programs of All-Inclusive Care for the Elderly (PACE).

Existing § 460.72(c)(1), Emergency and disaster preparedness procedures, states that the PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the patients, staff, or the public. Existing § 460.72(c)(2) defines emergencies to include, but not be limited to: fire; equipment, water, or power failure; care-related emergencies; and natural disasters likely to occur in the organization's geographic area.

We propose incorporating the language from § 460.72(c)(1) into § 460.84(b). Existing § 460.72(c)(2), which defines the various emergencies, would be incorporated into § 460.84(b) as well. The statement in current § 460.72(c)(2), that "an organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location" would not be added to the proposed rule because we are proposing that PACE organizations utilize an "all hazards" approach as proposed in § 460.84(a)(1).

Existing § 460.72(c)(3), which states that "a PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and patients to ensure that staff demonstrate a knowledge of emergency procedures, including informing patients what to do, where to go, and whom to contact in case of an emergency," would be incorporated into

proposed § 460.84(d)(1). The existing requirements for having available emergency medical equipment, for having staff who know how to use the equipment, and having a documented plan to obtain emergency medical assistance from outside sources in current § 460.72(c)(4) would be relocated to proposed § 460.84(b)(9). Finally, current § 460.72(c)(5), which states that the PACE organization must test the emergency and disaster plan at least annually and evaluate and document its effectiveness would be addressed by proposed § 460.84(d)(2). The current version of § 460.72(c)(1) through (c)(5) would be removed.

We are proposing that PACE organizations would adhere to the same requirements for emergency preparedness as hospitals, with three exceptions.

The first difference between the proposed hospital emergency preparedness requirements and the proposed PACE emergency preparedness requirements is that we are not proposing that PACE organizations provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we are proposing for hospitals at § 482.15(b)(1). The second difference between the proposed hospital emergency preparedness requirements and the proposed PACE emergency preparedness requirements is that we propose adding at § 460.84(b)(3), a requirement for a PACE organization to have policies and procedures to inform state and local officials about PACE patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric conditions and home environment. Such policies and procedures must be in accord with the HIPAA Privacy

Rule, as appropriate. This proposed requirement recognizes that many of the frail PACE patients may be unable to evacuate from their homes without assistance during an emergency.

Finally, the third difference between the proposed requirements for hospitals and the proposed requirements for PACE organizations is that, at § 460.84(c)(7), we propose to require these organizations to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring these organizations to provide information regarding their occupancy, as we propose for hospitals (§ 482.15(c)(7)), since the term occupancy usually refers to bed occupancy in an inpatient facility.

G. Emergency Preparedness Regulations for Transplant Centers (§ 482.78)

Transplant centers are located within hospitals that meet the requirements for Conditions of Participation (CoPs) in Medicare. Therefore, transplant centers must meet all hospital CoPs at § 482.1 through § 482.57. In addition, unless otherwise specified, heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers must meet all requirements for transplant centers at § 482.72 through § 482.104.

Transplant centers are responsible for providing organ transplantation services from the time of the potential transplant candidate's initial evaluation through the recipient's post-transplant follow-up care. In addition, if a center performs living donor transplants, the center is responsible for the care of the living donor from the time of the initial evaluation through post-surgical follow-up care.

Organs are viable for transplantation for a limited time after organ recovery. Although kidneys may remain viable for transplantation for more than 24 hours, other organs remain viable for only a few hours. Thus, according to the Organ Procurement and Transplantation

Network (OPTN) longstanding policy, if a transplant center must turn down an organ for one of its patients, the organ may go to the next patient on the waiting list at another transplant center (Organ Distribution: Organ Procurement, Distribution and Allocation, http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_6.pdf) . In such a situation, the patient on the waiting list of the transplant center experiencing an emergency may die before an organ becomes available again. In fact, according to the OPTN, about 18 patients die every day waiting for an organ transplant. (http://optn.transplant.hrsa.gov/)

There are 770 Medicare-approved transplant centers. These centers provide specialized services that are not available at all hospitals. Thus, we believe that it is crucial for every transplant center to make arrangements with one or more other Medicare-approved transplant centers to provide transplantation services and other care to its patients during an emergency. Making such arrangements would increase the likelihood that if an organ became available for one of the transplant center's waiting list patients during an emergency, the patient would receive the transplant. Further, having such arrangements with other transplant centers would increase the odds that during an emergency, a transplant center's patients would receive critically important post-transplant care to prevent graft failure.

Our regulations at § 482.68 currently require that a transplant center that has a Medicare provider agreement meet the hospital CoPs specified in § 482.1 through § 482.57. Our proposed hospital CoP, "Emergency preparedness," at § 482.15, would apply to transplant centers. We also propose to add a new transplant center CoP at § 482.78, "Emergency preparedness". A transplant center would be required to comply with the proposed emergency preparedness hospital requirements at § 482.15, as well as the proposed CoP for emergency preparedness for transplant centers at § 482.78. We propose at § 482.78(a) that a transplant center have an

agreement with at least one other Medicare-approved transplant center to provide transplantation services and other care for its patients during an emergency. Ideally, the Medicare-approved transplant center that agrees to provide care for a center's patients during an emergency would perform the same type of organ transplant as the center seeking the agreement. However, we recognize that this may not always be feasible. Under some circumstances, a transplant center may wish to establish an agreement for the provision of post-transplant care and follow-up for its patients with a center that is Medicare-approved for a different organ type.

We believe a transplant center entering into an agreement for the provision of services during an emergency would be in the best position to judge whether post-transplant care could be competently provided during an emergency by a Medicare-approved transplant center that transplanted a different organ type. We expect that transplant centers establishing such agreements would consider the types of services the other center had the ability to provide during an emergency.

We also propose at § 482.78(a) that the agreement between the transplant center and another Medicare-approved transplant center that agreed to provide care during an emergency would have to address, at a minimum: (1) the circumstances under which the agreement would be activated; and (2) the types of services that would be provided during an emergency.

Currently, under the transplant center CoP at § 482.100, Organ procurement, a transplant center is required to ensure that the hospital in which it operates has a written agreement for the receipt of organs with the hospital's designated Organ Procurement Organization (OPO) that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. We propose at § 482.78(b) to require transplant centers to ensure that the written agreement required under § 482.100 also addresses the duties and responsibilities of the

hospital and the OPO during an emergency. We have included a similar requirement for OPOs at § 486.360(c) in this proposed rule. We would expect the transplant center, the hospital in which it is located, and the designated OPO to collaborate in identifying their specific duties and responsibilities during emergency situations and include them in the agreement.

We are not proposing to require transplant centers to provide basic subsistence needs for staff and patients, as we are proposing for hospitals at § 482.15(b)(1). Also, we are not proposing to require transplant centers to separately comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials. This requirement would be applicable to inpatient providers since the overnight provision of care could be challenged in an emergency. Transplant centers would have to meet this requirement since the transplant patient would be under the care and responsibility of the hospital.

H. Emergency Preparedness Requirements for Long Term Care (LTC) Facilities (§ 483.73)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to patients that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to patients: skilled nursing care and related services for patients who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who due to their mental or physical condition require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities must meet certain requirements located at part 483, Subpart B, Requirements for Long Term Care Facilities. SNFs must be certified as meeting the requirements of section 1819(a) through (d) of the Act. NFs must be certified as meeting section 1919(a) through (d) of the Act. A LTC facility may be both Medicare and Medicaid approved.

LTC facilities provide a substantial amount of care to Medicare and Medicaid beneficiaries, as well as "dual eligible individuals" who qualify for both Medicare and Medicaid. As of March 1, 2013, there were 15,157 LTC facilities and these facilities provided care for about 1.7 million patients.

The current requirements for LTC facilities contain specific requirements for emergency preparedness set out at 42 CFR 483.75(m)(1) and (2). Section 483.75(m)(1) states that a "facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents." We are proposing that this language be incorporated into proposed § 483.73(a)(1). Existing § 483.75(m)(2) states that a "facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures." These requirements would be incorporated into proposed § 483.73(d)(1)and (d)(2). Sections § 483.75(m)(1) and (2) would be removed.

These requirements are not sufficient to ensure that facilities are prepared for more widespread disasters that may affect most or all of the other health care facilities in their area and that may tax the ability of local, state, and federal emergency management officials to provide assistance. For example, current LTC facility requirements do not require facilities to conduct a risk assessment or to have a plan, policies, or procedures to ensure continuity of facility

operations during emergencies. We believe the additional requirements in this proposed rule would ensure facilities would be prepared for the emergencies they may face now and in the future. Thus, our proposed emergency preparedness requirements for LTC facilities are identical to those we are proposing for hospitals at § 482.15, with two exceptions. Specifically, at § 483.73(a)(1), we propose that LTC facilities would establish emergency plans utilizing an "all-hazards" approach, which in an emergency situation, would include a directive to account for missing residents.

In addition, long term care facilities are unlike many of the inpatient care providers. Many of the residents can be expected to have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the residents' residences or homes. We believe this changes the nature of the relationship and duty to the residents and their families or representatives. Section § 483.73(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of residents under the facility's care. We also believe that the residents and their families or representatives require more information about the facility's emergency plan. Specifically, long term care facilities should be required to determine what information in their emergency plan is appropriate to share with its residents and their families or representatives and that the facility have a means by which that information is disseminated to those individuals. The facility should also determine the appropriate time for that information to be disseminated. We are not indicating what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its residents and their families or

representatives and the most efficient manner in which to share that information. Therefore, we propose to add an additional requirement at § 483.73(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives."

Also, as discussed in section II.A.4 of the preamble we are proposing at §483.73(e)(1)(i) that LTC facilities must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that LTC facilities test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the LTC facility anticipates it will require during an emergency.

In addition to the emergency energy requirements discussed earlier, we also believe that LTC facilities should consider their individual residents' power needs. For example, some residents could have motorized wheelchairs that they need for mobility or require a continuous positive airway pressure or CPAP machine due to sleep apnea. In §483.73(a)(1) and (3), we propose that the LTC facility address, among other things, its resident population and continuity of operations in its emergency plan. The LTC facility must also base its emergency plan on a risk assessment, utilizing an all-hazards approach. We believe that the currently proposed requirements encompass consideration of individual residents' power needs and should be included in LTC facilities' risk assessments and emergency plans. However, we are also soliciting comments on whether there should be a specific requirement for "residents' power needs" in the LTC requirements.

I. Emergency Preparedness Regulations for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) (§ 483.475)

Section 1905(d) of the Act created the ICF/IID benefit to fund "institutions" with four or more beds to serve people with [intellectual disability] or other related conditions. To qualify for Medicaid reimbursement, ICFs/IID must be certified and comply with CoPs at 42 CFR part 483, Subpart I, § 483.400 through § 483.480. As of March 2013, there were 6,442 ICFs/IID, serving approximately 129,000 patients, and all patients receiving ICF/IID services must qualify financially for Medicaid assistance. Patients with intellectual disabilities who receive care provided by ICFs/IID may have additional emergency planning and preparedness requirements. For example, some care recipients are non-ambulatory, or may experience additional mobility or sensory disabilities or impairments, seizure disorders, behavioral challenges, or mental health challenges.

Some ICFs/IID are small and serve only a few patients. However, we do not believe small ICFs/IID or ICFs/IID in general would have difficulty meeting the proposed requirements. In fact, small facilities might find it easier than large facilities to develop an emergency preparedness plan and emergency preparedness policies and procedures. As an example, an ICF/IID with only four patients is likely to have a sufficient number of its own vehicles available during an emergency to evacuate patients and staff, eliminating the need to contract with an outside entity to provide transportation during an emergency situation or disaster.

Because ICFs/IID vary widely in size and the services they provide, we expect that the risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. Nevertheless, we believe

each of them has the capability to comply fully with the requirements so that the health and safety of its patients are protected in the event of an emergency situation or disaster.

Thus, we propose requiring that ICFs/IID meet the same requirements we are proposing for hospitals, with two exceptions. At § 483.475(a)(1), we propose that ICFs/IID utilize an all hazards approach, including consideration for missing clients. We believe that in the event of a natural or man-made disaster, ICFs/IID would maintain responsibility for care of their own patient population but would not receive patients from the community. Also, because we recognize that all ICFs/IID patients have special needs, we propose requiring ICFs/IID to "address the special needs of its client population …" at § 483.475(a)(3).

In addressing the special needs of its client population, we believe that ICFs/IID should consider their individual residents' power needs. For example, some residents could have motorized wheelchairs that they need for mobility or require a continuous positive airway pressure or CPAP machine due to sleep apnea. We believe that the currently proposed requirements at §483.475(a)(a risk assessment utilizing an all-hazards approach and that the facility address the special needs of its client population) encompass consideration of individual residents' power needs and should be included in ICFs/IID's risk assessments and emergency plans. However, we are also soliciting comments on whether there should be a specific requirement for "residents' power needs" in the ICFs/IID CoPs.

As we stated earlier, the purpose of this proposed rule is to establish requirements to ensure that Medicare/Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during more widespread local, state, and national emergencies. We do not believe the existing requirements for ICFs/IID are sufficiently comprehensive to protect patients during an emergency that impacts the larger community. For example, they do

not require facilities to plan for sheltering in place. However, in developing this proposed rule, we have been careful not to remove emergency preparedness requirements that are more rigorous than those we are proposing.

The current regulations for ICFs/IID include requirements for emergency preparedness. Specifically, § 483.430(c)(2) and (c)(3) contain specific requirements to ensure that direct care givers are available at all times to respond to illness, injury, fire, and other emergencies. However, we do not propose to relocate these existing facility staffing requirements at § 483.430(c)(2) and § 483.430(c)(3) because they address staffing issues based on the number of patients per building and patient behaviors, such as aggression. Such requirements, while related to emergency preparedness tangentially, are not within the scope of our proposed emergency preparedness requirements for ICFs/IID.

Current § 483.470, Physical environment, includes a standard for emergency plan and procedures at § 483.470(h) and a standard for evacuation drills at § 483.470(i). The standard for emergency plan and procedures at current § 483.470(h)(1) requires facilities to develop and implement detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing clients. This requirement would be relocated to proposed § 483.475(a)(1). Existing § 483.470(h)(1) would be removed.

Currently § 483.470(h)(2) states, with regard to a facility's emergency plan, that the facility must communicate, periodically review the plan, make the plan available, and provide training to the staff. These requirements are covered in proposed § 483.475(d). Current § 483.470(h)(2) would be removed.

ICFs/IID are unlike many of the inpatient care providers. Many of the clients can be expected to have long term or extended stays in these facilities. Due to the long term nature of

their stays, these facilities essentially become the clients' residences or homes. We believe this changes the nature of the relationship and duty to the clients and their families or representatives. Section 483.475(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of clients under the facility's care. We also believe that the clients and their families or representatives require more information about the facility's emergency plan. Specifically, ICFs/IID should be required to determine what information in their emergency plan is appropriate to share with its clients and their families or representatives and that facilities have a means by which that information is disseminated to those individuals. The facility should also determine the appropriate time for that information to be disseminated. We are not indicating what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its clients and their families or representatives and the most efficient manner in which to share that information. Therefore, we propose to add an additional requirement at § 483.475(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives."

The standard for disaster drills set forth at existing § 483.470(i)(1) specifies that facilities must hold evacuation drills at least quarterly for each shift of personnel under varied conditions to ensure that all personnel on all shifts are trained to perform assigned tasks; ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and evaluate the effectiveness of their emergency and disaster plans and procedures.

Currently § 483.470(i)(2) further specifies that facilities must evacuate patients during at least one drill each year on each shift; make special provisions for the evacuation of patients with physical disabilities; file a report and evaluation on each evacuation drill; and investigate all problems with evacuation drills, including accidents, and take corrective action. Further, during fire drills, facilities may evacuate patients to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code. Finally, at existing § 483.470(i)(3), facilities must meet the requirements of paragraphs § 483.470(i)(1) and (2) for any live-in and relief staff they utilize. Because these existing requirements are so extensive, we propose cross referencing § 483.470(i) (redesignated as § 483.470(h)) at proposed § 483.475(d).

J. Emergency Preparedness Regulations for Home Health Agencies (HHAs) (§ 484.22)

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in the Medicare program. Home health services are covered for qualifying elderly and people with disabilities who are beneficiaries under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services include skilled nursing care, physical, occupational, and speech therapy, medical social work and home health aide services which must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home.

As of March 1, 2013, there were 12,349 HHAs participating in the Medicare program. The majority of HHAs are for-profit, privately owned agencies. The effective delivery of quality home health services is essential to the care of illnesses and prevention of hospitalizations.

With so many patients depending on the services of HHAs nationwide, it is imperative that HHAs have processes in place to address the safety of patients and staff and the continued

provision of services in the event of a disaster or emergency. However, there are no existing emergency preparedness requirements contained under the HHA Medicare regulations at part 484, Subparts B and C.

Thus, we propose to add emergency preparedness requirements at § 484.22, pursuant to which HHAs would be required to comply with some of the requirements that we propose to require for hospitals. We are proposing additional requirements under the HHA policies and procedures that would apply to HHAs but not to hospitals to address the unique circumstances under which HHAs provide services.

First, because HHAs provide health care in patients' homes, we propose at § 484.22(b)(1) that an HHA have policies and procedures that include plans for its patients during a natural or man-made disaster. We propose that the HHA include individual emergency preparedness plans for each patient as part of the comprehensive patient assessment at § 484.55.

Second, because we learned from the experience of Hurricane Katrina that many medically compromised people were unable to escape their homes to seek safe shelter, at § 484.22(b)(2), we propose requiring an HHA to have policies and procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Regulations, as appropriate. Although we do not propose how such notification would take place, we expect that maintaining an accurate list of HHA patients would be necessary. However, we believe the potential need for assistance with such factors as transportation or evacuation, for example, could be addressed as an ongoing process of evaluating the patient's medical and psychiatric condition and home environment.

We are not proposing to require that HHAs meet all of the same requirements that we are proposing for hospitals. Since HHAs provide health care services only in patients' homes, we are not including proposed requirements for policies and procedures for the provision of subsistence needs (§ 482.15(b)(1)); safe evacuation (§ 482.15(b)(3)); and a means to shelter in place (§ 482.15(b)(4)). We would not expect an HHA to be responsible for sheltering HHA patients in their homes or sheltering staff at an HHA main or branch offices. We do not propose to require that HHAs comply with the proposed hospital requirement at § 482.15(b)(8) regarding the provision of care and treatment at alternate care sites identified by emergency management officials. This proposed requirement would be applicable only to inpatient providers. With respect to communication, we have not included proposed requirements for HHAs to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 as we are proposing for hospitals at § 482.15(c)(5). We have also modified the proposed requirement for hospitals at § 482.15(c)(7) by eliminating the reference to providing information regarding the facility's occupancy. The term occupancy usually refers to bed occupancy in an inpatient facility. Instead, at § 484.22(c)(6), we would require HHAs to provide information about the HHA's needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.

In developing its policies and procedures, we would expect an HHA to consider whether it would accept new referrals during a disaster or emergency situation, and how it would care for new patients. We also would urge HHAs to include a method for providing information to all new patients and their families about the role the HHA would play in the event of an emergency.

Overall, our expectation for HHAs is that they would work closely with other HHAs and with the hospitals in their referral areas to plan for disasters and emergency situations.

K. Emergency Preparedness Regulations for Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§ 485.68)

Section 1861(cc) of the Act defines the term "comprehensive outpatient rehabilitation facility" (CORF) and lists the requirements that a CORF must meet to be eligible for Medicare participation. By definition, a CORF is a non-residential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, sick, and persons with disabilities, at a single fixed location, by or under the supervision of a physician. As of March 2013, there were 272 Medicare-certified CORFs in the U.S.

Section 1861(cc)(2)(J) of the Act also states that the CORF must meet other requirements that the Secretary finds necessary in the interest of the health and safety of a CORF's patients. Under this authority, the Secretary has established in regulations, at part 485, Subpart B, requirements that a CORF must meet to participate in the Medicare program.

Currently § 485.64 "Conditions of Participation: Disaster procedures " includes emergency preparedness requirements CORFs must meet. The regulations state that the CORF must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. The regulation requires that all personnel be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

Currently § 485.64(a) requires a CORF to have a written disaster plan that is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. The other elements under § 485.64(a) require that CORFs have: (1) procedures for prompt transfer of casualties and records; (2) procedures for notifying community emergency personnel; (3)

instructions regarding the location and use of alarm systems and signals and firefighting equipment; and (4) specification of evacuation routes and procedures for leaving the facility.

Currently § 485.64(b) requires each CORF to: (1) provide ongoing training and drills for all personnel associated with the CORF in all aspects of disaster preparedness; and (2) orient and assign specific responsibilities regarding the facility's disaster plan to all new personnel within 2 weeks of their first workday.

Although these requirements are important, they do not address the coordination across providers and suppliers and across the various federal, state, and local emergency response systems necessary to ensure the health and safety of CORF patients during an emergency.

Despite CORFs being non-residential treatment facilities, we believe they should comply with the same requirements that would be required for hospitals, with appropriate exceptions.

At § 485.68(a)(5), we propose that CORFs develop and maintain the emergency preparedness plan with assistance from fire, safety, and other appropriate experts. We do not propose to require CORFs to provide basic subsistence needs for staff and patients as we are proposing for hospitals at § 482.15(b)(1). Because CORFs are outpatient facilities, we are not proposing that CORFs have a system to track the location of staff and patients under the CORF's care both during and after the emergency as we propose to require for hospitals at § 482.15(b)(2).

At § 482.15(b)(3), we propose that hospitals have policies and procedures for safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for CORFs, which serve only outpatients. Therefore, at § 485.68(b)(1), we are proposing to require that CORFs have policies and

procedures for evacuation from the CORF, including staff responsibilities and needs of the patients.

Because CORFs are outpatient facilities that provide specific, limited services to patients, we are not proposing that CORFS have arrangements with other CORFs or other providers to receive patients in the event of limitations or cessation of operations. Finally, we do not propose to require CORFs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials.

With respect to communication, we would not require CORFs to comply with the proposed requirement for hospitals at § 482.15(c)(5) that would require a hospital to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. In addition, CORFs would not be required to comply with the proposed requirement at § 482.15(c)(6), which would state that a hospital must have a means of providing information about the general condition and location of patients as permitted under 45 CFR 164.510(b)(4).

We propose including in the CORF emergency preparedness provisions a requirement for CORFs to have a method for sharing information and medical documentation for patients under the CORF's care with other health care providers, as necessary, to ensure continuity of care (see proposed § 485.68(c)(4)). However, we would expect CORFs to implement this requirement only for patients receiving care at the facility at the time of the disaster or emergency situation. Given that CORFs are primarily providers of a limited range of outpatient services, we do not expect a CORF to know the whereabouts of its patients who are living in the community, as we would expect of hospices, HHAs, and PACE facilities. An additional modification from what has been proposed for hospitals at § 482.15(c)(7), at § 485.68(c)(5), we propose to require

CORFs to have a communication plan that include a means of providing information about the CORF's needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring CORFs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

Our goal is to ensure that we incorporate existing CORF disaster preparedness requirements into our proposed emergency preparedness rule. Although we believe the current CORF disaster preparedness requirements are largely reflected in the language we propose for other providers and suppliers, there are specific instances in which the existing CORF requirements are more stringent, such as the requirement to assign specific disaster preparedness tasks to new personnel within two weeks of their first work day. This existing requirement at § 485.64(b)(2) would be relocated to proposed § 485.68(d)(1).

Currently § 485.64 requires a CORF to develop and maintain its disaster plan with assistance from fire, safety, and other appropriate experts. We have incorporated this requirement at proposed § 485.68(a)(5). Currently § 485.64(a)(3) would require that the training program include instruction in the location and use of alarm systems and signals and firefighting equipment. We have incorporated these requirements at proposed § 485.68(d)(1). We propose to remove current § 485.64.

L. Emergency Preparedness Regulations for Critical Access Hospitals (CAHs) (§ 485.625)

Sections 1820 and 1861(mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. We have implemented these provisions in 42 CFR part 485, Subpart F, Conditions of Participation for Critical Access Hospitals (CAHs). As of March 1, 2013, there are 1,332 CAHs that must meet

the CAH CoPs and 95 CAHs with psychiatric or rehabilitation distinct part units (DPUs) that must meet the hospital CoPs in order to receive payment for services provided to Medicare or Medicaid patients in the DPU.

CAHs are small, generally rural, limited-service facilities with low patient volume. The intent of designating facilities as "critical access hospitals" is to preserve access to primary care and emergency services that meet community needs.

A CAH is not required to be staffed if there are no inpatients in the facility. However, in the event of an emergency, existing requirements state there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact and available onsite within 30 minutes on a 24-hour basis or, under certain circumstances, within 60 minutes. CAHs currently are required to coordinate with emergency response systems in the area to provide 24-hour emergency coverage. We believe the existing requirements provide only a limited framework for protecting the health and safety of CAH patients in the event of a major disaster. They do not include the requirements we propose that we believe will ensure a well-coordinated emergency preparedness system of care.

CAHs are required at existing § 485.623(c), "Standard: Emergency procedures," to assure the safety of patients in non-medical emergencies by training staff in handling emergencies, including prompt reporting of fires; extinguishing of fires; protection and, where necessary, evacuation of patients, personnel, and guests; and cooperation with firefighting and disaster authorities. CAHs must provide for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas; provide for fuel and water supply; and take other appropriate measures that are consistent with the particular conditions of the area in

which the CAH is located. Since CAHs are required to provide emergency services on a 24-hour a day basis, they must keep equipment, supplies, and medication used to treat emergency cases readily available.

We propose to remove the current standard at § 485.623(c) and relocate these requirements into the appropriate sections of a new CoP entitled, "Condition of Participation: Emergency Preparedness" at § 485.625, which would include the same requirements that we propose for hospitals. Since CAHs function as acute care providers in rural and remote communities, we believe that they should be prepared in the event of a disaster to provide critical care to individuals in their communities. Although CAHs are much smaller than most Medicare- and Medicaid-participating hospitals, we do not expect them to have difficulty meeting the same requirements we propose for hospitals. CAHs can draw upon a large number of resources at the federal, state, and local level for assistance in meeting the requirements.

We propose to relocate current § 485.623(c)(1) to proposed § 485.625(d)(1). We propose to incorporate current § 485.623(c)(2) into § 485.625(b)(1). Current § 485.623(c)(3) would be included in proposed § 485.625(b)(1). Current § 485.623(c)(4) would be reflected by the use of the term "all-hazards" in proposed § 485.625(a)(1). Section 485.623(d) would be redesignated as § 485.623 (c).

Also, as discussed in section II.A.4 of the preamble we are proposing at § 485.625(e)(1)(i) that CAHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that CAHs test their

emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the CAH anticipates it will require during an emergency.

M. Emergency Preparedness Regulation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (§ 485.727)

Under the authority of section 1861(p) of the Act, the Secretary has established CoPs that clinics, rehabilitation agencies, and public health agencies must meet when they provide outpatient physical therapy (OPT) and speech-language pathology (SLP) services. Under section 1861(p) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals receiving OPT and SLP services from these entities. The CoPs are set forth at part 485, Subpart H.

Section 1861(p) of the Act describes "outpatient physical therapy services" to mean physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient. The patient must be under the care of a physician.

The term "outpatient physical therapy services" also includes physical therapy services furnished to an individual by a physical therapist (in the physical therapist's office or the patient's home) who meets licensing and other standards prescribed by the Secretary in regulations, other than under arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. The term also

includes SLP services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement.

As of March 1, 2013, there are 2,256 clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language pathology services. In the remainder of this proposed rule and throughout the requirements, we use the term "organizations" instead of "clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services" for consistency with current regulatory language. Most of these providers are small facilities operated by a group of three or more physicians, as required at § 485.703 under the definition of "clinic", practicing medicine together, as well as various other rehabilitation professionals.

At § 485.727(b)(1), we are proposing to require that organizations have policies and procedures for evacuation from the organization, including staff responsibilities and needs of the patients.

We believe these organizations comply with a provision similar to our proposed requirement for hospitals at § 482.15(c)(7) which states that a communication plan must include a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee. At § 485.727(c)(5), we propose to require that these organizations to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction (local and state agencies) or the Incident Command Center, or designee. We do not propose to require these organizations to provide information regarding their occupancy, as we proposed for hospitals, since the term "occupancy" usually refers to bed occupancy in an inpatient facility.

The current regulations at § 485.727, "Disaster preparedness," require these organization to have a disaster plan. The plan must be periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster. Additionally, current § 485.727(a) requires that the facility have a plan in operation with procedures to be followed in the event of fire, explosion, or other disaster. We believe these requirements are addressed throughout the proposed CoP, and we do not propose including the specific language in our proposed rule.

However, existing § 485.727(a) also requires that the plan be developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. Because this existing requirement is specific to existing disaster preparedness requirements for these organizations, we have relocated the language to proposed § 485.727(a)(6).

Existing requirements at § 485.727(a) also state that the disaster plan must include: (1) transfer of casualties and records; (2) the location and use of alarm systems and signals; (3) methods of containing fire; (4) notification of appropriate persons, and (5) evacuation routes and procedures. Because transfer of casualties and records, notification of appropriate persons, and evacuation routes are addressed under policies and procedures in our proposed language, we do not propose to relocate these requirements. However, because the requirements for location and use of alarm systems and signals and methods of containing fire are specific for these organizations, we propose relocating these requirements to § 485.727(a)(4).

Currently § 485.727(b) specifies requirements for staff training and drills. This requirement states that all employees must be trained, as part of their employment orientation, in all aspects of preparedness for any disaster. This disaster program must include orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly

and correctly carries out his or her assigned role in case of a disaster. Because these requirements are addressed in proposed § 485.727(d), we do not propose to relocate them but merely to address them in that paragraph. Current § 485.727, "Disaster preparedness," would be removed.

N. Emergency Preparedness Regulations for Community Mental Health Centers (CMHCs) (§ 485.920)

A Community Mental Health Center (CMHC) as defined in section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements in the state in which it is located and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act. Section 4162 of Pub. L. 101-508 (OBRA 1990), which amended section 1861(ff)(3)(A) and 1832(a)(2)(J) of the Act, includes CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective for services provided on or after October 1, 1991. Section 1866(e)(2) of the Act and 42 CFR part 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements but only with respect to providing partial hospitalization services. In 2010 there were 207 Medicare-certified CMHCs serving approximately 27,738 Medicare beneficiaries.

Pursuant to 42 CFR 410.2 and 410.110, a CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates that it provides the following core services:

- Outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of the CMHC's service area who have been discharged from inpatient treatment at a mental health facility.
- 24 hour-a-day emergency care services.

- Day treatment, or other partial hospitalization services, or psychosocial rehabilitation services.
- Screening for clients being considered for admission to state mental health facilities to determine the appropriateness of such admission. However, effective March 1, 2001, the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000 allows CMHCs to provide these services by contract if state law precludes the entity from providing the screening services.
- Meets applicable licensing or certification requirements for CMHCs in the state in which it is located.
- Provides at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act.

To qualify for Medicare reimbursement, CMHCs must comply with requirements for coverage of partial hospitalization services at § 410.110 and conditions for Medicare payment of partial hospitalization services at § 424.24(e). We will soon finalize the first health and safety CoPs for CMHCs, and while CMS is cognizant of the overall burden, we believe it is appropriate to also require CMHCs to meet the same emergency preparedness requirements as other outpatient facilities. Consistent with our proposed requirements for other Medicare and Medicaid participating providers and suppliers, we would require that CMHCs comply with emergency preparedness requirements to ensure a well-coordinated emergency response in the event of a disaster or emergency situation. We are proposing that CMHCs meet the same emergency preparedness requirements we propose for hospitals, with a few exceptions.

Since CMHCs are outpatient facilities, we would expect that in an emergency, the CMHC would instruct clients and staff not to report to the facility. In the event that clients and

staff were in the facility when a disaster or emergency situation occurred, we would expect the CMHC to encourage clients and staff to leave the facility to seek safe shelter in the community. We would expect most clients and staff to return to their homes.

Additionally, at § 485.920(c)(7), we propose to require these CMHCs to have a communication plan that include a means of providing information about the CMHCs needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.

Some CMHCs are small facilities with just a few clients and may be located in rural areas. These CMHCs could find it challenging to develop a well-coordinated emergency preparedness plan. However, we believe even small CMHCs would be able to develop an appropriate emergency preparedness plan with the assistance of federal, state, and local community resources.

O. Emergency Preparedness Regulations for Organ Procurement Organizations (OPOs) (§ 486.360)

Section 1138(b) of the Act and 42 CFR part 486, subpart G establish that OPOs must be certified by the Secretary as meeting the requirements to be an OPO and designated by the Secretary for a specific Donation Service Area (DSA). The current OPO CfCs do not contain any emergency preparedness requirements.

There are currently 58 Medicare certified OPOs that are responsible for identifying potential organ donors in hospitals, assessing their suitability for donation, obtaining consent from next-of-kin, managing potential donors to maintain organ viability, coordinating recovery of organs, and arranging for transport of organs to transplant centers. If an emergency affects an

OPO's ability to provide its services, organ procurement services to its entire DSA may be affected.

Our proposed requirements for OPOs to develop and maintain an emergency preparedness plan, are similar to those proposed for hospitals, with some exceptions.

Since potential donors generally are located within hospitals, at proposed § 486.360(a)(3), instead of addressing the patient population as proposed for hospitals at § 482.15(a)(3), we propose that the OPO address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. That is, we would expect an OPO to consider the type of hospitals it serves when it develops its emergency plan, for example, a large hospital with a trauma center located in a major metropolitan area or a small rural hospital lacking an operating room.

Because the services provided by OPOs are so different from the services provided by a hospital and because potential donors generally are located within hospitals, we propose only two requirements for OPOs at § 486.360(b): (1) a system to track the location of staff during and after an emergency; and (2) a system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

Since OPOs' potential donors generally are located within hospitals and since OPOs do not have physical structures in which to house patients, OPOs would not be expected to have policies and procedures to address the provision of subsistence needs for staff and patients. Instead, we believe these responsibilities would rest upon the hospital.

In addition, at § 486.360(c), we are proposing only three requirements for an OPO's communication plan. An OPO's communication plan would include: (1) names and contact information for staff; entities providing services under arrangement; volunteers; other OPOs; and transplant and donor hospitals in the OPO's DSA; (2) contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance; and (3) primary and alternate means for communicating with the OPO's staff, federal, state, tribal, regional, or local emergency management agencies. We believe the additional proposed requirements regarding communication would specifically be a hospital's responsibility in caring for its patient population.

Unlike the requirement we have proposed for hospitals at § 482.15(d)(2)(i) and (iii), which would be required to conduct both a mock disaster drill and a tabletop exercise, we propose at § 486.360(d)(2)(i) that an OPO would be required only to conduct a tabletop exercise. Since the OPO's patients reside in the hospital, we expect the OPO to show due consideration for its emergency response efforts by engaging in such a tabletop exercise. However, the OPO typically does not have physical possession of patients to fully engage in a mock disaster drill as proposed for hospitals. Since an OPO does not deal directly with patients, a mock disaster drill would be unnecessary.

Finally, at § 486.360(e), we propose that each OPO have agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. We also propose that the OPO include within its agreements with hospitals required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

P. Emergency Preparedness Regulations for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§ 491.12)

Section 1861(aa) sets forth the Rural Health Clinic and Federally Qualified Health Center services covered by the Medicare and Medicaid program. "RHCs" must be located in an area that is both rural and underserved.

Conditions for Certification for RHCs and Conditions of Coverage for FQHCs are found at 42 CFR part 491, Subpart A. Current emergency preparedness requirements are found at § 491.6.

Currently, an RHC is staffed with personnel that are required to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses and to have available the drugs and biologicals commonly used in life-saving procedures. The definition of a "first response" is a service that is commonly provided in a physician's office. FQHCs are required to provide emergency care either on site or through clearly defined arrangements for access to health care for medical emergencies during and after the FQHC's regularly scheduled hours. Therefore, FQHCs must provide for access to emergency care at all times. Clinics and centers have varying hours and days of operation based on staff and anticipated patient load.

We are aware of the difficulties that rural communities have attracting and retaining a variety of professionals, including health care professionals. However, there is a present and growing need for all providers and suppliers to develop plans to care for their staff and patients during a disaster. We propose that the RHCs' and FQHCs' emergency preparedness plans must address the type of services the facility has the capacity to provide in an emergency. We expect that they would evaluate their ability to provide services based on, but not limited to, the

facility's size, available human and material resources, geographic location, and ability to coordinate with community resources. Thus, while Medicare providers or suppliers in a large metropolitan community may be better able to provide the majority of its services during an emergency event, rural, providers and suppliers, especially those in frontier areas, may find it far more challenging to provide similar services during an emergency.

We believe many RHCs and FQHCs would be able to develop a comprehensive emergency plan that addresses "all-hazards" policies and procedures, a communication plan, and training and testing by drawing upon a variety of resources that can provide technical assistance. For example, HRSA's Office of Rural Health Policy (ORHP), guide entitled, "Rural Health Communities and Emergency Preparedness," that is available on HRSA's website at: ftp://ftp.hrsa.gov/ruralhealth/RuralPreparedness.pdf is a good source.

Although RHCs and FQHCs currently do not have specific requirements for emergency preparedness, they have requirements for "Emergency Procedures" found at § 491.6, under "Physical plant and environment." At § 491.6(c)(1), the RHC or FQHC must train staff in handling non-medical emergencies. This requirement would be addressed at proposed § 491.12(d)(1). At § 491.6(c)(2), the RHC or FQHC must place exit signs in appropriate locations. This requirement would be incorporated into our proposed requirement at § 491.12(b)(1), which would require RHCs and FQHCs to have policies and procedures for safe evacuation from the facility which includes appropriate placement of exit signs. Finally, at § 491.6(c)(3), the RHC or FQHC must take other appropriate measures that are consistent with the particular conditions of the area in which the facility is located. This requirement would be addressed throughout the proposed CoP for RHCs and FQHCs, particularly proposed

§ 491.12(a)(1), which requires the RHCs and FQHCs to perform a risk assessment based on an "all-hazards" approach. Current § 491.6(c) would be removed.

We are proposing emergency preparedness requirements based on the requirements that we are proposing for hospitals, modified to address the specific characteristics of RHCs and FQHCs. We do not propose to require RHC/FQHCs to provide basic subsistence needs for staff and patients. Also, unlike that proposed for hospitals at § 482.15(b)(2), we are not proposing that RHCs/FQHCs have a system to track the location of staff and patients in the facility's care both during and after the emergency.

At § 482.15(b)(3), we propose that hospitals have policies and procedures for safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for RHCs/FQHCs, which serve only outpatients. Therefore, at § 491.12(b)(1), we are proposing to require that RHCs/FQHCs have policies and procedures for evacuation from the RHC/FQHC, including appropriate placement of exit signs, staff responsibilities, and needs of the patients.

Unlike the requirement that is being proposed for hospitals at § 482.15(b)(7), we are not proposing that RHCs/FQHCs have arrangements with other RHCs/FQHCs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to RHC/FQHC patients. We do not propose to require RHC/FQHCs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites.

In addition, we would not require RHCs/FQHCs to comply with the proposed requirement for hospitals found at § 482.15(c)(5), which would require that a hospital have a

means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. Modified from what has been proposed for hospitals at § 482.15(c)(7), at § 491.12(c)(5), we propose to require RHCs/FCHCs to have a communication plan that would include a means of providing information about the RHCs/FQHCs needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose requiring RHCs/FQHCs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

Q. Emergency Preparedness Regulation for End-Stage Renal Disease (ESRD) Facilities (§ 494.62)

Sections 1881(b), 1881(c), and 1881(f)(7) of the Act establish requirements for End-Stage Renal Disease (ESRD) facilities. ESRD is a kidney impairment that is irreversible and permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. There are 5,923 Medicare-participating ESRD facilities in the U.S.

We addressed emergency preparedness requirements for ESRD facilities in the April 15, 2008 final rule (73 FR 20370) entitled, "Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule". Emergency preparedness requirements are located at § 494.60(d), Condition: Physical environment, Standard: Emergency preparedness. We propose to relocate these existing requirements to proposed § 494.62, Emergency preparedness.

Current regulations include the requirement that dialysis facilities be organized into ESRD Network areas. Our regulations describe these networks at § 405.2110 as

"CMS-designated ESRD Networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients." The ESRD Networks have an important role in an ESRD facility's response to emergencies, as they often arrange for alternate dialysis locations for patients and provide information and resources during emergency situations. As noted earlier, we do not propose incorporating the ESRD Network requirements into this proposed rule. We do not propose to require ESRD facilities to provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we are proposing for hospitals at § 482.15(b)(1).

At § 494.62(b), we propose to require facilities to address in their policies and procedures, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters in the facility's geographic area.

At § 482.15(b)(3), we propose that hospitals have policies and procedures for the safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for ESRD facilities, which serve only outpatients. Therefore, at § 494.62(b)(2), we are proposing to require that ESRD facilities have policies and procedures for evacuation from the facility, including staff responsibilities and needs of the patients.

At § 494.62(b)(6), we are proposing to require ESRD facilities to develop arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients. Experience has shown that ESRD facilities tend to use hospitals as back-up when hospital space and personnel need to be used to care for the sickest patients in the community during such emergencies. Thus, we want to emphasize that an organized system of patient care among ESRD facilities during and surrounding emergency events encompasses having a robust system for back-up care available at the various dialysis centers.

At § 494.62(c)(7), dialysis facilities would be required to comply with the proposed requirement for hospitals at § 482.15(c)(7), with one exception. At § 494.62(c)(7), we propose to require dialysis facilities to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We do not propose to require dialysis facilities to provide information regarding their occupancy, as we proposed for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

At § 494.62(d)(1)(i), we propose to require ESRD facilities to ensure that staff can demonstrate knowledge of various emergency procedures, including: informing patients of what to do; where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working

phone number under such emergency conditions); and how to disconnect themselves from the dialysis machine if an emergency occurs.

We would relocate existing requirements for patient training from § 494.60(d)(2) to proposed § 494.62(d)(3), patient orientation. In addition, the facility would have to ensure that, at a minimum, patient care staff maintained current CPR certification and ensure that nursing staff were properly trained in the use of emergency equipment and emergency drugs. With respect to emergency preparedness, the relevance of these requirements has already been established, and since they are existing regulations, they are standard business practice in ESRD facilities.

Current § 494.60(d) would be redesignated. Current requirements for emergency plans at § 494.60 are captured within proposed § 494.62(a). Current language that defines an emergency for dialysis facilities found at § 494.60(d) would be incorporated into proposed § 494.62(b). We would relocate existing requirements for emergency equipment and emergency drugs found at existing § 494.60(d)(3) to § 494.62(b)(9). We would relocate the existing requirement at § 494.60(d)(4)(i) that requires the facility to have a plan to obtain emergency medical system assistance when needed to proposed § 494.62(b)(8). We would relocate the current requirements at § 494.60(d)(4)(iii) for contacting the local emergency preparedness agency at least annually to ensure that the agency is aware of dialysis facility's needs in the event of an emergency to proposed § 494.62(a)(4). We would also redesignate the current § 494.60(e) as § 494.60(d).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Factors Influencing ICR Burden Estimates

Please note that under this proposed rule, a hospital's ICRs would differ from the ICRs of other Medicare or Medicaid provider and supplier types. A significant factor in the burden for each provider or supplier type would be whether the type of facility provides inpatient services, outpatient services, or both. Moreover, even where the proposed regulatory requirements are the same, certain factors would greatly affect the burden for different providers and suppliers. Current Medicare or Medicaid regulations for some providers and suppliers include requirements similar to those in this proposed regulation. For example, existing regulations for RNHCIs and

dialysis facilities require both types of facilities to have written disaster plans that address emergencies (42 CFR 403.742(a)(4) and 42 CFR 494.60(d)(4), respectively).

Further, some accrediting organizations (AOs) that have deeming authority for Medicare providers and suppliers have emergency preparedness standards. Those organizations are: The Joint Commission (TJC), the American Osteopathic Association (AOA), the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the American Association for Accreditation for Ambulatory Surgery Facilities, Inc. (AAAASF), and Det Norske Veritas Healthcare, Inc. (DNVHC). Each of these AOs has deeming authority for different types of facilities; for example, TJC has comprehensive emergency preparedness requirements for hospitals. Thus, as noted in the hospital discussion later in this section, we anticipate that TJC-accredited hospitals would have a smaller burden associated with this proposed rule than many other providers or suppliers.

In addition, many facilities already have begun preparing for emergencies. According to a study by Niska and Burt, virtually all hospitals already have plans to respond to natural disasters (Niska, R.W. and Burt, C.W. "Bioterrorism and Mass Casualty Preparedness in Hospitals: United States, 2003," CDC, Advance Data, September 27, 2005 found at http://www.cdc.gov/nchs/data/ad/ad364.pdf).

Hospitals, as well as other health care providers, also receive grant funding for disaster or emergency preparedness from the federal and state governments, as well as other private and non-profit entities. However, we were unable to determine the amount of funding that has been granted to hospitals, the number of hospitals that received funding, or whether that funding would continue in a predictable manner. We also do not know how the hospitals spent this funding. Therefore, in determining the burden for this proposed rule, we did not take into

account any funding a hospital or other health care provider might have received from sources other than Medicare or Medicaid.

B. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

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 March 1, 2013. We have not included data for health care facilities that are not Medicare or Medicaid certified.

Unless otherwise indicated, we obtained all salary information for the different positions identified in the following assessments from the May 2011 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics at http://www.bls.gov/oes/current/oes_nat.htm. We calculated the estimated hourly rates based upon the national median salary for that particular position, including benefits. 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. For example, based on our experience with CAHs, they usually pay their administrators less than the mean hourly wage for Health Service Managers in general medical and surgical hospitals. Thus, we considered the impact of the rural

nature of CAHs to estimate the hourly wage for CAH administrators and calculated total compensation by adding in an amount for fringe benefits. According to the Bureau of Labor Statistics, wages and salaries accounted for about 70 percent of total employee compensation. (Bureau of Labor Statistics News Release, "Employer Cost Index—December 2011, retrieved from www.bls.gov/news.release/pdf/eci.pdf). Thus, we calculated total compensation using the assumption that salary accounts for 70 percent of total compensation. We would welcome any comments on the accuracy of our compensation estimates. Many health care providers and suppliers could reduce their burden by partnering or collaborating with other facilities to develop their emergency management plans or programs. In estimating the burden associated with this proposed rule, we also took into consideration the many free or low cost emergency management resources health care facilities have available to them. Following is a list of some of the available resources:

Department of Health and Human Services (HHS)

- http://www.phe.gov

Office of the Assistant Secretary for Preparedness and Response (ASPR)

- http://www.phe.gov/about

Health Resources and Services Administration-Emergency Preparedness and Continuity of Operations

- http://www.hrsa.gov/emergency/

Centers for Medicare and Medicaid Services (CMS)

- www.cms.hhs.gov/Emergency/

Centers for Disease Control and Prevention – Emergency Preparedness & Response

- www.emergency.cdc.gov

Food and Drug Administration (FDA) – Emergency Preparedness and Response

- http://www.fda.gov/EmergencyPreparedness/default.htm

Substance Abuse and Mental Health Services Administration (SAMHSA) – Disaster Readiness and Response

- http://www.samhsa.gov/Disaster/

National Institute for Occupational Safety and Health (NIOSH) – Business Emergency Management Planning

- www.cdc.gov/niosh/topics/emres/business.html

Department of Labor (DOL), Occupational Safety and Health Administration (OSHA)– Emergency Preparedness and Response

- www.osha.gov/SLTC/emergencypreparedness

Federal Emergency Management Agency (FEMA)--State Offices and Agencies of Emergency Management – Contact Information

- http://www.fema.gov/about/contact/statedr.shtm
- http://www.fema.gov/plan-prepare-mitigate

Department of Homeland Security (DHS)

- http://www.dhs.gov/training-technical-assistance

We will discuss the burden for each provider and supplier type included in this proposed rule in the order in which they appear in the CFR.

C. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 403.748)

Proposed § 403.748(a) would require Religious Nonmedical Health Care Institutions (RNHCIs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan must meet the requirements specified at

§ 403.748(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment requirement in § 403.748(a)(1).

The current RNHCI CoPs already require RNHCIs to have a written disaster plan that addresses "loss of power, water, sewage, and other emergencies" (42 CFR 403.742(a)(4)). In addition, the CoPs also require RNHCIs' to include measures to evaluate facility safety issues, including physical environment, in their quality assessment and performance improvement (QAPI) program (42 CFR 403.732(a)(1)(vi)). We expect that all RNHCIs have considered some of the risks likely to happen in their facility. However, we expect that all RNHCIs would need to review any existing risk assessment and perform the tasks necessary to ensure their assessment is documented and utilize a facility-based and community based all-hazards approach.

We have not designated any specific process or format for RNHCIs to use in conducting their risk assessment because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that they would obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with RNHCIs, we expect that complying with this requirement would require the involvement of an administrator, the director of nursing, and the head of maintenance. It is important to note that RNHCIs do not provide medical care to their patients. Depending upon the state in which they are located, RNHCIs may not be licensed and may not have licensed or certified staff. RNHCIs generally do not compensate their staff at the same level we have used to determine the burden for other health care providers and suppliers. Therefore, for the purpose of estimating the burden, we have used lower hourly wages for the RNHCI staff than for other providers and suppliers whose staff must comply with licensing and certification standards.

We expect that to perform a risk assessment, the RNHCI's administrator, the director of nursing, and the head of maintenance would attend an initial meeting; review relevant sections of the current risk assessment; prepare comments; attend a follow-up meeting; perform a final review, and approve the risk assessment. We expect that the director of nursing would coordinate the meetings, review and critique the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that it is approved.

We estimate that it would require 9 burden hours for each RNHCI to complete the risk assessment at a cost of $265. There are 16 RNHCIs. Therefore, it would require an estimated 144 annual burden hours (9 burden hours for each RNHCI x 16 RNHCIs = 144 burden hours) for all 16 RNHCIs to comply with this requirement at a cost of $4,240 ($265 estimated cost for each RNHCI x 16 RNHCIs = $4,240 estimated cost).

After conducting a risk assessment, RNHCIs would need to review, revise, and, if necessary, develop new sections for their emergency plans. The current RNHCI CoPs require RNHCIs to have a written disaster plan for emergencies (42 CFR § 403.742(a)(4)). However, based on our experience with RNHCIs, their plans likely would address only evacuation from their facilities. We expect that all RNHCIs would need to review, revise, and develop new sections for their plans.

We expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require substantially more time to complete the plan than to complete the risk assessment. We estimate that complying with this requirement would require 12 burden hours for each RNHCI at a cost of $348. Therefore, for all 16 RNHCIs to comply with these requirements would require an estimated 192 burden hours (12 burden hours for each RNHCI x

16 RNHCIs = 192 burden hours) at a cost of $5,568 ($348 estimated cost for each RNHCI x 16 RNHCIs = $5,568 estimated cost).

Under this proposed rule, RNHCIs would be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden associated with this requirement, we would expect that RNHCIs already review their plans annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Proposed § 403.748(b) would require RNHCIs to develop and implement emergency preparedness policies and procedures in accordance with their emergency plan based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. These policies and procedures would have to be reviewed and updated at least annually. At a minimum, we propose that the policies and procedures be required to address the requirements specified in § 403.748(b)(1) through (8). The RNHCIs would need to review their policies and procedures and compare them to their emergency plan, risk assessment, and communication plan. Most RNHCIs would need to revise their existing policies and procedures or develop new policies and procedures.

The current RNHCI CoPs require them to have written policies concerning their services (42 CFR § 403.738). Thus, some RNHCIs may have some emergency preparedness policies and procedures. However, based on our experience with RNHCIs, most of their emergency preparedness policies address only evacuation from the facility.

We expect that these tasks would involve the administrator, the director of nursing, and the head of maintenance. All three would need to review and comment on the RNHCI's current policies and procedures. The director of nursing would revise or develop new policies and procedures, as needed, ensure that they are approved, and compile and disseminate them to the appropriate parties. We estimate that it would require 6 burden hours for each RNHCI to comply with this requirement at a cost of $164. Thus, it would require 96 burden hours (6 burden hours for each RNHCI x 16 RNHCIs = 96 burden hours) for all 16 RNHCIs to comply with the requirements in §403.748(b)(1) through (8) at a cost of $2,624 ($164 estimated cost for each RNHCI x 16 RNHCIs = $2,624 estimated cost).

Proposed § 403.748(c) would require RNHCIs 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. We propose that the communication plan include the information specified at § 403.748(c)(1) through (7). The burden associated with complying with this requirement would be the resources required to review and, if necessary, revise an existing communication plan or develop a new plan. Based on our experience with RNHCIs, we expect that these activities would require the involvement of the RNHCI's administrator, the director of nursing, and the head of maintenance. We estimate that complying with this requirement would require 4 burden hours for each RNCHI at a cost of $116. Thus, it would require an estimated 64 burden hours (4 burden hours for each RNHCI x 16 RNHCIs =64 burden

hours) at a cost of $1,856 ($116 estimated cost for each RNHCI x 16 RNHCIs = $1,856 estimated cost).

We propose that RNHCIs would also have to review and update their emergency preparedness communication plan at least annually. We believe that RNHCIs already review their emergency preparedness communication plans periodically. Thus, complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Proposed § 403.748(d) would require RNHCIs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We are proposing that a RNHCI meet the requirements specified at § 403.748(d)(1) and (2). Section 403.748(d)(1) would require RNHCIs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the RNHCI would have to provide training at least annually. Based on our experience, all RNHCIs have some type of emergency preparedness training program. However, all RNHCIs would need to compare their current emergency preparedness training programs to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and revise or, if necessary, develop new sections for their training programs.

We expect that complying with these requirements would require the involvement of the RNHCI administrator and the director of nursing. We estimate that it would require 7 burden hours for each RNHCI to develop an emergency training program at a cost of $218. Thus, it would require an estimated 112 burden hours (7 burden hours for each RNHCI x 16 RNHCIs =

112 burden hours) at a cost of $3,488 ($218 estimated cost for each RNHCI x 16 RNHCI = $3,488 estimated cost).

We are proposing that RNHCIs also review and update their emergency preparedness training and testing programs at least annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with this requirement would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not calculated an estimate of the burden.

Proposed § 403.748(d)(2) would require RNHCIs to conduct a paper-based, tabletop exercise at least annually. The RNHCI must also analyze its response to and maintain documentation of all tabletop exercises and emergency events, and revise its emergency plan, as needed.

The burden associated with complying with this requirement would be the resources RNHCIs would need to develop the scenarios for the exercises and the necessary documentation. Based on our experience with RNHCIs, RNHCIs already conduct some type of exercise periodically to test their emergency preparedness plans. However, we expect that RNHCIs would not be fully compliant with our proposed requirements. We expect that the director of nursing would develop the scenarios and required documentation. We estimate that these tasks would require 3 burden hours at a cost of $72 for each RNCHI. Based on this estimate, for all 16 RNHCIs to comply with these requirements would require 48 burden hours (3 burden hours

for each RNHCI x 16 RNHCIs = 48 burden hours) at a cost of $1,152 ($72 estimated cost for each RNHCI x 16 RNHCI = $1,152 estimated cost).

TABLE 2: BURDEN HOURS AND COST ESTIMATES FOR ALL 16 RNHCIS TO COMPLY WITH THE ICRs CONTAINED IN § 403.748 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§403.748(a)(1)	0938-New	16	16	9	144	**	4,240	0	4,240
§403.748(a)(1)-(4)	0938-New	16	16	12	192	**	5,568	0	5,568
§403.748(b)	0938-New	16	16	6	96	**	2,624	0	2,624
§403.748(c)	0938-New	16	16	4	64	**	1,856	0	1,856
§403.748(d)(1)	0938-New	16	16	7	112	**	3,488	0	3,488
§403.748(d)(2)	0938-New	16	16	3	48	**	1,152	0	1,152
Totals		16	108	41	656				18,928

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

D. ICRs Regarding Condition for Coverage: Emergency Preparedness (§ 416.54)

Proposed § 416.54(a) would require Ambulatory Surgical Centers (ASCs) to develop and maintain an emergency preparedness plan and review and update that plan at least annually. We propose that the plan must meet the requirements contained in § 416.54(a)(1) through (4).

We will discuss the burden for these activities individually below beginning with the risk assessment requirement in § 416.54(a)(1). We expect that each ASC would conduct a thorough risk assessment. This would require the ASC to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that an ASC would consider its location and geographical area; patient population, including those with special needs; and the type of services the ASC has the ability to provide in an emergency. The ASC also would need to identify the measures it must take to ensure continuity of its operation, including delegations and succession plans.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. There are 5,354 ASCs. The current regulations covering

ASCs include some emergency preparedness requirements; however, those requirements primarily are related to internal emergencies, such as a fire.

A significant factor in determining the burden is the accreditation status of an ASC. Of the 5,354 ASCs, 3,786 are non-accredited and 1,568 are accredited. Of the 1,568 accredited ASCs, we estimate that 350 are accredited by The Joint Commission (TJC), 876 by the AAAHC, and additional facilities are accredited by the AOA or the AAAASF. The accreditation standards for these organizations vary in their requirements related to emergency preparedness. The AOA's standards are very similar to the current ASC regulations. AAAASF does have some emergency preparedness requirements, such as requirements for responses or written protocols for security emergencies, for example, intruders and other threats to staff or patients; power failures; transferring patients; and emergency evacuation of the facility. However, the accreditation standards for both the AOA and AAAASF would not significantly satisfy the ICRs contained in this proposed rule. Therefore, for the purpose of determining the burden imposed on ASCs by this proposed rule, we will include the ASCs that are accredited by both the AOA and AAAASF with the non-accredited ASCs.

TJC and AAAHC's accreditation standards contain more extensive emergency preparedness requirements than the accreditation standards of either AOA or AAAASF. For example, TJC standards contain requirements for risk assessments and an emergency management plan. AAAHC's standards include requirements for both internal and external emergencies and drills for the facility's internal emergency plan. Therefore, in discussing the individual burden requirements in this proposed rule, we will discuss the burden for the estimated 1,226 accredited ASCs by either the AAHC or TJC (876 AAAHC-accredited ASCs + 350 TJC-accredited ASCs = 1,226 ASCs accredited by TJC or AAAHC) separately from the

remaining 4,128 (ASCs that are not accredited by an accrediting organization or accredited by the AOA and AAAASF). For some requirements, only the TJC accreditation standards are significantly like those in the proposed rule. For those requirements, we will analyze the 350 TJC-accredited ASCs separately from the 5,004 non TJC-accredited ASCs (5,354 ASCs – 350 TJC-accredited ASCs = 5,004 non TJC-accredited ASCs).

For the purpose of determining the burden for the TJC-accredited ASCs, we used TJC's Comprehensive Accreditation Manual for Ambulatory Care: The Official Handbook 2008 (CAMAC). Concerning the requirement for a risk assessment in proposed § 416.54(a)(1), in the chapter entitled "Management of the Environment of Care" (EC), ASCs are required to conduct comprehensive, proactive risk assessments (CAMAC, CAMAC Refreshed Core, January 2007, (CAMAC), TJC Standard EC.1.10, EP 4, p. EC-9). In addition, ASCs must conduct a hazard vulnerability analysis (HVA) (CAMAC, Standard EC.4.10, EP 1, p. EC-12). The HVA requires the identification of potential emergencies and the effects those emergencies could have on the ASC's operations and the demand for its services (CAMAC, p. EC-12). We expect that TJC-accredited ASCs already conduct a risk assessment that complies with these requirements. If there are any tasks these ASCs need to complete to satisfy the requirement for a risk assessment, we expect that the burden imposed by this proposed requirement would be negligible. For the 350 TJC-accredited ASCs, the risk assessment requirement would constitute a usual and customary business practice. While this requirement is subject to the PRA, we expect that complying with this requirement would constitute a usual and customary business practice as defined at 5 CFR 1320.3(b)(2). Therefore, we have not estimated the amount of regulatory burden.

For the purpose of determining the burden for the 876 AAAHC-accredited ASCs, we used the Accreditation Handbook for Ambulatory Health Care 2008 (AHAHC). The AAAHC standards do not contain a specific requirement for the ASC to perform a risk assessment. However, in discussing the requirement for drills, the AAAHC notes that such drills should be appropriate to the facility's activities and environment (AHAHC, Accreditation Association for Ambulatory Health Care, Inc., Core Standards, Chapter 8. Facilities and Environment, Element E, p. 37). Therefore, we expect that in fulfilling this core standard that the 876 AAAHC-accredited ASCs have performed some type of risk assessment. However, we do not expect that this would satisfy the requirement for a documented, facility-based and community-based risk assessment that addressed the elements required for the emergency plan. Therefore, the 876 AAAHC-accredited ASCs would be included in the burden analysis with the ASCs that are non-accredited or are accredited by AOA and AAAASF for the risk assessment requirement for 5,004 non TJC-accredited ASCs (5,354 total ASCs - 350 TJC-accredited ASCs = 5,004 non TJC-accredited ASCs).

We expect that all ASCs have already performed at least some of the work needed for a risk assessment. However, many probably have not performed a thorough risk assessment. Therefore, we expect that all non TJC-accredited ASCs would perform thorough reviews of their current risk assessments, if they have them, and revise them to ensure they have updated the assessments and that they have included all of the requirements in proposed § 416.54(a).

We have not designated any specific process or format for ASCs to use in conducting their risk assessments because we believe that ASCs, as well as other health care providers and suppliers, need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect health care facilities to, at a minimum, include input from all of

their major departments in the process of developing their risk assessments. Based on our experience working with ASCs, we expect that conducting the risk assessment would require the involvement of an administrator and a quality improvement nurse. We expect that to comply with the requirements of this subsection, both of these individuals would need to attend an initial meeting, review the current assessment, prepare their comments, attend a follow-up meeting, perform a final review, and approve the risk assessment. In addition, we expect that the quality improvement nurse would coordinate the meetings; perform an initial review of the current risk assessment; provide suggestions or a critique of the risk assessment; coordinate comments; revise the original risk assessment; develop any necessary sections for the risk assessment; and ensure that the appropriate parties approve the new risk assessment. We estimate that complying with this risk assessment requirement would require 8 burden hours for each ASC at a cost of $477. Based on that estimate, it would require 40,032 burden hours (8 burden hours for each ASC x 5,004 non TJC-accredited ASCs = 40,032 burden hours) for all non TJC-accredited ASCs to comply with this risk assessment requirement at a cost of $2,386,908 ($477 estimated cost for each ASC x 5,004 ASCs = $2,386,908 estimated cost).

After conducting the risk assessment, ASCs would be required to develop and maintain emergency preparedness plans in accordance with § 416.54(a)(1) through (4). All TJC-accredited ASCs must already comply with many of the requirements in proposed § 416.54(a). All TJC-accredited ASCs are already required to develop and maintain a "written emergency management plan describing the process for disaster readiness and emergency management" (CAMAC, Standard EC.4.10, EP 3, EC-13). We expect that the TJC-accredited ASCs already have emergency preparedness plans that comply with these requirements. If there are any activities required to comply with these requirements, we expect that the burden would be

negligible. Thus, for 350 TJC-accredited ASCs, this requirement would constitute a usual and customary business practice for these ASCs in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for those ASCs.

AAAHC-accredited ASCs are required to have a "comprehensive emergency plan to address internal and external emergencies" (AHAC, Chapter 8. Facilities and Environment, Element D, p. 37). However, we do not believe that this requirement ensures compliance with all of the requirements for an emergency plan. We will include the 876 AAAAHC-accredited ASCs in the burden analysis for this requirement.

We expect that the 5,004 non TJC-accredited ASCs have developed some type of emergency preparedness plan. However, under this proposed rule, all of these ASCs would have to review their current plans and compare them to the risk assessments they performed in accordance with proposed § 416.54(a)(1). The ASCs would then need to update, revise, and in some cases, develop new sections to ensure that their plans incorporate their risk assessments and address all of the proposed requirements. The ASC would also need to review, revise, and, in some cases, develop the delegations of authority and succession plans that ASCs determine are necessary for the appropriate initiation and management of their emergency preparedness plans.

The burden associated with this requirement would be the time and effort necessary to develop an emergency preparedness plan that complies with all of the requirements in proposed § 416.54(a)(1) through (4). Based upon our experience with ASCs, we expect that the administrator and the quality improvement nurse who would be involved in the risk assessment would also be involved in developing the emergency preparedness plan. We estimate that complying with this requirement would require 11 burden hours for each ASC at a cost of $653.

Therefore, based on that estimate, for the 5,004 non TJC-accredited ASCs to comply with the requirements in this section would require burden hours (11 burden hours for each non TJC-accredited ASC x 5,004 non TJC-accredited ASCs = 55,044 burden hours) at a cost of $3,267,612 ($653 estimated cost for each non TJC-accredited ASC x 5,004 non TJC-accredited ASCs = $3,267,612).

All of the ASCs would also be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden for this requirement, we would expect that ASCs would review their plans annually. All ASCs have a professional staff person, generally a quality improvement nurse, whose responsibility entails ensuring that the ASC is delivering quality patient care and that the ASC is complying with regulations concerning patient care. We expect that the quality improvement nurse would be primarily responsible for the annual review of the ASC's emergency preparedness plan. We expect that complying with this requirement would constitute a usual and customary business practice for ASCs in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis.

Section 416.54(b) proposes that each ASC be required to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan set forth in paragraphs (c) of this section. We would require ASCs to review and update these policies and procedures at least annually. These policies and procedures would be required to include, at a minimum, the requirements listed at § 416.54(b)(1) through (7). We expect that ASCs would develop emergency preparedness policies and procedures based upon their risk assessments, emergency preparedness plans, and communication plans.

Therefore, ASCs would need to thoroughly review their emergency preparedness policies and procedures and compare them to all of the information previously noted. The ASCs would then need to revise, or in some cases, develop new policies and procedures that would ensure that the ASCs' emergency preparedness plans address the specific proposed elements.

The TJC accreditation standards already require many of the specific elements that are required in this subsection. For example, in the chapter entitled "Leadership" (LD), TJC-accredited ASCs are required to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMAC, Standard LD.3.90, EP 1, p. LD-12a). In addition, TJC-accredited ASCs must already address or perform a HVA; processes for communicating with and assigning staff under emergency conditions; provision of subsistence or critical needs; evacuation of the facility; and alternate sources for fuel, water, electricity, etc. (CAMAC, Standard EC.4.10, EPs 1, 7-10, 12, and 20, pp. EC-12-13). They must also critique their drills and modify their emergency management plans in response to the critiques (CAMAC, Standard EC.4.20, EPs 12-16, pp. EC-14-14a). In the chapter entitled, "Management of Information" (IM), they are required to protect and preserve the privacy and confidentiality of sensitive data (CAMAC, Standard IM.2.10, EPs 1 and 9, p. IM-6). If TJC-accredited ASCs have any tasks required to satisfy these requirements, we expect they would constitute only a negligible burden. For the 350 TJC-accredited ASCs, the requirement for emergency preparedness policies and procedures would constitute a usual and customary business practice in accordance with 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for these 350 TJC-accredited ASCs.

AAAHC standards require ASCs to have "the necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services

sought or provided" (AHAHC, Chapter 8. Facilities and Environment, Element B, p. 37). Although, we expect that AAAHC-accredited ASCs probably already have policies and procedures that address at least some of the requirements, we expect that they will sustain a considerable burden in satisfying all of the requirements. We will include the AAAHC-accredited ASCs with the non-accredited ASCs in determining the burden for the requirements in proposed §416.54(b).

We expect that all of the 5,004 non TJC-accredited ASCs have some emergency preparedness policies and procedures. However, we expect that all of these ASCs would need to review their policies and procedures and revise their policies and procedures to ensure that they address all of the proposed requirements. We expect that the quality improvement nurse would initially review the ASC's emergency preparedness policies and procedures. The quality improvement nurse would send any recommendations for changes or additional policies or procedures to the ASC's administrator. The administrator and quality improvement nurse would need to make the necessary revisions and draft any necessary policies and procedures. We estimate that for each non TJC-accredited ASC to comply with this proposed requirement would require 9 burden hours at a cost of $505. For all 5,004 ASCs to comply with this requirement would require an estimated 45,036 burden hours (9 burden hours for each non TJC-accredited ASC x 5,004 non TJC-accredited ASCs = 45,036) at a cost of $2,527,020. ($505 estimated cost for each non TJC-accredited ASC x 5,004 ASCs = $2,527,020 estimated cost).

Proposed § 416.54(c) would require each ASC to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. We also propose that ASCs would have to review and update these plans at least annually. These communication plans would have to include the information listed in § 416.54(c)(1) through (7).

The burden associated with developing and maintaining an emergency preparedness communication plan would be the time and effort necessary to review, revise, and, if necessary, develop new sections for the ASC's emergency preparedness communications plan to ensure that it satisfied these requirements.

The TJC-accredited ASCs are required to have a plan that "identifies backup internal and external communication systems in the event of failure during emergencies" (CAMAC, Standard EC.4.10, EP 18, p. EC-13). There are also requirements for identifying, notifying, and assigning staff, as well as notifying external authorities (CAMAC, Standard EC.4.10, EPs 7-9, p. EC-13). In addition, the facility's plan must provide for controlling information about patients (CAMAC, Standard EC.4.10, EP 10, p. EC-13). If any revisions or additions are necessary to satisfy the proposed 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, the proposed requirements for the emergency preparedness communication plan would constitute a usual and customary business practice for ASCs as stated in 5 CFR 1320.3(b)(2). Thus, we will not include this activity by these TJC-accredited ASCs in the burden analysis.

The AAAHC standards do not have a specific requirement for a communication plan for emergencies. However, AAAHC-accredited ASCs are required to have the "necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services sought or provided (AAAHC, 8. Facilities and Environment, Element B, p. 37) and "a comprehensive emergency plan to address internal and external emergencies" (AAAHC, 8. Facilities and Environment, Element D, p. 37). Since communication is vital to any ASC's operations, we expect that communications would be included in the AAAHC-accredited

ASC's plans and procedures. However, we do not believe that these requirements ensure that the AAAHC-accredited ASCs are already fully satisfying all of the requirements. Therefore, we will include the AAAHC-accredited ASCs in with the non-accredited ASCs in determining the burden for these requirements for a total of 5,004 non TJC-accredited ASCs (5,354 total ASCs – 350 TJC accredited ASCs).

We expect that all non TJC-accredited ASCs currently 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. We expect that all ASCs already satisfy the requirements in proposed § 416.54(c)(1) through (4). However, for the requirements in proposed § 416.54(c)(5) through (7), all ASCs would need to review, revise, and, if necessary, develop new sections for their plans to ensure that they include all of the proposed requirements. We expect that this would require the involvement of the ASC's administrator and a quality improvement nurse. We estimate that complying with this proposed requirement would require 4 burden hours at a cost of $227. Therefore, for all non TJC-accredited ASCs to comply with the requirements in this section would require an estimated 20,016 burden hours (4 hours for each non TJC-accredited ASC x 5,004 non TJC-accredited ASCs = 20,016 burden hours) at a cost of $1,135,908 ($227 estimated cost for each non TJC-accredited ASC x 5,004 non TJC-accredited ASCs = $1,135,908 estimated cost).

We also propose that ASCs must review and update their emergency preparedness communication plans at least annually. We believe that ASCs already review their emergency

preparedness communication plans periodically. Therefore, complying with this requirement would constitute a usual and customary business practice for ASCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 416.54(d) would require ASCs to develop and maintain emergency preparedness training and testing programs that ASCs must review and update at least annually. Specifically, ASCs must meet the requirements listed at proposed § 416.54(d)(1) and (2).

The burden associated with complying with these requirements would be the time and effort necessary for an ASC to review, update, and, in some cases, develop new sections for its emergency preparedness training program. We expect that all ASCs already provide training on their emergency preparedness policies and procedures. However, all ASCs would need to review their current training and testing programs and compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans.

Proposed § 416.54(d)(1) would require ASCs to provide initial training in their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. ASCs would have to ensure that their staff can demonstrate knowledge of emergency procedures. Thereafter, ASCs would have to provide the training at least annually. TJC-accredited ASCs must provide an initial orientation to their staff and independent practitioners (CAMAC, Standard 2.10, HR-8). They must also provide "on-going education, including in-services, training, and other activities" to maintain and improve staff competence (CAMAC, Standard 2.30, HR-9). We expect that these TJC-accredited ASCs include some training on their facilities' emergency preparedness policies and procedures in their current training programs. However, these requirements do not contain

any requirements for training volunteers. Thus, TJC accreditation standards do not ensure that TJC-accredited ASCs are already fulfilling all of the proposed requirements, and we expect that the TJC-accredited ASCs will incur a burden complying with these requirements. Therefore, we will include these TJC-accredited ASCs in determining the burden for these requirements.

The AAAHC-accredited ASCs are already required to ensure that "all health care professionals have the necessary and appropriate training and skills to deliver the services provided by the organization" (AAAHC, Chapter 4. Quality of Care Provided, Element A, p. 28). Since these ASCs are required to have an emergency plan that addresses internal and external emergencies, we expect that all of the AAAHC-accredited ASCs already are providing some training on their emergency preparedness policies and procedures. However, this requirement does not include any requirement for annual training or for any training for staff that are not health care professionals. This AAAHC-accredited requirement does not ensure that these ASCs are already complying with the proposed requirements. Therefore, we will include these AAAHC-accredited ASCs in determining the information collection burden for these requirements.

Based upon our experience with ASCs, we expect that all 5,354 ASCs have some type of emergency preparedness training program. We also expect that these ASCs would need to review their training programs and compare them to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. The ASCs would then need to make any necessary revisions to their training programs to ensure they comply with these requirements. We expect that complying with this requirement would require the involvement of an administrator and a quality improvement nurse. We estimate that for each ASC to develop a comprehensive emergency training program would require 6 burden hours at a cost of $329.

Therefore, the estimated annual burden for all 5,354 ASCs to comply with these requirements is 32,124 burden hours (6 burden hours x 5,354 ASCs =32,124 burden hours) at a cost of $1,761,466 ($329 estimated cost for each ASC x 5,354 ASCs = $1,761,466 estimated cost).

We propose that ASCs would also have to review and update their emergency preparedness training programs at least annually. For the purpose of determining the burden for this requirement, we would expect that ASCs would review their emergency preparedness training program annually. We expect that all ASCs have a quality improvement nurse responsible for ensuring that the ASC is delivering quality patient care and that the ASC is complying with patient care regulations. We expect that the quality improvement nurse would be primarily responsible for the annual review of the ASC's emergency preparedness training program. Thus, complying with this requirement would constitute a usual and customary business practice for ASCs in accordance with 5 CFR 1320.3(b)(2). Thus, we will not include this activity in this burden analysis.

Proposed § 416.54(d)(2) would require ASCs to participate in a community mock disaster drill and, if one was not available, conduct an individual, facility-based mock disaster drill, at least annually. ASCs would also have to conduct a paper-based, tabletop exercise at least annually. If the ASC experiences an actual natural or man-made emergency that requires activation of their emergency plan, the ASC would be exempt from the requirement for a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. ASCs would also be required to analyze their response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, ASCs would need to develop a scenario for each drill and exercise. ASCs would also need to develop the documentation necessary for

recording what happened during drills, exercises, and emergency events and analyze their responses to these events.

TJC-accredited ASCs are required to regularly test their emergency management plans at least twice a year, critique each exercise, and modify their emergency management plans in response to those critiques (CAMAC, Standard EC.4.20, EP 1 and 12-16, p. EC-14-14a). In addition, the scenarios for these drills should be realistic and related to the priority emergencies the ASC identified in its HVA (CAMAC, Standard EC.4.20, EP 5, p. EC-14). However, the EPs for this standard do not contain any requirements for the drills to be community-based; for there to be a paper-based, tabletop exercise; or for the ASCs to maintain documentation of these drills, exercises, or emergency events. These TJC accreditation requirements do not ensure that TJC-accredited ASCs are already complying with these requirements. Therefore, the TJC-accredited ASCs will be included in the burden estimate.

The AAAHC-accredited ASCs already are required to perform at least four drills annually of their internal emergency plans (AAAHC, Chapter 8. Facilities and Environment, Element E, p. 37). However, there is no requirement for a paper-based, tabletop exercise; for a community-based drill; or for the ASCs to maintain documentation of their drills, exercises, or emergency events. This AAAHC accreditation requirement does not ensure that AAAHC-accredited ASCs are already complying with these requirements. Therefore, the AAAHC-accredited ASCs will be included in the burden estimate.

Based on our experience with ASCs, we expect that all of the 5,354 ASCs would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and analyze these events, as well as any emergency events. Although we believe many ASCs may have developed scenarios and documentation for

whatever type of drills or exercises they had previously performed, we expect all ASCs would need to ensure that the testing of their emergency preparedness plans comply with these requirements. Based upon our experience with ASCs, we expect that complying with this requirement would require the involvement of an administrator and a quality improvement nurse. We estimate that for each ASC to comply would require 5 burden hours at a cost of $278. Therefore, for all 5,354 ASCs to comply with this requirement would require an estimated 26,770 burden hours (5 burden hours for each ASC x 5,354 ASCs = 26,770 burden hours) at a cost of $1,488,412 ($278 estimated cost for each ASC x 5,354 ASCs = $1,488,412 estimated cost).

TABLE 3: BURDEN HOURS AND COST ESTIMATES FOR ALL 5,354 ASCs TO COMPLY WITH THE ICRs CONTAINED IN §416.54 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§416.54(a)(1)	0938-New	5,004	5,004	8	40,032	**	2,386,908	0	2,386,908
§416.54(a)(1)-(4)	0938-New	5,004	5,004	11	55,044	**	3,267,612	0	3,267,612
§416.54(b)	0938-New	5,004	5,004	9	45,036	**	2,527,020	0	2,527,020
§416.54(c)	0938-New	5,004	5,004	4	20,016	**	1,135,908	0	1,135,908
§416.54(d)(1)	0938-New	5,354	5,354	6	32,124	**	1,758,176	0	1,758,176
§416.54(d)(2)	0938-New	5,354	5,354	5	26,770	**	1,488,412	0	1,488,412
Totals		5,354	30,724		219,022				12,564,036

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

E. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 418.113)

Proposed § 418.113(a) would require hospices to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan meet the criteria listed in proposed § 418.113(a)(1) through (4).

Although proposed § 418.113(a) is entitled "Emergency Plan" and the requirement for the plan is stated first, the emergency plan must include and be based upon a risk assessment. Therefore, since hospices must perform their risk assessments before beginning, or at least before they complete, their plans, we will discuss the burden related to performing the risk assessment first.

Proposed § 113(a)(1) would require all hospices to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that in performing a risk assessment, a hospice would need to consider its physical location, the geographic area in which it is located, and its patient population.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. There are 3,773 hospices. There are 2,584 hospices that provide care only to patients in their homes and 1,189 hospices that offer inpatient care directly

(inpatient hospices). When we use the term “inpatient hospice,” we are referring to a hospice that operates its own inpatient care facility; that is, the hospice provides the inpatient care itself. By “outpatient hospices”, we are referring to hospices that only provide in-home care, and contract with other facilities to provide inpatient care. The current requirements for hospices contain emergency preparedness requirements for inpatient hospices only (42 CFR 418.110). Inpatient hospices must have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice’s ability to provide care," as stated in 42 CFR 418.110(c)(1)(ii). Thus, we expect inpatient hospices already have performed some type of risk assessment during the process of developing their disaster preparedness plan. However, these risk assessments may not be documented or may not address all of the requirements under proposed § 418.113(a). Therefore, we believe that all inpatient hospices would have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities’ risk assessments comply with these requirements.

We have not designated any specific process or format for hospices to use in conducting their risk assessments because we believe hospices need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we believe that in the process of developing a risk assessment, health care institutions should include representatives from or obtain input from all of their major departments. Based on our experience with hospices, we expect that conducting the risk assessment would require the involvement of the hospice’s administrator and an interdisciplinary group (IDG). The current Hospice CoPs require every hospice to have an IDG that includes a physician, registered nurse, social worker, and pastoral or other counselor. The responsibilities of one of a hospice’s IDGs, if they have more than one,

include the establishment of "policies governing the day-to-day provision of hospice care and services" (42 CFR 418.56(a)(2)). Thus, we believe the IDG would be involved in performing the risk assessment.

We expect that members of the IDG would attend an initial meeting; review any existing risk assessment; develop comments and recommendations for changes to the assessment; attend a follow-up meeting; perform a final review; and approve the risk assessment. We expect that the administrator would coordinate the meetings, perform an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary staff approves the new risk assessment. We believe it is likely that the administrator would spend more time reviewing and working on the risk assessment than the other individuals in the IDG. We estimate it would require 10 burden hours to review and update the risk assessment at a cost of $496. There are 1,189 inpatient hospices. Therefore, based on that estimates, it would require 11,890 burden hours (10 burden hours for each inpatient hospice x 1,189 inpatient hospices 11,890 burden hours) for all inpatient hospices to comply with this requirement at a cost of $589,744 ($496 estimated cost for each inpatient hospice x 1,189 inpatient hospices = $589,744 estimated cost).

There are no emergency preparedness requirements in the current hospice CoPs for hospices that provide care to patients in their homes. However, it is standard practice for health care facilities to plan and prepare for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices have considered at least some of the risks they might experience, we anticipate that these facilities would require more time than an inpatient hospice to perform a risk assessment. We estimate that each hospice that provides care to

patients in their homes would require 12 burden hours to develop its risk assessment at a cost of $593. Therefore, based on that estimate, for all 2,584 hospices that provide care to patients in their homes, it would require 31,008 burden hours (12 burden hours for each hospice x 2,584 hospices =31,008 burden hours) to comply with this requirement at a cost of $1,532,312 ($593 estimated cost for each hospice x 2,584 hospices = $1,532,312 estimated cost). Based on the previous calculations, we estimate that for all 3,773 hospices to develop a risk assessment would require 42,898 burden hours at a cost of $2,122,056.

After conducting the risk assessments, hospices would have to develop and maintain emergency preparedness plans that they would have to review and update at least annually. We expect all hospices to compare their current emergency plans, if they have them, to the risk assessments they performed in accordance with proposed § 418.113(a)(1). In addition, hospices would have to comply with the requirements in § 418.113(a)(1) through (4). They would then need to review, revise, and, if necessary, develop new sections of their plans to ensure they comply with these requirements.

The current hospice CoPs require inpatient hospices to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care" (42 CFR 418.110(c)(1)(ii)). We believe that all inpatient hospices already have some type of emergency preparedness or disaster plan. However, their plans may not address all likely medical and non-medical emergency events identified by the risk assessment. Further, their plans may not include strategies for addressing likely emergency events or address their patient population; the type of services they have the ability to provide in an emergency; or continuity of operations, including delegations of authority and succession plans. We expect that an inpatient hospice would have to

review its current plan and compare it to its risk assessment, as well as to the other requirements we propose. We expect that most inpatient hospices would need to update and revise their existing emergency plans, and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this proposed requirement would be the time and effort necessary to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with inpatient hospices, we expect that these activities would require the involvement of the hospice's administrator and an IDG, that is, a physician, registered nurse, social worker, and counselor. We believe that developing the plan would require more time to complete than the risk assessment.

We expect that these individuals would have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the facility's plan, attend a follow-up meeting, perform a final review, and approve the emergency plan. We expect that the administrator would probably coordinate the meetings, perform an initial review of the current emergency plan, provide a critique of the emergency plan, offer suggested revisions, coordinate comments, develop the new emergency plan, and ensure that the necessary parties approve the new emergency plan. We expect the administrator would probably spend more time reviewing and working on the emergency plan than the other individuals. We estimate that it would require 14 burden hours for each inpatient hospice to develop its emergency preparedness plan at a cost of $742. Based on this estimate, it would require 16,646 burden hours (14 burden hours for each inpatient hospice x 1,189 inpatient hospices = 16,646 burden hours) for all inpatient hospices to complete

their plans at a cost of $882,238 ($742 estimated cost for each inpatient hospice x 1,189 inpatient hospices = $882,238 estimated cost).

As discussed earlier, we have no current regulatory requirement for hospices that provide care to patients in their homes to have emergency preparedness plans. However, it is standard practice for health care providers to plan for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices already have some type of emergency or disaster plan, each hospice would need to review its emergency plan to ensure that it addressed the risks identified in its risk assessment and complied with the proposed requirements. We expect that an administrator and the individuals from the hospice's IDG would be involved in reviewing, revising, and developing a facility's emergency plan. However, since there are no current requirements for hospices that provide care to patients in their homes have emergency plans, we believe it would require more time for each of these hospices than for inpatient hospices to complete an emergency plan. We estimate that for each hospice that provides care to patients in their homes to comply with this proposed requirement would require 20 burden hours at an estimated cost of $1,046. Based on that estimate, for all 2,584 of these hospices to comply with this requirement would require 51,680 burden hours (20 burden hours for each hospice x 2,584 hospices = 51,680 burden hours) at a cost of $2,702,864 ($1,046 estimated cost for each hospice x 2,584 hospices = $2,702,864 estimated cost). We estimate that for all 3,773 hospices to develop an emergency preparedness plan would require 68,326 burden hours at a cost of $3,585,102.

Hospices would also be required to review and update their emergency preparedness plans at least annually. The current hospice CoPs require inpatient hospices to periodically review and rehearse their disaster preparedness plan with their staff, including non-employee

staff (42 CFR 418.110(c)(1)(ii)). For purposes of this burden estimate, we would expect that under this proposed rule, inpatient hospices would review their emergency plans prior to reviewing them with all of their employees and that this review would occur annually.

We expect that all hospices, both inpatient and those that provide care to patients in their homes, have an administrator who is responsible for the day-to-day operation of the hospice. Day-to-day operations would include ensuring that all of the hospice's plans are up-to-date and in compliance with relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in health care organizations to have a professional employee, generally an administrator, who periodically reviews their plans and procedures. We expect that complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2). Thus, we will not include this activity in the burden analysis.

Proposed § 418.113(b) would require each hospice to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. It would also require hospices to review and update these policies and procedures at least annually. At a minimum, the hospice's policies and procedures would be required to address the requirements listed at § 418.113((b)(1) through (6).

We expect that all hospices have some emergency preparedness policies and procedures because the current hospice CoPs for inpatient hospices already require them to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care" (42 CFR 418.110(c)(1)(ii)). In addition, the responsibilities for at least one of a hospice's IDGs, if they

have more than one, include the establishment of "policies governing the day-to-day provision of hospice care and services" (42 CFR 418.56(a)(2)). However, we also expect that all inpatient hospices would need to review their current policies and procedures, assess whether they contain everything required by their facilities' emergency preparedness plans, and revise and update them as necessary.

The burden associated with reviewing, revising, and updating a hospice's emergency policies and procedures would be the resources needed to ensure they comply with these requirements. Since at least one of a hospice's IDGs would be responsible for developing policies that govern the daily care and services for hospice patients (42 CFR 418.56(a)(2)), we expect that an IDG would be involved with reviewing and revising a hospice's existing policies and procedures and developing any necessary new policies and procedures. We estimate that an inpatient hospice's compliance with this requirement would require 8 burden hours at a cost of $399. Therefore, based on that estimate, all 1,189 inpatient hospices' compliance with this requirement would require 9,512 burden hours (8 burden hours for each inpatient hospice x 1,189 inpatient hospices = 9,512 burden hours) at a cost of $474,411 ($399 estimated cost for each inpatient hospice x 1,189 inpatient hospices = $474,411 estimated cost).

Although there are no existing regulatory requirements for hospices that provide care to patients in their homes to have emergency preparedness policies and procedures, it is standard practice for health care organizations to prepare for common emergencies, such as fires, power outages, and storms. We expect that these hospices already have some emergency preparedness policies and procedures. However, under this proposed rule, the IDG for these hospices would need to accomplish the same tasks as described earlier for inpatient hospices to ensure that these policies and procedures comply with the proposed requirements.

We estimate that each hospice's compliance with this requirement would require 9 burden hours at a cost of $454. Therefore, based on that estimate, all 2,584 hospices' that provide care to patients in their homes to comply with this requirement would require 23,256 burden hours (9 burden hours for each hospice x 2,584 hospices = 23,256 burden hours) at a cost of $1,173,136 ($454 estimated cost for each hospice x 2,584 hospices = $1,173,136 estimated cost).

Thus, we estimate that development of emergency preparedness policies and procedures for all 3,773 hospices would require 32,768 burden hours at a cost of $1,647,547.

Proposed § 418.113(c) would require a hospice to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Hospices would also have to review and update their plans at least annually. The communication plan would have to include the requirements listed at § 418.113(c)(1) through (7).

We believe that all hospices already have some type of emergency preparedness communication plan. Although only inpatient hospices have a current requirement for disaster preparedness (42 CFR 418.110(c)), it is standard practice for health care organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the organization (for example, cell phones); and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many hospices, both inpatient hospices and hospices that provide care to patients in their homes, may not have formal, written emergency preparedness communication plans. We expect that all hospices would need to review, update, and in some cases, develop new sections for their plans

to ensure that those plans include all of the elements we propose requiring for hospice communication plans.

The burden associated with complying with this requirement would be the resources required to ensure that the hospice's emergency communication plan complied with these requirements. Based upon our experience with hospices, we anticipate that satisfying these requirements would require only the involvement of the hospice's administrator. Thus, for each hospice, we estimate that complying with this requirement would require 3 burden hours at a cost of $165. Therefore, based on that estimate, compliance with this requirement for all 3,773 hospices would require 11,319 burden hours (3 burden hours for each hospice x 3,773 hospices = 11,319 burden hours) at a cost of $622,545 ($165 estimated cost for each hospice x 3,773 hospices = $622,545 estimated cost).

We are proposing that a hospice review and update its emergency preparedness communication plan at least annually. We believe that all hospices already review their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for hospices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 418.113(d) would require each hospice to develop and maintain an emergency preparedness training and testing program that would be reviewed and updated at least annually. Proposed § 418.113(d)(1) would require hospices to provide initial training in emergency preparedness policies and procedures to all hospice employees, consistent with their expected roles, and maintain documentation of the training. The hospice would also have to ensure that their employees could demonstrate knowledge of their emergency procedures. Thereafter, the hospice would have to provide emergency preparedness training at least annually.

Hospices would also be required to periodically review and rehearse their emergency preparedness plans with their employees, with special emphasis placed on carrying out the procedures necessary to protect patients and others.

Under current regulations, all hospices are required to provide an initial orientation and in-service training and educational programs, as necessary, to each employee (§ 418.100(g)(2) and (3)). They must also provide employee orientation and training consistent with hospice industry standards (42 CFR 418.78(a)). In addition, inpatient hospices must periodically review and rehearse their disaster preparedness plans with their staff, including non-employee staff (42 CFR 418.110(c)(1)(ii)). We expect that all hospices already provide training to their employees on the facility's existing disaster plans, policies, and procedures. However, under this proposed rule, all hospices would need to review their current training programs and compare their contents to their updated emergency preparedness plans, policies and procedures, and communications plans. Hospices would then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with the aforementioned requirements would be the time and effort necessary for a hospice to bring itself into compliance with the requirements in this section. We expect that compliance with this requirement would require the involvement of a registered nurse. We expect that the registered nurse would compare the hospice's current training program with the facility's emergency preparedness plan, policies and procedures, and communication plan, and then make any necessary revisions, including the development of new training material, as needed. We estimate that these tasks would require 6 burden hours at a cost of $252. Based on this estimate, compliance by all 3,773 hospices would require 22,638 burden hours (6 burden hours for each hospice x 3,773 hospices = 22,638 burden hours) at a cost of

$950,796 ($252 estimated cost for each hospice x 3,773 hospices = $950,796 estimated cost).

We are proposing that hospices also be required to review and update their emergency preparedness training programs at least annually. We believe that hospices already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for hospices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 418.113(d)(2) would require hospices to participate in a community mock disaster drill, and if one were not available, conduct an individual, facility-based mock disaster drill, and a paper-based, tabletop exercise at least annually. Hospices would also be required to analyze their responses to and maintain documentation of all their drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a hospice would need to develop scenarios for their drills and exercises. A hospice also would have to develop the required documentation.

Hospices would also have to periodically review and rehearse their emergency preparedness plans with their staff (including nonemployee staff), with special emphasis on carrying out the procedures necessary to protect patients and others (§ 418.110(c)(1)(ii)). However, this periodic rehearsal requirement does not ensure that hospices are performing any type of drill or exercise annually or that they are documenting their responses. In addition, there is no requirement in the current CoPs for outpatient hospices to have an emergency plan or for these hospices to test any emergency procedures they may currently have. We believe that developing the scenarios for these drills and exercises and the documentation necessary to record the events during drills, exercises, and emergency events would be new requirements for all hospices.

The associated burden would be the time and effort necessary for a hospice to comply with these requirements. We expect that complying with these requirements would require the involvement of a registered nurse. We expect that the registered nurse would develop the necessary documentation and the scenarios for the drills and exercises. We estimate that these tasks would require 4 burden hours at an estimated cost of $168. Based on this estimate, in order for all 3,773 hospices to comply with these requirements, it would require 15,092 burden hours (4 burden hours for each hospice x 3,773 hospices = 15,092 burden hours) at a cost of $633,864 ($168 estimated cost for each hospice x 3,773 hospices = $633,864 estimated cost).

Thus, for all 3,773 hospices to comply with all of the requirements in § 418.113, it would require an estimated 193,041 burden hours at a cost of $10,444,148.

TABLE 4: BURDEN HOURS AND COST ESTIMATES FOR ALL 3,773 HOSPICES TO COMPLY WITH THE ICRs IN §418.113 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/Maintenance Costs ($)	Total Cost ($)
§418.113(a)(1) (inpatient)	0938-New	1,189	1,189	10	11,890		589,744		589,744
§418.113(a)(1) (outpatient)	0938-New	2,584	2,584	12	31,008		1,532,312		1,532,312
§418.113(a)(1)-(4) (inpatient)	0938-New	1,189	1,189	14	16,646		882,238		882,238
§418.113(a)(1)-(4) (outpatient)	0938-New	2,584	2,584	20	51,680		2,702,864		2,702,864
§418.113(b) (inpatient)	0938-New	1,189	1,189	8	9,512		474,411		474,411
§418.113(b) (outpatient)	0938-New	2,584	2,584	9	23,256		1,173,136		1,173,136
§418.113(c)	0938-New	3,773	3,773	3	11,319		622,545		622,545
§418.113(d)(1)	0938-New	3,773	3,773	6	22,638		950,796		950,796
§418.113(d)(2)	0938-New	3,773	3,773	4	15,092		633,864		633,864
Totals		3,773	22,638		193,041				10,444,148

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

F. ICRs Regarding Emergency Preparedness (§ 441.184)

Proposed § 441.184(a) would require Psychiatric Residential Treatment Facilities (PRTFs) to develop and maintain emergency preparedness plans and review and update those plans at least annually. We propose that these plans meet the requirements listed at § 441.184(a)(1) through (4).

Section § 441.184(a)(1) would require each PRTF to develop a documented, facility-based and community-based risk assessment that would utilize an all-hazards approach. We expect that all PRTFs have already performed some of the work needed for a risk assessment because it is standard practice for health care facilities to prepare for common hazards, such as fires and power outages, and disasters or emergencies common in their geographic area, such as snowstorms or hurricanes. However, many PRTFs may not have documented their risk assessments or performed one that would comply with all of our proposed requirements. Therefore, we expect that all PRTFs would have to review and revise their current risk assessments.

We have not designated any specific process or format for PRTFs to use in conducting their risk assessments because we believe that PRTFs need maximum flexibility to determine the best way to accomplish this task. However, we expect that PRTFs would include representation from or seek input from all of their major departments. Based on our experience with PRTFs, we expect that conducting the risk assessment would require the involvement of the PRTF's administrator, a psychiatric registered nurse, and a clinical social worker. We expect that all of these individuals would attend an initial meeting, review their current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the psychiatric registered nurse

would coordinate the meetings, perform an initial review, offer suggested revisions, coordinate comments, develop a new risk assessment, and ensure that the necessary parties approve the new risk assessment. We also expect that the psychiatric registered nurse would spend more time reviewing and working on the risk assessment than the other individuals. We estimate that in order for each PRTF to comply, it would require 8 burden hours at a cost of $394. There are currently 387 PRTFs. Therefore, based on that estimate, compliance by all PRTFs would require 3,096 burden hours (8 burden hours for each PRTF x 387 PRTFs = 3,096 burden hours) at a cost of $152,478 ($394 estimated cost for each PRTF x 387 PRTFs = $152,478 estimated cost).

After conducting the risk assessment, § 441.184(a)(1) through (4) would require PRTFs to develop and maintain an emergency preparedness plan. Although it is standard practice for health care facilities to have some type of emergency preparedness plan, all PRTFs would need to review their current plans and compare them to their risk assessments. Each PRTF would need to update, revise, and, in some cases, develop new sections to complete its emergency preparedness plan.

Based upon our experience with PRTFs, we expect that the administrator and psychiatric registered nurse who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect it would require substantially more time to complete the plan than the risk assessment. We expect that the psychiatric nurse would be the most heavily involved in reviewing and developing the PRTF's emergency preparedness plan. We also expect that a clinical social worker would review the drafts of the plan and provide comments on it to the psychiatric registered nurse. We estimate that for each PRTF to comply with this requirement would require 12 burden hours at a cost of $634. Thus, we estimate that it would require 4,644 burden hours (12 burden hours for each PRTF x 387

PRTFs = 4,644 burden hours) for all PRTFs to comply with this requirement at a cost of $245,358 ($634 estimated cost per PRTF x 387 PRTFs = $245,358 estimated cost).

PRTFs also would be required to review and update their emergency preparedness plans at least annually. We believe that PRTFs are already reviewing their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(b) would require each PRTF to develop and implement emergency preparedness policies and procedures, based on their emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We also propose requiring PRTFs to review and update these policies and procedures at least annually. At a minimum, we would require that the PRTF's policies and procedures address the requirements listed at § 441.184(b)(1) through (8).

Since we expect that all PRTFs already have some type of emergency plan, we also expect that all PRTFs have some emergency preparedness policies and procedures. However, we expect that all PRTFs would need to review their policies and procedures; compare them to their risk assessments, emergency preparedness plans, and communication plans they developed in accordance with § 441.183(a)(1), (a) and (c), respectively; and then revise their policies and procedures accordingly.

We expect that the administrator and a psychiatric registered nurse would be involved in reviewing and revising the policies and procedures and, if needed, developing new policies and procedures. We estimate that it would require 9 burden hours at a cost of $498 for each PRTF to comply with this requirement. Based on this estimate, it would require 3,483 burden hours

(9 burden hours for each PRTF x 387 PRTFs = 3,483 burden hours) for all PRTFs to comply with this requirement at a cost of $192,726 ($498 estimated cost per PRTF x 387 PRTFs = $192,726 estimated cost).

We are also proposing that PRTFs review and update their emergency preparedness policies and procedures at least annually. We believe that PRTFs are already reviewing their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(c) would require each PRTF to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. PRTFs also would have to review and update these plans at least annually. The communication plan would have to include the information set out in § 441.184(c)(1) through (7).

We expect that all PRTFs have some type of emergency preparedness communication plan. It is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their residents. However, most PRTFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all PRTFs would need to review and, if needed, revise their plans.

Based on our experience with PRTFs, we anticipate that satisfying these requirements would require the involvement of the PRTF's administrator and a psychiatric registered nurse to review, revise, and if needed, develop new sections for the PRTF's emergency preparedness

communication plan. We estimate that for each PRTF to comply would require 5 burden hours at a cost of $286. Based on that estimate, for all PRTFs to comply would require 1,935 burden hours (5 burden hours for each PRTF x 387 PRTFs = 1,935 burden hours) at a cost of $110,682 ($286 estimated cost for each PRTF x 387 PRTFs = $110,682 estimated cost).

PRTFs must also review and update their emergency preparedness communication plans at least annually. We believe that PRTFs are already reviewing their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(d) would require PRTFs to develop and maintain emergency preparedness training programs and review and update those programs at least annually. Proposed § 441.184(d)(1) would require PRTFs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The PRTF would also have to ensure that their staff could demonstrate knowledge of the emergency procedures. Thereafter, the PRTF would have to provide emergency preparedness training at least annually.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness training program. However, PRTFs would need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans and update and, in some cases, develop new sections for their training programs.

We expect that complying with this requirement would require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would review the PRTF's current training program; determine what tasks would need to be performed and what materials would need to be developed; and develop the necessary materials. We estimate that for each PRTF to comply with the requirements in this section would require 10 burden hours at a cost of $460. Based on this estimate, for all PRTFs to comply with this requirement would require 3,870 burden hours (10 burden hours for each PRTF x 387 PRTFs = 3,870 burden hours) at a cost of $178,020 ($460 estimated cost for each PRTF x 387 PRTFs = $178,020 estimated cost).

PRTFs would also be required to review and update their emergency preparedness training program at least annually. We believe that PRTFs are already reviewing their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PRTFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 441.184(d)(2) would require PRTFs to participate in a community mock disaster drill, and if one were not available, conduct an individual, facility-based mock disaster drill, and a paper-based, tabletop exercise at least annually. PRTFs would also have to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. However, if a PRTF experienced an actual natural or man-made emergency that required activation of its emergency plan, that PRTF would be exempt from engaging in a community or an individual, facility-based mock disaster drill for 1 year following the onset of the actual emergency event. To comply with this requirement,

PRTFs would need to develop scenarios for each drill and exercise and the documentation necessary to record and analyze drills, exercises, and actual emergency events.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness testing program and most, if not all, PRTFs already conduct some type of drill or exercise to test their emergency preparedness plans. We also expect that they have already developed some type of documentation for drills, exercises, and emergency events. However, we do not expect that all PRTFs are conducting both a drill and a paper-based, tabletop exercise annually or have developed the appropriate documentation. Thus, we will analyze the burden of these requirements for all PRTFs.

Based on our experience with PRTFs, we expect that the same individual who developed the emergency preparedness training program would develop the scenarios for the drill and the exercise and the accompanying documentation. We estimate that for each PRTF to comply with the requirements in this section would require 3 burden hours at a cost of $138. We estimate that for all PRTFs to comply would require 1,161 burden hours (3 burden hours for each PRTF x 387 PRTFs = 1,161 burden hours) at a cost of $53,406 ($138 estimated cost for each PRTF x 387 PRTFs = $53,406 estimated cost).

Based on the previous analysis, for all 387 PRTFs to comply with the ICRs in this proposed rule would require 18,189 burden hours at a cost of $932,670.

TABLE 5: BURDEN HOURS AND COST ESTIMATES FOR ALL 387 PRTFs TO COMPLY WITH THE ICRs CONTAINED IN § 441.184 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§441.184(a)(1)	0938-New	387	387	8	3,096	**	152,478	0	152,478
§441.184(a)(1)-(4)	0938-New	387	387	12	4,644	**	245,358	0	245,358
§441.184(b)	0938-New	387	387	9	3,483	**	192,726	0	192,726
§441.184(c)	0938-New	387	387	5	1,935	**	110,682	0	110,682
§441.184(d)(1)	0938-New	387	387	10	3,870	**	178,020	0	178,020
§441.184(d)(2)	0938-New	387	387	3	1,161	**	53,406	0	53,406
Totals		387	2,322		18,189				932,670

G. ICRs Regarding Emergency Preparedness (§ 460.84)

Proposed § 460.84(a) would require the Program for the All-Inclusive Care for the Elderly (PACE) organizations to develop and maintain emergency preparedness plans and review and update those plans at least annually. We propose that each plan must meet the requirements listed at § 460.84(a)(1) through (4).

Section § 460.84(a)(1) would require PACE organizations to develop documented, facility-based and community-based risk assessments utilizing an all-hazards approach. We believe that the performance of a risk assessment is a standard practice, and that all of the PACE organizations have already conducted some sort of risk assessment based on common emergencies the organization might encounter, such as fires, loss of power, loss of communications, etc. Therefore, we believe that each PACE organization should have already performed some sort of risk assessment.

Under the current regulations, PACE organizations are required to establish, implement, and maintain procedures for managing medical and non-medical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public (§ 460.72(c)(1)).

The definition of "emergencies" includes natural disasters that are likely to occur in the PACE organization's area (§ 460.72(c)(2)). PACE organizations are required to plan for emergencies involving participants who are in their center(s) at the time of an emergency, as well as participants receiving services in their homes.

For the purpose of determining the burden, we will assume that a PACE organization's risk assessment, emergency plan, policies and procedures, communication plan, and training and testing program would apply to all of a PACE organization's centers. Based on the existing PACE regulations, we expect that they already assess their physical structure(s), the areas in which they are located, and the location(s) of their participants. However, these risk assessments may not be documented or address all of our proposed requirements. Therefore, we expect that all 91 PACE organizations would have to review, revise, and update their current risk assessments.

We have not designated any specific process or format for PACE organizations to use in conducting their risk assessments because we believe that they would be able to determine the best way for their facilities to accomplish this task. However, we expect that they would include representation or input from all of their major departments. Based on our experience with PACE organizations, we expect that conducting the risk assessment would require the involvement of the PACE organization's program director, medical director, home care coordinator, quality improvement nurse, social worker, and a driver. We expect that these individuals would either attend an initial meeting or be asked to individually review relevant sections of the current risk assessment and prepare and forward their comments to the quality assurance nurse. After initial comments are received, some would attend a follow-up meeting, perform a final review, and ensure the new risk assessment was approved by the appropriate individuals. We expect that the

quality improvement nurse would coordinate the meetings, review the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the quality improvement nurse and the home care coordinator would spend more time reviewing and developing the risk assessment than the other individuals.

We estimate that complying with the requirement to conduct a risk assessment would require 14 burden hours at a cost of $761. For all 91 PACE organizations to comply with this requirement would require an estimated 1,274 burden hours (14 burden hours for each PACE organization x 91 PACE organizations = 1,274 burden hours) at a cost of $69,251 ($761 estimated cost for each PACE organization x 91 PACE organizations = $69,251 estimated cost).

After conducting a risk assessment, PACE organizations would have to develop and maintain emergency preparedness plans that satisfied all of the requirements in § 460.84(a)(1) through (4). In addition to the requirement to establish, implement, and maintain procedures for managing emergencies and disasters, current regulations require PACE organizations to have a governing body or designated person responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that an emergency preparedness plan would be an essential component of such a comprehensive, systemic operational plan. However, this regulatory requirement does not guarantee that all PACE organizations have developed a plan that complies with our proposed requirements.

Thus, we expect that all PACE organizations would need to review their current plans and compare them to their risk assessments. PACE organizations would need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans.

Based upon our experience with PACE organizations, we expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require more time to complete the plan. We expect that the quality improvement nurse would have primary responsibility for reviewing and developing the PACE organization's emergency preparedness plan. We expect that the program director, home care coordinator, and social worker would review the current plan, provide comments, and assist the quality improvement nurse in developing the final plan. Other staff members would work only on the sections of the plan that would be relevant to their areas of responsibility.

We estimate that for each PACE organization to comply with the requirement for an emergency preparedness plan would require 23 burden hours at a cost of $1,239. We estimate that for all PACE organizations to comply would require 2,093 burden hours (23 burden hours for each PACE Organization x 91 PACE organizations = 2,093 burden hours) at a cost of $112,749 ($1,239 estimated cost for each PACE organization x 91 PACE organizations = $112,749 estimated cost).

PACE organizations would also be required to review and update their emergency preparedness plans at least annually. We believe that PACE organizations are already reviewing their emergency preparedness plans periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(b) would require each PACE organization to develop and implement emergency preparedness policies and procedures based on the emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the

communication plan at (c) of this section. It would also require PACE organizations to review and update these policies and procedures at least annually. At a minimum, we would require that a PACE organization's policies and procedures address the requirements listed at § 460.84(b)(1) through (9).

Current regulations already require that PACE organizations establish, implement, and maintain procedures for managing emergencies and disasters (§ 460.72(c)). The definition of "emergencies" includes medical and nonmedical emergencies, such as natural disasters likely to occur in a PACE organization's area (42 CFR 460.72(c)(2)). In addition, all PACE organizations must have a governing body or a designated person who functions as the governing body responsible for developing policies on participant health and safety (§ 460.62(a)(6)). Thus, we expect that all PACE organizations have some emergency preparedness policies and procedures. However, these requirements do not ensure that all PACE organizations have policies and procedures that would comply with our proposed requirements.

The burden associated with the proposed requirements would be the resources needed to review, revise, and, if needed, develop new emergency preparedness policies and procedures. We expect that the program director, home care coordinator, and quality improvement nurse would be primarily responsible for reviewing, revising, and if needed, developing any new policies and procedures needed to comply with our proposed requirements. We estimate that for each PACE organization to comply with our proposed requirements would require 12 burden hours at a cost of $598. Therefore, based on this estimate, for all PACE organizations to comply would require 1,092 burden hours (12 burden hours for each PACE organization x 91 PACE organizations = 1,092 burden hours) at a cost of $54,418 ($598 estimated cost for each PACE organization x 91 PACE organizations = $54,418 estimated cost).

We propose that each PACE organization must also review and update its emergency preparedness policies and procedures at least annually. We believe that PACE organizations are already reviewing their emergency preparedness policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(c) would require each PACE organization to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Each PACE organization would also have to review and update this plan at least annually. The communication plan must include the information set out at § 460.84(c)(1) through (7).

All PACE organizations must have a governing body (or a designated person who functions as the governing body) that is responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that the PACE organizations' comprehensive, systemic operational plans would include at least some of our proposed requirements. In addition, it is standard practice in the health care industry to 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; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. Thus, we expect that all PACE organizations have some type of emergency preparedness communication plan. However, each PACE organization would need to review its current plan and revise or, in some cases, develop new sections to comply with our proposed requirements.

Based on our experience with PACE organizations, we expect that the home care coordinator and the quality assurance nurse would be primarily responsible for reviewing, and if needed, revising, and developing new sections for the communication plan. We estimate that for each PACE organization to comply with the proposed requirements would require 7 burden hours at a cost of $315. Therefore, based on this estimate, for all PACE organizations to comply with this requirement would require 637 burden hours (7 burden hours for each PACE organization x 91 PACE organizations = 637 burden hours) at a cost of $28,665 ($315 estimated cost for each PACE organization x 91 PACE organizations = $28,665 estimated cost).

Each PACE organization must also review and update its emergency preparedness communication plan at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(d) would require PACE organizations to develop and maintain emergency preparedness training and testing programs and review and update those programs at least annually. We propose that each PACE organization would have to meet the requirements listed at § 460.84(d)(1) and (2).

Proposed § 460.84(d)(1) would require PACE organizations to provide initial training on their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles and maintain documentation of this training. PACE organizations would also have to ensure that their staff could demonstrate knowledge of the

emergency procedures. Thereafter, PACE organizations would be required to provide this training annually.

Current regulations require PACE organizations to provide periodic orientation and appropriate training to their staffs and participants in emergency procedures (§ 460.72(c)(3)). However, these requirements do not ensure that all PACE organizations would be in compliance with our proposed requirements. Thus, each PACE organization would need to review its current training program and compare the training program to its risk assessment, emergency preparedness plan, policies and procedures, and communication plan. The PACE organization would also need to revise and, in some cases, develop new sections to ensure that its emergency preparedness training program complied with our proposed requirements. We expect that the quality assurance nurse would review all elements of the PACE organization's training program and determine what tasks would need to be performed and what materials would need to be developed to comply with our proposed requirements. We expect that the home care coordinator would work with the quality assurance nurse to develop the revised and updated training program. We estimate that for each PACE organization to comply with the proposed requirements would require 12 burden hours at a cost of $540. Therefore, it would require an estimated 1,092 burden hours (12 burden hours for each PACE organization x 91 PACE organizations = 1,092 burden hours) to comply with this requirement at a cost of $49,140 ($540 estimated cost for each PACE organization x 91 PACE organizations = $49,140 estimated cost).

PACE organizations would also be required to review and update their emergency preparedness training program at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business

practice for PACE organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 460.84(d)(2) would require PACE organizations to participate in a community mock disaster drill at least annually. If a community mock disaster drill was not available, the PACE organization would have to conduct an individual, facility-based mock disaster drill. They would also be required to conduct a paper-based, tabletop exercise at least annually. PACE organizations would also be required to analyze their responses to, and maintain documentation of, all drills, exercises, and any emergency events they experienced. If a PACE organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. To comply with these requirements, PACE organizations would need to develop a specific scenario for each drill and exercise. The PACE organizations would also have to develop the documentation necessary for recording and analyzing their response to all drills, exercises, and emergency events.

Current regulations require each PACE organization to conduct a test of its emergency and disaster plan at least annually (42 CFR 460.72(c)(5)). They also must evaluate and document the effectiveness of their emergency and disaster plans. Thus, PACE organizations already conduct at least one test annually of their plans. We expect that as part of testing their emergency plans annually, PACE organizations would develop a scenario for and document the testing. However, this does not ensure that all PACE organizations would be in compliance with all of our proposed requirements, especially the proposed requirement for conducting a paper-

based, tabletop exercise; performing a community-based mock disaster drill; and using different scenarios for the drill and the exercise.

The 91 PACE organizations would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and analyze their response to all drills, exercises, and any emergency events. Based on our experience with PACE organizations, we expect that the same individuals who developed their emergency preparedness training programs would develop the required documentation. We expect the quality improvement nurse would spend more time on these activities than the health care coordinator. We estimate that this activity would require 5 burden hours for each PACE organization at a cost of $225. We estimate that for all PACE organizations to comply with these requirements would require 455 burden hours (5 burden hours for each PACE organization x 91 PACE organizations = 455 burden hours) at a cost of $20,475 ($225 estimated cost for each PACE organization x 91 PACE organizations = $20,475 estimated cost).

TABLE 6: BURDEN HOURS AND COST ESTIMATES FOR ALL 91 PACE ORGANIZATIONS TO COMPLY WITH THE ICRs CONTAINED IN § 460.84 EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§460.84(a)(1)	0938-New	91	91	14	1,274	**	69,251	0	69,251
§460.84(a)(1)-(4)	0938-New	91	91	23	2,093	**	112,749	0	112,749
§460.84(b)	0938-New	91	91	12	1,092	**	54,418	0	54,418
§460.84(c)	0938-New	91	91	7	637	**	28,665	0	28,665
§460.84(d)(1)	0938-New	91	91	12	1,092	**	49,140	0	49,140
§460.84(d)(2)	0938-New	91	91	5	455	**	20,475	0	20,475
Totals		91	546		6,643				334,698

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

H. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 482.15)

Proposed § 482.15(a) would require hospitals to develop and maintain emergency preparedness plans. We propose that hospitals be required to review and update their emergency preparedness plans at least annually and meet the requirements set out at § 482.15(a)(1) through (4).

Note that we obtain data on the number of hospitals, both accredited and non-accredited, from the CMS CASPER data system, which are updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited hospitals shown may not equal the number of hospitals at the time of this proposed rule's publication. In addition, some hospitals may have chosen to be accredited by more than one accrediting organization.

There are approximately 4,928 Medicare-certified hospitals. This includes 107 critical access hospitals (CAHs) that have rehabilitation or psychiatric distinct part units (DPUs) as of March 27, 2013. The services provided by CAH psychiatric or rehabilitation DPUs must comply with the hospital Conditions of Participation (CoPs) (42 CFR 485.647(a)). RNHCIs and CAHs that do not have DPUs have been excluded from this number and are addressed separately in this analysis. Of the 4,928 hospitals reported in CMS' CASPER data system, approximately 4,587 are accredited hospitals and the remainder is non-accredited hospitals. Three organizations have accrediting authority for these hospitals: TJC, formerly known as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the AOA, and DNVHC.

Accreditation can substantially affect the burden a hospital would sustain under this proposed rule. The Joint Commission accredits 3,410 hospitals. Many of our proposed requirements are similar or virtually identical to the standards, rationales, and elements of

performance (EPs) required for TJC accreditation. The TJC standards, rationales, and elements of performance (EPs) are on the TJC website at http://www.jointcommission.org/.

The other two accrediting organizations, AOA and DNVHC, accredit 185 and 176 hospitals, respectively. The AOA hospital accreditation requirements do not emphasize emergency preparedness. In addition, these hospitals account for less than 5 percent of all of the hospitals. Thus, for purposes of determining the burden, we have included the 185 AOA-accredited hospitals and the 176 DNVHC-accredited hospitals in with the hospitals that are not accredited. Therefore, unless indicated otherwise, we have analyzed the burden for the 3,410 TJC-accredited hospitals separately from the remaining 1,518 non TJC-accredited hospitals (4,928 hospitals – 3,410 TJC-accredited hospitals = 1,518 non TJC-accredited hospitals).

We have used TJC's "Comprehensive Accreditation Manual for Hospitals: The Official Handbook 2008 (CAMH)" to determine the burden for TJC-accredited hospitals. In the chapter entitled, "Management of the Environment of Care" (EC), hospitals are required to plan for managing the consequences of emergencies (CAMH, Standard EC.4.11, CAMH Refreshed Core, January 2008, p. EC-13a). Individual standards have EPs, which provide the detailed and specific performance expectations, structures, and processes for each standard (CAMH, CAMH Refreshed Core, January 2008, p. HM-6). The EPs for Standard EC.4.11 require, among other things, that hospitals conduct a hazard vulnerability analysis (HVA) (CAMH, Standard EC.4.11, EP 2, CAMH Refreshed Core, January 2008, p. EC-13a). Performing an HVA would require a hospital to identify the events that could possibly affect demand for the hospital's services or the hospital's ability to provide services. A TJC-accredited hospital also must determine the likeliness of the identified risks occurring, as well as their consequences. Thus, we expect that

TJC-accredited hospitals already conduct an HVA that complies with our proposed requirements and that any additional tasks necessary to comply would be minimal. Therefore, for TJC-accredited hospitals, the risk assessment requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(a)(1) would require that hospitals perform a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. We expect that most non TJC-accredited hospitals have already performed at least some of the work needed for a risk assessment. The Niska and Burt article indicated that most hospitals already have plans for natural disasters. However, many may not have thoroughly documented this activity or performed as thorough a risk assessment as needed to comply with our proposed requirements.

We have not designated any specific process or format for hospitals to use in conducting a risk assessment because we believe that hospitals need the flexibility to determine how best to accomplish this task. However, we expect that hospitals would obtain input from all of their major departments when performing a risk assessment. Based on our experience, we expect that conducting a risk assessment would require the involvement of at least a hospital administrator, the risk management director, the chief medical officer, the chief of surgery, the director of nursing, the pharmacy director, the facilities director, the health information services director, the safety director, the security manager, the community relations manager, the food services director, and administrative support staff. We expect that most of these individuals would attend an initial meeting, review relevant sections of their current risk assessment, prepare and send their comments to the risk management director, attend a follow-up meeting, perform a final review, and approve the new risk assessment.

We expect that the risk management director would coordinate the meetings, review and comment on the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the hospital administrator would spend more time reviewing the risk assessment than most of the other individuals.

We estimate that the risk assessment would require 36 burden hours to complete at a cost of $2,923 for each non-TJC accredited hospital. There are approximately 1,518 non TJC-accredited hospitals. Therefore, it would require an estimated 54,648 burden hours (36 burden hours for each non TJC-accredited hospitals x 1,518 non TJC-accredited hospitals = 54,648 burden hours) for all non TJC-accredited hospitals to comply at a cost of $4,437,114 ($2,923 estimated cost for each non TJC-hospital x 1,518 non TJC-accredited hospitals = $4,437,114 estimated cost).

Proposed § 482.15(a)(1) through (4) would require hospitals to develop and maintain emergency preparedness plans. We expect that all hospitals would compare their risk assessments to their emergency plans and revise and, if necessary, develop new sections for their plans. TJC-accredited hospitals must develop and maintain written Emergency Operations Plans (EOPs) (CAMH, Standard EC.4.12, EP 1, CAMH Refreshed Care, January 2008, p. EC-13b). The EOP should describe an "all-hazards" approach to coordinating six critical areas: communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities during emergencies (CAMH, Standard EC.4.13 – EC.4.18, CAMH Refreshed Core, January 2008, pp. EC-13b – EC-13g). Hospitals also must include in their EOP "[r]esponse strategies and actions to be activated during the emergency" and "[r]ecovery strategies and actions designed to help restore the systems that are

critical to resuming normal care, treatment and services" (CAMH, Standard EC.4.11, EPs 7 and 8, p. EC-13a). In addition, hospitals are required to have plans to manage "clinical services for vulnerable populations served by the hospital, including patients who are pediatric, geriatric, disabled or have serious chronic conditions or addictions" (CAMH, Standard EC.4.18, EP 2, p. EC-13g). Hospitals also must plan how to manage the mental health needs of their patients (CAMH, Standard EC.4.18, EP 4, EC-13g). Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this proposed rule. If a TJC-accredited hospital needed to complete additional tasks to comply with the proposed requirement, we believe that the burden would be negligible. Therefore, for TJC-accredited hospitals, this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that most, if not all, non TJC-accredited hospitals already have some type of emergency preparedness plan. The Niska and Burt article noted that the majority of hospitals have plans for natural disasters; incendiary incidents; and biological, chemical, and radiological terrorism. In addition, all hospitals must already meet the requirements set out at 42 CFR 482.41, including emergency power, lighting, gas and water supply requirements as well as specified Life Safety Code provisions. However, those existing plans may not be fully compliant with our proposed requirements. Thus, it would be necessary for non TJC-accredited hospitals to review their current plans and compare them to their risk assessments and revise, update, or, in some cases, develop new sections for their emergency plans.

Based on our experience with hospitals, we expect that the same individuals who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we estimate that it would require substantially more time to

complete an emergency preparedness plan. We estimate that complying with this requirement would require 62 burden hours at a cost of $5,085 for each non TJC-accredited hospital. There are approximately 1,518 non TJC-accredited hospitals. Therefore, based on this estimate, it would require 94,116 burden hours for all non TJC-accredited hospitals (62 burden hours for each non TJC-accredited hospitals x 1,518 non TJC-accredited hospitals = 94,116 burden hours) to complete an emergency preparedness plan at a cost of $7,719,030 ($5,085 estimated cost for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = $7,719,030 estimated cost).

Under this proposed rule, a hospital also would be required to review and update its emergency preparedness plan at least annually. We believe that hospitals already review their emergency preparedness plans periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for hospitals and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Under proposed § 482.15(b), we would require each hospital to develop and implement emergency preparedness policies and procedures based on its emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We would also require hospitals to review and update these policies and procedures at least annually. At a minimum, we would require that the policies and procedures address the requirements at § 482.15(b)(1) through (8).

We would expect all hospitals to review their emergency preparedness policies and procedures and compare them to their emergency plans, risk assessments, and communication plans. We expect that hospitals would then review, revise, and, if necessary, develop new policies and procedures that comply with our proposed requirements.

The CAMH's chapter entitled, "Leadership" (LD), requires TJC-accredited hospital leaders to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMH, Standard LC.3.90, EP 1, CAMH Refreshed Core, January 2008, p. LD-15). Thus, we expect that TJC-accredited hospitals already have some policies and procedures related to our proposed requirements. As discussed later, many of the requirements in proposed § 482.15(b) has a corresponding requirement in the TJC hospital accreditation standards. Hence, we will discuss each proposed section individually.

Proposed § 482.15(b)(1) would require hospitals to have policies and procedures for the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited hospitals are required to make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMH, Standard EC.4.14, EPs 1-8 and 10-11, p. EC-13d). In addition, hospitals must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases when their usual supply is disrupted or compromised (CAMH, Standard EC.4.17, EPs 1-5, p. EC-13f). Thus, we expect that TJC-accredited hospitals would be in compliance with our proposed provision of subsistence requirements in proposed § 482.15(b)(1).

Proposed § 482.15(b)(2) would require hospitals to have policies and procedures to track the location of staff and patients in the hospital's care both during and after an emergency. TJC-accredited hospitals must plan for communicating with patients and their families at the beginning of and during an emergency (CAMH, Standard EC.4.13, EPs 1, 2, and 5, p. EC-13c). We expect that TJC-accredited hospitals would be in compliance with proposed §482.15(b)(2).

Proposed § 482.15(b)(3) would require hospitals to have policies and procedures for a plan for the safe evacuation from the hospital. TJC-accredited hospitals are required to make

plans to evacuate patients as part of managing their clinical activities (CAMH, Standard EC.4.18, EP 1, p. EC-13g). They also must plan for the evacuation and transport of patients, as well as their information, medications, supplies, and equipment, to alternative care sites (ACSs) when the hospital cannot provide care, treatment, and services in their facility (CAMH, Standard EC.4.14, EPs 9-11, p. EC-13d). Proposed § 482.15(b)(3) also would require hospitals to have "primary and alternate means of communication with external sources of assistance." TJC-accredited hospitals must plan for communicating with external authorities once the hospital initiates its emergency response measures (CAMH, Standard EC.4.13, EP 4, p. EC-13c). Thus, TJC-accredited hospitals would be in compliance with most of the requirements in proposed § 482.15(b)(3). However, we do not believe these requirements would ensure compliance with the proposed requirement that the hospital establish policies and procedures for staff responsibilities.

Proposed § 482.15(b)(4) would require hospitals to have policies and procedures that address a means to shelter in place for patients, staff, and volunteers who remain at the facility. The rationale for CAMH Standard EC.4.18 states, "a catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMH, Standard EC.4.18, p. EC-13f). We expect that TJC-accredited hospitals would be in compliance with our proposed shelter in place requirement in §482.15(b)(4).

Proposed § 482.15(b)(5) would require hospitals to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available. The CAMH chapter entitled "Management of Information" requires TJC-accredited hospitals to have storage and retrieval systems for their clinical/service and hospital-specific information

(CAMH, Standard IM.3.10, EP 5, CAMH Refreshed Core, January 2008, p. IM-10) and to ensure the continuity of their critical information "needs for patient care, treatment, and services (CAMH, Standard IM.2.30, Rationale for IM.2.30, CAMH Refreshed Core, January 2008, p. IM-8). They also must ensure the privacy and confidentiality of patient information (CAMH, Standard IM.2.10, CAMH Refreshed Core, January 2008, p. IM-7) and have plans for transporting and tracking patients' clinical information, including transferring information to ACSs (CAMH Standard EC.4.14, EP 11, p. EC-13d and Standard EC.4.18, EP 6, pp. EC-13d and EC-13g, respectively). Therefore, we expect that TJC-accredited hospitals would be in compliance with the requirements we propose in § 482.15(b)(5).

Proposed § 482.15(b)(6) would require hospitals to have policies and procedures that address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state and federally-designated health care professionals to address surge needs during an emergency. TJC-accredited hospitals must already define staff roles and responsibilities in their EOPs and ensure that they train their staffs for their assigned roles (CAMH, Standard EC.4.16, EPs 1 and 2, p. EC-13e). The rationale for Standard EC.4.15 indicates that the "hospital determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated." In addition, in the chapter entitled "Medical Staff" (MS), hospitals "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMH, Standard MS.4.110, CAMH Refreshed Care, January 2008, p. MS-27). Finally, in the chapter entitled "Management of Human Resources" (HR), hospitals "may assign disaster responsibilities to volunteer practitioners" (CAMH, Standard HR.1.25, CAMH Refreshed Core, January 2008, p. HR-5). Although TJC accreditation requirements partially address our proposed requirements, we do not

believe these requirements would ensure compliance with all requirements in proposed in § 482.15(b)(6).

Proposed § 482.15(b)(7) would require hospitals to have policies and procedures that would address the development of arrangements with other hospitals or other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. TJC-accredited hospitals must plan for the sharing of resources and assets with other health care organizations (CAMH, Standard EC.4.14, EPs 7 and 8, p. EC-13d). However, we would not expect TJC-accredited hospitals to be substantially in compliance with the requirements we propose in § 482.15(b)(7) based on compliance with TJC accreditation standards alone.

Proposed § 482.15(b)(8) would require hospitals to have policies and procedures that address the hospital's role under an "1135 waiver" (that is, a waiver of some federal rules pursuant to §1135 of the Social Security Act) in the provision of care and treatment at an ACS identified by emergency management officials. TJC-accredited hospitals must already have plans for transporting patients, as well as their associated information, medications, equipment, and staff to ACSs when the hospital cannot support their care, treatment, and services on site (CAMH, Standard EC.4.14, EPs 10 and 11, p. EC-13d). We expect that TJC-accredited hospitals would be in compliance with the requirements we propose in § 482.15(b)(8).

In summary, we expect that TJC-accredited hospitals have developed and are maintaining policies and procedures that would comply with the requirements in proposed § 482.15(b), except for proposed §§ 482.15(b)(3), (6), and (7). Later we will discuss the burden on TJC-accredited hospitals with respect to these provisions. We expect that any modifications that TJC-accredited hospitals would need to make to comply with the remaining proposed requirements

would not impose a burden above that incurred as part of usual and customary business practices. Thus, with the exception of the proposed requirements set out at § 482.15(b)(3), (b)(6), and (b)(7), the proposed requirements would constitute usual and customary business practices and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The burden associated with proposed § 482.15(b)(3), (b)(6), and (b)(7) would be the resources required to develop written policies and procedures that comply with the proposed requirements. We expect that the risk management director would review the hospital's policies and procedures initially and make recommendations for revisions and development of additional policies or procedures. We expect that representatives from the hospital's major departments would make revisions or draft new policies and procedures based on the administrator's recommendation. The appropriate parties would then need to compile and disseminate these new policies and procedures.

We estimate that complying with these requirements would require 17 burden hours for each TJC-accredited hospital at a cost of $1,423. For all 3,410 TJC-accredited hospitals to comply with these requirements would require an estimated 57,970 burden hours (17 burden hours for each TJC-accredited hospital x 3,410 TJC-accredited hospitals = 57,970 burden hours) at a cost of $4,852,430 (1,423 estimated cost for each TJC-accredited hospital x 3,410 TJC-accredited hospitals = $4,852,430 estimated cost).

The 1,518 non TJC-accredited hospitals would need to review their policies and procedures, ensure that their policies and procedures accurately reflect their risk assessments, emergency preparedness plans, and communication plans, and incorporate any of our proposed requirements into their policies and procedures. We expect that the risk management director would coordinate the meetings, review and comment on the current policies and procedures,

suggest revisions, coordinate comments, develop the policies and procedures, and ensure that the necessary parties approve it. We expect that the hospital administrator would spend more time reviewing the policies and procedures than most of the other individuals.

We estimate that complying with this requirement would require 33 burden hours for each non TJC-accredited hospital at an estimated cost of $2,623. Based on this estimate, for all 1,518 non TJC-accredited hospitals to comply with these requirements would require 50,094 burden hours (33 burden hours for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = 50,094 burden hours) at a cost of $3,981,714 ($2,623 estimated cost for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = $3,981,714 estimated cost).

In addition, we expect that there would be a burden as a result of proposed § 482.15(b)(7). Proposed § 482.15(b)(7) would require hospitals to develop and maintain policies and procedures that address a hospital's development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. We expect that hospitals would base those arrangements on written agreements between the hospital and other hospitals and other providers. Thus, in addition to the burden related to developing the policies and procedures, hospitals would also sustain a burden related to developing the written agreements related to those arrangements.

All 4,928 hospitals would need to identify other hospitals and other providers with which they could have agreements, negotiate and draft the agreements, and obtain all necessary authorizations for the agreements. For the purpose of determining the burden, we will assume that hospitals would have written agreements with two other hospitals and other providers. Based on our experience with hospitals, we expect that complying with this requirement would

primarily require the involvement of the hospital's administrator and risk management director. We also expect that a hospital attorney would assist with drafting the agreements and reviewing those documents for any legal implications. We estimate that complying with this requirement would require 8 burden hours for each hospital at an estimated cost of $719. Thus, it would require an estimated 39,424 burden hours (8 burden hours for each hospital x 4,928 hospitals = 39,512 burden hours) for all hospitals to comply with this requirement at a cost of $3,543,232 ($719 estimated cost for each hospital x 4,928 hospitals = $3,543,232 estimated cost).

Based upon the previous estimates, for all hospitals to be in compliance with all of the requirements in § 482.15(b) it would require 147,488 burden hours at a cost of $12,377,376.

Proposed § 482.15(b) would also require hospitals to review and update their emergency preparedness policies and procedures at least annually. We believe hospitals are already reviewing and updating their emergency preparedness policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for both TJC-accredited and non TJC-accredited hospitals and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(c) would require each hospital to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The plan would have to be reviewed and updated at least annually. The communication plan would have to include the information listed at § 482.15(c)(1) through (7).

We expect that all hospitals currently have some type of emergency preparedness communication plan. We expect that under this proposed rule, hospitals would review their current communication plans, compare them to their emergency preparedness plans and emergency policies and procedures, and revise their communication plans, as necessary.

It is standard practice for health care facilities to maintain contact information for staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility; and have a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. However, under this proposed rule, all hospitals would need to review and update their plans to ensure compliance with our proposed requirements.

The TJC-accredited hospitals are required to establish emergency communication strategies (CAMH, Standard EC.4.13, p. EC-13b). In addition, TJC-accredited hospitals are specifically required to ensure communication with staff, external authorities, patients, and their families (CAMH, Standard EC.4.13, EPs 1-5, p. EC-13c). TJC-accredited hospitals also are required to establish "back-up communications systems and technologies" for such activities (CAMH, Standard EC.4.13, EP 14, p. EC-13c). Moreover, TJC-accredited hospitals are required specifically to define "the circumstances and plans for communicating information about patients to third parties (such as other health care organizations) . . ." (CAMH, Standard EC.4.13, EP 12, p. EC-13c). Thus, we expect that that TJC-accredited hospitals would be in compliance with proposed § 482.15(c)(1) through (c)(4). In addition, the rationale for EC.4.13 states, "the hospital maintains reliable surveillance and communications capability to detect emergencies and communicate response efforts to hospital response personnel, patient and their families, and external agencies (CAMH, Standard EC.4.13, pp. EC-13b – 13c). We expect that most, if not all, TJC-accredited hospitals would be in compliance with proposed § 482.15(c)(5) through (c)(7). Therefore, we expect that TJC-accredited hospitals already have developed and are currently maintaining emergency communication plans that would satisfy the requirements contained in proposed § 482.15(c). Therefore, compliance with this requirement would

constitute a usual and customary business practice and would not be subject to PRA in accordance with 5 CFR 1320.3(b)(2).

Most, if not all, non TJC-accredited hospitals would be substantially in compliance with proposed § 482.15(c)(1) through (c)(4). Nevertheless, non TJC-accredited hospitals would need to review, update, and in some cases, develop new sections for their emergency communication plans to ensure they are in compliance with all of the proposed requirements in this subsection. We expect that this activity would require the involvement of the hospital's administrator, the risk management director, the facilities director, the health information services director, the security manager, and administrative support staff. We estimate that complying with this requirement would require 10 burden hours at a cost of $757 for each of the 1,518 non TJC-accredited hospitals. Therefore, based on this estimate, for non TJC-accredited hospitals to comply with this requirement would require 15,180 burden hours (10 burden hours for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals =15,180 burden hours) at a cost of $1,149,126 ($757 estimated cost for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = $1,149,126 estimated cost).

Proposed § 482.15(c) also would require hospitals to review and update their emergency preparedness communication plans at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness communication plans periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(d) would require hospitals to develop and maintain emergency preparedness training and testing programs and review and update those plans at least annually. The hospital would be required to meet the requirements in § 482.15(d)(1) and (2).

Proposed § 482.15(d)(1) would require hospitals to provide initial and thereafter annual training on their emergency preparedness policies and procedures to all and new existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. Hospitals must also maintain documentation of all of this training.

The burden for proposed § 482.15(d)(1) would be the time and effort necessary to develop a training program and the materials needed for the required initial and annual training. We expect that all hospitals would review their current training programs and compare them to their risk assessments, emergency plans, policies and procedures, and communication plans as set forth in § 482.15(a)(1), (a), (b), and (c), respectively. Hospitals would need to revise and, if necessary, develop new sections or material to ensure that their training programs comply with our proposed requirements.

The TJC-accredited hospitals are required to define staff roles and responsibilities in their EOP and train their staff for their assigned roles during emergencies (CAMH, EC.4.16, EPs 1-2, p. EC-13e). In addition, the TJC-accredited hospitals are required to provide an initial orientation, which includes information that the hospital has determined are key elements the staff need before they provide care, treatment, or services to patients (CAMH, Standard HR.2.10, EPs 1-2, CAMH Refreshed Core, January 2008, p. HR-10). We would expect that an orientation to the hospital's EOP would be part of this initial training. TJC-accredited hospitals also must provide on-going training to their staff, including training on specific job-related safety (CAMH, Standard HR-2.30, EP 4, CAMH Refreshed Core, January 2008, p. HR-11), and we expect that emergency preparedness is part of such on-going training.

Although TJC requirements do not specifically address training for individuals providing services under arrangement or training for volunteers consistent with their expected roles, it is

standard practice for health care facilities to provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. If a hospital does not already provide such training, we would expect the additional burden to be negligible. Thus, for the TJC-accredited hospitals, the proposed requirements would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the non TJC-accredited hospitals have some type of emergency preparedness training program and provide training to their staff regarding their duties and responsibilities under their emergency plans. However, under this proposed rule, non TJC-accredited hospitals would need to compare their existing training programs with their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. They also would need to revise, update, and, if necessary, develop new sections and new material for their training programs.

To develop their training programs, hospitals could draw upon the resources of federal, state, and local emergency preparedness agencies, as well as state and national health care associations and organizations. In addition, hospitals could develop partnerships with other hospitals and health care facilities to develop the necessary training. Some hospitals might also choose to purchase off-the-shelf emergency training programs or hire consultants to develop the programs for them. However, for purposes of estimating a burden for these requirements, we will assume that hospitals would use their own staff.

Based on our experience with hospitals, we expect that complying with this requirement would require the involvement of the hospital administrator, the risk management director, a health care trainer, and administrative support staff. We estimate that it would require 40 burden hours for each hospital to develop an emergency preparedness training program at a cost of

$2,094 for each non TJC-accredited hospital. We estimate that it would require 60,720 burden hours (40 burden hours for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = 60,720 burden hours) to comply with this requirement at a cost of $3,178,692 ($2,094 estimated cost for each hospital x 1,518 non TJC-accredited hospitals = $3,178,692 estimated cost).

Proposed § 482.15(d) would also require hospitals to review and update their emergency preparedness training program at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Hospitals also would be required to maintain documentation of their training. Based on our experience, we believe it is standard practice for hospitals to document the training they provide to their staff, individuals providing services under arrangement, and volunteers. Therefore, compliance with this requirement would constitute a usual and customary business practice for the hospitals and not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 482.15(d)(2) would also require hospitals to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, hospitals would have to conduct an individual, facility-based mock disaster drill. Hospitals also would be required to analyze their responses to, and maintain documentation of, all drills, exercises, and emergency events. If a hospital experienced an actual emergency which required activation of its emergency plan, it would be exempt from the requirement for a community or individual, facility-based disaster drill for 1 year following the onset of the emergency (proposed § 482.15(d)(2)(ii)). Thus, to satisfy the burden for these

requirements, hospitals would need to develop a scenario for each drill and exercise, as well as the documentation necessary for recording what happened. If a hospital participated in a community mock disaster drill, it probably would not need to develop a scenario for that drill. However, for the purpose of determining the burden, we will assume that hospitals would need to develop at least two scenarios annually, one for a drill and one for an exercise.

The TJC-accredited hospitals are required to test their EOP twice a year (CAMH, Standard EC.4.20, EP 1, p. EC-14a). In addition, TJC-accredited hospitals must analyze all drills and exercises, identify deficiencies and areas for improvement, and modify their EOPs in response to the analysis of those tests (CAMH, Standard EC.4.20, EPs 15-17, p. EC-14b). Therefore, we expect that TJC-accredited hospitals have already developed scenarios for drills and have the documentation needed for the analysis of their responses. Since tabletop exercises generally do not require as much preparation as drills and do not require different documentation than drills, we expect that any change a hospital needed to make to conduct a tabletop exercise would be minimal.

We expect that it would be a usual and customary business practice for the TJC-accredited hospitals to comply with the proposed requirement to prepare scenarios for emergency preparedness drills and exercises and to develop the necessary documentation. Thus, compliance with this requirement would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the remaining non TJC-accredited hospitals have some type of emergency preparedness training program and that most, if not all, of them already conduct some type of drill or exercise to test their emergency preparedness plans. In addition, many hospitals participate in mock drills and exercises held by their communities, counties, and states. We also expect that many of these

hospitals have already developed the required documentation for recording the events, and analyzing their responses to, their drills, exercises, and emergency events. However, we do not believe that all non-TJC accredited hospitals would be in compliance with our proposed requirements. Thus, we will analyze the burden for non TJC-accredited hospitals.

The non TJC-accredited hospitals would be required to develop scenarios for a drill and an exercise and the documentation necessary to record and analyze their responses to drills, exercises, and emergency events. Based on our experience with hospitals, we expect that the same individuals who developed the emergency preparedness training program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the health care trainer would spend more time developing the scenarios and documentation. Thus, for each of the 1,518 non TJC-accredited hospitals to comply with these requirements, we estimate that it would require 9 burden hours at a cost of $523. Based on this estimate, for all 1,518 non TJC-accredited hospitals to comply would require 13,662 burden hours (9 burden hours for each non TJC-accredited hospital x 1,518 non TJC-accredited hospitals =13,662 burden hours) at a cost of $793,914 ($523 estimated cost for each non TJC-accredited hospital x 1,518 non TJC-accredited hospital = $793,914 estimated cost).

TABLE 7: BURDEN HOURS AND COST ESTIMATES FOR ALL 4,928 HOSPITALS TO COMPLY WITH THE ICRs CONTAINED IN § 482.15 CONDITION: EMERGENCY PREPAREDNESS

1800141075	**OMB Control No.**	**Respondents**	**Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Hourly Labor Cost of Reporting ($)**	**Total Labor Cost of Reporting ($)**	**Total Capital/ Maintenance Costs ($)**	**Total Cost ($)**
§482.15(a)(1)	0938-New	1,518	1,518	36	54,648	**	4,437,114	0	4,437,114
§482.15(a)(1)-(4)	0938-New	1,518	1,518	62	94,116	**	7,719,030	0	7,719,030
§482.15(b) (TJC-accredited)	0938-New	3,410	3,410	17	57,970	**	4,852,430	0	4,852,430

§482.15(b) (Non TJC-accredited)	0938-New	1,518	1,518	33	50,094	**	3,981,714	0	3,981,714
§482.15(b)(7)	0938-New	4,928	4,928	8	39,424	**	3,543,232	0	3,543,232
§482.15(c)	0938-New	1,518	1,518	10	15,180	**	1,449,126	0	1,449,126
§482.15(d)(1)	0938-New	1,518	1,518	40	60,720	**	3,178,692	0	3,178,692
§482.15(d)(2)	0938-New	1,518	1,518	9	13,662	**	793,914	0	793,914
Totals		4,928	17,446		385,814				29,655,252

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

I. ICRs Regarding Condition of Participation: Emergency Preparedness for Transplant Centers (§ 482.78)

Proposed § 482.78 would require transplant centers to have policies and procedures that address emergency preparedness. Proposed § 482.78(a) would require transplant centers or the hospitals in which they operate to have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. We propose that the agreements must address, at a minimum, the circumstances under which the agreement would be activated and the types of services that would be provided during an emergency.

"Transplantation services and related care" would include all of a center's transplant-related activities, ranging from the evaluation of potential transplant recipients and living donors through post-operative care of transplant recipients and living donors. If the agreement does not include all services normally provided by the receiving transplant center, the agreement should state precisely what services the receiving transplant center would provide during an emergency.

We would also expect each transplant center to ensure that its agreement with another transplant center is sufficient to provide its patients with the care they would need during any period in which the transplant center could not provide its services due to an emergency. If not,

we would expect the transplant center to make additional agreements, when possible, to ensure all services are available for its patients during an emergency.

For the purpose of determining a burden for this requirement, we expect that each transplant center would develop an agreement with one other transplant center to provide transplantation services and related care to its patients and living donors in an emergency.

Based on our experience with transplant centers, we expect that developing this agreement would require the involvement of an administrator, the transplant center medical director, the clinical transplant coordinator, and a hospital attorney. We believe the clinical transplant coordinator would be primarily responsible for initially identifying what types of services the center's patients would need to have provided by another transplant center during an emergency, as well as which transplant center(s) could provide such services. We expect that all of the individuals we have identified would have to attend an initial meeting to approve the list of services needed by the center's patients and the transplant center(s) to contact. The hospital attorney would be primarily responsible for drafting an agreement with input from the transplant center medical director. We estimate that it would require 15 burden hours for each transplant center to develop an agreement with another transplant center to provide services for its patients and living donors during an emergency, if applicable, at a cost of $1,388.

According to CMS' Center for Medicaid, Children's Health Insurance Program (CHIP), and Survey and Certification (CMCS), there are currently 770 transplant programs or transplant centers. CMS uses the terms transplant centers and transplant programs interchangeably (70 FR 6145 and 72 FR 15210). Therefore, based on the previous estimate, for all 770 transplant centers to comply with the requirement for an agreement, it would require 11,550 burden hours (15 burden hours for each transplant center x 770 transplant centers = 11,550 burden hours) at a

cost of $1,068,760 ($1,388 estimated cost for each transplant center x 770 transplant centers = $1,068,760 estimated cost).

Proposed § 482.78(b) would require a transplant center to ensure that the written agreement between the hospital in which it is located and the hospital's designated OPO as required under § 482.100 addresses the duties and responsibilities of the hospital and the OPO during an emergency. We expect that transplant centers would propose language; review any language proposed by the hospital, the OPO, or both; and approve the final agreement.

The burden associated with ensuring that the duties and responsibilities of the hospital and OPO during an emergency are addressed in the agreement would be the resources needed to draft, review, revise, and approve the language. Based on our experience with transplant centers, we expect that accomplishing these tasks would require the involvement of an administrator, the transplant center medical director, the clinical transplant coordinator, and a hospital attorney. We expect that the medical director and the clinical transplant coordinator would be primarily responsible for drafting, reviewing, revising, and approving the language of the agreement. A hospital attorney would be primarily responsible for drafting and reviewing any proposed language before the agreement was approved. The attorney would also brief the administrator and the administrator would approve the language. Thus, we estimate that it would require 15 burden hours for each transplant center to comply with the requirement to ensure that the duties and responsibilities of the hospital and OPO are identified in these agreements at a cost of $1,388. A hospital can have multiple transplant centers, but the agreement is between the hospital and the OPO. Therefore, we will use 238 hospitals for this burden analysis. This is the number of hospitals, according to CASPER, that have transplant programs. Based on this estimate, for 238 hospitals to comply with this requirement would require 3,570 burden hours

(15 burden hours for each hospital x 238 hospitals= 3,570 burden hours) at a cost of $330,344 ($1,388 estimated cost for each hospital x 238 hospitals = $330,344 estimated cost).

TABLE 8: BURDEN HOURS AND COST ESTIMATES FOR ALL 770 TRANSPLANT CENTERS TO COMPLY WITH THE ICRs CONTAINED IN § 482.78 CONDITION: EMERGENCY PREPAREDNESS FOR TRANSPLANT CENTERS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§482.78(a)		770	770	15	11,550	**	1,068,760	0	1,068,760
§482.78(b)		238	238	15	3,570	**	330,344	0	330,344
Totals		770	1008		15,120				1,399,104

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

J. ICRs Regarding Emergency Preparedness (§ 483.73)

Proposed § 483.73 sets forth the emergency preparedness requirements for long term care (LTC) facilities. LTC facilities would be required to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually (§ 483.73(a)). The emergency plan would have to include and be based upon a documented, facility-based and community based risk assessment that utilizes an all-hazards approach and must address missing residents (§ 483.73(a)(1)). LTC facilities would be required to develop and maintain emergency preparedness policies and procedures based on their emergency preparedness plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan that is required in paragraph (c) of this section (§ 483.73(b)). Proposed § 483.73(d) would require LTC facilities to develop and maintain emergency preparedness training and testing programs.

We would usually be required to estimate the information collection requirements (ICRs) for these proposed requirements in accordance with chapter 35 of title 44, United States Code.

However, 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. Section 1819(d), as implemented by section 4201 of OBRA ’87, requires that SNFs “be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5)).” Section 1819(f)(5)(C) of the Act, requires the Secretary to establish criteria for assessing a SNF’s compliance with the requirement in subsection (d) with respect for disaster preparedness. Nursing facilities have the same requirement in sections 1919(d) and (f)(5)(C), as implemented by OBRA ’87.

All of the proposed requirements in this rule relate to disaster preparedness. We believe this waiver still applies to those revisions we have proposed to existing requirements in part 483 subpart B. Thus, the ICRs for the proposed requirements in § 483.73 are not subject to the PRA.

K. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 483.475)

Proposed § 483.475(a) would require Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) to develop and maintain an emergency preparedness plan that would have to be reviewed and updated at least annually. We propose that the plan would include the elements set out at § 483.475(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment.

Proposed § 483.475(a)(1) would require each ICFs/IID to develop a documented, facility-based and community-based risk assessment utilizing an all-hazard approach, including missing clients. We expect an ICF/IID to identify the medical and non-medical emergency events it

could experience in the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. In performing the risk assessment, we expect that an ICF/IID would need to consider its physical location, the geographical area in which it is located, and its client population.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. The current CoPs for ICFs/IID already require ICFs/IID to "develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fires, severe weather, and missing clients" (42 CFR 483.470(h)(1)). During the process of developing these detailed written plans and procedures, we expect that all ICFs/IID have already performed some type of risk assessment. However, as discussed earlier in the preamble, the current requirement is primarily designed to ensure the health and safety of the ICF/IID clients during emergencies that are within the facility or in the facility's local area. We do not expect that this requirement would be sufficient to protect the health and safety of clients during more widespread local, state, or national emergencies. In addition, an ICF/IID current risk assessment may not address all of the elements required in proposed § 483.475(a). Therefore, all ICFs/IID would have to conduct a thorough review of their current risk assessments, if they have them, and then perform the necessary tasks to ensure that their risk assessments comply with the requirements of this section.

We have not designated any specific process or format for ICFs/IID to use in conducting their risk assessments because we expect ICFs/IID would need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, an ICF/IID would include representatives from, or obtain input from, all of the major departments in their facilities. Based on our experience with

ICFs/IID, we expect that conducting the risk assessment would require the involvement of the ICF/IID administrator and a professional staff person, such as a registered nurse. We expect that both individuals would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator would coordinate the meetings, perform an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also expect that the administrator would spend more time reviewing and working on the risk assessment. Thus, we estimate that complying with this requirement would require 10 burden hours to complete at a cost of $461. There are currently 6,442 ICFs/IID. Therefore, it would require an estimated 51,536 burden hours (8 burden hours for each ICF/IID x 6,442 ICFs/IID = 51,536 burden hours) for all ICFs/IID to comply with this requirement at a cost of $2,969,762 ($461 estimated cost for each ICF/IID x 6,442 ICFs/IID = $2,969,762 estimated cost).

Under this proposed rule, ICFs/IID would be required to develop emergency preparedness plans that addressed the emergency events that could affect not only their facilities but also the communities in which they are located. An ICF/IID current disaster plan might not address all of the medical and non-medical emergency events identified by its risk assessment, include strategies for addressing those emergency events, or address its patient population. It may not specify the type of services the ICF/IID has the ability to provide in an emergency, or continuity of operations, including delegation of authority and succession plans. Thus, we expect that each ICFs/IID would have to review its current plans and compare them to its risk

assessments. Each ICF/IID would then need to update, revise, and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this requirement would be the resources needed to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with ICFs/IID, we expect that the same individuals who were involved in the risk assessment would be involved in developing the facility's new emergency preparedness plan. We also expect that developing the plan would require more time to complete than the risk assessment. We estimate that it would require 9 burden hours at a cost of $525 for each ICF/IID to develop an emergency plan that complied with the requirements in this section. Based on this estimate, it would require 57,978 burden hours (9 burden hours for each ICF/IID x 6,442 ICFs/IID = 57,978 burden hours) to complete the plan at a cost of $3,382,050 ($525 estimated cost for each ICF/IID x 6,442 ICFs/IID = $3,382,050 estimated cost).

The ICF/IID also would be required to review and update its emergency preparedness plan at least annually. We believe that ICFs/IID already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(b) would require each ICF/IID to develop and implement emergency preparedness policies and procedures, based on its emergency plan set forth in paragraph (a) of this section, the risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. We would also require the ICF/IID to review and update these policies and procedures at least annually. At a minimum, the ICF/IID policies and procedures would be required to address the requirements listed at § 483.475(b)(1) through (8).

We expect all ICFs/IID to compare their current emergency preparedness policies and procedures to their emergency preparedness plans, risk assessments, and communication plans. They would then need to revise and, if necessary, develop new policies and procedures to ensure they comply with the requirements in this section.

We expect that all ICFs/II already have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for ICFs/IID require them to have "written . . . procedures to meet all potential emergencies and disasters" (§ 483.470(h)(1)). In addition, we expect that all ICFs/IID already have procedures that comply with some of the other proposed requirements in this section. For example, as will be discussed later, current regulations require ICFs/IID to perform drills, evaluate the effectiveness of those drills, and take corrective action for any problems they detect (§ 483.470(i)). We expect that all ICFs/IID have developed procedures for safe evacuation from and return to the ICF/IID (§ 483.475(b)(4)) and a process to document and analyze drills and revise their emergency plan when they detect problems.

We expect that each ICF/IID would need to review its current disaster policies and procedures and assess whether they incorporate all of the elements we are proposing. Each ICF/IID also would need to revise, and, if needed, develop new policies and procedures.

The burden incurred by reviewing, revising, updating and, if necessary, developing new emergency policies and procedures would be the resources needed to ensure that the ICF/IID policies and procedures complied with the proposed requirements of this subsection. We expect that these tasks would involve the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply would require 9 burden hours at a cost of $525. Based on this estimate, for all 6,442 ICFs/IID to comply with this requirement would require 57,978 burden hours (9 burden hours for each ICF/IID x 6,442 ICFs/IID = 57,978 burden hours) at a cost of

$3,382,050 ($525 estimated cost for each ICF/IID x 6,442 ICFs/IID = $3,382,050 estimated cost).

We expect ICFs/IID to review and update their emergency preparedness policies and procedures at least annually. We believe that ICFs/IID already review their policies and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(c) would require each ICF/IID to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The ICF/IID would also have to review and update the plan at least annually. The communication plan must include the information set out at § 483.475(c)(1) through (7).

We expect all ICFs/IID to compare their current emergency preparedness communications plans, if they have them, to the requirements in this section. ICFs/IID also would need to perform any tasks necessary to ensure that they document their communication plans and that those plans comply with the proposed requirements of this subsection.

We expect that all ICFs/IID have some type of emergency preparedness communication plan. The current CoPs require ICFs/IID to have written disaster plans and procedures for all potential emergencies (§ 483.470(h)(1)). We expect that an integral part of these plans and procedures would include communication. Further, it is standard practice for health care organizations to maintain contact information for both staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility (for example, cell phones); and have a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their clients.

However, many ICFs/IID may not have a formal, written emergency preparedness communication plan, or their plan may not comply with all the elements we are requiring.

The burden associated with complying with this requirement would be the resources required to ensure that the ICF/IID emergency communication plan complied with the proposed requirements. Based upon our experience with ICFs/IID, we anticipate that meeting the requirements in this section would primarily require the involvement of the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply with the proposed requirement would require 6 burden hours at a cost of $350. Therefore, for all 6,442 ICFs/IID to comply with this requirement would require an estimated 38,652 burden hours (6 burden hours for each ICF/IID x 6,442 ICFs/IID = 38,652 burden hours) at a cost of $2,254,700 ($350 estimated cost for each ICF/IID x 6,442 ICFs/IID = $2,254,700 estimated cost).

ICFs/IID would also have to review and update their emergency preparedness communication plans at least annually. We believe that ICFs/IID already review their plans, policies, and procedures periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(d) would require ICFs/IID to develop and maintain emergency preparedness training and testing programs that would have to be reviewed and updated at least annually. Each ICF/IID would also have to meet the requirements for evacuation drills and training at § 483.470(i).

To comply with the requirements at § 483.475(d)(1), an ICF/IID would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff,

individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the ICF/IID would have to provide emergency preparedness training at least annually.

The ICFs/IID would need to compare their current emergency preparedness training programs' contents to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and then revise and, if necessary, develop new sections for their training programs to ensure they complied with the proposed requirements. The current ICFs/IID CoPs require ICFs/IID to periodically review and provide training to their staff on the facility's emergency plan (§ 483.470(h)(2)). In addition, staff on all shifts must be trained to perform the tasks to which they are assigned for evacuations (§ 483.470(i)(1)(i)). We expect that all ICFs/IID have emergency preparedness training programs for their staff. However, under this proposed rule, each ICF/IID would need to review its current training program and compare its contents to its updated emergency preparedness plan, policies and procedures, and communications plan. Each ICF/IID also would need to revise and, if necessary, develop new sections for their training program to ensure it complied with the proposed requirements.

The burden would be the time and effort necessary to comply with the proposed requirements. We expect that a registered nurse would be primarily involved in reviewing the ICF/IID current training program and the ICF/IID updated emergency preparedness plan, policies and procedures, and communication plan; determining what tasks would need to be performed to comply with the proposed requirements of this subsection; accomplishing those tasks, and developing an updated training program. We expect the administrator would work with the registered nurse to update the training program. We estimate that it would require

7 burden hours for each ICF/IID to develop an emergency training program at a cost of $363. Therefore, it would require an estimated 45,094 burden hours (7 burden hours for each ICF/IID x 6,442 ICFs/IID = 45,094 burden hours) to comply with this requirement at a cost of $2,338,446 ($363 estimated cost for each ICF/IID x 6,442 ICFs/IID = $2,338,446 estimated cost).

ICFs/IID would have to review and update their emergency preparedness training program at least annually. We believe that ICFs/IID already review their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 483.475(d)(2) would require ICFs/IID to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. The ICFs/IID would also be required to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. If an ICF/IID experienced an actual natural or man-made emergency that required activation of its emergency plan, the ICF/IID would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. To comply with this requirement, an ICF/IID would need to develop scenarios for each drill and exercise. An ICF/IID also would have to develop the required documentation.

The current ICF/IID CoPs require them to "hold evacuation drills at least quarterly for each shift and under varied conditions to . . . evaluate the effectiveness of emergency and disaster plans and procedures" (§ 483.470(i)(1)). In addition, ICFs/IID must "actually evacuate clients during at least one drill each year on each shift . . . file a report and evaluation on each evacuation drill . . . and investigate all problems with evacuation drills, including accidents, and

take corrective action" (42 CFR 483.470(i)(2)). Thus, all 6,450 ICFs/IID already conduct quarterly drills. However, the current CoPs do not indicate the type of drills ICFs/IID must perform. In addition, although the CoPs require that a report and evaluation be filed, this requirement does not ensure that ICFs/IID have developed the type of paperwork we propose requiring or that scenarios are used for each drill or table top exercise. For the purpose of determining a burden for these requirements, all ICFs/IID would have to develop scenarios, one for the drill and one for the table top exercise, and all ICFs/IID would have to develop the necessary documentation.

The burden associated with these requirements would be the resources the ICF/IID would need to comply with the proposed requirements. We expect that complying with these requirements would likely require the involvement of a registered nurse. We expect that the registered nurse would develop the required documentation. We also expect that the registered nurse would develop the scenarios for the drill and exercise. We estimate that these tasks would require 4 burden hours at a cost of $188. Based on this estimate, for all 6,442 ICFs/IID to comply, it would require 25,768 burden hours (4 burden hours for each ICF/IID x 6,442 ICFs/IID = 25,768 burden hours) at a cost of $1,211,096 ($188 estimated cost for each ICF/IID x 6,442 ICFs/IID = $1,211,096 estimated cost).

TABLE 9: BURDEN HOURS AND COST ESTIMATES FOR ALL 6,442 ICFs/IID TO COMPLY WITH THE ICRs CONTAINED IN § 485.475 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§483.475(a)(1)		6,442	6,442	8	51,536	**	2,969,762	0	2,969,762
§483.475(a)(1)-(4)		6,442	6,442	9	57,978	**	3,382,050	0	3,382,050
§483.475(b)		6,442	6,442	9	57,978	**	3,382,050	0	3,382,050
§483.475(c)		6,442	6,442	6	38,652	**	2,254,700	0	2,254,700
§483.475(d)(1)		6,442	6,442	7	45,094	**	2,338,446	0	2,338,446

§483.475(d)(2)		6,442	6,442	4	25,768	**	1,211,096	0	1,211,096
Totals		6,442	38,652		277,006				15,538,104

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

L. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 484.22)

Proposed § 484.22(a) would require home health agencies (HHAs) to develop and maintain emergency preparedness plans. Each HHA also would be required to review and update the plan at least annually. Specifically, we propose that the plan meet the requirements listed at § 484.22(a)(1) through (4). We will discuss the burden for these activities individually, beginning with the risk assessment.

Accreditation may substantially affect the burden a HHA would experience under this proposed rule. HHAs are accredited by three different accrediting organizations (AOs): The Joint Commission (TJC), The Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care, Inc. (ACHC). After reviewing the accreditation standards for all three AOs, neither the standards for CHAP nor the ones for ACHC appeared to ensure substantial compliance with our proposed requirements in this rule. Therefore, the HHAs accredited by CHAP and ACHC will be included with the non-accredited HHAs for the purposed of determining the burden for this proposed rule.

There are currently 12,349 HHAs. There are 1,734 TJC-accredited HHAs. A review of TJC deeming standards indicates that the 1,734 TJC-accredited HHAs already perform certain tasks or activities that would partially or completely satisfy our proposed requirements. Therefore, since TJC accreditation is a significant factor in determining the burden, we will analyze the burden for the 1,734 TJC-accredited HHAs separately from the 10,615 non TJC-accredited HHAs (12,349 HHAs – 1,734 TJC-accredited HHAs = 10,615 non TJC-accredited HHAs), as appropriate. Note that we obtain data on the number of HHAs, both accredited and non-accredited, from the CMS CASPER data system, which is updated periodically by the

individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited HHAs may not equal the total number of HHAs.

Section 484.22(a)(1) would require that HHAs develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. To perform this risk assessment, an HHA would need to identify the medical and non-medical emergency events the HHA could experience and how the HHA's essential business functions and ability to provide services could be impacted by those emergency events based on the risks to the facility itself and the community in which it is located. We would expect HHAs to consider the extent of their service area, including the location of any branch offices. An HHA with an existing risk assessment would need to review, revise and update it to comply with our proposed requirements.

For TJC accreditation standards, we used TJC's CAMHC Refreshed Core, January 2008 pages from the Comprehensive Accreditation Manual for Home Care 2008 (CAMHC). In the chapter entitled, "Environmental Safety and Equipment Management" (EC), TJC accreditation standards require HHAs to conduct proactive risk assessments to "evaluate the potential adverse impact of the external environment and the services provided on the security of patients, staff, and other people coming to the organization's facilities" (CAMHC, Standard EC.2.10, EP 3, p. EC-7). These proactive risk assessments should evaluate the risk to the entire organization, and the HHA should conduct one of these assessments whenever it identifies any new external risk factors or begins a new service (CAMHC, Standard EC.2.10, p. EC-7). Moreover, TJC-accredited HHAs are required to develop and maintain "a written emergency management plan describing the process for disaster readiness and emergency management . . ." (CAMHC,

Standard EC.4.10, EP 3, p. EC-9). In addition, TJC requires that these plans provide for "processes for managing . . . activities related to care, treatment, and services (for example, scheduling, modifying, or discontinuing services; controlling information about patients; referrals; transporting patients) . . . logistics relating to critical supplies . . . communicating with patient" during an emergency (CAMHC, Standard EC.4.10, EP 10, p. EC-9-10). We expect that any HHA that has conducted a proactive risk assessment and developed an emergency management plan that satisfies the previously described TJC accreditation requirements has already conducted a risk assessment that would satisfy our proposed requirements. Any tasks needed to comply with our proposed requirements would not result in any additional burden. Thus, for the 1,734 TJC-accredited HHAs, the risk assessment requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

It is standard practice for health care facilities to prepare for common internal and external medical and non-medical emergencies, based on their location, structure, and the services they provide. We believe that the 10,615 non TJC-accredited HHAs have conducted some type of risk assessment. However, those risk assessments are unlikely to satisfy all of our proposed requirements. Therefore, we will analyze the burden for the 10,615 non TJC-accredited HHAs to comply.

We have not designated any specific process or format for HHAs to use in conducting their risk assessments because we believe that HHAs need the flexibility to determine the best way to accomplish this task. However, we expect that HHAs would include representatives from or input from all of their major departments. Based on our experience working with HHAs, we expect that conducting the risk assessment would require the involvement of an HHA

administrator, the director of nursing, director of rehabilitation, and the office manager. We expect that these individuals would attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator and the director of nursing, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the director of nursing would coordinate the meetings, review the current risk assessment, provide suggestions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the director of nursing would spend more time developing the facility's new risk assessment than the other individuals. We estimate that the risk assessment would require 11 burden hours for each non TJC-accredited HHA to complete at a cost of $605. There are currently about 10,615 non TJC-accredited HHAs. We estimate that for all non TJC-accredited HHAs to comply with this requirement would require 116,765 burden hours (11 burden hours for each non TJC-accredited HHA x 10,615 non TJC-accredited HHAs = 116,765 burden hours) at a cost of $6,422,075 ($605 estimated cost for each non TJC-accredited HHA x 10,615 non TJC-accredited HHAs = $6,422,075 estimated cost).

After conducting a risk assessment, HHAs would have to develop an emergency preparedness plan that complied with § 484.22(a)(1) through (4). As discussed earlier, TJC already has accreditation standards similar to the requirements we propose at § 484.22(a). Thus, we expect that TJC-accredited HHAs have an emergency preparedness plan that would satisfy most of our proposed requirements. Although the current HHA CoPs require that there be a qualified person who "is authorized in writing to act in the absence of the administrator" (§ 484.14(c)), the TJC standards do not specifically address delegations of authority or succession plans. Furthermore, TJC standards do not address persons-at-risk. Therefore, we

expect that the 1,734 TJC-accredited HHAs would incur some burden due to reviewing, revising, and in some cases, developing new sections for their emergency preparedness plans. However, we will analyze the burden for TJC-accredited HHAs separately from the 10,615 non TJC-accredited HHAs because we expect the burden for TJC-accredited HHAs to be substantially less.

We expect that the 10,615 non TJC-accredited HHAs already have some type of emergency preparedness plan, as well as delegations of authority and succession plans. However, we also expect that their plans do not comply with all of our proposed requirements. Thus, all non TJC-accredited HHAs would need to review their current plans and compare them to their risk assessments. They also would need to update, revise, and, in some cases, develop new sections for their emergency plans.

Based on our experience with HHAs, we expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We estimate that complying with this requirement would require 10 burden hours for each TJC-accredited HHA at a cost of $546. Therefore, for all 1,734 TJC-accredited HHAs to comply would require an estimated 17,340 burden hours (10 burden hours for each TJC-accredited HHA x 1,734 TJC-accredited HHAs = 17,340 burden hours) at a cost of $946,764 ($546 estimated cost for each HHA x 1,734 TJC-accredited HHAs = $946,764 estimated cost).

We estimate that complying with this requirement would require 15 burden hours for each of the 10,615 non TJC-accredited HHAs at a cost of $819. Therefore, for all 10,615 non TJC-accredited HHAs to comply would require an estimated 159,225 burden hours (15 burden hours for each non TJC-accredited HHA x 10,615 non TJC-accredited HHAs = 159,225 burden

hours) at a cost of $8,693,685 ($819 estimated cost for each non TJC-accredited HHA x 10,615 non TJC-accredited HHAs = $8,693,685 estimated cost).

Based on these estimates, for all 12,349 HHAs to develop an emergency preparedness plan that complies with our proposed requirements would require 176,565 burden hours at a cost of $9,640,449.

We would also require HHAs to review and update their emergency preparedness plans at least annually. We believe that HHAs are already reviewing and updating their emergency preparedness plans periodically. Hence, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 484.22(b) would require each HHA to develop and implement emergency preparedness policies and procedures based on the emergency plan, risk assessment, communication plan as set forth in § 484.22(a), (a)(1), and (c), respectively. The HHA would also have to review and update its policies and procedures at least annually. We would require that, at a minimum, these policies and procedures address the requirements listed at § 484.22(b)(1) through (6).

We expect that HHAs would review their emergency preparedness policies and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. HHAs would need to revise or, in some cases, develop new policies and procedures to ensure they complied with all of the proposed requirements.

In the chapter entitled, "Leadership," TJC accreditation standards require that each HHA's "leaders develop policies and procedures that guide and support patient care, treatment, and services" (CAMHC, Standard LD.3.90, EP 1, p. LD-13). In addition, TJC accreditation

standards and EPs specifically require each HHA to develop and maintain an emergency management plan that provides processes for managing activities related to care, treatment, and services, including scheduling, modifying, or discontinuing services (CAMHC, Standard EC.4.10, EP 10, EC-9); identify backup communication systems in the event of failure due to an emergency event (CAMHC, Standard EC.4.10, EP 18, EC-10); and develop processes for critiquing tests of its emergency preparedness plan and modifying the plan in response to those critiques (CAMHC, Standard EC.4.20, EPs 15-17, p. EC-11).

We expect that the 1,734 TJC-accredited HHAs already have emergency preparedness policies and procedures that address some of the proposed requirements at § 484.22(b). However, we do not believe that TJC accreditation requirements ensure that TJC-accredited HHAs' policies and procedures address all of our proposed requirements for emergency policies and procedures. Thus, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in our analysis of the burden for proposed § 484.22(b).

Under proposed § 484.22(b)(1), the HHA's individual plans for patients during a natural or man-made disaster would be included as part of the comprehensive patient assessment, which would be conducted according to the provisions at § 484.55. We expect that HHAs already collect data during the comprehensive patient assessment that they would need to develop for each patient's emergency plan. At § 484.22(b)(2), we propose requiring each HHA to have procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patients' medical and psychiatric condition and home environment.

Existing HHA regulations already address some aspects of proposed § 484.22(b)(1) and (b)(2). For example, regulations at § 484.18 make it clear that HHAs are expected to accept

patients only on the basis of a reasonable expectation that they can provide for the patients' medical, nursing, and social needs in the patients' home. Moreover, the plan of care for each patient must cover any safety measures necessary to protect the patient from injury § 484.18(a). Thus, the activities necessary to be in compliance with § 484.22(b)(1) and (2) would constitute usual and customary business practices for HHA and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that all 12,349 HHAs (1,734 TJC-accredited HHAs + 10,615 non TJC-accredited HHAs = 12,349 HHAs) have some emergency preparedness policies and procedures. However, we also expect that all HHAs would need to review their policies and procedures and revise and, if necessary, develop new policies and procedures that complied with our proposed requirements set out at § 484.22(3) through (6). We expect that a professional staff person, most likely the director of nursing, would review the HHA's policies and procedures and make recommendations for changes or development of additional policies and procedures. The administrator or director of nursing would brief representatives of most of the HHA's major departments and assign staff to make necessary revisions and draft any new policies and procedures. We estimate that complying with this requirement would require 18 burden hours for each HHA at a cost of $996. Thus, for all 12,349 HHAs to comply with all of our proposed requirements would require an estimated 222,282 burden hours (18 burden hours for each HHA x 12,349 HHAs = 222,282 burden hours) at a cost of $12,299,604 ($996 estimated cost for each HHA x 12,349 HHAs = $12,299,604 estimated cost).

We are also proposing that HHAs review and update their emergency preparedness policies and procedures at least annually. The current HHA CoPs already require that "a group of professional personnel . . . reviews the agency's policies governing scope of services offered"

(42 CFR 484.16). Thus, we believe that complying with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

In proposed § 484.22(c), each HHA would be required to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. We propose that each HHA review and update its communication plan at least annually. We would require that the emergency communication plan include the information listed at § 484.22(c)(1) through (6).

It is standard practice for health care facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method of sharing information and medical documentation with other health care providers to ensure continuity of care for patients.

All TJC-accredited HHAs are required to identify backup communication systems for both internal and external communication in case of failure due to an emergency (CAMHC, Standard EC.4.10, EP 18, p. EC-10). They are required to have processes for notifying their staff when the HHA initiates its emergency plan (CAMHC, Standard EC.4.10, EP 7, p. EC-9); identifying and assigning staff to ensure that essential functions are covered during emergencies (CAMHC, Standard EC.4.10, EP 9, p. EC-9); and activities related to care, treatment, and services, such as controlling information about their patients (CAMHC, Standard EC.4.10, EP 10, p. EC-9). However, we do not believe these requirements ensure that all TJC-accredited HHAs are already in compliance with our proposed requirements. Thus, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in assessing the burden for this requirement.

We expect that all 12,349 HHAs maintain some contact information, an alternate means of communication, and a method for sharing information with other health care facilities. However, this would not ensure that all HHAs would be in compliance with our proposed requirements for communication plans. Thus, we will analyze the burden for this requirement for all 12,349 HHAs.

The burden associated with complying with this requirement would be the time and effort necessary for each HHA to review its existing communication plan, if any, and revise it; and, if necessary, to develop new sections for the emergency preparedness communication plan to ensure that it complied with our proposed requirements. Based on our experience with HHAs, we expect that these activities would require the involvement of the HHA's administrator, director of nursing, director of rehabilitation, and office manager. We estimate that complying with this requirement would require 10 burden hours for each HHA at a cost of $520. Thus, for all 12,349 HHAs to comply with these requirements would require an estimated 123,490 burden hours (10 burden hours for each HHA x 12,349 HHAs = 123,490 burden hours) at a cost of $6,421,480 ($520 estimated cost for each HHA x 12,349 HHAs = $6,421,480 estimated cost).

We propose requiring HHAs to review and update their emergency preparedness communication plans at least annually. We believe that HHAs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 484.22(d) would require each HHA to develop and maintain an emergency preparedness training and testing program. Each HHA would also have to review and update its

training and testing program at least annually. We propose requiring that each HHA meet the requirements listed at § 484.22(d)(1) and (2).

Proposed § 484.22(d)(1) states that each HHA would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the HHA would have to provide emergency preparedness training at least annually. Each HHA would also have to ensure that their staff could demonstrate knowledge of their emergency procedures.

Based on our experience with HHAs, we expect that all 12,349 HHAs have some type of emergency preparedness training program. The 1,734 TJC-accredited HHAs are already required to provide both an initial orientation to their staff before they can provide care, treatment, or services (CAMHC, Standard HR.2.10, EP 2, p. HR-6) and "ongoing in-services, training or other staff activities [that] emphasize job-related aspects of safety . . ." (CAMHC, Standard HR.2.30, EP 4, p. HR-8). Since emergency preparedness is a critical aspect of job-related safety, we expect that TJC-accredited HHAs would ensure that their orientations and ongoing staff training would include the facility's emergency preparedness policies and procedures.

However, we expect that under proposed § 484.22(d), all HHAs would need to compare their training and testing programs with their risk assessments, emergency preparedness plans, emergency policies and procedures, and emergency communication plans. We expect that most HHAs would need to revise and, in some cases, develop new sections for their training programs to ensure that they complied with our proposed requirements. In addition, HHAs would need to provide an orientation and annual training in their facilities' emergency preparedness policies

and procedures to individuals providing services under arrangement and volunteers, consistent with their expected roles. Hence, we will analyze the burden of these proposed requirements for all 12,349 HHAs.

Based on our experience with HHAs, we expect that complying with this requirement would require the involvement of an administrator, the director of training, director of nursing, director of rehabilitation, and the office manager. We expect that the director of training would spend more time reviewing, revising or developing new sections for the training program than the other individuals. We estimate that it would require 16 burden hours for each HHA to develop an emergency preparedness training and testing program at a cost of $756. Thus, for all 12,349 HHAs to comply would require an estimated 197,584 burden hours (16 burden hours for each HHA x 12,349 HHAs = 197,584 burden hours) at a cost of $9,335,844 ($756 estimated cost for each HHA x 12,349 HHAs = $9,335,844 estimated cost).

We also propose requiring HHAs to review and update their emergency preparedness training programs at least annually. We believe that HHAs already review their training and testing programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for HHAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 484.22(d)(2) would require each HHA to conduct drills and exercises to test its emergency plan. Each HHA would have to participate in a community mock disaster drill and conduct a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, each HHA would have to conduct an individual, facility-based mock disaster drill at least annually. If an HHA experienced an actual natural or man-made emergency that required activation of the emergency plan, it would be exempt from engaging in a

community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Each HHA would also be required to analyze its responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise its emergency plan as needed. For the purposes of determining the burden for these requirements, we expect that all HHAs would have to comply with all of the proposed requirements.

The burden associated with complying with this requirement would be the time and effort necessary to develop the scenarios for the drill and the exercise and the required documentation. All TJC-accredited HHAs are required to test their emergency management plan once a year; the test cannot be a tabletop exercise (CAMHC, Standard EC.4.20, EP 1 and Note 1, p. EC-11). The TJC also requires HHAs to critique the drills and modify their emergency management plans in response to those critiques (CAMHC, Standard EC.4.20, EPs 15-17, p. EC-11). Therefore, TJC-accredited HHAs already prepare scenarios for drills, develop documentation to record the events during drills, critique them, and modify their emergency preparedness plans in response. However, TJC standards do not describe what type of drill HHAs must conduct or require a tabletop exercise annually. Thus, TJC accreditation standards would not ensure that TJC-accredited HHAs would be in compliance with our proposed requirements. Therefore, we will include the 1,734 TJC-accredited HHAs with the 10,615 non TJC-accredited HHAs in our analysis of the burden for these requirements.

Based on our experience with HHAs, we expect that the same individuals who are responsible for developing the HHA's training and testing program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the director of nursing would spend more time on these activities than would the other individuals. We estimate that it would require 8 burden hours for each HHA to comply with the proposed requirements at

an estimated cost of $373. Thus, for all 12,349 HHAs to comply with the requirements in this section would require an estimated 98,792 burden hours (8 burden hours for each HHA x 12,349 HHAs = 98,792 burden hours) at a cost of $4,606,177 ($373 estimated cost for each HHA x 12,349 HHAs = $4,606,177 estimated cost).

Based upon the previous analysis, we estimate that it would require 909,855 burden hours for all HHAs to comply with the ICRs contained in this proposed rule at a cost of $51,034,965.

TABLE 10: BURDEN HOURS AND COST ESTIMATES FOR ALL 12,349 HHAS TO COMPLY WITH THE ICRs CONTAINED IN § 484.22 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§484.22(a)(1)	0938-New	10,615	10,615	11	116,765	**	6,422,075	0	6,422,075
§484.22(a)(1)-(4) (TJC-accredited)	0938-New	1,734	1,734	10	17,340	**	946,764	0	946,764
§484.22(a)(1)-(4) (Non TJC-accredited)	0938-New	10,615	10,615	18	159,225	**	8,693,685	0	8,693,685
§484.22(b)	0938-New	12,349	12,349	18	222,282	**	12,299,604	0	12,299,604
§484.22(c)	0938-New	12,349	12,349	10	123,490	**	6,421,480	0	6,421,480
§484.22(d)(1)	0938-New	12,349	12,349	16	197,584	**	9,335,844	0	9,335,844
§484.22(d)(2)	0938-New	12,349	12,349	8	98,792	**	4,606,177	0	4,606,177
Total					935,478				48,725,629

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

M. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.68)

Proposed § 485.68(a) would require all Comprehensive Outpatient Rehabilitation Facilities (CORFs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We propose that the plan meet the requirements listed at § 485.68(a)(1) through (5).

Proposed § 485.68(a)(1) would require a CORF to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The CORFs would need to identify the medical and non-medical emergency events they could experience. The current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (§ 485.64). We expect that all CORFs have performed some type of risk assessment during the process of developing their disaster policies and procedures. However, their risk assessments may not meet our proposed requirements. Therefore, we expect that all CORFs would need to review their existing risk assessments and perform the tasks necessary to ensure that those assessments meet our proposed requirements.

We have not designated any specific process or format for CORFs to use in conducting their risk assessments because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that CORFs would obtain input from all of their major departments.

Based on our experience with CORFs, we expect that conducting the risk assessment would require the involvement of the CORF's administrator and a therapist. The type of therapists at each CORF varies, depending upon the services offered by the facility. For the purposes of determining the burden, we will assume that the therapist is a physical therapist. We

expect that both the administrator and the therapist would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review and critique the risk assessment, coordinate comments, develop the new risk assessment, and ensure that it was approved.

We estimate that complying with this requirement would require 8 burden hours at a cost of $485. There are currently 272 CORFs. Therefore, it would require an estimated 2,176 burden hours (8 burden hours for each CORF x 272 CORFs = 2,176 burden hours) for all CORFs to comply at a cost of $131,920 ($485 estimated cost for each CORF x 272 CORFs = $131,920 estimated cost).

After conducting the risk assessment, each CORF would need to review, revise, and, if necessary, develop new sections for its emergency plan so that it complied with our proposed requirements. The current CoPs for CORFs require them to have a written disaster plan (§ 485.64) that must be developed and maintained with the assistance of appropriate experts and address, among other things, procedures concerning the transfer of casualties and records, notification of outside emergency personnel, and evacuation routes (§ 485.64(a)). Thus, we expect that all CORFs have some type of emergency preparedness plan. However, we also expect that all CORFs would need to review, revise, and develop new sections for their plans to ensure that their plans complied with all of our proposed requirements.

Based on our experience with CORFs, we expect that the administrator and physical therapist who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect that it would require more time to

complete the emergency plan than to complete the risk assessment. We estimate that complying with this requirement would require 11 burden hours at a cost of $677 for each CORF. Therefore, it would require an estimated 2,992 burden hours (11 burden hours for each CORF x 272 CORFs = 2,992 burden hours) for all CORFs to complete an emergency preparedness plan at a cost of $184,144 ($677 estimated cost for each CORF x 272 CORFs = $184,144 estimated cost).

The CORF also would be required to review and update its emergency preparedness plan at least annually. We believe that CORFs already review their plans periodically. Therefore, compliance with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(b) would require CORFs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.68(a), (a)(1), and (c), respectively. We would also require CORFs to review and update these policies and procedures at least annually. We would require that a CORF's policies and procedures address, at a minimum, the requirements listed at § 485.68(b)(1) through (4).

We expect that all CORFs have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (42 CFR 485.64). However, all CORFs would need to review their policies and procedures and compare them to their risk assessments, emergency preparedness plans, and communication plans. Most CORFs would need to revise their existing policies and

procedures or develop new policies and procedures to ensure they complied with all of our proposed requirements.

We expect that both the administrator and the therapist would attend an initial meeting, review relevant policies and procedures, make recommendations for changes, attend a follow-up meeting, perform a final review, and approve the policies and procedures. We expect that the administrator would coordinate the meetings, coordinate the comments, and ensure that they are approved.

We estimate that it would take 9 burden hours for each CORF to comply with this requirement at a cost of $549. Therefore, it would take all CORFs 2,448 burden hours (9 burden hours for each CORF x 272 CORFs = 2,448 burden hours) to comply with this requirement at a cost of $149,328 ($549 estimated cost for each CORF x 272 CORFs = $149,328 estimated cost).

Proposed § 485.68(b) also proposes that CORFs review and update their emergency preparedness policies and procedures at least annually. We believe that CORFs already review their policies and procedures periodically. Therefore, we believe that complying with this requirement would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(c) would require CORFs to develop and maintain emergency preparedness communication plans that complied with both federal and state law and that would be reviewed and updated at least annually. We propose that a CORF's communication plan include the information listed in § 485.68(c)(1) through (5). Current CoPs require CORFs to have a written disaster plan that must include, among other things, "procedures for notifying community emergency personnel" (§ 486.64(a)(2)). In addition, it is standard practice in the health care industry to maintain contact information for staff and outside sources of assistance;

alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many CORFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all CORFs would need to review, update, and in some cases, develop new sections for their plans to ensure they complied with all of our proposed requirements.

Based on our experience with CORFs, we anticipate that satisfying the requirements in this section would primarily require the involvement of the CORF's administrator with the assistance of a physical therapist to review, revise, and, if needed, develop new sections for the CORF's emergency preparedness communication plan. We estimate that it would take 8 burden hours for each CORF to comply with this requirement at a cost of $485. Therefore, it would take 2,176 burden hours (8 burden hours for each CORF x 272 CORFs = 2,176 burden hours) for all CORFs to comply at a cost of $131,920 ($485 estimated cost for each CORF x 272 CORFs = $131,920 estimated cost).

We propose that each CORF would also have to review and update its emergency preparedness communication plan at least annually. We believe that compliance with this requirement would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(d) would require CORFs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We propose that each CORF would have to satisfy the requirements listed at § 485.68(d)(1) and (2).

Proposed § 485.68(d)(1) would require that each CORF provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, each CORF would have to provide emergency preparedness training at least annually. Each CORF would also have to ensure that its staff could demonstrate knowledge of its emergency procedures. All new personnel would have to be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. In addition, the training program would have to include instruction in the location and use of alarm systems and signals and firefighting equipment.

The current CORF CoPs at § 485.64 require CORFs to ensure that all personnel are knowledgeable, trained, and assigned specific responsibilities regarding the facility's disaster procedures. Section § 485.64(b)(1) specifies that CORFs must also "provide ongoing training . . . for all personnel associated with the facility in all aspects of disaster preparedness". In addition, § 485.64(b)(2) specifies that "all new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday".

In evaluating the requirement for proposed § 485.68(d)(1), we expect that all CORFs have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, under this proposed rule, all CORFs would need to compare their current training programs to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. CORFs would then need to revise, and in some cases, develop new material for their training programs.

We expect that these tasks would require the involvement of an administrator and a physical therapist. We expect that the administrator would review the CORF's current training

program to identify necessary changes and additions to the program. We expect that the physical therapist would work with the administrator to develop the revised and updated training program. We estimate it would require 8 burden hours for each CORF to develop an emergency training program at a cost of $485. Therefore, for all CORFs to comply would require an estimated 2,176 burden hours (8 burden hours for each CORF x 272 CORFs = 2,176 burden hours) at a cost of $131,920 ($485 estimated cost for each CORF x 272 CORFs = $131,920 estimated cost).

We also propose that each CORF review and update its emergency preparedness training program at least annually. We believe that CORFs already review their training programs periodically. Thus, complying with the requirement for an annual review of the emergency preparedness training program would constitute a usual and customary business practice for CORFs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.68(d)(2) would require CORFs to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the CORF would have to conduct an individual, facility-based mock disaster drill at least annually. If a CORF experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. CORFs would also be required to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a CORF would need to develop scenarios for these drills and exercises. The current CoPs at § 485.64(b)(1) require CORFs to "provide ongoing . . . drills for all personnel associated with the facility in all aspects of disaster

preparedness". However, the current CoPs do not specify the type of drill, how often the CORF must conduct drills, or that a CORF must use scenarios for their drills and tabletop exercises.

Based on our experience with CORFs, we expect that the same individuals who develop the emergency preparedness training program would develop the scenarios for the drills and exercises, as well as the accompanying documentation. We expect that the administrator would spend more time on these tasks than the physical therapist. We estimate that for each CORF to comply with the proposed requirements would require 6 burden hours at a cost of $366. Therefore, for all 272 CORFs to comply would require an estimated 1,632 burden hours (6 burden hours for each CORF x 272 CORFs = 1,632 burden hours) at a cost of $99,552 ($366 estimated cost for each CORF x 272 CORFs = $99,552 estimated cost).

Based on the previous analysis, for all 272 CORFs to comply with the ICRs contained in this proposed rule would require 13,600 total burden hours at a total cost of $828,784.

TABLE 11: BURDEN HOURS AND COST ESTIMATES FOR ALL 272 CORFS TO COMPLY WITH THE ICRs CONTAINED IN § 485.68 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§485.68(a)(1)	0938--New	272	272	8	2,176	**	131,920	0	131,920
§485.68(a)(2-(4)	0938--New	272	272	11	2,992	**	184,144	0	184,144
§485.68(b)	0938--New	272	272	9	2,448	**	149,328	0	149,328
§485.68(c)	0938--New	272	272	8	2,176	**	131,920	0	131,920
§485.68(d)(1)	0938--New	272	272	8	2,176	**	131,920	0	131,920
§485.68(d)(2)	0938--New	272	272	6	1,632	**	99,552	0	99,552
Totals		272	1,632		13,600				828,784

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

N. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.625)

Proposed § 485.625(a) would require critical access hospitals (CAHs) to develop and maintain a comprehensive emergency preparedness program that utilizes an all-hazards approach and would have to be reviewed and updated at least annually. Each CAH's emergency plan would have to include the elements listed at § 485.625(a)(1) through (4).

Proposed § 485.625(a)(1) would require each CAH to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. CAHs would need to review their existing risk assessments and perform any tasks necessary to ensure that it complied with our proposed requirements.

There are approximately 1,322 CAHs. CAHs with distinct part units were included in the hospital burden analysis. Approximately 402 CAHs are accredited either by TJC (370) or by the AOA (32); the remainder are non-accredited CAHs. Many of the TJC and AOA accreditation

standards for CAHs are similar to the requirements in this proposed rule. For purposes of determining the burden, we have analyzed the burden for the 370 TJC-accredited and 32 AOA-accredited CAHs separately from the non-accredited CAHs. Note that we obtain data on the number of CAHs, both accredited and non-accredited, from the CMS CASPER database, which is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited CAHs may not equal the total number of CAHs.

For purposes of determining the burden for TJC-accredited CAHs, we used TJC's Comprehensive Accreditation Manual for Critical Access Hospitals: The Official Handbook 2008 (CAMCAH). In the chapter entitled, "Management of the Environment of Care" (EC), Standard EC.4.11 requires CAHs to plan for managing the consequences of emergency events (CAMCAH, Standard EC.4.11, CAMCAH Refreshed Care, January 2008, pp. EC-10 - EC-11). CAHs are required to perform a hazard vulnerability analysis (HVA), which requires each CAH to, among other things, "identify events that could affect demand for its services or its ability to provide those services, the likelihood of those events occurring, and the consequences of those events" (Standard EC.4.11, EP 2, p. EC-10a). The HVA "should identify potential hazards, threats, and adverse events, and assess their impact on the care, treatment, and services [the CAH] must sustain during an emergency," and the HVA "is designed to assist [CAHs] in gaining a realistic understanding of their vulnerabilities, and to help focus their resources and planning efforts" (CAMCAH, Emergency Management, Introduction, p. EC-10). Thus, we expect that TJC-accredited CAHs already conduct a risk assessment that would comply with the requirements we propose. Thus, for the 370 TJC-accredited CAHs, the risk assessment

requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

For purposes of determining the burden for AOA-accredited CAHs, we used the AOA's Healthcare Facilities Accreditation Program: Accreditation Requirements for Critical Access CAHs 2007 (ARCAH). In Chapter 11 entitled, "Physical Environment," CAHs are required to have disaster plans, external disaster plans that include triaging victims, and weapons of mass destruction response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.05-6, pp. 11-38 through 11-41, respectively). In addition, AOA-accredited CAHs must "coordinate with federal, state, and local emergency preparedness and health authorities to identify likely risks for their area . . . and to develop appropriate responses" (ARCAH, Standard 11.02.02, p. 11-5). Thus, we believe that to develop their plans, AOA-accredited CAHs already perform some type of risk assessment. However, the AOA standards do not require a documented facility-based and community-based risk assessment, as we propose. Therefore, we will include the 32 AOA-accredited CAHs with non-accredited CAHs in determining the burden for our proposed risk assessment requirement.

The CAH CoPs currently require CAHs to assure the safety of their patients in non-medical emergencies (§ 485.623) and to take appropriate measures that are consistent with the particular conditions in the area in which the CAH is located (42 CFR 485.623(c)(4)). To satisfy this requirement in the CoPs, we expect that CAHs have already conducted some type of risk assessment. However, that requirement does not ensure that CAHs have conducted a documented, facility-based, and community-based risk assessment that would satisfy our proposed requirements.

We believe that under this proposed rule, the 952 non TJC-accredited CAHs (1,322 CAHs - 370 TJC-accredited CAHs = 952 non TJC-accredited CAHs) would need to review, revise, and, in some cases, develop new sections for their current risk assessments to ensure compliance with all of our requirements.

We have not designated any specific process or format for CAHs to use in conducting their risk assessments because we believe that CAHs need the flexibility to determine the best way to accomplish this task. However, we expect that CAHs would include representatives from or obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with CAHs, we expect that these activities would require the involvement of a CAH's administrator, medical director, director of nursing, facilities director, and food services director. We expect that these individuals would attend an initial meeting, review relevant sections of the current risk assessment, provide comments, attend a follow-up meeting, perform a final review, and approve the new or updated risk assessment. We expect the administrator would coordinate the meetings, perform an initial review of the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approved it.

We estimate that the risk assessment requirement would require 15 burden hours to complete at a cost of $949. We estimate that for the 952 non TJC-accredited CAHs to comply with the proposed risk assessment requirement would require 14,280 burden hours (15 burden hours for each CAH x 952 non TJC-accredited CAHs = 14,280 burden hours) at a cost of $903,448 ($949 estimated cost for each non TJC-accredited CAH x 952 non TJC-accredited CAHs = $903,448 estimated cost).

After conducting the risk assessment, CAHs would have to develop and maintain emergency preparedness plans that complied with proposed § 485.625(a)(1) through (4). We would expect all CAHs to compare their emergency plans to their risk assessments and then revise and, if necessary, develop new sections for their emergency plans to ensure that they complied with our proposed requirements.

The TJC-accredited CAHs must develop and maintain an Emergency Operations Plan (EOP) (CAMCAH Standard EC.4.12, p. EC-10a). The EOP must cover the management of six critical areas during emergencies: communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities (CAMCAH, Standards EC.4.12 through 4.18, pp. EC-10a-EC-10g). In addition, as discussed earlier, TJC-accredited CAHs also are required to conduct an HVA (CAMCAH, Standard EC.4.11, EP 2, p. EC-10a). Therefore, we expect that the 370 TJC-accredited CAHs already have emergency preparedness plans that would satisfy our proposed requirements. If a CAH needed to complete additional tasks to comply with the proposed requirement, the burden would be negligible. Thus, for the 370 TJC-accredited CAHs, this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The AOA-accredited CAHs must work with federal, state, and local emergency preparedness authorities to identify the likely risks for their location and geographical area and develop appropriate responses to assure the safety of their patients (ARCAH, Standard 11.02.02, p. 11-5). Among the elements that AOA-accredited CAHs must specifically consider are the special needs of their patient population, availability of medical and non-medical supplies, both internal and external communications, and the transfer of patients to home or other health care settings (ARCAH, Standard 11.02.02, p. 11-5). In addition, there are requirements for disaster

and disaster response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.06, pp. 11-38 through 11-40). There also are specific requirements for plans for responses to weapons of mass destruction, including chemical, nuclear, and biological weapons; communicable diseases, and chemical exposures (ARCAH, Standards 11.07.02 and 11.07.05-11.07.06, pp. 11-39 through 11-41). However, the AOA accreditation requirements require only that CAHs assess their most likely risks (ARCAH, Standard 11-02.02, p. 11-5), and we are proposing that CAHs be required to conduct a risk assessment utilizing an all-hazards approach. Thus, we expect that AOA-accredited CAHs would have to compare their risk assessments they conducted in accordance with proposed § 485.625(a)(1) to their current plans and then revise, and in some cases develop new sections for, their plans. Therefore, we will assess the burden for these 32 AOA-accredited CAHs with the non-accredited CAHs.

The CAH CoPs require all CAHs to ensure the safety of their patients during non-medical emergencies (§ 485.623). They are also required to provide, among other things, for evacuation of patients, cooperation with disaster authorities, emergency power and lighting in their emergency rooms and for flashlights and battery lamps in other areas, an emergency water and fuel supply, and any other appropriate measures that are consistent with their particular location (§ 485.623). Thus, we believe that all CAHs have developed some type of emergency preparedness plan. However, we also expect that the 920 non-accredited CAHs would have to review their current plans and compare them to their risk assessments and revise and, in some cases, develop new sections for their current plans to ensure that their plans would satisfy our proposed requirements.

Based on our experience with CAHs, we expect that the same individuals who were involved in conducting the risk assessment would be involved in developing the emergency

preparedness plan. We expect that these individuals would attend an initial meeting, review relevant sections of the current emergency preparedness plan(s), prepare and send their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the administrator would coordinate the meetings, perform an initial review, coordinate comments, revise the plan, and ensure that the necessary parties approve the new plan. We estimate that complying with this requirement would require 26 burden hours at a cost of $1,620. Therefore, we estimate that for all 952 non TJC-accredited CAHs (920 non-accredited CAHs + 32 AOA-accredited CAHs = 952 non TJC-accredited CAHs) to comply with this requirement would require 24,752 burden hours (26 burden hours for each non TJC-accredited CAH x 952 non TJC-accredited CAHs = 24,752 burden hours) at a cost of $1,542,240 ($1,620 estimated cost for each non TJC-accredited CAH x 952 non TJC-accredited CAHs = $1,542,240 estimated cost).

Under this proposed rule, CAHs also would be required to review and update their emergency preparedness plans at least annually. The CAH CoPs already require CAHs to perform a periodic evaluation of their total program at least once a year (§ 485.641(a)(1)). Hence, all CAHs should already have an individual or team responsible that is for the periodic review of their total program. Therefore, we believe that this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Under proposed § 485.625(b), we would require CAHs to develop and maintain emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.625(a), (a)(1), and (c), respectively. We would also require CAHs to review and update these policies and procedures at least

annually. These policies and procedures would have to address, at a minimum, the requirements listed at § 485.625(b)(1) through (8).

We expect that all CAHs would review their policies and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. The CAHs would need to revise, and, in some cases, develop new policies and procedures to incorporate all of the provisions previously noted and address all of our proposed requirements.

The CAMCAH chapter entitled, "Leadership" (LD), requires TJC-accredited CAH leaders to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMCAH, Standard LC.3.90, EP 1, CAMCAH Refreshed Core, January 2008, p. LD-11). Thus, we expect that TJC-accredited CAHs already have some policies and procedures for the activities and processes required for accreditation, including their EOP. As discussed later, many of the required elements we propose have a corresponding requirement in the CAH TJC accreditation standards.

We propose at § 485.625(b)(1) that CAHs have policies and procedures that address the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited CAHs must make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMCAH, Standard EC.4.14, EPs 1-4, p. EC-10d). In addition, they must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases where their usual supply is disrupted or compromised (CAMCAH, Standard EC.4.17, EPs 1-5, p. EC-10f). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement concerning subsistence needs at § 485.625(b)(1).

We are proposing at § 485.625(b)(2) that CAHs have policies and procedures for a system to track the location of staff and patients in the CAH's care both during and after an emergency. TJC-accredited CAHs must plan for communicating with their staff, as well as patients and their families, at the beginning of and during an emergency (CAMCAH, Standard EC.4.13, EPs 1, 2, and 5, p. EC-10c). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement.

Proposed § 485.625(b)(3) would require CAHs to have a plan for the safe evacuation from the CAH. TJC-accredited CAHs are required to make plans to evacuate patients as part of managing their clinical activities (CAMCAH, Standard EC.4.18, EP 1, p. EC-10g). They also must plan for the evacuation and transport of patients, their information, medications, supplies, and equipment to alternative care sites (ACSs) when the CAH cannot provide care, treatment, and services in its facility (CAMCAH, Standard EC.4.14, EPs 9-11, p. EC-10d). We expect that TJC-accredited CAHs that comply with these requirements would be in compliance with our proposed requirement.

We are proposing at § 485.625(b)(4) that CAHs have policies and procedures for a means to shelter in place for patients, staff, and volunteers who remain in the facility. The rationale for CAMCAH Standard EC.4.18 states, "[a] catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMCAH, Standard EC.4.18, p. EC-10f). Therefore, we expect that TJC-accredited CAHs would be substantially in compliance with our proposed requirement.

Proposed § 485.625(b)(5) would require CAHs to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available.

The CAMCAH chapter entitled "Management of Information" (IM), requires TJC-accredited CAHs to have storage and retrieval systems for their clinical/service and CAH-specific information (CAMCAH, Standard IM.3.10, EP 5, CAMCAH Refreshed Core, January 2008, p. IM-11), as well as to ensure the continuity of their critical information for patient care, treatment, and services (CAMCAH, Standard IM.2.30, CAMCAH Refreshed Core, January 2008, p. IM-9). They also must ensure the privacy and confidentiality of patient information (CAMCAH, Standard IM.2.10, CAMCAH Refreshed Core, January 2008, p. IM-7). In addition, TJC-accredited CAHs must have plans for transporting patients and their clinical information, including transferring information to ACSs (CAMCAH Standard EC.4.14, EP 10 and 11, p. EC-10d and Standard EC.4.18, EP 6, pp. EC-10g, respectively). Therefore, we expect that TJC-accredited CAHs would be substantially in compliance with proposed § 485.625(b)(5).

Proposed § 485.625(b)(6) would require CAHs to have policies and procedures that addressed the use of volunteers in an emergency or other emergency staffing strategies. TJC-accredited CAHs must define staff roles and responsibilities in their EOP and ensure that they train their staff for their assigned roles (CAMCAH, Standard EC.4.16, EPs 1 and 2, p. EC-10e). Also, the rationale for Standard EC.4.15 indicates that the CAH "determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated" (CAMCAH, Standard EC.4.15, Rationale, p. EC-10d). In addition, in the chapter entitled "Medical Staff" (MS), CAHs "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMCAH, Standard MS.4.110, CAMCAH Refreshed Care, January 2008, p. MS-20). Finally, in the chapter entitled "Management of Human Resources" (HR), CAHs "may assign disaster responsibilities to volunteer practitioners" (CAMCAH, Standard HR.1.25, CAMCAH Refreshed Core, January 2008, p. HR-6). Although

the TJC accreditation requirements address some of our proposed requirements, we do not believe TJC-accredited CAHs would be in compliance with all requirements in proposed § 485.625(b)(6).

Based upon the previous discussion, we expect that the activities required for compliance by TJC-accredited CAHs with § 485.625(b)(1) through (b)(5) constitutes usual and customary business practices for PRAs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

However, we do not believe TJC-accredited CAHs would be substantially in compliance with proposed § 485.625(b)(6) through (8). We will discuss the burden for TJC-accredited CAHs to comply with these requirements later in this section.

The AOA accreditation standards also contain requirements for policies and procedures related to safety and disaster preparedness. The AOA-accredited CAHs are required to maintain plans and performance standards for disaster preparedness (ARCAH, Standard 11.00.02 Required Plans and Performance Standards, p. 11-2). They also must have "written procedures for possible situations to be followed by each department and service within the CAH and for each building used for patient treatment or housing" (ARCAH, Standard 11.07.01 Disaster Plans, Explanation, p.11-38). AOA-accredited CAHs also are required to have a safety team or committee that is responsible for all issues related to safety within the CAH (ARCAH, Standard 11.02.03, p. 11-7). The individuals or team would be responsible for all policies and procedures related to safety in the CAH (ARCAH, Standard 11.02.03, Explanation, p. 11-7). We expect that these performance standards and procedures are similar to some of our proposed requirements for policies and procedures.

In regard to proposed § 485.625(b)(1), AOA-accredited CAHs are required to consider "pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations" and "provisions if gas, water, electricity supply is shut off to the community" when they are developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 5 and 11, pp. 11-5 and 11-6, respectively). In addition, CAHs are required "to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care" (ARCAH, Standard 11.03.22 Emergency Gas and Water, p. 11-22 through 11-23). However, these standards do not specifically address all of the proposed requirements in this subsection.

In regard to proposed § 485.625(b)(2), AOA-accredited CAHs are required to consider how they will communicate with their staff within the CAH when developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Element 7, p. 11-6). They also are required to have a "call tree" in their external disaster plan that must be updated at least annually (ARCAH, Standard 11.07.04 Staff Call Tree, p. 11-40). However, these requirements do not sufficiently cover the requirements to track the location of staff and patients during and after an emergency.

In regard to proposed § 485.625(b)(3), which requires policies and procedures regarding the safe evacuation from the facility, AOA-accredited CAHs are required to consider the "transfer or discharge of patients to home, other healthcare settings, or other CAHs" and the "transfer of patients with CAH equipment to another CAH or healthcare setting" (ARCAH, Standard 11.02.02 Building Safety, Elements 12 and 13, p. 11-6). AOA-accredited CAHs also are required to consider in their emergency plans how to maintain communication with external entities should their telephones and computers either cease to operate or become overloaded

(ARCAH, Standard 11.02.02, Element 6, p. 11-6). AOA-accredited CAHs must also "develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations" (ARCAH, Standard 11.02.02 Building Safety, pp. 11-4 through 11-7). However, we do not believe these requirements are detailed enough to ensure that AOA-accredited CAHs are compliant with our proposed requirements.

In regard to proposed § 485.625(b)(4), AOA-accredited CAHs are required to consider the special needs of their patient population and the security of those patients and others that come to them for care when they develop their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 2 and 3, p. 11-5). In addition, as described earlier, they also must consider the food, pharmaceuticals, and other supplies and equipment they may need during an emergency in developing their emergency plan (ARCAH, Standard 11.02.02, Element 5, p. 11-5). However, these requirements do not specifically mention volunteers and CAHs are required only to consider these elements in developing their plans.

Therefore, we believe that AOA-accredited CAHs have likely already incorporated many of the elements necessary to satisfy the requirements in proposed § 485.625(b); however, they would need to thoroughly review their current policies and procedures and perform whatever tasks are necessary to ensure that they complied with all of our proposed requirements for emergency policies and procedures. Because we expect that AOA-accredited CAHs already comply with many of our proposed requirements, we will include the AOA-accredited CAHs with the TJC-accredited CAHs in determining the burden.

The burden for the 32 AOA-accredited CAHs and the 370 TJC-accredited CAHs to comply with all of the requirements in proposed § 485.625(b) would be the resources required to develop written policies and procedures that comply with all of our proposed requirements for

emergency policies and procedures. Based on our experience working with CAHs, we expect that accomplishing these activities would require the involvement of an administrator, the medical director, director of nursing, facilities director, and food services director. We expect that the administrator would review the policies and procedures and make recommendations for necessary changes or additional policies or procedures. The CAH administrator would brief other staff and assign staff to make necessary revisions or draft new policies and procedures and disseminate them to the appropriate parties. We estimate that complying with this requirement would require 10 burden hours for each TJC and AOA-accredited CAH at a cost of $624. For all 402 TJC and AOA-accredited CAHs to comply with these requirements would require an estimated 4,020 burden hours (10 burden hours for each TJC or AOA-accredited CAH x 402 TJC and AOA-accredited CAHs = 4,020 burden hours) at a cost of $327,228 ($814 estimated cost for each TJC or AOA-accredited CAH x 402 TJC and AOA-accredited CAHs = $327,228 estimated cost).

We expect that the 920 non-accredited CAHs already have developed some emergency preparedness policies and procedures. The current CAH CoPs require CAHs to develop, maintain, and review policies to ensure quality care and a safe environment for their patients (§ 485.627(a), § 485.635(a), and § 485.641(a)(1)(iii)). In addition, certain activities associated with our proposed requirements are addressed in the current CAH CoPs. For example, all CAHs are required to have agreements or arrangements with one or more providers or suppliers, as appropriate, to provide services to their patients (§ 485.635(c)).

The burden associated with the development of emergency policies and procedures would be the resources needed to review, revise, and if needed, develop emergency preparedness policies and procedures that include our proposed requirements. We believe the individuals and

tasks would be the same as described earlier for the TJC and AOA-accredited CAHs. However, the non-accredited CAHs would require more time to accomplish these activities. We estimate that a non-accredited CAH's compliance would require 14 burden hours at a cost of $860. For all 920 unaccredited CAHs to comply with this requirement would require an estimated 12,880 burden hours (14 burden hours for each non-accredited CAHs x 920 non-accredited CAHs = 12,880 burden hours) at a cost of $791,200 ($860 estimated cost for each non-accredited CAH x 920 non-accredited CAHs = $791,200 estimated cost).

Thus, for all 1,322 CAH to comply with the requirements in proposed § 485.625(b) would require 16,900 burden hours at a cost of $1,118,428.

Proposed § 485.625(b) would also require CAHs to review and update their emergency preparedness policies and procedures at least annually. As discussed earlier, TJC and AOA-accredited CAHs already periodically review their policies and procedures. In addition, the existing CAH CoPs require periodic reviews of the CAH's health care policies (§ 485.627(a), § 485.635(a), and § 485.641(a)(1)(iii)). Thus, compliance with this requirement would constitute a usual and customary business practice for all CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(c) would require CAHs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. We propose that CAHs review and update these plans at least annually. We propose that these communication plans include the information listed at § 485.625(c)(1) through (7).

We expect that all CAHs would review their emergency preparedness communication plans and compare them to their risk assessments and emergency plans. We also expect that CAHs would revise and, if necessary, develop new sections that would comply with our

proposed requirements. Based on our experience with CAHs, they generally have some type of emergency preparedness communication plan. Further, it is standard practice for health care facilities to 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; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. Thus, we believe that most, if not all, CAHs are already in compliance with proposed § 485.625(c)(1) through (3).

However, all CAHs would need to review and, if needed, revise and update their plans to ensure compliance with proposed § 485.625(c)(4) through (7). The TJC-accredited CAHs are required to establish strategies or plans for emergency communications (CAMCAH, Standard 4.13, p. EC-10b -10c). These plans must cover both internal and external communications and include back-up technologies and communication systems (CAMCAH, Standard 4.13, and EPs 1-14, p. EC-10b-EC-10c). However, we do not believe that these standards would ensure compliance with proposed § 485.625(c)(4) through (7). Thus, we will include the 365 TJC-accredited CAHs in the burden below.

The AOA-accredited CAHs must develop and implement communication plans to ensure the safety of their patients during emergencies (AOA Standard 11.02.02). These plans must specifically include both internal and external communications (AOA Standard 11.02.02, Elements 6, 7, and 10). Based on these standards, we do not believe they ensure compliance with proposed § 485.625(c)(4) through (7). Thus, we will include these 32 AOA-accredited CAHs in the burden below.

The burden associated with complying with this requirement would be the resources required to develop a communication plan that complied with the requirements of this section.

Based on our experience with CAHs, we expect that accomplishing these activities would require the involvement of an administrator, director of nursing, and the facilities director. We expect that the administrator would review the communication plan and make recommendations for necessary changes or additions. The director of nursing and the facilities director would meet with the administrator to discuss and revise or draft new sections for the CAH's existing emergency communication plan. We estimate that complying with this requirement would require 9 burden hours for each CAH at a cost of $519. We estimate that for all 1,322 CAHs to comply with the requirements for an emergency preparedness communication plan would require 11,898 burden hours (9 burden hours for each CAH x 1,322 CAHs = 11,898 burden hours) at a cost of $686,118 ($519 estimated cost for each CAH x 1,322 CAHs = $686,118 estimated cost).

Proposed § 485.625(c) also would require CAHs to review and update their emergency preparedness communication plans at least annually. All CAHs are required to evaluate their entire program at least annually (§ 485.641(a)). Therefore, compliance with this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(d) would require CAHs to develop and maintain emergency preparedness training and testing programs. We would also require CAHs to review and update their training and testing programs at least annually. We propose that a CAH comply with the requirements listed at § 485.625(d)(1) and (2).

Regarding § 485.625(d)(1), CAHs would have to provide initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff,

individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH would have to provide emergency preparedness training at least annually.

We expect that all CAHs would review their current training programs and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs would need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our proposed requirements.

Current CoPs require CAHs to train their staffs on how to handle emergencies (§ 485.623(c)(1)). However, this training primarily addresses internal emergencies, such as a fire inside the facility. In addition, both TJC and AOA require CAHs to provide their staff with training. TJC-accredited CAHs are required to provide their staff with both an initial orientation and on-going training (CAMCAH, Standards HR.2.10 and 2.30, pp. HR-8 and HR—9, respectively). On-going training must also be documented (CAMCAH, Standard HR.2.30, EP 8, p. HR-10). The AOA-accredited CAHs are required to provide an education program for their staff and physicians for the CAH's emergency response preparedness (AOA Standard 11.07.01). Each CAH also must provide an education program specifically for the CAH's response plan for weapons of mass destruction (AOA Standard 11.07.07).

Thus, we expect that all CAHs provide some emergency preparedness training for their staff. However, neither the current CoPs nor the TJC and AOA accreditation standards ensure compliance with all our proposed requirements. All CAHs would need to review their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then revise or, in some cases, develop new sections for their training programs to ensure

compliance with our proposed requirements. They also would need to revise, update, or, in some cases, develop new materials for the initial and ongoing training.

Based on our experience with CAHs, we expect that complying with our proposed requirement would require the involvement of an administrator, the director of nursing, and the facilities director. We expect that the director of nursing would perform the initial review of the training program, brief the administrator and the director of facilities, and revise or develop new sections for the training program, based on the group's decisions. We estimate that each CAH would require 14 burden hours to develop an emergency preparedness training program at a cost of $834. Therefore, for all 1,322 CAHs to comply with this requirement would require an estimated 18,508 burden hours (14 burden hours for each CAH x 1,322 CAHs = 18,508 burden hours) at a cost of $1,102,548 ($834 estimated cost for each CAH x 1,322 CAHs = $1,102,548 estimated cost).

Proposed § 485.625(d)(1) also would require CAHs to review and update their emergency preparedness training programs at least annually. Existing regulations require all CAHs to evaluate their entire program at least annually (§ 485.641(a)). Therefore, compliance with this proposed requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The CAHs also would be required to maintain documentation of their training. Based on our experience with CAHs, it is standard practice for them to document the training they provide to staff and other individuals. If a CAH needed to make any changes to their normal business practices to comply with this requirement, the burden would be negligible. Thus, compliance with this requirement would constitute a usual and customary business practice for CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.625(d)(2) would require CAHs to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the CAH would have to conduct an individual, facility-based mock disaster drill at least annually. CAHs also would be required to analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed. If a CAH experienced an actual natural or man-made emergency that required activation of the emergency plan, it would be exempt from the proposed requirement for an annual community or individual, facility-based mock disaster drill for 1 year following the onset of the emergency (proposed § 485.625(d)(2)(ii)). Thus, to meet these requirements, CAHs would need to develop scenarios for each drill and exercise and develop the required documentation.

If a CAH participated in a community mock disaster drill, it would likely not need to develop the scenario for that drill. However, for the purpose of determining the burden, we will assume that CAHs need to develop scenarios for both the drill and the exercise annually.

The TJC-accredited CAHs are required to test their EOP twice a year, either as a planned exercise or in response to an emergency (CAMCAH, Standard EC.4.20, EP 1, p. EC-12). These tests must be monitored, documented, and analyzed (CAMCAH, Standard EC.4.20, EPs 8-19, pp. EC-12 – EC-13). Thus, we believe that TJC-accredited CAHs already develop scenarios for these tests. We also expect that they also have developed the documentation necessary to record and analyze their tests and responses to actual emergency events. Therefore, compliance with this requirement would constitute a usual and customary business practice for TJC-accredited CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

The AOA-accredited CAHs are required to conduct two disaster drills annually (AOA Standard 11.07.03). In addition, AOA-accredited CAHs are required to participate in weapons of mass destruction drills, as appropriate (AOA Standard 11.07.09). We expect that since AOA-accredited CAHs already conduct disaster drills, they also develop scenarios for the drills. In addition, it is standard practice in the health care industry to document and analyze tests that a facility conducts. Thus, compliance with this requirement would constitute a usual and customary business practice for AOA-accredited CAHs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Based on our experience with CAHs, we expect that the 831 non-accredited CAHs already have some type of emergency preparedness training program and conduct some type of drills or exercises to test their emergency preparedness plans. However, this does not ensure that most CAHs already perform the activities needed to comply with our proposed requirements. Thus, we will analyze the burden for these requirements for the 920 non-accredited CAHs.

The 920 non-accredited CAHs would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the documentation necessary to record and later analyze the events that occurred during these tests and actual emergency events. Based on our experience with CAHs, we believe that the same individuals who developed the emergency preparedness training program would develop the scenarios for the tests and the accompanying documentation. We expect that the director of nursing would spend more time than would the other individuals developing the scenarios and the accompanying documentation. We estimate that it would require 8 burden hours for the 920 non-accredited CAHs to comply with these proposed requirements at a cost of $488. Therefore, for all 920 non-accredited CAHs to comply with these requirements would require an estimated 7,360 burden hours (8 burden hours for each

non-accredited CAH x 920 non-accredited CAHs = 7,360 burden hours) at a cost of $448,960 ($488 estimated cost for each non-accredited CAH x 920 non-accredited CAHs = $448,960 estimated cost).

TABLE 12: BURDEN HOURS AND COST ESTIMATES FOR ALL 1,322 CAHS TO COMPLY WITH THE ICRs CONTAINED IN § 485.625 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§485.625(a)(1)	0938-New	952	952	15	14,280	**	903,448	0	903,448
§485.625(a)(2)-(4)	0938-New	952	952	26	24,752	**	1,542,240	0	1,542,240
§485.625(b) (TJC and AOA-Accredited)	0938-New	402	402	10	4,020	**	327,228	0	327,228
§485.625(b) (Non-accredited)	0938-New	920	920	14	12,880	**	791,200	0	791,200
§485.625(c)	0938-New	1322	1322	9	11,898	**	686,118	0	686,118
§485.625(d)(1)	0938-New	1322	1322	14	18,508	**	1,102,548	0	1,102,548
§485.625(d)(2)	0938-New	920	920	8	7,360	**	448,960	0	448,960
Total			6,790		93,698				5,801,742

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

O. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.727)

Proposed § 485.727(a) would require clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (organizations) to develop and maintain emergency preparedness plans and review and update the plan at least annually. We are proposing that the plan comply with the requirements listed at § 485.727(a)(1) through (6).

Proposed § 485.727(a)(1) would require organizations to develop documented, facility-based and community-based risk assessment utilizing an all-hazards approach. Organizations

would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area.

The current CoPs for Organizations require these providers to have "a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster" (§ 485.727(a)). To comply with this CoP, we expect that all of these providers have already performed some type of risk assessment during the process of developing their disaster plans and policies and procedures. However, these providers would need to review their current risk assessments and make any revisions to ensure they complied with our proposed requirements.

We have not designated any specific process or format for these providers to use in conducting their risk assessments because we believe that they need the flexibility to determine the best way to accomplish this task. Providers of physical therapy and speech therapy services should include input from all of their major departments in the process of developing their risk assessments. Based on our experience with these providers, we expect that conducting the risk assessment would require the involvement of the organization's administrator and a therapist. The types of therapists at each Organization vary depending upon the services offered by the facility. For the purposes of determining the PRA burden, we will assume that the therapist is a physical therapist. We expect that both the administrator and the therapist would attend an initial meeting, review the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review and critique the current risk assessment initially, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator would spend more time reviewing and working on the risk

assessment than the physical therapist. We estimate that complying with this requirement would require 9 burden hours at a cost of $549. We estimate that it would require 20,034 burden hours (9 burden hours for each organization x 2,256 organizations = 20,304 burden hours) for all organizations to comply with this requirement at a cost of $1,238,544 ($549 estimated cost for each organization x 2,256 organizations = $1,238,544 estimated cost).

After conducting the risk assessment, each organization would need to develop and maintain an emergency preparedness plan and review and update it at least annually. Current CoPs require these providers to have a written disaster plan with accompanying procedures for fires, explosions, and other disasters (§ 485.727(a)). The plan must include or address the transfer of casualties and records, the location and use of alarm systems and signals, methods of containing fire, notification of appropriate persons, and evacuation routes and procedures (§ 485.727(a)). Thus, we expect that all of these organizations have some type of emergency preparedness plan and that these plans address many of our proposed requirements. However, all organizations would need to review their current plans and compare them to their risk assessments. Each organization would need to revise, update, and, in some cases, develop new sections to complete a comprehensive emergency preparedness plan that complied with our proposed requirements.

Based on our experience with these organizations, we expect that the administrator and physical therapist who were involved in developing the risk assessment would be involved in developing the emergency preparedness plan. However, we expect it would require more time to complete the plan and that the administrator would be the most heavily involved in reviewing and developing the organization's emergency preparedness plan. We estimate that for each organization to comply would require 12 burden hours at a cost of $741. We estimate that it

would require 27,072 burden hours (12 burden hours for each organization x 2,256 organizations = 27,072 burden hours) to complete the plan at a cost of $1,671,696 ($741 estimated cost for each organization x 2,256 organizations = $1,671,696 estimated cost).

Each organization would also be required to review and update its emergency preparedness plan at least annually. We believe that these organizations already review their plans periodically. Thus, complying with this requirement would constitute a usual and customary business practice for organizations and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(b) would require organizations to develop and implement emergency preparedness policies and procedures based on their risk assessments, emergency plans, communication plans as set forth in § 485.727(a)(1), (a), and (c), respectively. It would also require organizations to review and update these policies and procedures at least annually. At a minimum, we would require that an organization's policies and procedures address the requirements listed at § 485.727(b)(1) through (4).

We expect that all organizations have emergency preparedness policies and procedures. As discussed earlier, the current CoPs require organizations to have procedures within their written disaster plan to be followed for fires, explosions, or other disasters (§ 485.727(a)). In addition, we expect that those procedures already address some of the specific elements required in this section. For example, the current requirements at § 485.727(a)(1) through (4) are similar to our proposed requirements at § 485.727(a)(1) through (5). However, all organizations would need to review their policies and procedures, assess whether their policies and procedures incorporate all of the necessary elements of their emergency preparedness program, and, if

necessary, take the appropriate steps to ensure that their policies and procedures are in compliance with our proposed requirements.

We expect that the administrator and the physical therapist would be primarily involved with reviewing and revising the current policies and procedures and, if needed, developing new policies and procedures. We estimate that it would require 10 burden hours for each organization to comply at a cost of $613. We estimate that for all organizations to comply would require 22,560 burden hours (10 burden hours for each organization x 2,256 organizations = 23,550 burden hours) at a cost of $1,382,928 ($622 estimated cost for each organization x 2,256 organizations = $1,382,928 estimated cost).

We would require organizations to review and update their emergency preparedness policies and procedures at least annually. We believe that these providers already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(c) would require organizations to develop and maintain emergency preparedness communication plans that complied with both federal and state law and would be reviewed and updated at least annually. The communication plan would have to include the information listed at § 485.727(c)(1) through (5).

We expect that all organizations have some type of emergency preparedness communication plan. Current CoPs for these organizations already require them to have a written disaster plan with procedures that must include, among other things, "notification of appropriate persons" (§ 485.727(a)(4)). Thus, we expect that each organization has the contact information they would need to comply with this proposed requirement. In addition, it is

standard practice for health care facilities to 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; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many organizations may not have formal, written emergency preparedness communication plans or their plans may not be fully compliant with our proposed requirements. Therefore, we expect that all organizations would need to review, update, and, in some cases, develop new sections for their plans.

Based on our experience with these organizations, we anticipate that satisfying the requirements in this section would primarily require the involvement of the organization's administrator with the assistance of a physical therapist. We estimate that for each organization to comply would require 8 burden hours at a cost of $494. We estimate that for all 2,256 organizations to comply would require 18,048 burden hours (8 burden hours for each organizations x 2,256 organizations = 18,048 burden hours) at a cost of $1,114,464 ($494 estimated cost for each organization x 2,256 organizations = $1,114,464 estimated cost).

We are proposing that organizations must review and update their emergency preparedness communication plans at least annually. We believe that these organizations already review their emergency communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(d) would require organizations to develop and maintain emergency preparedness training and testing programs and review and update these programs at least

annually. Specifically, we are proposing that organizations comply with the requirements listed at § 485.727(d)(1) and (2).

With respect to § 485.727(d)(1), organizations would have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH would have to provide emergency preparedness training at least annually.

Current CoPs require organizations to ensure that "all employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures . . . "(42 CFR 485.727(b)). Thus, we expect that organizations already have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, organizations would need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans. Organizations would need to review, revise, and, in some cases, develop new material for their training programs so that they comply with our proposed requirements.

We expect that complying with this requirement would require the involvement of an administrator and a physical therapist. We expect that the administrator would primarily be involved in reviewing the organization's current training program and the current emergency preparedness program; determining what tasks would need to be performed and what materials would need to be developed to comply with our proposed requirements; and developing the materials for the training program. We expect that the physical therapist would work with the administrator to develop the revised and updated training program. We estimate that it would

require 8 burden hours for each organization to develop a comprehensive emergency training program at a cost of $494. Therefore, it would require an estimated 18,048 burden hours (8 burden hours for each organization x 2,256 organizations = 18,048 burden hours) to comply with this requirement at a cost of $1,114,464 ($494 estimated cost for each organization x 2,256 organizations = $1,114,464 estimated cost).

In § 485.727(d)(1), we also propose requiring that an organization must review and update its emergency preparedness training program at least annually. We believe that these providers already review their emergency preparedness training programs periodically. Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 485.727(d)(2) would require organizations to participate in a community mock disaster drill and a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the organization would have to conduct an individual, facility-based mock disaster drill at least annually. If an organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Organizations also would be required to analyze their response to and maintain documentation of all the drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed. To comply with this requirement, an organization would need to develop scenarios for their drills and exercises. An organization also would have to develop the documentation necessary for recording and analyzing their responses to drills, exercises, and actual emergency events.

The current CoPs require organizations to have a written disaster plan that is "periodically rehearsed" and have "ongoing . . . drills" (§ 485.727(a) and (b)). Thus, we expect that all 2,256 organizations currently conduct some type of drill or exercise of their disaster plan. However, the current organizations CoPs do not specify the type of drill, how they are to conduct the drills, or whether the drills should be community-based. In addition, there is no requirement for a paper-based, tabletop exercise. Thus, these requirements do not ensure that organizations would be in compliance with our proposed requirements. Therefore, we will analyze the burden from these requirements for all organizations.

The 2,256 organizations would be required to develop scenarios for a mock disaster drill and a paper-based, tabletop exercise and the necessary documentation. Based on our experience with organizations, we expect that the same individuals who develop the emergency preparedness training program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator would spend more time than the physical therapist developing the scenarios and the documentation. We estimate that for each organization to comply would require 3 burden hours at a cost of $183. Based on that estimate, it would require 6,768 burden hours (3 burden hours for each organization x 2,256 organizations = 6,768 burden hours) at a cost of $417,360 ($183 estimated cost for each organization x 2,256 organizations = $417,360 estimate cost).

TABLE 13: BURDEN HOURS AND COST ESTIMATES FOR ALL 2,256 ORGANIZATIONS TO COMPLY WITH THE ICRs CONTAINED IN § 485.727 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§485.727(a)(1)	0938-New	2,256	2,256	9	20,304	**	1,238,544	0	1,238,544
§485.727(a)(2)-	0938-	2,256	2,256	12	27,072	**	1,671,696	0	1,671,696

(4)	New								
§485.727(b)	0938-New	2,256	2,256	10	22,560	**	1,382,928	0	1,382,928
§485.727(c)	0938-New	2,256	2,256	8	18,048	**	1,114,464	0	1,114,464
§485.727(d)(1)	0938-New	2,256	2,256	8	18,048	**	1,114,464	0	1,114,464
§485.727(d)(2)	0938-New	2,256	2,256	3	6,768	**	417,360	0	417,360
Totals		2,256	13,536		112,800				6,939,456

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

P. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.920)

Proposed § 485.920(a) would require Community Mental Health Centers (CMHCs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. Specifically, we propose that the plan must meet the requirements listed at § 485.920(a)(1) through (4).

We expect all CMHCs to identify the likely medical and non-medical emergency events they could experience within the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. We expect that in performing the risk assessment, a CMHC would need to consider its physical location, the geographical area in which it is located and its patient population.

The burden associated with this proposed requirement would be the time and effort necessary to perform a thorough risk assessment. We expect that most, if not all, CMHCs have already performed at least some of the work needed for a risk assessment because it is standard practice for health care organizations to prepare for common emergencies, such as fires, interruptions in communication and power, and storms. However, many CMHCs may not have performed a risk assessment that complies with the proposed requirements. Therefore, we expect that most, if not all, CMHCs would have to perform a thorough review of their current

risk assessment and perform the tasks necessary to ensure that the facility's risk assessment complies with the proposed requirements.

We do not propose designating any specific process or format for CMHCs to use in conducting their risk assessments because we believe CMHCs need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, health care organizations would include representatives from or obtain input from all major departments. Based on our experience with CMHCs, we expect that conducting the risk assessment would require the involvement of the CMHC administrator, a psychiatric registered nurse, and a clinical social worker or mental health counselor. We expect that most of these individuals would attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator would coordinate the meetings, do an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. It is likely that the CMHC administrator would spend more time reviewing and working on the risk assessment than the other individuals. We estimate that complying with the proposed requirement to conduct a risk assessment would require 10 burden hours for a cost of $470. There are currently 207 CMHCs. Therefore, it would require an estimated 2,070 burden hours (10 burden hours for each CMHC x 207 CMHCs = 2,070 burden hours) for all CMHCs to comply with this requirement at a cost of $97,290 ($470 estimated cost for each CMHC x 207 CMHCs = $97,290 estimated cost).

After conducting the risk assessment, CMHCs would need to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. CMHCs would need to compare their current emergency plan, if they have one, to their risk assessment. They would then need to revise and, if necessary, develop new sections of their plan to ensure it complies with the proposed requirements.

It is standard practice for health care organizations to make plans for common disasters they may confront, such as fires, interruptions in communication and power, and storms. Thus, we expect that all CMHCs have some type of emergency preparedness plan. However, their plan may not address all likely medical and non-medical emergency events identified by the risk assessment. Further, their plans may not include strategies for addressing likely emergency events or address their patient population, the type of services they have the ability to provide in an emergency, or continuity of operation, including delegations of authority and succession plans. We expect that CMHCs would have to review their current plan and compare it to their risk assessment, as well as to the other requirements in proposed § 485.920(a). We expect that most CMHCs would need to update and revise their existing emergency plan and, in some cases, develop new sections to comply with our proposed requirements.

The burden associated with this requirement would be due to the resources needed to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with CMHCs, we expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We also expect that developing the plan would require more time to complete than the risk assessment. We expect that the administrator and a psychiatric nurse would spend more time reviewing and developing the CMHC's emergency preparedness plan.

We expect that the clinical social worker or mental health counselor would review the plan and provide comments on it to the administrator. We estimate that it would require 15 burden hours for a CMHC to develop its emergency plan at a cost of $750. Based on this estimate, it would require 3,105 burden hours (15 burden hours for each CMHC x 207 CMHCs = 3,105 burden hours) for all CMHCs to complete their plans at a cost of $155,250 ($750 estimated cost for each CMHC x 207 CMHCs = $155,250 estimated cost).

The CMHC would be required to review and update its emergency preparedness plan at least annually. For the purpose of determining the burden for this proposed requirement, we expect that the CMHCs will review and update their plans annually.

We expect that all CMHCs have an administrator that is responsible for the day-to-day operation of the CMHC. This would include ensuring that all of the CMHC's plans are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in the health care industry for facilities to have a professional staff person, generally an administrator, who periodically reviews their plans and procedures. We expect that complying with the requirement for an annual review of the emergency preparedness plan would constitute a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(b) would require CMHCs to develop and maintain emergency preparedness policies and procedures based on the emergency plan, the communication plan, and the risk assessment. We also propose requiring CMHCs to review and update these policies and

procedures at least annually. The CMHC's policies and procedures would be required to address, at a minimum, the requirements listed at § 485.920(b)(1) through (7).

We expect that all CMHCs would compare their current emergency preparedness policies and procedures to their emergency preparedness plan, communication plan, and their training and testing program. They would need to review, revise and, if necessary, develop new policies and procedure to ensure they comply with the proposed requirements. The burden associated with reviewing, revising, and updating the CMHC's emergency policies and procedures would be due to the resources needed to ensure they comply with the proposed requirements. We expect that the administrator and the psychiatric registered nurse would be involved with reviewing, revising and, if needed, developing any new policies and procedures. We estimate that for a CMHC to comply with this proposed requirement would require 12 burden hours at a cost of $630. Therefore, for all 207 CMHCs to comply with this proposed requirement would require an estimated 2,484 burden hours (12 burden hours for each CMHC x 207 CMHCs = 2,484 burden hours) at a cost of $130,410 ($630 estimated cost for each CMHC x 207 CMHCs = $130,410 estimated cost).

The CMHCs would be required to review and update their emergency preparedness policies and procedures at least annually. For the purpose of determining the burden for this requirement, we expect that CMHCs would review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC, which includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We also expect that the administrator is responsible for periodically reviewing the emergency preparedness policies and procedures as part of his or her responsibilities. We expect that

complying with the requirement for an annual review of the emergency preparedness policies and procedures would constitute a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(c) would require CMHCs to develop and maintain an emergency preparedness communications plan that complies with both federal and state law. The CMHC also would have to review and update this plan at least annually. The communication plan must include the information listed in § 485.920(c)(1) through (7).

We expect that all CMHCs would compare their current emergency preparedness communications plan, if they have one, to the proposed requirements. CMHCs would need to perform any tasks necessary to ensure that their communication plans were documented and in compliance with the proposed requirements.

We expect that all CMHCs have some type of emergency preparedness communications plan. However, their emergency communications plan may not be thoroughly documented or comply with all of the elements we are requiring. It is standard practice for health care organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communication in case there is a disruption in phone service to the facility (for example, cell phones); and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, we expect that all CMHCs would need to review, update, and in some cases, develop new sections for their plans to ensure that those plans include all of the elements we are requiring for CMHC communications plans.

The burden associated with complying with this proposed requirement would be due to the resources required to ensure that the CMHC's emergency communication plan complies with the requirements. Based upon our experience with CMHCs, we expect the involvement of the CMHC's administrator and the psychiatric registered nurse. For each CMHC, we estimate that complying with this requirement would require 8 burden hours at a cost of $415. Therefore, for all of the CMHCs to comply with this proposed requirement would require an estimated 1,656 burden hours (8 burden hours for each CMHC x 207 CMHCs = 1,656 burden hours) at a cost of $85,905 ($415 estimated cost for each CMHC x 207 CMHCs = $85,905 estimated cost).

We expect that CMHCs must also review and update their emergency preparedness communication plan at least annually. For the purpose of determining the burden for this proposed requirement, we expect that CMHCs would review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC. This includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator is responsible for periodically reviewing the CMHC's plans, policies, and procedures as part of his or her responsibilities. In addition, we expect that an annual review of the communication plan would require only a negligible burden. Complying with the proposed requirement for an annual review of the emergency preparedness communications plan constitutes a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(d) would require CMHCs to develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually. We would require the CMHC to meet the requirements contained in § 485.920(d)(1) and (2).

We expect that CMHCs would develop a comprehensive emergency preparedness training program. The CMHCs would need to compare their current emergency preparedness training program and compare its contents to the risk assessment and updated emergency preparedness plan, policies and procedures, and communications plan and review, revise, and, if necessary, develop new sections for their training program to ensure it complies with the proposed requirements.

The burden would be due to the resources the CMHC would need to comply with the proposed requirements. We expect that complying with this requirement would include the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would be primarily involved in reviewing the CMHC's current training program, determining what tasks need to be performed or what materials need to be developed, and developing the materials for the training program. We estimate that it would require 10 burden hours for each CMHC to develop a comprehensive emergency training program at a cost of $414. Therefore, it would require an estimated 2,070 burden hours (10 burden hours for each CMHC x 207 CMHCs = 2,070 burden hours) to comply with this proposed requirement at a cost of $85,698 ($414 estimated cost for each CMHC x 207 CMHCs = $85,698 estimated cost).

Proposed § 485.920(d)(1) would also require the CMHCs to review and update their emergency preparedness training program at least annually. For the purpose of determining the burden for this proposed requirement, we will expect that CMHCs would review their emergency preparedness training program annually. We expect that all CMHCs have a professional staff

person, probably a psychiatric registered nurse, who is responsible for periodically reviewing their training program to ensure that it is up-to-date and complies with the relevant federal, state, and local laws, regulations, and ordinances. In addition, we expect that an annual review of the CMHC's emergency preparedness training program would require only a negligible burden. Thus, we expect that complying with the proposed requirement for an annual review of the emergency preparedness training program constitutes a usual and customary business practice for CMHCs. As stated in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are not subject to the PRA.

Proposed § 485.920(d)(2) would require CMHCs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. CMHCs would be required to document the drills and the exercises. To comply with this proposed requirement, a CMHC would need to develop a specific scenario for each drill and exercise. A CMHC would have to develop the documentation necessary to record what happened during the drills and exercises.

Based on our experience with CMHCs, we expect that all 207 CMHCs have some type of emergency preparedness training program and most, if not all, of these CMHCs already conduct some type of drill or exercise to test their emergency preparedness plans. However, we do not know what type of drills or exercises they typically conduct or how often they are performed. We also do not know how, or if, they are documenting and analyzing their responses to these drills and tests. For the purpose of determining a burden for these proposed requirements, we will expect that all CMHCs need to develop two scenarios, one for the drill and one for the exercise, and develop the documentation necessary to record the facility's responses.

The associated burden would be the time and effort necessary to comply with the requirement. We expect that complying with this proposed requirement would likely require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse would develop the documentation necessary for both during the drill and the exercise and for the subsequent analysis of the CMHC's response. The psychiatric registered nurse would also develop the two scenarios for the drill and exercise. We estimate that these tasks would require 4 burden hours at a cost of $166. For all 207 CMHCs to comply with this proposed requirement would require an estimated 828 burden hours (4 burden hours for each CMHC x 207 CMHCs = 828 burden hours) at a cost of $34,362 ($166 estimated cost for each CMHC x 207 CMHCs = $34,362 estimated cost).

TABLE 14: BURDEN HOURS AND COST ESTIMATES FOR ALL 207 CMHCs TO COMPLY WITH THE ICRs CONTAINED IN § 485.920 EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Cost ($)
§485.920(a)(1)	0938-New	207	207	10	2,070	**	97,290	97,290
§485.920(a)(1)-(4)	0938-New	207	207	15	3,105	**	155,250	155,250
§485.920(b)	0938-New	207	207	12	2,484	**	130,410	130,410
§485.920(c)	0938-New	207	207	8	1,656	**	85,905	85,905
§485.920(d)(1)	0938-New	207	207	10	2,070	**	85,698	85,698
§485.920(d)(2)	0938-New	207	207	4	828	**	34,362	34,362
Totals		207	1,242		12,213			588,915

Q. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 486.360)

Proposed § 486.360(a) would require Organ Procurement Organizations (OPOs) to develop and maintain emergency preparedness plans that would have to be reviewed and updated at least annually. These plans would have to comply with the requirements listed in § 486.360(a)(1) through (4).

The current OPO Conditions for Coverage (CfCs) are located at 42 CFR 486.301 through 486.348. These CfCs do not contain any specific emergency preparedness requirements. Thus, for the purpose of determining the burden, we have analyzed the burden for all 58 OPOs for all of the ICRs contained in this proposed rule.

Proposed § 486.360(a)(1) would require OPOs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. OPOs would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area, including branch offices and hospitals in their donation services areas.

The burden associated with this requirement would be the time and effort necessary to perform a thorough risk assessment. Based on our experience with OPOs, we believe that all 58 OPOs have already performed at least some of the work needed for their risk assessments. However, these risk assessments may not be documented or may not address all of the elements required under proposed § 486.360(a). Therefore, we expect that all 58 OPOs would have to perform a thorough review of their current risk assessments and perform the necessary tasks to ensure that their risk assessment complied with the requirements of this proposed rule. Based on our experience with OPOs, we believe that conducting a risk assessment would require the involvement of the OPO's director, medical director, quality assessment and performance improvement (QAPI) director, and an organ procurement coordinator (OPC). We expect that

these individuals would attend an initial meeting; review relevant sections of the current assessment, prepare and send their comments to the QAPI director; attend a follow-up meeting; perform a final review; and approve the new risk assessment. We estimate that the QAPI Director probably would coordinate the meetings, review the current risk assessment, critique the risk assessment, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved it. We estimate that it would require 10 burden hours for each OPO to conduct a risk assessment at a cost of $822. Therefore, for all 58 OPOs to comply with the risk assessment requirement in this section would require an estimated 580 burden hours (10 burden hours for each OPO x 58 OPOs = 580 burden hours) at a cost of $47,676 ($822 estimated cost for each OPO x 58 OPOs = $47,676 estimated cost).

After conducting the risk assessment, OPOs would then have to develop emergency preparedness plans. The burden associated with this requirement would be the resources needed to develop an emergency preparedness plan that complied with the requirements in proposed § 486.360(a)(1) through (4). We expect that all OPOs have some type of emergency preparedness plan because it is standard practice in the health care industry to have a plan to address common emergencies, such as fires. In addition, based on our experience with OPOs (including the performance of the Louisiana OPO during the Katrina disaster), OPOs already have plans to ensure that services will continue to be provided in their donation service areas (DSAs) during an emergency. However, we do not expect that all OPOs would have emergency preparedness plans that would satisfy the requirements of this section. Therefore, we expect that all OPOs would need to review their current emergency preparedness plans and compare their plans to their risk assessments. Most OPOs would need to revise, and in some cases develop, new sections to ensure their plan satisfied the proposed requirements.

We expect that the same individuals who were involved in the risk assessment would be involved in developing the emergency preparedness plan. We expect that these individuals would attend an initial meeting, review relevant sections of the OPO's current emergency preparedness plan, prepare and send their comments to the QAPI director, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the QAPI Director would coordinate the meetings, perform an initial review of the current emergency preparedness plan, critique the emergency preparedness plan, coordinate comments, ensure that the appropriate individuals revise the plan, and ensure that the necessary parties approve the new plan.

Thus, we estimate that it would require 22 burden hours for each OPO to develop an emergency preparedness plan that complied with the requirements of this section at a cost of $1,772. Therefore, for all 58 OPOs to comply with this requirement would require an estimated 1,276 burden hours (22 burden hours for each OPO x 58 OPOs = 1,276 burden hours) at a cost of $102,776 ($1,772 estimated cost for each OPO x 58 OPOs = $102,776 estimated cost).

OPOs would also be required to review and update their emergency preparedness plans at least annually. We believe that all of the OPOs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(b) would require OPOs to develop and maintain emergency preparedness policies and procedures based on their risk assessments, emergency preparedness plans, emergency communication plan as set forth in proposed § 486.360(a)(1), (a), and (c), respectively. It would also require OPOs to review and update these policies and procedures at

least annually. The OPO's policies and procedures must address the requirements listed at § 486.360(b)(1) and (2).

The OPO CfCs already require the OPOs' governing boards to "develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including . . . the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for those services" (§ 486.324(e)). Thus, we expect that OPOs already have developed and implemented policies and procedures for their effective administration. However, since the current CfCs have no specific requirement that these policies and procedures address emergency preparedness, we do not believe that the OPOs have developed or implemented all of the policies and procedures that would be needed to comply with the requirements of this section.

The burden associated with the development of the emergency preparedness policies and procedures would be the resources needed to develop emergency preparedness policies and procedures that would include, but would not be limited to, the specific elements identified in this requirement. We expect that all OPOs would need to review their current policies and procedures and compare them to their risk assessments, emergency preparedness plans, emergency communication plans, and agreements and protocols, they have developed as required by this proposed rule. Following their reviews, OPOs would need to develop and implement the policies and procedures necessary to ensure that they initiate and maintain their emergency preparedness plans, agreements, and protocols.

Based on our experience with OPOs, we expect that accomplishing these activities would require the involvement of the OPO's director, medical director, QAPI director, and an Organ Procurement Coordinator (OPC). We expect that all of these individuals would review the

OPO's current policies and procedures; compare them to the risk assessment, emergency preparedness plan, agreements and protocols they have established with hospitals, other OPOs, and transplant programs; provide an analysis or comments; and participate in developing the final version of the policies and procedures.

We expect that the QAPI director would likely coordinate the meetings; coordinate and incorporate comments; draft the revised or new policies and procedures; and obtain the necessary signatures for final approval. We estimate that it would require 20 burden hours for each OPO to comply with the requirement to develop emergency preparedness policies and procedures at a cost of $1,482. Therefore, for all 58 OPOs to comply with this requirement would require an estimated 1,160 burden hours (20 burden hours for each OPO x 58 OPOs = 1,160 burden hours) at a cost of $85,956 (estimated cost for each OPO of $1,482 x 58 OPOs = $85,956 estimated cost).

OPOs also would be required to review and update their emergency preparedness policies and procedures at least annually. We believe that OPOs already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(c) would require OPOs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. The OPOs would have to review and update their plans at least annually. The communication plans would have to include the information listed in § 486.360(c)(1) through (3).

OPOs must operate 24 hours a day, seven days a week. OPOs conduct much of their work away from their office(s) at various hospitals within their DSAs. To function effectively,

OPOs must ensure that they and their staff at these multiple locations can communicate with the OPO's office(s), other OPO staff members, transplant and donor hospitals, transplant programs, the Organ Procurement and Transplantation Network (OPTN), other healthcare providers, other OPOs, and potential and actual donors' next-of-kin.

Thus, we expect that the nature of their work would ensure that all OPOs have already addressed at least some of the elements that would be required by this section. For example, due to the necessity of communication with so many other entities, we expect that all OPOs would have compiled names and contact information for staff, other OPOs, and transplant programs.

We also expect that all OPOs would have alternate means of communication for their staffs. However, we do not believe that all OPOs have developed formal plans that include all of the proposed elements contained in this requirement. The burden would be the resources needed to develop an emergency preparedness communications plan that would include, but not be limited to, the specific elements identified in this section. We expect that this would require the involvement of the OPO director, medical director, QAPI director, and OPC. We expect that all of these individuals would need to review the OPO's current plans, policies, and procedures related to communications and compare them to the OPO's risk assessment, emergency plan, and the agreements and protocols the OPO developed in accordance with proposed § 486.360(e), and the OPO's emergency preparedness policies and procedures. We expect that these individuals would review the materials described earlier, submit comments to the QAPI director, review revisions and additions, and give a final recommendation or approval for the new emergency preparedness communication plan. We also expect that the QAPI director would coordinate the meetings; compile comments; incorporate comments into a new communications plan, as appropriate; and ensure that the necessary individuals review and approve the new plan.

We estimate that it would require 14 burden hours to develop an emergency preparedness communication plan at a cost of $1,078. Therefore, it would require an estimated 812 burden hours (14 burden hours for each OPO x 58 OPOs = 812 burden hours) at a cost of $62,524 ($1,078 estimated cost for each OPO x 58 OPOs = $62,524 estimated cost).

We propose that OPOs must review and update their emergency preparedness communication plans at least annually. We believe that all of the OPOs already review their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(d) would require OPOs to develop and maintain emergency preparedness training and testing programs. OPOs also would be required to review and update these programs at least annually. In addition, OPOs must meet the requirements listed in § 486.360(d)(1) and (2).

In § 486.360(d)(1), we are proposing that OPOs be required to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. OPOs must also ensure that their staff can demonstrate knowledge of their emergency procedures. Thereafter, OPOs would have to provide emergency preparedness training at least annually.

Under existing regulations, OPOs are required to provide their staffs with the training and education necessary for them to furnish the services the OPO is required to provide, including applicable organizational policies and procedures and QAPI activities (§ 486.326(c)). However, since there are no specific emergency preparedness requirements in the current OPO CfCs, we

do not believe that the content of their existing training would comply with the proposed requirements.

We expect that OPOs would develop a comprehensive emergency preparedness training program for their staffs. Based upon our experience with OPOs, we expect that complying with this proposed requirement would require the OPO director, medical director, the QAPI director, an OPC, and the education coordinator. We expect that the QAPI director and the education coordinator would review the OPO's risk assessment, emergency preparedness plan, policies and procedures, and communication plan and make recommendations regarding revisions or new sections necessary to ensure that all appropriate information is included in the OPO's emergency preparedness training. We believe that the OPO director, medical director, and OPC would meet with the QAPI director and education coordinator and assist in the review, provide comments, and approve the new emergency preparedness training program.

We estimate that it would require 40 burden hours for each OPO to develop an emergency preparedness training program that complied with these requirements at a cost of $2,406. Therefore, we estimate that for all 58 OPOs to comply with this requirement would require 2,320 burden hours (40 burden hours for each OPO x 58 OPOs = 2,320 burden hours) at a cost of $139,548 ($2,406 estimated cost for each OPO x 58 OPOs = $139,548 estimated cost).

We propose that OPOs must review and update their emergency preparedness training programs at least annually. We believe that all of the OPOs already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for OPOs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 486.360(d)(2) would require OPOs to conduct a paper-based, tabletop exercise at least annually. OPOs also would be required to analyze their responses to and maintain documentation of all tabletop exercises and actual emergency events, and revise their emergency plans, as needed. To comply with this requirement, OPOs would have to develop scenarios for each tabletop exercise and the necessary documentation.

The OPO CfCs do not currently contain a requirement for OPOs to conduct a paper-based, tabletop exercise. However, OPOs are required to evaluate their staffs' performance and provide training to improve individual and overall staff performance and effectiveness (42 CFR 486.326(c)). Therefore, we expect that OPOs periodically conduct some type of exercise to test their plans, policies, and procedures, which would include developing a scenario for and documenting the exercise. Thus, compliance with these requirements would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

We expect that the QAPI director and the education coordinator would work together to develop the scenario for the exercise and the necessary documentation. We expect that the QAPI director would likely spend more time on these activities. We estimate that these tasks would require 5 burden hours for each OPO at a cost of $278. For all 58 OPOs to comply with these requirements would require an estimated 290 burden hours (5 burden hours for each OPO x 58 OPOs = 290 burden hours) at a cost of $16,124 ($278 estimated cost for each OPO x 58 OPOs = $16,124 estimated cost).

Proposed § 486.360(e) would require each OPO to have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. This

section would also require each OPO to include in the hospital agreements required under § 486.322(a), and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

The burden associated with the development of an agreement with another OPO and with the hospitals in the OPO's DSA would be the resources needed to negotiate, draft, and approve the agreement. For the purpose of determining a burden for this requirement, we will assume that each OPO would need to develop an agreement with one other OPO.

We expect that the OPO director, medical director, QAPI director, OPC, and an attorney would be involved in completing the tasks necessary to develop these agreements. We expect that all of these individuals would be involved in assessing the OPO's need for coverage of its DSA during emergencies and deciding with which OPO to negotiate an agreement. We also expect that the OPO director, QAPI director, and an attorney would be involved in negotiating the agreements and ensuring that the appropriate parties sign the agreements. The attorney would be responsible for drafting the agreement and making any necessary revisions.

We estimate that it would require 22 burden hours for each OPO to develop an agreement with another OPO to provide essential organ procurement services to all or a portion of its DSA during an emergency at a cost of $1,658. Therefore, it would require an estimated 1,276 burden hours (22 burden hours for each OPO x 58 OPOs = 1,276 burden hours) for all 58 OPOs to comply with this requirement at a cost of $96,164 ($1,658 estimated cost for each OPO x 58 OPOs = $96,164 estimated cost).

Proposed § 486.360(e) would also require OPOs to include in the agreements with hospitals required under § 486.322(a), and in the protocols with transplant programs required

under § 486.344(d), the duties and responsibilities of the hospital, transplant center, and the OPO in the event of an emergency. The current OPO CfCs do not contain a requirement for emergency preparedness to be covered in these agreements and protocols. However, based on our experience with OPOs, hospitals, and transplant centers, we expect that most, if not all of these agreements and protocols already address roles and responsibilities during an emergency.

Thus, for the purpose of determining an ICR burden for these requirements, we will assume that all 58 OPOs would need to draft a limited amount of new language for their agreements with hospitals and the protocols with transplant centers. We expect that an attorney would be primarily responsible for drafting the language for these agreements and protocols and making any necessary revisions required by the parties. The number of hospitals and transplant programs in each DSA would vary widely between the OPOs. However, we expect that the attorney would draft standard language for both types of documents. In addition, we expect that the OPO director, medical director, QAPI director, and OPC would work with the attorney in developing this standard language.

We estimate that it would require 13 burden hours for each OPO to comply with these requirements at a cost of $969. Therefore, it would require 754 burden hours (13 burden hours for each OPO x 58 OPOs = 754 burden hours) at a cost of $56,202 ($969 estimated cost for each OPO x 58 OPOs = $56,202 estimated cost).

Based on the previous analysis, for all 58 OPOs to comply with all of the ICRs in proposed § 486.360 would require 8,468 burden hours at a cost of $606,970.

TABLE 15: BURDEN HOURS AND COST ESTIMATES FOR ALL 58 OPOS TO COMPLY WITH THE ICRs CONTAINED IN § 486.360 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§486.360(a)(1)	0938-New	58	58	10	580	**	47,676	0	47,676
§486.360(a)(2)-(4)	0938-New	58	58	22	1,276	**	102,776	0	102,776
§486.360(b)	0938-New	58	58	20	1,160	**	85,956	0	85,956
§486.360(c)	0938-New	58	58	14	812	**	62,524	0	62,524
§486.360(d)(1)	0938-New	58	58	40	2,320	**	139,548	0	139,548
§486.360(d)(2)	0938-New	58	58	5	290	**	16,124	0	16,124
§486.360(e)	0938-New	58	58	35	2,030	**	152,366	0	152,366
Totals		58	406	146	8,468				606,970

R. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 491.12)

Proposed § 491.12(a) would require Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs) to develop and maintain emergency preparedness plans. The RHCs and FQHCs would also have to review and update their plans at least annually. We propose that the plan must meet the requirements listed at § 491.12(a)(1) through (4).

Proposed § 491.12(a)(1) would require RHCs/FQHCs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. RHCs/FQHCs would need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area. RHCs/FQHCs would need to review any existing risk assessments and then update and revise those assessments or develop new sections for them so that those assessments complied with our proposed requirements.

We obtained the total number of RHCs and FQHCs used in this burden analysis from the CMS CASPER data system, which the states update periodically. Due to variations in the timeliness of the data submission, all numbers in this analysis are approximate. There are currently 4,013 RHCs and 5,534 FQHCs. Thus, there are 9,547 RHC/FQHCs (4,013 RHCs + 5,534 FQHCs = 9,547 RHCs/FQHCs). Unlike RHCs, FQHCs are grantees under Section 330 of the Public Health Service Act. In 2007, the Health Resources and Services Administration

(HRSA) issued a Policy Information Notice (PIN) entitled "Health Center Emergency Management Program Expectations," that detailed the expectations HRSA has for section 330 grantees related to emergency management ("Health Center Emergency Management Program Expectations," Policy Information Notice (PIN), Document Number 2007-15, HRSA, August 22, 2007) (Emergency Management PIN). A review of the Emergency Management PIN indicates that some of its expectations are very similar to the requirements in this proposed rule. Therefore, since the expectations in the Emergency Management PIN are a significant factor in determining the burden for FQHCs, we will analyze the burden for the 5,534 FQHCs separately from the 4,013 RHCs where the burden would be significantly different.

Based on our experience with RHCs, we expect that all 4,013 RHCs have already performed at least some of the work needed to conduct a risk assessment. It is standard practice for health care facilities to prepare for common emergencies, such as fires, power outages, and storms. In addition, the current Rural Health Clinic Conditions for Certification and the FQHC Conditions for Coverage (RHC/FQHC CfCs) already require each RHC and FQHC to assure "the safety of patients in case of non-medical emergencies by . . . taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located" (§ 491.6(c)(3)).

Further, in accordance with the Emergency Management PIN, FQHCs should have initiated their "emergency management planning by conducting a risk assessment such as a Hazard Vulnerability Analysis" (HVA) (Emergency Management PIN, p. 5). The HVA should identify potential emergencies or risks and potential direct and indirect effects on the facility's operations and demands on their services and prioritize the risks based on the likelihood of each risk occurring and the impact or severity the facility would experience if the risk occurs

(Emergency Management PIN, p. 5). FQHCs are also "encouraged to participate in community level risk assessments and integrate their own risk assessment with the local community" (Emergency Management PIN, p. 5).

Despite these expectations and the existing Medicare regulations for RHCs/FQHCs, some RHC/FQHC risk assessments may not comply with all proposed requirements. For example, the expectations for FQHCs do not specifically address our proposed requirement to address likely medical and non-medical emergencies. In addition, participation in a community-based risk assessment is only encouraged, not required. We expect that all 4,013 RHCs and 5,534 FQHCs will need to compare their current risk assessments with our proposed requirements and accomplish the tasks necessary to ensure their risk assessments comply with our proposed requirements. However, we expect that FQHCs would not be subject to as many burden hours as RHCs.

We have not designated any specific process or format for RHCs or FQHCs to use in conducting their risk assessments because we believe that RHCs and FQHCs need flexibility to determine the best way to accomplish this task. However, we expect that these health care facilities would include input from all of their major departments. Based on our experience with RHCs/FQHCs, we expect that conducting the risk assessment would require the involvement of the RHC/FQHC's administrator, a physician, a nurse practitioner or physician assistant, and a registered nurse. We expect that these individuals would attend an initial meeting, review the current risk assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator would coordinate the meetings, review the current risk assessment, provide an analysis of the risk assessment, offer suggested revisions, coordinate comments, develop the new

risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator would spend more time reviewing the risk assessment than the other individuals.

We estimate that it would require 10 burden hours for each RHC to conduct a risk assessment that complied with the requirements in this section at a cost of $712. We estimate that for all RHCs to comply with our proposed requirements would require 40,130 burden hours (10 burden hours for each RHC x 4,013 RHCs = 39,410 burden hours) at a cost of $2,857,256 ($712 estimated cost for each RHC x 4,013 RHCs = $2,857,256 estimated cost).

We estimate that it would require 5 burden hours for each FQHC to conduct a risk assessment that complied with our proposed requirements at a cost of $356. We estimate that for all 5,534 FQHCs to comply would require 27,670 burden hours (5 burden hours for each FQHC x 5,534 FQHCs = 27,670 burden hours) at a cost of $1,970,104 ($356 estimated cost for each FQHC x 5,534 FQHCs = $1,970,104 estimated cost).

Based on those estimates, compliance with this proposed requirement for all RHCs and FQHCs would require 67,800 burden hours at a cost of $4,827,360.

After conducting the risk assessment, RHCs/FQHCs would have to develop and maintain emergency preparedness plans that complied with proposed § 491.12(a)(1) through (4) and review and update them annually. It is standard practice for healthcare facilities to plan for common emergencies, such as fires, hurricanes, and snowstorms. In addition, as discussed earlier, we require all RHCs/FQHCs to take appropriate measures to ensure the safety of their patients in non-medical emergencies, based on the particular conditions present in the area in which they are located (§ 491.6(c)(3)). Thus, we expect that all RHCs/FQHCs have developed some type of emergency preparedness plan. However, under this proposed rule, all RHCs/FQHCs would have to review their current plans and compare them to their risk

assessments. The RHCs/FQHCs would need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans that meet our proposed requirements.

The Emergency Management PIN contains many expectations for an FQHC's emergency management plan (EMP). For example, it states that the FQHC's EMP "is necessary to ensure the continuity of patient care" during an emergency (Emergency Management PIN, p. 6) and should contain plans for "assuring access for special populations (Emergency Management PIN, p. 7). The FQHC's EMP also should address continuity of operations, as appropriate (Emergency Management PIN, p. 6). In addition, FQHCs should use an "all-hazards approach" so that these facilities can respond to all of the risks they identified in their risk assessment (Emergency Management PIN, p. 6). Based on the expectations in the Emergency Management PIN, we expect that FQHCs likely have developed emergency preparedness plans that comply with many, if not all, of the elements with which their plans would need to comply under this proposed rule. However, we expect that FQHCs would need to compare their current EMP to our proposed requirements and, if necessary, revise or develop new sections for their EMP to bring it into compliance. We expect that FQHCs would have less of a burden than RHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who were involved in developing the risk assessments would be involved in developing the emergency preparedness plans. However, we expect that it would require more time to complete the plans than the risk assessments. We expect that the administrator would have primary responsibility for reviewing and developing the RHC/FQHC's EMP. We expect that the physician, nurse practitioner, and registered nurse would review the draft plan and provide comments to the administrator. We estimate that for each RHC to comply with this requirement would require 14 burden hours at a cost of $949. Therefore, it would require an estimated

56,182 burden hours (14 burden hours for each RHC x 4,013 RHCs = 56,182 burden hours) to complete the plan at a cost of $3,808,337 ($949 estimated cost for each RHC x 4,013 RHCs = $3,808,337 estimated cost).

We estimate that it would require 8 burden hours for each FQHC to comply with our proposed requirements at a cost of $530. Based on that estimate, it would require 44,272 burden hours (8 burden hours for each FQHC x 5,534 FQHCs = 44,272 burden hours) to complete the plan at a cost of $2,933,020 ($530 estimated cost for each FQHC x 5,534 FQHCs = $2,933,020 estimated cost).

Based on the previous estimates, for all RHCs and FQHCs to develop an emergency preparedness plan that complies with our proposed requirements would require 100,454 burden hours at a cost of $6,741,357.

Each RHC/FQHC also would be required to review and update its emergency preparedness plan at least annually. We believe that RHCs and FQHCs already review their emergency preparedness plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for RHCs and FQHCs and would not subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(b) would require RHCs/FQHCs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 491.12(a), (a)(1), and (c), respectively. We would also require RHCs/FQHCs to review and update these policies and procedures at least annually. At a minimum, we would require that the RHC/FQHC's policies and procedures address the requirements listed at § 491.12(b)(1) through (4).

We expect that all RHCs/FQHCs have some emergency preparedness policies and procedures. All RHCs and FQHCs are required to have emergency procedures related to the safety of their patients in non-medical emergencies (§ 491.6(c)). They also must set forth in writing their organization's policies (§ 491.7(a)(2)). In addition, current regulations require that a physician, in conjunction with a nurse practitioner or physician's assistant, develop the facility's written policies (§ 491.8(b)(ii) and (c)(i)). However, we expect that all RHCs/FQHCs would need to review their policies and procedures, assess whether their policies and procedures incorporate their risk assessments and emergency preparedness plans and make any changes necessary to comply with our proposed requirements.

We expect that FQHCs already have policies and procedures that would comply with some of our proposed requirements. Several of the expectations of the Emergency Management PIN address specific elements in proposed § 491.12(b). For example, the PIN states that FQHCs should address, as appropriate, continuity of operations, staffing, surge patients, medical and non-medical supplies, evacuation, power supply, water and sanitation, communications, transportation, and the access to and security of medical records (Emergency Management PIN, p. 6). In addition, FQHCs should also continually evaluate their EMPs and make changes to their EMPs as necessary (Emergency Management PIN, p. 7). These expectations also indicate that FQHCs should be working with and integrating their planning with their state and local communities' plans, as well as other key organizations and other relationships (Emergency Management PIN, p. 8). Thus, we expect that burden for FQHCs from the requirement for emergency preparedness policies and procedures would be less than the burden for RHCs.

The burden associated with our proposed requirements would be reviewing, revising, and, if needed, developing new emergency preparedness policies and procedures. We expect

that a physician and a nurse practitioner would primarily be involved with these tasks and that an administrator would assist them. We estimate that for each RHC to comply with our proposed requirements would require 12 burden hours at a cost of $968. Based on that estimate, for all 4,013 RHCs to comply with these requirements would require 48,156 burden hours (12 burden hours for each RHC x 4,013 RHCs = 48,156 burden hours) at a cost of $3,884,584 ($968 estimated cost for each RHC x 4,013 RHCs = $3,884,584 estimated cost).

As discussed earlier, we expect that FQHCs would have less of a burden from developing their emergency preparedness policies and procedures due to the expectations set out in the Emergency Management PIN. Thus, we estimate that for each FQHC to comply with the proposed requirements would require 8 burden hours at a cost of $608. Based on that estimate, for all 5,534 FQHCs to comply with these requirements would require 44,272 burden hours (8 burden hours for each FQHC x 5,534 FQHCs = 44,272 burden hours) at a cost of $3,364,672 ($608 estimated cost for each FQHC x 5,534 FQHCs = $3,364,672 estimated cost).

Based on the previous estimates, for all RHCs and FQHCs to develop emergency preparedness policies and procedures that comply with our proposed requirements would require 92,428 burden hours at a cost of $7,249,256.

We propose that RHCs/FQHCs review and update their emergency preparedness policies and procedures at least annually. We believe that RHCs and FQHCs already review their emergency preparedness policies and procedures periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(c) would require RHCs/FQHCs to develop and maintain an emergency preparedness communication plan that complied with both federal and state law.

RHCs/FQHCs would also have to review and update these plans at least annually. We propose that the communication plan must include the information listed in § 491.12(c)(1) through (5).

We expect that all RHCs/FQHCs have some type of emergency preparedness communication plan. It is standard practice for health care facilities to maintain contact information for staff and outside sources of assistance; alternate means of communication in case there is an interruption in the facility's phone services; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for patients. As discussed earlier, RHCs and FQHCs are required to take appropriate measures to ensure the safety of their patients during non-medical emergencies (§ 491.6(c)). We expect that an emergency preparedness communication plan would be an essential element in any emergency preparedness preparations. However, some RHCs/FQHCs may not have a formal, written emergency preparedness communication plan or their plan may not include all the requirements we propose.

The Emergency Management PIN contains specific expectations for communications and information sharing (Emergency Management PIN, pp. 8-9). "A well-defined communication plan is an important component of an effective EMP" (Emergency Management PIN, p. 8). In addition, FQHCs are expected to have policies and procedures for communicating with both internal stakeholders (such as patients and staff) and external stakeholders (such as federal, tribal, state, and local agencies), and for identifying who will do the communicating and what type of information will be communicated (Emergency Management PIN, p. 8). FQHCs should also identify alternate communications systems in the event that their standard communications systems become unavailable, and the FQHC should identify these alternate systems in their EMP (Emergency Management PIN, p. 9). Thus, we expect that all FQHCs would have a formal

communication plan for emergencies and that those plans would contain some of our proposed requirements. However, we expect that all FQHCs would need to review, revise, and, if needed, develop new sections for their emergency preparedness communication plans to ensure that their plans are in compliance. We expect that these tasks will require less of a burden for FQHCs than for the RHCs.

The burden associated with complying with this requirement would be the resources required to review, revise, and, if needed, develop new sections for the RHC/FQHC's emergency preparedness communication plan. Based on our experience with RHCs/FQHCs, as well as the requirements in current regulations for a physician to work in conjunction with a nurse practitioner or a physician assistant to develop policies, we anticipate that satisfying the requirements in this section would require the involvement of the RHC/FQHC's administrator, a physician, and a nurse practitioner or physician assistant. We expect that the administrator and the nurse practitioner or physician assistant would be primarily involved in reviewing, revising, and if needed, developing new sections for the RHC/FQHC's emergency preparedness communication plan.

We estimate that for each RHC to comply with the proposed requirements would require 10 burden hours at a cost of $734. Based on that estimate, for all 4,013 RHCs to comply would require 40,130 burden hours (10 burden hours for each RHC x 4,013 RHCs = 40,130 burden hours) at a cost of $3,443,154 ($734 estimated cost for each RHC x 4,013 RHCs = $3,443,154 estimated cost).

We estimate that for a FQHC to comply with the proposed requirements would require 5 burden hours at a cost of $367. Based on this estimate, for all 5,534 FQHCs to comply would require 27,670 burden hours (5 burden hours for each FQHC x 5,534 FQHCs = 27,670 burden

hours) at a cost of $2,030,978 ($367 estimated cost for each FQHC x 5,534 FQHCs = $2,030,978 estimated cost).

We propose that RHCs/FQHCs also review and update their emergency preparedness communication plans at least annually. We believe that RHCs/FQHCs already review their emergency preparedness communication plans periodically. Thus, compliance with this requirement would constitute a usual and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(d) would require RHCs/FQHCs to develop and maintain emergency preparedness training and testing programs and review and update these programs at least annually. We propose that an RHC/FQHC would have to comply with the requirements listed in § 491.12(d)(1) and (2).

Proposed § 491.12(d)(1) would require each RHC and FQHC to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. Each RHC and FQHC would also have to ensure that its staff could demonstrate knowledge of those emergency procedures. Thereafter, each RHC and FQHC would be required to provide emergency preparedness training annually.

Based on our experience with RHCs and FQHCs, we expect that all 9,045 RHC/FQHCs already have some type of emergency preparedness training program. The current RHC/FQHC regulations require RHCs and FQHCs to provide training to their staffs on handling emergencies (§ 491.6(c)(1)). In addition, FQHCs are expected to provide ongoing training in emergency management and their facilities' EMP to all of their employees (Emergency Management PIN, p. 7). However, neither the current regulations nor the PIN's expectations for FQHCs address

initial training and ongoing training, frequency of training, or requirements that individuals providing services under arrangement and volunteers be included in the training. RHCs/FQHCs would need to review their current training programs; compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then take the necessary steps to ensure that their training programs comply with our proposed requirements.

We expect that each RHC and FQHC has a professional staff person who is responsible for ensuring that the facility's training program is up-to-date and complies with all federal, state, and local laws and regulations. This individual would likely be an administrator. We expect that the administrator would be primarily involved in reviewing the RHC/FQHC's emergency preparedness program; determining what tasks need to be performed and what materials need to be developed to bring the training program into compliance with our proposed requirements; and making changes to current training materials and developing new training materials. We expect that the administrator would work with a registered nurse to develop the revised and updated training program. We estimate that it would require 10 burden hours for each RHC or FQHC to develop a comprehensive emergency training program at a cost of $526. Therefore, it would require an estimated 95,470 burden hours (10 burden hours for each RHC/FQHC x 9,547 RHCs/FQHCs = 95,470 burden hours) to comply with this requirement at a cost of $5,021,722 ($526 estimated cost for each RHC/FQHC x 9,547 RHCs/FQHCs = $5,021,722 estimated cost).

Proposed § 491.12(d) would also require that RHCs/FQHCs develop and maintain emergency preparedness training and testing programs that would be reviewed and updated at least annually. We believe that RHCs/FQHCs already review their emergency preparedness programs periodically. Therefore, compliance with this requirement would constitute a usual

and customary business practice for RHCs/FQHCs and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 491.12(d)(2) would require RHCs/FQHCs to participate in a community mock disaster drill and conduct a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, RHCs/FQHCs would have to conduct an individual, facility-based mock disaster drill at least annually. RHCs/FQHCs would also be required to analyze their responses to and maintain documentation of drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. If an RHC or FQHC experienced an actual natural or man-made emergency that required activation of its emergency plan, it would be exempt from the requirement for a community or individual, facility-based mock drill for 1 year following the onset of the actual event. However, for purposes of determining the burden for these requirements, we will assume that all RHCs/FQHCs would have to comply with all of these proposed requirements.

The burden associated with complying with these requirements would be the resources the RHC or FQHC would need to develop the scenarios for the drill and exercise and the documentation necessary for analyzing and documenting their drills, tabletop exercises, as well as any emergency events.

Based on our experience with RHCs/FQHCs, we expect that most of the 9,547 RHCs/FQHCs already conduct some type of testing of their emergency preparedness plans and develop scenarios and documentation for their testing and emergency events. For example, FQHCs are expected to conduct some type of testing of their EMP at least annually (Emergency Management PIN, p. 7). However, we do not believe that all RHCs/FQHCs have the appropriate documentation for drills, exercises, and emergency events or that they conduct both a drill and a

tabletop exercise annually. Thus, we will analyze the burden associated with these requirements for all 9,547 RHCs/FQHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who are responsible for developing the RHC/FQHC's training and testing program would develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator and a registered nurse would be primarily involved in accomplishing these tasks. We estimate that for each RHC/FQHC to comply with the requirements in this section would require 5 burden hours at a cost of $276. Based on this estimate, for all 9,547 RHCs/FQHCs to comply with the requirements in this section would require 47,735 burden hours (5 burden hours for each RHC/FQHC x 9,547 RHCs/FQHCs = 47,735 burden hours) at a cost of $2,634,972 ($276 estimated cost for each RHC/FQHC x 9,547 RHC/FQHCs = $2,634,972 estimated cost).

TABLE 16: BURDEN HOURS AND COST ESTIMATES FOR ALL 9,547 RHC/FQHCS TO COMPLY WITH THE ICRs CONTAINED IN §491.12 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/Maintenance Costs ($)	Total Cost ($)
§491.12(a)(1) (RHCs)	0938-New	4,013	4,013	10	40,130	**	2,857,256	0	2,857,256
§491.12(a)(1) (FQHCs)	0938-New	5,534	5,534	5	27,670	**	1,970,104	0	1,970,104
§491.12(a)(1)-(4) (RHCs)	0938-New	4,013	4,013	14	56,182	**	3,808,337	0	3,808,337
§491(a)(1) – (4) (FQHCs)	0938-New	5,534	5,534	8	44,272	**	2,933,020	0	2,933,020
§491.12(b) (RHCs)	0938-New	4,013	4,013	12	48,156	**	3,884,584	0	3,884,584
§491.12(b) (FQHCs)	0938-New	5,534	5,534	8	44,272	**	3,364,672	0	3,364,672
§491.12(c) (RHCs)	0938-New	4,013	4,013	10	40,130	**	3,443,154	0	3,443,154
§491.12(c) (FQHCs)	0938-New	5,534	5,534	5	27,670	**	2030,978	0	2030,978
§491.12(d)(1)	0938-New	9,547	9,547	10	95,470	**	5,021,722	0	5,021,722
§491.12(d)(2)	0938-New	9,547	9,547	5	47,735	**	2,634,972	0	2,634,972

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/Maintenance Costs ($)	Total Cost ($)
Totals			57,282		471,687				31,948,799

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

S. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 494.62)

Proposed § 494.62(a) would require dialysis facilities to develop and maintain emergency preparedness plans that would have to reviewed and updated at least annually. Proposed § 494.62 would require that the plan include the elements set out at § 494.62(a)(1) through (4).

Proposed § 494.62(a)(1) would require dialysis facilities to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The risk assessment should address the medical and non-medical emergency events the facility could experience both within the facility and within the surrounding area. The dialysis facility would have to consider its location and geographical area; patient population, including, but not limited to, persons-at-risk; and the types of services the dialysis facility has the ability to provide in an emergency. The dialysis facility also would need to identify the measures it would need to take to ensure the continuity of its operations, including delegations of authority and succession plans.

The burden associated with this requirement would be the resources needed to perform a thorough risk assessment. The current CfCs already require dialysis facilities to "implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failure, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area" (§ 494.60(d)). Thus, to be in compliance with this CfC, we believe that all dialysis facilities would have already performed some type of risk assessment during the process of developing their emergency

preparedness processes and procedures. However, these risk assessments may not be as thorough or address all of the elements required in proposed § 494.62(a). For example, the current CfCs do not require dialysis facilities to plan for man-made disasters. Therefore, we believe that all dialysis facilities would have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities' risk assessments complied with the requirements of this section.

Based on our experience with dialysis facilities, we expect that conducting the risk assessment would require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a PCT. We believe that all of these individuals would attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review and approve the risk assessment. We believe that the administrator would probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also believe that the administrator would probably spend more time reviewing and working on the risk assessment than the other individuals involved in performing the risk assessment. Thus, we estimate that complying with this requirement to conduct and develop a risk assessment would require 12 burden hours at a cost of $838. There are currently 5,923 dialysis facilities. Therefore, it would require an estimated 71,076 burden hours (12 burden hours for each dialysis facility x 5,923 dialysis facilities = 71,076 burden hours) for all dialysis facilities to comply with this requirement at a cost of $4,963,474 ($838 estimated cost for each dialysis facility x 5,923 dialysis facilities = $4,963,474 estimated cost).

After conducting the risk assessment, each dialysis facility would then have to develop and maintain an emergency preparedness plan that the facility must evaluate and update at least annually. This emergency plan would have to comply with the requirements at proposed § 494.62(a)(1) through (4).

Current CfCs already require dialysis facilities to "have a plan to obtain emergency medical system assistance when needed. . ." and "evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary" (§ 494.60(d)(4)). Thus, we expect that all dialysis facilities have some type of emergency preparedness or disaster plan. In addition, dialysis facilities must also "implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area" (§ 494.60(d)). We expect that the facility would incorporate many, if not all, of these processes and procedures into its emergency preparedness plan. We expect that each dialysis facility has some type of emergency preparedness plan and that plan should already address many of these requirements. However, all of the dialysis facilities would have to review their current plans and compare them to the risk assessment they performed pursuant to proposed § 494.62(a)(1). The dialysis facility would then need to update, revise, and, in some cases, develop new sections to complete an emergency preparedness plan that addressed the risks identified in their risk assessment and the specific requirements contained in this subsection. The plan would also address how the dialysis facility would continue providing its essential services, which are the services that the dialysis facility would continue to provide despite an emergency. The dialysis facility would also need to review, revise, and, in some

cases, develop delegations of authority or succession plans that the dialysis facility determined were necessary for the appropriate initiation and management of their emergency preparedness plan.

The burden associated with this requirement would be the time and effort necessary to develop the emergency preparedness plan. Based upon our experience with dialysis facilities, we expect that developing the emergency preparedness plan would require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a PCT. We believe that all of these individuals would probably have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the assessment, attend a follow-up meeting, and then perform a final review and approve the risk assessment. We believe that the administrator would probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved the new risk assessment. We also believe that the administrator, medical director, and nurse manager would probably spend more time reviewing and working on the risk assessment than the other individuals involved in developing the plan. The social worker and PCT would likely just review the plan or relevant sections of it. In addition, since the medical director's responsibilities include participation in the development of patient care policies and procedures (42 CFR 494.150(c)), we expect that the medical director would be involved in the development of the emergency preparedness plan. We estimate that complying with this requirement would require 10 burden hours at a cost of $776 for each dialysis facility. There are 5,923 dialysis facilities. Therefore, it would require an estimated 59,230 burden hours (10 burden hours for

each dialysis facility x 5,923 dialysis facilities = 59,230 burden hours) to complete the plan at a cost of $4,596,248 ($776 estimated cost for each dialysis facility x 5,923 dialysis facilities = $4,596,248 estimated cost).

Each dialysis facility would also be required to review and update its emergency preparedness plan at least annually. We believe that dialysis facilities already review their emergency preparedness plans periodically. The current CfCs already requires dialysis facilities to evaluate the effectiveness of their emergency and disaster plans and update them as necessary (42 CFR 494.60(d)(4)(ii)). Thus, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(b) would require dialysis facilities to develop and implement emergency preparedness policies and procedures based on the emergency plan, the risk assessment, and communication plan as set forth in § 494.62(a), (a)(1), and (c), respectively. These emergencies would include, but would not be limited to, fire, equipment or power failures, care-related emergencies, water supply interruptions, and natural and man-made disasters that are likely to occur in the facility's geographical area. Dialysis facilities would also have to review and update these policies and procedures at least annually. The policies and procedures would be required to address, at a minimum, the requirements listed at § 494.62(b)(1) through (9).

We expect that all dialysis facilities have some emergency preparedness policies and procedures. The current CfCs at 42 CFR 494.60(d) already require dialysis facilities to have and "implement processes and procedures to manage medical and nonmedical emergencies . . . [that] include, but not limited to, fire, equipment or power failures, care-related emergencies, water

supply interruption, and natural disasters likely to occur in the facility's geographic area". In addition, we expect that dialysis facilities already have procedures that would satisfy some of the requirements in this section. For example, each dialysis facility is already required at 42 CFR 494.60(d)(4)(iii) to "contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency". However, all dialysis facilities would need to review their policies and procedures, assess whether their policies and procedures incorporated all of the necessary elements of their emergency preparedness program, and then, if necessary, take the appropriate steps to ensure that their policies and procedures encompassed these requirements.

The burden associated with the development of these emergency policies and procedures would be the time and effort necessary to comply with these requirements. We expect the administrator, medical director, and the nurse manager would be primarily involved with reviewing, revising, and if needed, developing any new policies and procedures that were needed. The remaining individuals would likely review the sections of the policies and procedures that directly affect their areas of expertise. Therefore, we estimate that complying with this requirement would require 10 burden hours at a cost of $776 for each dialysis facility. There are 5,923 dialysis facilities. Therefore, it would require an estimated 59,230 burden hours (10 burden hours for each dialysis facility x 5,923 dialysis facilities = 59,230 burden hours) to complete the plan at a cost of $4,596,248 ($768 estimated cost for each dialysis facility x 5,923 dialysis facilities = $4, 596,248 estimated cost).

The dialysis facility must also review and update its emergency preparedness policies and procedures at least annually. We believe that dialysis facilities already review their emergency preparedness policies and procedures periodically. In addition, the current CfCs already require

(at 42 CFR 494.150(c)(1)) the medical director to participate in a periodic review of patient care policies and procedures. Thus, compliance with this requirement would constitute a usual and customary business practice for dialysis facilities and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(c) would require dialysis facilities to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The dialysis facility must also review and update this plan at least annually. The communication plan must include the information listed at § 494.62(c)(1) through (7).

We expect that all dialysis facilities have some type of emergency preparedness communication plan. A communication plan would be an integral part of any emergency preparedness plan. Current CfCs already require dialysis facilities to have a written disaster plan (42 CFR 494.60(d)(4)). Thus, each dialysis facility should already have some of the contact information they would need to have in order to comply with this section. In addition, we expect that it is standard practice in the healthcare 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 or text-messaging devices; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients. However, many dialysis facilities may not have formal, written emergency preparedness communication plans. Therefore, we expect that all dialysis facilities would need to review, update, and in some cases, develop new sections for their plans to ensure that those plans included all of the previously-described required elements in their emergency preparedness communication plan.

The burden associated with complying with this requirement would be the resources required to review and revise the dialysis facility's emergency preparedness communication plan to ensure that it complied with these requirements. Based upon our experience with dialysis facilities, we anticipate that satisfying these requirements would primarily require the involvement of the dialysis facility's administrator, medical director, and nurse manager. For each dialysis facility, we estimate that complying with this requirement would require 4 burden hours at a cost of $357. Therefore, for all of the dialysis facilities to comply with this requirement would require an estimated 23,692 burden hours (4 burden hours for each dialysis facility x 5,923 dialysis facilities = 23,692 burden hours) at a cost of $2,114,511 ($357 estimated cost for each dialysis facility x 5,923 dialysis facilities = $2,114,511 estimated cost).

Each dialysis facility would also have to review and update its emergency preparedness communication plan at least annually. For the purpose of determining the burden for this requirement, we would expect that dialysis facilities would review their emergency preparedness communication plans annually. We believe that all dialysis facilities have an administrator that would be primarily responsible for the day-to-day operation of the dialysis facility. This would include ensuring that all of the dialysis facility's policies, procedures, and plans were up-to-date and complied with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator would be responsible for periodically reviewing the dialysis facility's plans, policies, and procedures as part of his or her work responsibilities. Therefore, we expect that complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d) would require dialysis facilities to develop and maintain emergency preparedness training, testing and patient orientation programs that would have to be evaluated

and updated at least annually. The dialysis facility would have to comply with the requirements located at § 494.62(d)(1) through (3).

Proposed § 494.62(d)(1) would require that dialysis facilities provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the dialysis facility would have to provide emergency preparedness training at least annually.

Current CfCs already require dialysis facilities to "provide training and orientation in emergency preparedness to the staff" (42 CFR 494.60(d)(1)) and "provide appropriate orientation and training to patients . . ." in emergency preparedness (42 CFR 494.60(d)(2)). In addition, the dialysis facility's patient instruction would have to include the same matters that are specified in the current CfCs (42 CFR 494.60(d)(2)). Thus, dialysis facilities should already have an emergency preparedness training program for new employees, as well as ongoing training for all their staff and patients. However, all dialysis facilities would need to review their current training programs and compare their contents to their updated emergency preparedness programs, that is, the risk assessment, emergency preparedness plan, policies and procedures, and communications plans that they developed pursuant to proposed § 494.62(a) through (c). Dialysis facilities would then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with complying with this requirement would be the time and effort necessary to develop the required training program. We expect that complying with this requirement would require the involvement of the administrator, medical director, and the nurse manager. In fact, the medical director's responsibilities include, among other things, staff

education and training (42 CFR 494.150(b)). We estimate that it would require 7 burden hours for each dialysis facility to develop an emergency training program at a cost of $559. Therefore, it would require an estimated 41,461 burden hours (7 burden hours for each dialysis facility x 5,923 dialysis facilities = 41,461 burden hours) to comply with this requirement at a cost of ($559 estimated cost for each dialysis facility x 5,923 dialysis facilities = $3,310,957 estimated cost).

The dialysis facility must also review and update its emergency preparedness training program at least annually. We believe that dialysis facilities already review their emergency preparedness training programs periodically. Therefore, compliance with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d)(2) requires dialysis facilities to participate in a mock disaster drill and conduct a paper-based, tabletop exercise at least annually. If a community mock disaster drill was not available, the dialysis facility would have to conduct an individual, facility-based mock disaster drill at least annually. If the dialysis facility experienced an actual natural or man-made emergency that required activation of their emergency plan, the dialysis facility would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event. Dialysis facilities would also be required to analyze their responses to and maintain document of all drills, tabletop exercises, and emergency events. To comply with this requirement, a dialysis facility would need to develop scenarios for each drill and exercise. A dialysis facility would also have to develop the documentation necessary for recording and analyzing the drills, tabletop exercises, and emergency events.

The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (42 CFR 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, dialysis facilities should have already been developing scenarios for testing their plans. Thus, complying with this requirement would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed § 494.62(d)(3) would require dialysis facilities to provide appropriate orientation and training to patients, including the areas specified in proposed § 494.62(d)(1). Proposed § 494.62(d)(1) specifically would require that staff demonstrate knowledge of emergency procedures including the emergency information they must give to their patients. Thus, the burden associated with this section would already be included in the burden estimate for § 494.62(d)(1).

TABLE 17: BURDEN HOURS AND COST ESTIMATES FOR ALL 5,923 DIALYSIS FACILITIES TO COMPLY WITH THE ICRs CONTAINED IN § 494.62 CONDITION: EMERGENCY PREPAREDNESS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§494.62(a)(1)	0938-New	5,923	5,923	12	71,076	**	4,963,474	0	4,834,422
§494.62(a)(2)-(4)	0938-New	5,923	5,923	10	59,230	**	4,596,248	0	4,476,744
§494.62(b)	0938-New	5,923	5,923	10	59,230	**	4,596,248	0	4,476,744
§494.62(c)	0938-New	5,923	5,923	4	23,692	**	2,114,511	0	2,059,533
§494.62(d)	0938-New	5,923	5,923	7	41,461	**	3,310,957	0	3,224,871
Totals		5,923	29,615		254,689				19,581,438

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

T. Summary of Information Collection Burden

Based on the previous analysis, the first year's burden for complying with all of the requirements in this proposed rule would be 3,018,124 burden hours at a cost of $185,908,673. For subsequent years, if there is any additional burden, it would be negligible.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced earlier, access CMS' Web site at http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786–1326.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs,

Regulations Development Group,

Attn.: William Parham, (CMS-3178-P),

Room C4-26-05, 7500 Security Boulevard,

Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: CMS Desk Officer, CMS-3178-P, Fax (202) 395-6974.

IV. Regulatory Impact Analysis

A. Statement of Need

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

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. There are two Presidential Directives, HSPD-5 and HSPD-21, instructing agencies to coordinate their emergency preparedness activities with each other. Although these directives do not specifically require Medicare providers and suppliers to adopt measures, they have set the stage for what we expect from our providers and suppliers in regard to their roles in a more unified emergency preparedness system.

Homeland Security Presidential Directive (HSPD-5): Management of Domestic Incidents authorizes the Department of Homeland to develop and administer the National Incident Management System (NIMS).

Homeland Security Presidential Directive (HSPD-21) addresses public health and medical preparedness. The directive establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which builds upon principles set forth in "Biodefense for the 21st Century (April 2004), "National Strategy for Homeland Security" (October 2007), and the "National Strategy to Combat Weapons of Mass Destruction" (December 2002). The directive

aims to transform our national approach to protecting the health of the American people against all disasters.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995 Pub. L. 104-4), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S. C. 804(2)).

Executive Orders 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). The total projected cost of this rule would be $225 million in the first year, and the subsequent projected annual cost would be approximately $ 41 million.

Published reports after Hurricane Katrina reported that the Louisiana Attorney General investigated approximately 215 deaths that occurred in hospitals and nursing homes following Katrina. Since nearly all hospitals and nursing homes are certified to participate in the Medicare program, we estimate that at least a small percentage of these lives could be saved as a result of emergency preparedness measures in a single disaster of equal magnitude. Katrina is an extreme example of a natural disaster, so we also considered other more common disasters. The United

States experiences numerous natural disasters annually, including, in particular, tornadoes and flooding. Based on data from the National Oceanic and Atmospheric Administration, the United States experiences an annual average of 56 fatalities as a result of tornadoes (http://www.spc.noaa.gov/wcm/ustormaps/1981-2010-stateavgfatals.png). On average, floods kill about 140 people each year (United States Department of the Interior, United States Geological Survey Fact Sheet "Flood Hazards—A National Threat" January, 2006, at Http://pubs.usgs.gov/fs/2006/3026/2006-3026.pdf). Floods may be caused by both natural and manmade processes, including hurricanes, severe storms, snowmelt, and dam or levee failure. According to the National Weather Service, in 2010 there were a cumulative 490 deaths and 2,369 injuries and in 2011 there were a cumulative 1,096 deaths and 8,830 injuries as a result of severe weather events such as tornadoes, floods, winter storms, and others. Although we are unable to specifically quantify the number of lives saved as a result of this proposed rule, all of the data we have read regarding emergency preparedness indicate that implementing the requirements in this proposed rule could have a significant impact on protecting the health and safety of individuals served by providers and suppliers that participate in the Medicare and Medicaid programs. We believe it is crucial for all providers and suppliers to have an emergency disaster plan that is integrated with other local, state and federal agencies to effectively address both natural and manmade disasters. Therefore, we believe that it is essential to require providers and suppliers to conduct a risk assessment, to develop an emergency preparedness plan based on the assessment, and to comply with the other requirements we propose to minimize the disruption of services for the community and ensure continuity of care in the event of a disaster.

We believe that this proposed rule would be an economically significant regulatory action under section 3(f)(1) of Executive Order 12866, since it may lead to impacts of greater than $100 million in the first year following the rule's effective date.

This proposed rule would establish a regulatory framework with which Medicare- and Medicaid-participating providers and suppliers would have to comply to ensure that the varied providers and suppliers of healthcare are adequately prepared to respond to natural and man-made disasters.

Several factors influenced our estimates of the economic impact to the providers and suppliers covered by this proposed rule. These factors are discussed under section III. of this proposed rule (Collection of Information Requirements). In addition, we have used the same data source for the RIA that we used to develop the PRA burden estimates, that is, the CMS Online Survey, Certification, and Reporting System (OSCAR).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act generally defines a "small entity" as: (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity.") HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA,

we estimate that most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $35.5 million in any 1 year. For purposes of the RFA, a majority of hospitals are considered small entities due to their non-profit status. Individuals and states are not included in the definition of a small entity. Since the cost associated with this proposed rule is less than $46,000 for hospitals and $4,000 for other entities, the Secretary has determined that this proposed will not have a significant economic impact on a substantial number of small entities."

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Since the cost associated with this proposed rule is less than $46,000 for hospitals, this this proposed will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately $141 million. This omnibus proposed rule contains mandates that would impose a one-time cost of approximately $225 million. Thus, we have assessed the various costs and benefits of this proposed rule. It is clear that a number of providers and suppliers would be affected by the implementation of this proposed rule and that a substantial number of those entities would be required to make changes in their operations. This

proposed rule would not mandate any new requirements for state, local or tribal governments. For the private sector facilities, this regulatory impact section constitutes the analysis required under UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it develops a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule will not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise implicate federalism.

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

C. Anticipated Effects on Providers and Suppliers: General Provisions

This proposed rule would require each of the Medicare- and Medicaid-participating providers and suppliers discussed in previous sections to perform a risk analysis; establish an emergency preparedness plan, emergency preparedness policies and procedures, and an emergency preparedness communication plan; train staff in emergency preparedness, and test the emergency plan. The economic impact would differ between hospitals and the various other providers and suppliers, depending upon a variety of factors, including existing regulatory requirements and accreditation standards.

We discuss the economic impact for each provider and supplier type included in this proposed rule in the order in which they appear in the CFR. Most of the economic impact of this proposed rule would be due to the cost for providers and suppliers to comply with the information collection requirements. Thus, we discuss most of the economic impact under the

Collection of Information Requirements section of this proposed rule. We provide a chart at the end of the RIA section of the total regulatory impact for each provider/supplier.

As stated in the ICR section, we obtained all salary information from the May 2011 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 and calculated the added value of benefits using the estimation that salary accounts for 70 percent of compensation, based on BLS information (Bureau of Labor Statistics News Release, "Employer Cost Index—December 2011, retrieved from www.bls.gov/news.release/pdf/eci.pdf) .

1. Subsistence Requirement

This proposed rule would require all inpatient providers to meet the subsistence needs of staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, and supplies, alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions.

Based on our experience, we expect inpatient providers to currently have food, water, and supplies, alternate sources of energy to provide electrical power, and the maintenance of temperatures for the safe and sanitary storage of such provisions as a routine measure to ensure against weather related and non-disaster power failures. Thus, we believe that this requirement is a usual and customary business practice for inpatient providers and we have not assigned any impact for this requirement.

Further, we expect that most providers have agreements with their vendors to receive supplies within 24 to 48 hours in the event of an emergency, as well as arrangements with back-up vendors in the event that the disaster affects the primary vendor. We considered proposing a requirement that providers must keep a larger quantity of food and water on hand in the event of

a disaster. However, we believe that a provider should have the flexibility to determine what is adequate based on the location and individual characteristics of the facility. While some providers may have the storage capacity to stockpile supplies that would last for a longer duration, other may not. Thus, we believe that to require such stockpiling would create an unnecessary economic impact on some health care providers.

We expect that when inpatient providers determine their supply needs, they would consider the possibility that volunteers, visitors, and individuals from the community may arrive at the facility to offer assistance or seek shelter.

Based on the previous factors, we have not estimated a cost for a stockpile of food and water.

2. Generator Location and Testing

This proposed rule would require hospitals, CAHs, and LTC facilities to test and maintain their emergency and standby power systems in such a way to ensure proper operation in the event they are needed. The 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA) states that the alternate source of power (for example, generator) must be located in an appropriate area to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures. Since hospitals, CAHs and LTC facilities are currently required to comply with the referenced LSC, we have not assigned any additional burden for this requirement.

In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110 and NFPA 101, we propose that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of

the power load the hospital anticipates it will require during an emergency. As a result of lessons learned from hurricane Sandy, we believe that this annual 4 hour test will more closely reflect the actual conditions that would be experienced during a disaster of the magnitude of hurricane Sandy. Also, later editions of NFPA 110 require 4 hours of continuous generator testing every 36 months to provide reasonable assurance emergency power systems are capable of running under load during an emergency. In order to provide further assurance that generators will be capable of operating during an emergency, 4 hours of continuous generator testing will be required every 12 months. We have also proposed the same emergency and standby power requirements for CAHs and LTC facilities.

We have estimated the cost in this section for these additional testing requirements. Based on information from the U.S. Bureau of Labor Statistics and the U.S. Energy Information Administration, we have calculated the cost for the generator testing as follows:

- Labor: 6 hours (1-hour preparation, 4 hour run-time, 1 hour restoration) x $25.45 an hour =$152.70
- Fuel: Diesel cost of $3.85 per gallon x 72 gallon per hour x 4 hour of testing=$1,108.80

Therefore, we estimate the total cost to each hospital, CAH and LTC facility to comply with this requirement would be $1,262. However, we request information on this proposal and in particular on how we might better estimate costs in light of the existing LSC and other state and federal requirements.

D. Condition of Participation: Emergency Preparedness for Religious Nonmedical Health Care Institutions (RNHCIs)

1. Training and Testing (§ 403.748(d))

We discuss the majority of the economic impact for this requirement in the ICR section, which is estimated at $18,928.

2. Testing (§ 403.748(d)(2))

Proposed § 403.748(d)(2) would require RHNCIs to conduct a paper-based, tabletop exercise at least annually. RHNCIs must analyze their response and maintain documentation of all tabletop exercises, and emergency events, and revise their emergency plan as needed.

We expect that the cost associated with this requirement would be limited to the staff time needed to participate in the tabletop exercises. We estimate that approximately 4 hours of staff time would be required of the administrator and director of nursing, and 2 hours of staff time for the head of maintenance to coordinate facility evacuations and protocols for transporting residents to alternate sites. We believe that other staff members would be required to spend a minimal amount of time during these exercises and such staff time would be considered a part of regular on-going training for RHNCI staff. We estimate that it would require 10 hours of staff time for each of the 16 RNHCIs to conduct exercises at a cost of $330. Therefore, it would require an estimated total impact of $5,280 each year after the initial year for all RNHCIs to comply with proposed § 403.748(d)(2). For the initial year, we estimate $24,208 as the total economic impact and cost estimates for all 16 RNHCIs to comply with the requirements in this proposed rule.

E. Condition for Coverage: Emergency Preparedness for Ambulatory Surgical Centers (ASCs)--Testing (§ 416.54(d)(2))

Proposed § 416.54(d)(2) would require ASCs to participate in a community mock disaster drill at least annually. If a community mock disaster drill were not available, the ASC would be required to conduct a facility-based mock disaster drill at least annually and maintain

documentation of all mock disaster drills. ASCs also would be required to conduct a paper-based, tabletop exercise at least annually. ASCs also would be required to maintain documentation of the exercise.

State, Tribal, Territorial, and local public health and medical systems comprise a critical infrastructure that is integral to providing the early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal Government. There are currently three programs at HHS addressing education and training in the area of public health emergency preparedness and response: the Centers for Public Health Preparedness (CPHP), the Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN).

As discussed earlier in this preamble, ASCs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this proposed requirement. Thus, we believe that the cost associated with this requirement would be limited to the staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator and risk assurance nurse. We believe that other staff members would be required to spend a minimal amount of time during these exercises and the training would be considered as part of regular on-going training for ASC staff. We estimate that the administrator and quality assurance nurse would spend about 4 hours each on an annual basis to participate in the disaster drills (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 8 hours for an estimated cost of $500 for each of the 5,354 ASCs and a total cost estimate of $2,677,000

for all ASCs ($500 x 5,354 ASCs) each year after the first year. We estimate $15,241,036 ($2,677,000 impact cost+ $12,564,036 ICR burden) as the total economic impact and cost estimates for all ASCs to comply with the requirements in this proposed rule.

F. Condition of Participation: Emergency Preparedness for Hospices--Testing (§ 418.113(d)(2))

Proposed § 418.113(d)(2)(i) through(iii) would require hospices to participate in mock drills and tabletop exercises at least annually. In addition, hospices are to conduct a paper-based, tabletop exercise at least annually. We believe that the administrator would be responsible for participating in community-wide disaster drills and would be the primary person to organize a facility-wide drill and tabletop exercise with the assistance of one member of the IDG. We believe that the registered nurse would most likely represent the IDG on the drills and exercises. While we expect that all staff would be involved in the drills and exercises, we would consider their involvement as part of their regular staff training. However, for the purpose of this analysis we assume that the administrator would spend approximately 3 hours annually to participate in a community or facility-wide drill and 1 hour to participate in a tabletop exercise above their regular and ongoing training. We also assume that the registered nurse would spend 3 hours to participate in an annual drill and 1 hour to participate in a tabletop exercise. Thus, we estimate that each hospice would spend $388. The total estimate for all hospices to comply with this requirement after the initial year would total $1,463,924 ($388 x 3,773 hospices). We estimate the total economic impact and cost estimates for all 3,773 hospices to comply with the requirements in this proposed rule for the initial year would be $11,908,072 ($1,463,924 impact cost + $10,444,148 ICR burden).

G. Emergency Preparedness for Psychiatric Residential Treatment Facilities (PRTFs)--Training and Testing (§ 441.184(d))

Proposed § 441.184(d)(2)(i) through (iii) would require PRTFs to participate in a community or facility-based mock disaster drill and a tabletop exercise annually. We propose that if a community drill is not available, the PRTF would be required to conduct a facility-based mock disaster drill. We estimate that the cost associated with this requirement is the time that it would take key personnel to participate in the mock drill and tabletop exercise. We further estimate that the drill and exercise would involve the administrator and registered nurse to spend about 4 hours each on an annual basis to participate (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 4 hours for the administrator and 4 hours for the registered nurse at a combined estimated cost of $360 per facility. The total annual cost for all 387 PRTFs would be $139,320. The total cost for the first year to comply with the requirement would be $1,071,990 ($139,320 impact cost + $932,670 ICR burden).

H. Emergency Preparedness for Program for the All-Inclusive Care for the Elderly (PACE) Organizations--Training and Testing (§ 460.84(d))

Proposed § 460.84(d)(2)(i) through (iii) would require PACE organizations to conduct a mock community or facility-wide drill and a paper-based, tabletop exercise annually. Since PACE organizations are currently required to conduct a facility-wide drill annually, we are only estimating economic impact for the annual tabletop drill. We expect that both the home-care coordinator and the quality-improvement nurse would each spend 1 hour to conduct the tabletop exercise. Thus, we estimate the economic impact hours to be 2 hours for each PACE organization (total impact hours=182) at an estimated cost of $90 for each organization. The

total annual cost for all PACE organizations is $8,190 ($90 x 91 providers). The total cost for all PACE organizations to comply with the requirements in the first year would be $342, 888 ($8,190 impact cost + $334,698 ICR burden).

I. Condition of Participation: Emergency Preparedness for Hospitals

1. Medical Supplies (§ 482.15(b)(1))

We propose that hospitals must maintain medical supplies. The American Hospital Association (AHA) recommends that individual hospitals have a 24-hour supply of pharmaceuticals and that they develop a list of required medical and surgical equipment and supplies. TJC standards require a hospital to have a 48 to 72 hour stockpile of medication and supplies.

The Department of Homeland Security (DHS) Act of 2002 established the Strategic National Stockpile (SNS) Program to work with governmental and non-governmental partners to upgrade the nation's public health capacity to respond to a national emergency. The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications and medical supplies.

The SNS, and other federal agencies, http://emergency.cdc.gov/stockpile/index.asp, have plans to address the medical needs of an affected population in the event of a disaster. The SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (for example, a terrorist attack, flu outbreak, or earthquake) severe enough to cause local supplies to run out. After federal and local authorities agree that the SNS is needed, medicines can be delivered to any state in the U.S. within 12 hours. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as

quickly as possible. States have the discretion to decide where to distribute the supplies in the event of multiple events.

However, prudent emergency planning requires that some supplies be maintained in-hospital for immediate needs. The Federal Metropolitan Medical Response System (MMRS) guidelines call for MMRS communities to be self-sufficient for 48 hours. We encourage hospitals to work with stakeholders (state boards of pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications they may need. Based on our experience with hospitals, we believe that they would have on hand a 2 to 3 day supply of medical supplies at the onset of a disaster. After such time, supplies could be replenished from the SNS and other federal agencies. Therefore, based on the previous information, we are not assessing additional burden for medical supplies.

2. Training Program (§ 482.15(d)(1))

Proposed § 482.15(d)(1) would require hospitals to develop and maintain an emergency preparedness training program and review and update it at least annually. Based on our experience with health care facilities, we expect that all health care facilities provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. Since such training is required for the TJC-accredited hospitals, the proposed requirements for developing an emergency preparedness-training program and the materials they plan to use in providing initial and on-going annual training would constitute a usual and customary business practice for TJC-accredited hospitals.

However, under this proposed rule, non TJC-accredited hospitals would need to review their existing training program and appropriately revise, update, or develop new sections and new material for their training program. The economic impact associated with this requirement

is the staff time required for non-TJC accredited hospitals to review, update or develop a training program. We discuss the economic impact for this requirement in the ICR section.

3. Testing (§ 482.15(d)(2)(i) through (iii))

Proposed § 482.15(d)(2)(i) through (iii) would require hospitals to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually.

State, tribal, territorial, and local public health and medical systems comprise a critical infrastructure that is integral in providing early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal government. There are currently four programs at HHS addressing education and training in the area of public health emergency preparedness and response. The programs are the Centers for Public Health Preparedness (CPHP), The Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN). As discussed earlier in this preamble, hospitals can use these and other resources, such as tools offered by the DHS, to assist them in complying with this proposed requirement. Thus, for non-TJC accredited hospitals, the costs associated with this requirement would be primarily due to the staff time needed to participate in the community-wide and facility-based disaster drills, and the tabletop exercises. We believe that appreciable staff time would be required of the risk management director, facilities director, safety director, and security manager. We expect that other staff members would be required to spend a minimal amount of time during these exercises, which would be considered a part of regular on-going training for hospital staff. We estimate that the risk management director, facilities director, safety director and security

manager would spend about 12 hours each (8 hours for a disaster drill and 4 hours for a tabletop exercise) on an annual basis to meet the proposed requirement.

Thus, we have estimated the economic impact for the 1,518 non-TJC accredited hospitals. We anticipate that complying with this requirement would require 48 hours for an estimate of $3,360 for each non TJC-accredited hospital. Therefore, for all non TJC-accredited hospitals to comply with this requirement would require 72,864 total economic impact hours (48 economic impact hours per non TJC-accredited hospital x 1,518 non TJC-accredited hospitals = 72,864 total economic impact hours) at an estimated total cost of $5,100,480 ($3,360 per non TJC-accredited hospital x 1,518 hospitals = $5,100,480).

Based on TJC's standards, the TJC-accredited hospitals are currently required to test their emergency operations plan twice a year. Therefore, for TJC-accredited hospitals to conduct disaster drills and tabletop exercises would constitute a usual and customary business practice and we will not include this activity in the economic impact analysis.

4. Generator Testing (§482.15(e))

Section § 482.15(e) would require hospitals to test each emergency generator and any associated essential electric systems for a minimum of 4 continuous hours at least once every 12 months under a full electrical load anticipated to be required during an emergency. The intent of this requirement is to provide an increased assurance that a generator and associated essential electrical systems will function during an emergency and are capable of running under a full electrical load required during an emergency for an extended period of time. AO's, including TJC, DNV, and HFAP; currently require accredited hospitals to test their generators/emergency power supply system once for 4 continuous hours every 36 months. Therefore, the cost of the existing testing requirement was deducted from the cost calculation for accredited hospitals.

However, under this proposed rule, non-accredited hospitals would be required to run their emergency generators an additional 4 hours, with an additional 1 hour for preparation, and an additional 1 hour for restoration.

For non-accredited hospitals, we estimate labor cost to be $132,696 (6 hours x $25.45/hr ($152.70) x 869 non-accredited hospitals). We estimate fuel cost to be $963,547 (72 gallon/hr x $3.85/gallon x 4 hours ($1,108.80) x 869 non-accredited hospitals) for non-accredited hospitals. Thus for non-accredited hospitals, we estimate the total cost to comply with this requirement to be $1,096,243.

For accredited hospitals, we estimate labor cost to be $413,206 (2 (6 hours x $25.45/hr)/3 ($101.80)) x 4,059 accredited hospitals). We estimate fuel cost to be $3,000,413 (2 (72 gallon/hr x $3.85/gallon x 4 hours) /3 ($739.2)) x 4,059 accredited hospitals) for accredited hospitals. Thus for accredited hospitals, we estimate the total cost to comply with this requirement to be $3,413,619.

Therefore, the total economic impact of this rule on hospitals would be $39,265,594 ($5,100,480 disaster drills impact cost + $4,509,862 generator impact cost + $29,655,252 ICR burden).

J. Condition of Participation: Emergency Preparedness for Transplant Centers

There is no additional economic impact to discuss in this section for transplant centers. All transplant centers are located within a hospital and, thus, would not have to stockpile supplies in an emergency or conduct a mock disaster drill or a tabletop exercise.

K. Emergency Preparedness Long Term Care (LTC) Facilities

1. Subsistence (§ 483.73(b)(1))

Section § 483.73(b)(1) would require LTC facilities to provide subsistence needs for staff and residents, whether they evacuate or shelter in place, including, but not limited to, food, water, and medical supplies alternate sources of energy for the provision of electrical power, and maintenance of temperatures for the safe and sanitary storage of such provisions.

As stated earlier in this section, each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. The federal responsibility ceases at the delivery of the push-packs to state-designated airports. It is then the responsibility of the state to break down and transport the components of the push-pack to the affected community. It is also at the state's discretion where to deliver push-pack material in the event of multiple events.

We expect that a 1- to 2-day supply would be sufficient because various national agencies with stockpiles of medicine, medical supplies, food and water can be mobilized within 12 hours and supplies can be replenished or provided within 48 hours. Thus, for the sake of this impact analysis, we assume that, at a minimum, a LTC facility would have a 2-day supply of food and potable water for the patients and staff at the onset of a disaster and will not assign a cost to this requirement.

We encourage LTC facilities to work with stakeholders (State Boards of Pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications that may be needed and plan to provide access to all healthcare partners during an event.

2. Training and Testing (§ 483.73(d))

Section § 483.73(d)(2)(i) through (iii) would require LTC facilities to participate in or conduct a mock disaster drill and a tabletop exercise at least annually. The current requirements for LTC facilities already mandate that these facilities periodically review their procedures with existing staff, and carry out unannounced staff drills (42 CFR 483.75(m)(2)). Thus, we expect that complying with the requirement for an annual community or facility-wide mock disaster drill and tabletop would constitute a minimal economic impact, if any, after the first year.

3. Generator Testing (§ 483.73(e))

Proposed § 483.73(e) would require LTC facilities to test each emergency generator for a minimum of 4 continuous hours at least once every 12 months. We estimate labor cost to be $2,314,474 (6 hours x $25.45/hr ($152.70) x 15,157 LTC facilities). We estimate fuel cost to be $16,806,082 (72 gallon/hr x $3.85/gallon x 4 hours ($1,108.80) x 15,157 facilities). Therefore, we anticipate that complying with this requirement would cost an estimated $19,120,556.

L. Condition of Participation: Emergency Preparedness for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)

1. Testing (§ 483.475(d)(2))

Proposed § 483.475(d)(2)(i) through (iii) would require ICFs/IID to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. The current ICF/IID CoPs require them to conduct evacuation drills at least quarterly for each shift and under varied conditions to evaluate the effectiveness of emergency and disaster plans and procedures" (42 CFR 483.470(i) and (i)(iii)). In addition, ICFs/IID must evacuate clients during at least one drill each year on each shift, file a report and evaluation on each evacuation drill and investigate all problems with evacuation drills, including accidents, and take corrective action

(42 CFR 483.470(i)(2)). Thus, all 6,450 ICFs/IID already conduct quarterly drills. We estimate that any additional economic impact for an ICF/IID to conduct both a drill and an exercise would be minimal, if any. Therefore, the cost of this proposed rule for all ICFs/IID would be limited to the ICR burden of $15,538,104 as discussed in the COI section.

M. §484.22 Condition of Participation: Emergency Preparedness for Home Health Agencies (HHAs)--Training and Testing (§ 484.22(d))

We discuss the majority of the economic impact for this requirement in the COI section which is estimated to be $48,725,629.

Proposed § 484.22(d)(2)(i) through (iii) would require HHAs to participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, we would require the HHA to conduct an individual, facility-based mock disaster drill at least annually and maintain documentation of all mock disaster drills. We would also require the HHA to maintain documentation of the exercises.

There are currently two programs at HHS addressing education and training in the area of public health emergency preparedness and response: the Centers for Public Health Preparedness (CPHP), and National Laboratory Training Network (NLTN).

As discussed earlier in this preamble, HHAs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this requirement. Thus, we believe that the cost associated with this requirement would be limited to the staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator and director of training. We believe that other staff members would be required to spend a minimal amount of time during these exercises and the training would be considered as part of regular on-

going training for HHA staff. We estimate that the administrator would spend about 1 hour on the community-wide disaster drill and 1 hour on the tabletop drill (a total of 2 hours to participate in drills). We also estimate that the director of training would spend a total of 3 hours on an annual basis to participate in the disaster drills (2 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill). All TJC accredited HHAs are required annually to test their emergency management program by conducting drills and documenting their results. Thus, we anticipate that only non-TJC accredited HHAs would need to comply with this requirement. We anticipate that it would require 5 hours for each of the 10,615 non-JC-accredited HHAs, with an estimated cost of $2,897,895. Therefore, the total economic impact of this rule on HHAs would be $51,623,524 ($2,897,895 impact cost + $48,725,629 ICR burden).

N. Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities (CORFs)--Testing (§ 485.68(d)(2)(i) through (iii))

Proposed § 485.68(d)(2)(i) through (iii) would require CORFs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually and document the drills and exercises. To comply with this requirement, a CORF would need to develop a specific scenario for each drill and exercise.

The current CoPs require CORFs to provide ongoing drills for all personnel associated with the facility in all aspects of disaster preparedness (42 CFR 485.64(b)(1)). Thus, for the purpose of this analysis, we believe that CORFs would incur minimal or no additional cost to comply with this requirement. Thus, we estimate the cost for all 272 CORFs to comply with this requirement would be limited to the ICR burden of $828,784 discussed in the COI section.

O. Condition of Participation: Emergency Preparedness for Critical Access Hospitals (CAHs)

1. Testing (§ 485.625(d)(2))

Proposed § 485.625(d)(2)(i) through (iii) would require CAHs to conduct annual community or facility-based drills and tabletop exercises. Accredited CAHs are currently required to conduct such drills and exercises. Although we believe that non-accredited CAHs are currently participating in such drills and exercises, we are not convinced that it is at the level that would be required under this proposed rule. Thus, we will analyze the economic impact for these requirements for the 920 non-accredited CAHs. As discussed earlier in this preamble, CAHs would have access to various training resources and emergency preparedness initiatives to use in complying with this requirement. Thus, we believe that the cost associated with this requirement would be limited to staff time to participate in the community-wide and facility-wide trainings, and tabletop exercises. We believe that appreciable staff time would be required of the administrator, facilities director, director of nursing and nursing education coordinator. We believe that other staff members would be required to spend a minimal amount of time during these exercises that would be considered as part of regular on-going training for hospital staff. We estimate that the administrator, facilities director, and the director of nursing would spend approximately a total of 20 hours on an annual basis to participate in the disaster drills. Thus, we anticipate that complying with this requirement would require 20 hours for an estimated cost of $1,132 for each of the 920 non-accredited CAHs. Therefore, for all non-accredited CAHs to comply with this requirement, it would require 18,400 total economic impact hours (20 economic impact hours per non-accredited CAH x 920 non-accredited CAH) at an estimated total cost of $1,041,440 ($1,132 x 920).

2. Generator Testing (§485.625(e))

Proposed §485.625(e) would require CAHs to test each emergency generator for a minimum of 4 continuous hours at least once every 12 months. AO's, including TJC, DNV, and HFAP; currently require accredited CAHs to test their generators/emergency power supply system once for 4 continuous hours every 36 months. Therefore, the cost of the existing testing requirement was deducted from the cost calculation for accredited CAHs. However, under this proposed rule, non-accredited CAHs would be required to run their emergency generators an additional 4 hours, with an additional 1 hour for preparation, and an additional 1 hour for restoration.

For non-accredited CAHs, we estimate labor cost to be $139,721 (6 hours x $25.45/hr ($152.70) x 915 non-accredited CAHs). We estimate fuel cost to be $1,014,552 (72 gallon/hr x $3.85/gallon x 4 hours ($1,108.80) x 915 non-accredited CAHs) for non-accredited CAHs. Thus for non-accredited CAHs, we estimate the total cost to comply with this requirement to be $1,154,273.

For accredited CAHs, we estimate labor cost to be $41,433 (2 (6 hours x $25.45/hr) / 3 ($101.80)) x 407 accredited CAHs). We estimate fuel cost to be $300,854 (2 (72 gallon/hr x $3.85/gallon x 4 hours) /3 ($739.2)) x 407 accredited CAHs) for accredited CAHs. Thus for accredited CAHs, we estimate the total cost to comply with this requirement to be $342,287.

Therefore, the total economic impact of this rule on CAHs would be $8,339,742 ($1,041,440 disaster drills impact cost +$1,496,560 generator impact cost + $5,801,742 ICR burden).

P. Condition of Participation: Emergency Preparedness for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology ("Organizations")--Testing (§ 485.727(d)(2)(i) through (iii))

Current CoPs require these organizations to ensure that employees are trained in all aspects of preparedness for any disaster. They are also required to have ongoing drills and exercises to test their disaster plan. Rehabilitation Agencies would need to review their current activities and make minor adjustment to ensure that they comply with the new requirement. Therefore, we expect that the economic impact to comply with this requirement would be minimal, if any. Therefore, the total economic impact of this rule on these organizations would be limited to the estimated ICR burden of $6,939,456.

Q. Condition of Participation: Emergency Preparedness for Community Mental Health Centers (CMHCs)--Training and Testing (§ 485.920(d))

Proposed § 485.920(d)(2) would require CMHCs to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. We estimate that to comply with the requirement to participate in a community mock disaster drill or to conduct an individual facility-based mock drill and a tabletop exercise annually would primarily require the involvement of the administrator and a registered nurse. We estimate that the administrator would spend approximately 4 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill. We also estimate that a nurse would spend about 3 hours on an annual basis to participate in the disaster drills (2 hours to participate in a community or facility-wide drill and 1 hour to participate in a tabletop drill). Thus, we anticipate that complying with this requirement would require 8 hours for each CMHC at an estimated cost of $415 for each facility. The economic impact for all 207 CMHCs would be 1656 (8 impact hours

x 207 CMHCs) total economic impact hours at a total estimated cost of $85,905 ($415 x 207 CMHCs). Therefore, the total economic impact of this rule on CMHCs would be $674,820 ($85,905 impact cost + $588,915 ICR burden).

R. Conditions of Participation: Emergency Preparedness for Organ Procurement Organizations (OPOs)--Training and Testing (§ 486.360(d)(2)(i) through (iii))

The OPO CfCs do not currently contain a requirement for OPOs to conduct mock disaster drills or paper-based, tabletop exercises. We estimate that these tasks would require the quality assessment and performance improvement (QAPI) director and the education coordinator to each spend 1 hour to participate in the tabletop exercise. Thus, the total annual economic impact hours for each OPO would be 2 hours. The total cost would be $107 for a (QAPI coordinator hourly salary and the Education Coordinator to participate in the tabletop exercise. The economic impact for all OPOs would be 116 (2 impact hours x 58 OPOs) total economic impact hours at an estimated cost of $6,206 ($107 x 58 OPOs). Therefore, the total economic impact of this rule on OPOs would be $613,176 ($6,206 impact cost + $606,970 ICR burden).

S. Emergency Preparedness: Conditions for Certification for Rural Health Clinics (RHCs) and Conditions for Coverage for Federally Qualified Health Clinics (FQHCs)

1. Training and Testing (§ 491.12 (d))

We expect RHCs and FQHCs to participate in their local and state emergency plans and training drills to identify local and regional disaster centers that could provide shelter during an emergency.

We propose that an RHC/FQHC must review and update its emergency preparedness policies and procedures at least annually. For purposes of determining the economic impact for this requirement, we expect that RHCs/FQHCs would review their emergency preparedness

policies and procedures annually. Based on our experience with Medicare providers and suppliers, health care facilities generally have a compliance officer or other staff member who reviews the facility's program periodically to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. We believe that complying with the requirement for an annual review of the emergency preparedness policies and procedures would constitute a minimal economic impact, if any.

2. Testing (§ 491.12(d)(2)(i) through (iii))

Proposed § 491.12(d)(2)(i) through (iii) would require RHCs/FQHCs to participate in a community or facility-wide mock disaster drill and a tabletop exercise at least annually. We have stated previously that FQHCs are currently required to conduct annual drills. We believe that for FQHCs to comply with these requirements would constitute a minimal economic impact, if any. Thus, we are estimating the economic impact for RHCs to comply with these requirements to conduct mock drills and tabletop exercises. We estimate that a RHCs administrator would spend 4 hours annually to participate in the disaster drills. Also, we estimate that a nurse coordinator (registered nurse) would each spend 4 hours on an annual basis to participate in the disaster drills (3 hours to participate in a community or facility-wide drill and 1 hour to participate in a table-top drill). Thus, we anticipate that complying with this requirement would require 8 hours for each RHC for an estimated cost of $452 per facility. The total annual cost for 4,013 RHCs would be $1,813,876. Therefore, the total economic impact of this rule on RHCs/FQHCs would be $33,762,675 ($1,813,876 impact cost + $31,948,799 ICR burden).

T. Condition of Participation: Emergency Preparedness for End-Stage Renal Disease Facilities (Dialysis Facilities)--Testing (§ 494.62(d)(2)(i) through (iv))

Proposed § 494.62(d)(2) would require dialysis facilities to participate in or conduct a mock disaster drill and a paper-based, tabletop exercise at least annually. The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (§ 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, we believe that dialysis facilities are currently participating in community or facility-wide drills. Therefore, for the purpose of this impact analysis, we estimate that dialysis facilities would need to add the tabletop exercise to their emergency preparedness activities. We estimate that it would require 1 hour each for the administrator (hourly wage of $74.00) and the nurse manager (hourly wage of $64.00) to conduct the annual tabletop exercise. Thus, for the 5,923 dialysis facilities to comply with the proposed requirements for conducting tabletop exercises, we estimate 11,846 economic impact hours. We estimate the total cost to be $138 for each facility, with a total economic impact of $817,374 ($138 x 5,923 facilities). Therefore, the total economic impact of this rule on ESRD facilities would be $20,398,812 ($817,374 impact cost + $19,581,438 ICR burden).

U. Summary of the Total Costs

The following is a summary of the total providers and the annual cost estimates for all providers to comply with the requirements in this rule.

TABLE 18--TOTAL ANNUAL COST TO PARTICIPATE IN DISASTER DRILLS AND TEST GENERATORS ACROSS THE PROVIDERS

Facility	Number of Participants	Total Cost (in $)
RNHCI	16	5,280
ASC	5,354	2,677,000
Hospices	3,773	1,463,924
PRTFs	387	139,320
PACE	91	8,190
Hospital	4,928	9,769,771
LTC	15,157	19,128,134
HHAs	12,349	2,897,895
CAHs	1,322	2,541,639
CMHCs	207	85,905
OPOs	58	6,206
RHCs & FQHCs	9,547	1,813,876
ESRD	5,923	817,374
Total	83,802	41,354,514

Based upon the ICR and RIA analyses, it would require all 83,802 providers and suppliers covered by this emergency preparedness proposed rule to comply with all of its requirements an estimated total first-year cost of $225,268,957.

TABLE 19--TOTAL ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS PROPOSED RULE

Facility	Number of Participants	Total Cost in Year 1 (in $)	Total Cost in Year 2 and thereafter (in $)
RNHCI	16	24,208	5,280
ASC	5,354	15,241,036	2,677,000
Hospices	3,773	10,076,910	1,463,924
PRTFs	387	1,071,990	139,320
PACE	91	342,888	8,190
Hospital	4,928	39,265,594	9,769,771
Transplant Center	770	1,399,104	0
LTC	15,157	19,128,134	19,128,134
ICF/IID	6,442	15,538,104	0
HHAs	12,349	51,623,524	2,897,895
CORFs	272	828,784	0
CAHs	1,322	8,339,742	2,541,639
Organizations	2,256	6,939,456	0
CMHCs	207	674,820	85,905

Facility	Number of Participants	Total Cost in Year 1 (in $)	Total Cost in Year 2 and thereafter (in $)
OPOs	58	613,176	6,206
RHCs & FQHCs	9,547	33,762,675	1,813,876
ESRD Facilities	5,923	20,398,812	817,374
Total	68,852	225,268,957	$41,354,514

The previous summaries include only the upfront and routine costs associated with emergency risk assessment, development and updating of policies and procedures, development and maintenance of communication plans, disaster training and testing, and generator testing (as specified). If these preparations are effective, they will lead to increased amounts of life-saving and morbidity-reducing activities during emergency events. These activities impose cost on society; for example, if complying with this proposed rule's requirements allows an ESRD facility to remain open during and immediately after a natural disaster, there would be associated increases in provision of dialysis services, thus entailing labor, material and other costs. As discussed in the next section ("Benefits of the Proposed Rule"), it is difficult to predict how disaster responses would be different in the presence of this proposed rule than in its absence, so we have been unable to quantify the portion of costs that will be incurred during emergencies. We request comments and data regarding this issue.

Moreover, we have not estimated any costs for generator backup, on the assumption that such backup is already required for virtually all inpatient and many outpatient facilities, either for TJC or other accreditation, or under state or local codes. We request information on this assumption and in particular on any situations or provider types for which this could turn out to be unnecessarily costly.

V. Benefits of the Proposed Rule

The U.S. Department of Health and Human Services, in its Program Guidance for emergency preparedness grants, stated, "as frontline entities in response to mass casualty incidents, hospitals and other healthcare providers such as health centers, rural hospitals and private physicians will be looked to for minimizing the loss of life and permanent disabilities.

Hospitals and other healthcare provider organizations must be able to work not only inside their own walls, but also as a team during an emergency to respond efficiently. Hospitals currently, either through experience or empirical evidence, gain knowledge that causes them to become very adept at flexing their systems to respond in an emergency. Because we live under the threat of mass casualties occurring at anytime and anywhere with consequences that may be different than the day-to-day occurrences, the healthcare system must be prepared to respond to these events by working as a team or community system."

This proposed rule is intended to help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters. The devastation of the Gulf Coast by Hurricane Katrina is one of the most horrific disasters in our nation's history. In those chaotic early days following the disaster in the greater New Orleans area, hundreds of thousands of people were adversely impacted, and health care services were not available for many who needed them. The recent disaster caused by hurricane Sandy has shown that additional safeguards should be in place to secure lifesaving equipment, such as generators. There is no reason to think that future disasters might not be as large or larger, as illustrated by the tsunami that hit Japan in 2011.

In the event of such disasters, vulnerable populations are at greatest risk for negative consequences from healthcare disruptions. According to one study, children and adolescents with chronic conditions are at increased risk of adverse outcomes following a natural disaster (Rath, Barbara, et. al. "Adverse Health Outcomes after Hurricane Katrina among Children and Adolescents with Chronic Conditions" Journal of Health Care for the Poor and Underserved 18:2, May 2007 pp. 405-417). Another study reports that more than 200,000 people with chronic medical conditions were displaced by Hurricane Katrina (Kopp, Jeffrey, et.al. "Kidney Patient

Care in Disasters: Lessons from the Hurricanes and Earthquake of 2005" Clin J Am Soc Nephrol 2:814-824, 2007.) Individuals requiring mental health treatments are another at-risk population that can be adversely impacted by health care disruptions following an emergency or disaster. A 2008 study concluded that many Hurricane Katrina survivors with mental disorders experienced unmet treatment needs, including frequent disruptions of existing care and widespread failure to initiate treatment for new-onset disorders (Wang, P.S., et.al. "Disruption of Existing Mental Health Treatments and Failure to Initiate New Treatment After Hurricane Katrina. American Journal of Psychiatry, 165(1), 34-41)" (2006).

Hospital closures during Sandy resulted in up to a 25 percent increase in emergency department visits at numerous centers in New York and a 70-percent increase in ambulance traffic. A proportion of this increase was due to populations being unable to receive routine care. Not only do vulnerable populations experience disruptions in care, they may also incur increased costs for care, especially when those who require ongoing medical treatment during disasters are required to visit emergency departments for treatment and/or hospitalization. Emergency department visits incur a copay for most beneficiaries. Similar costs are also incurred by patients for hospitalizations. The literature shows that natural catastrophes disproportionately affect ill and socioeconomically disadvantaged populations that are most at risk (Abdel-Kader K, Unrah ML. Disaster and end-stage renal disease: targeting vulnerable patients for improved outcomes. Kidney Int. 2009;75:1131-1133; Zoraster R, Vanholder R, Sever MS. Disaster management of chronic dialysis patients. Am J Disaster Med. 2007;2(2):96-106; and Redlener I, Reilly M. Lessons from Sandy—Preparing Health Systems for Future Disasters. N ENGL J MED. 367;24:2269-2271).

We know that advance planning improves disaster response. In 2007, Modern Healthcare reported on a healthcare system's response to encroaching wildfires in California. Staff from a San Diego hospital and adjacent nursing facility transported 202 patients and ensured all patients were out of harm's way. The facilities were ready because of protocols and evacuation drills instituted after a prior event that allowed them to be prepared (Vesely, R. (2007). Wildfires worry hospitals. Modern Healthcare, 37(43), 16).

Therefore, we believe that it is essential to require providers and suppliers to conduct a risk assessment, to develop an emergency preparedness plan based on the assessment, and to comply with the other requirements we propose to minimize the disruption of services for the community and ensure continuity of care in the event of a disaster. As noted previously, we have varied our requirements by provider type and understand that the degree of vulnerability of patients in a disaster will vary according to provider type. For example, patients with scheduled outpatient appointments such as someone coming in for speech therapy or routine clinic services is likely more self-reliant in a disaster than someone in a hospital ICU or someone who is homebound and receiving services from an HHA.

Overall, we believe that rule would reduce the risk of mortality and morbidity associated with disasters. We believe it very likely that some kind of disaster will occur in coming decades in which substantial numbers of lives will be saved by current emergency preparedness as supplemented by the additional measures we propose here. In New Orleans it seems very likely that dozens of lives could have been saved by competent emergency planning and execution. While New Orleans has a unique location below sea level, everywhere in the United States is vulnerable to weather emergencies and other potential natural or manmade disasters. We have not prepared an estimate in either quantitative or dollar terms of the potential life-saving benefits

of this proposed rule. There are several reasons for this, most notably the difficulty of estimating how many additional lives would be saved from emergency preparedness contingency planning and training. While we are unable to estimate the number of lives that could be saved by emergency planning and execution, Table 20 provides the number of Medicare FFS beneficiaries receiving services from some of the provider types affected by this proposed rule during the month of July 2013. We are unable to provide volume data for those patients in Medicare Advantage plans or the Medicaid population. However, one could assume the July 2013 summary is representative of an average month during the year. In the event of a disaster, the fee-for-service patients represented in Table 20 could be at risk and therefore, we could assume that they could benefit from the additional emergency preparedness measures proposed in this rule.

TABLE 20—NUMBER OF MEDICARE FFS PATIENTS WHO RECEIVED SERVICES IN JULY 2013

Provider Type	Number of FFS Patients
Hospitals	6,910,496
Community Mental Health Center	84,959
Comprehensive Outpatient Rehabilitation Facility	4,045
Critical Access Hospital	655,757
HHA	1,033,909
Hospice	312,799
Hospital based chronic renal disease facility	10,239
Non hospital renal disease treatment center	274,638
Religious Nonmedical Health Care Institution	44
Renal disease treatment center	8,261
Rural health clinic (free standing)	261,067
Rural health clinic (provider based)	291,180
Skilled Nursing Facility	538,189

Note: In July 2013 there were 8,949,161 distinct patients.

Benefits from effective disaster planning would not only accrue to individuals requiring health care services. Health care facilities themselves may benefit from improved ability to maintain or resume delivering services. After Hurricane Katrina, 94 dialysis facilities closed for

at least one week. Almost 2 years later, in June, 2007, 17 dialysis facilities remained closed (Kopp et al, 2007). Following hurricane Sandy, $180 million of the $810 million damages reported by the New York City Health and Hospitals Corporation was due to lost revenue. Lost revenue from Long Beach Medical Center hospital and nursing home was estimated at $1.85 million a week after closing due to damage from hurricane Sandy (http://www.modernhealthcare.com/article/20121208/MAGAZINE/312089991#ixzz2adUDjFIE?trk=tynt).

Finally, taxpayers and insurance companies may benefit from effective emergency preparedness. After Hurricane Ike, it was estimated that the cost to Medicare for ESRD patients presenting to the ED for dialysis instead of their usual facility was, on average, $6,997 per visit. Those ESRD patients who did not require dialysis were billed $482 on average (McGinley et al, 2012). The usual cost for these patients as reimbursed through Medicare is in the order of $250 to 300 per visit. Many of these costs or lost revenues may be mitigated by effective emergency preparedness planning. For a non-ESRD individual who cannot receive care from his or her office-based physician but must instead go to an emergency room, not only are the individual's costs increased, but reimbursement through Medicare, Medicaid or private insurance is also increased. AHRQ's Medical Expenditure Panel Survey from 2008 notes that the average expense for an office based visit was $199 versus $922 for an emergency room visit (Machlin, S., and Chowdhury, S. "Expenses and Characteristics of Physician Visits in Different Ambulatory Care Settings, 2008." Statistical Brief #318. March 2011. Agency for Healthcare Research and Quality, Rockville, MD. http://www.meps.ahrq.gov/mepsweb/data_files/publications/st318/stat318.pdf).

With the annualized costs of the rule's emergency preparedness requirements estimated to be approximately $80 million depending on the discount rate used (see the accounting statement table that follows) and the rule generating additional, unquantified costs associated with the life-saving activities that become implementable as a result of the preparedness requirements, this proposed rule would have to result in at least $80 million in average yearly benefits, principally derived from reductions in morbidity and mortality, for the benefits to equal or exceed costs. ASPR and CMS conducted an analysis of the impact of Superstorm Sandy on ESRD patients using Medicare claims. Preliminary results have identified increases in ESRD treatment disruptions, emergency department visits, hospitalizations, and 30-day mortality for ESRD patients living in the areas affected by the storm. This analysis supports other research and experience that clearly demonstrates a relationship between dialysis disruptions and higher rates of adverse events. Adoption of the requirements in this proposed rule would better enable individual facilities to: anticipate threats; rapidly activate plans, processes and protocols; quickly communicate with their patients, other facilities and state or local officials to ensure continuity of care for these life maintaining services; and reduce healthcare system stress by remaining open or re-opening quickly following closure. This would decrease the rate of interrupted dialysis, thereby reducing preventable ED visits, hospitalizations, and mortality during and following disasters. We welcome comments that may help us quantify potential morbidity reductions, lives saved, and other benefits of the proposed rule.

W. Alternatives Considered

1. No Regulatory Action

As previously discussed, the status quo is not a desirable alternative because the current regulatory requirements for Medicare and Medicaid providers and suppliers addressing

emergency and disaster preparedness are insufficient to protect beneficiaries and other patients during a disaster.

2. Defer to Federal, State, and Local Laws

Another alternative we considered would be to propose a regulation that would require Medicare providers and suppliers to comply with local, state and federal laws regarding emergency/disaster planning. Various federal, state and local entities (FEMA, the National Response Plan (NRP), CDC, the Assistant Secretary for Preparedness and Response (ASPR), et al) have disaster management plans that provide an integrated process that involves all local and regional emergency responders. We also considered allowing health care providers to voluntarily implement a comprehensive emergency preparedness program utilizing grant funding from the Office of the Assistant Secretary for Preparedness and Response, (ASPR). Based on a 2010 survey of the American College of Healthcare Executives (ACHE), less than 1 percent of hospital CEOs identified "disaster preparedness" as a top priority. Also, a 2012 survey of 1,202 community hospital CEOs (found at: http://www.ache.org/Pubs/Releases/2013/Top-Issues-Confronting-Hospitals-2012.cfm) of ASPR's Hospital Preparedness Program (HPP) showed that disaster preparedness was not identified as a top issue. We believe that absent conditions of participation/certification/coverage, providers and suppliers would not consistently adhere to the various local, state and federal emergency preparedness requirements. Moreover, many such instructions are unclear as to what is mandatory or only strongly recommended, and written in ways that leave compliance difficult or impossible to determine consistently across providers. Such inconsistent application of local, state, and federal requirements could compound the problems faced by governments, health care organizations, and citizens during a disaster. In

addition, CMS regulations would enable CMS to survey and enforce the emergency preparedness requirements using standard processes and criteria.

3. Back-up power for Outpatient Facilities

A potential regulatory alternative would involve requiring a power backup of some kind for outpatient facilities such as FQHCs and ESRD clinics. Some state codes, for example, require power backup, not generator backup, in such facilities. There are a number of ramifications of such options including, for example, preservation of refrigerated drugs and biologics, and the potential costs of replacing such items if power is not maintained for the duration of the emergency. For example, the current backup power would normally be expected to last for hours, not days.

4. Outpatient Tracking Systems

Under another regulatory alternative, we would require facilities to have systems in place to keep track of outpatients; the benefits of this alternative would depend on whether such systems would have any chance of success in any emergency that led to substantial numbers of refugees before, during, or after the event. As an illustrative example, most southern states have hurricane evacuation systems in place. It is not uncommon for a million people or more to evacuate before a major hurricane arrives. In this or other situations, would it even be possible, and if so using what methods, for a hospital outpatient facility, an ESRD clinic, a Community Mental Health Center, or an FQHC to attempt to track patients? We would appreciate comments that focus on both costs and benefits of such efforts.

5. Request for Comments on Alternative Approaches to Implementation

We request information and comments on the following issues:

- Targeted approaches to emergency preparedness—covering one or a subset of provider classes to learn from implementation prior to extending the rule to all groups.
- A phase in approach— implementing the requirements over a longer time horizon, or differential time horizons for the respective provider classes. We are proposing to implement all of the requirements 1 year after the final rule is published.
- Variations of the primary requirements—for example, we have proposed requiring two annual training exercises—it would be instructive to receive public feedback on whether both should be required annually, semiannually, or if training should be an annual or semiannual requirement.
- Integration with current requirements-- we are soliciting comment on how the proposed requirements will be integrated with/satisfied by existing policies and procedures which regulated entities may have already adopted.

6. Conclusion

We currently have regulations for Medicare and Medicaid providers and suppliers to protect the health and safety of Medicare beneficiaries and others. We revise these regulations on an as-needed basis to address changes in clinical practice, patient needs, and public health issues. The responses to the various past disasters demonstrated that our current regulations are in need of improvement in order to protect patients, residents, and clients during an emergency and that emergency preparedness for health care providers and suppliers is an urgent public health issue.

Therefore, we are promulgating emergency preparedness requirements that will be consistent and enforceable for all Medicare and Medicaid providers and suppliers. This proposed rule addresses the three key elements needed to ensure that health care is available during emergencies: safeguarding human resources, ensuring business continuity, and protecting

physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

X. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circular/a004/a-4.pdf), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on the number of lives affected or saved as a result of this regulation.

TABLE 21-- ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Benefits				
Qualitative	Help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters.			
Costs*				
Annualized Monetized ($million/year)	86	2013	7%	2014 - 2018
	83	2013	3%	2014 - 2018
Qualitative	Costs of performing life-saving and morbidity-reducing activities during emergency events.			

*The cost estimation is adjusted from 2011 to 2013 year dollars using the CPI-W published by Bureau of Labor Statistics in June 2013.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 403--SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for Part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.742 [Amended]

2. Amend §403.742 by:

A. Removing paragraphs (a)(1), (4), and (5).

B. Redesignating paragraphs (a)(2) and (3) as paragraphs (a)(1) and (2), respectively.

C. Redesignating paragraphs (a)(6) through (8) as paragraphs (a)(3) through (5), respectively.

3. Add § 403.748 to subpart G to read as follows:

§ 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal and State emergency preparedness requirements. The RNHCI must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk

assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the RNHCI has the ability to provide in an emergency; and, continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the RNHCI's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the RNHCI's care both during and after the emergency.

(3) Safe evacuation from the RNHCI, which includes the following

(i) Consideration of care needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Ensures records are secure and readily available.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) Communication plan. The RNHCI must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under agreement.

(iii) Next of kin, guardian or custodian.

(iv) Other RNHCIs.

(v) Volunteers.

(2) Contact information for the following

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RNHCI's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The RNHCI must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The RNHCI must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

PART 416--AMBULATORY SURGICAL SERVICES

4. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 416.41 [Amended]

5. Amend § 416.41 by removing paragraph (c).

6. Add § 416.54 to subpart C to read as follows:

§ 416.54 Condition for coverage: Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal and State emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the ASC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the ASC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of

this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the ASC's care both during and after the emergency.

(2) Safe evacuation from the ASC, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the ASC.

(4) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Ensures records are secure and readily available.

(5) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other ASCs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to ASC patients.

(7) The role of the ASC under a waiver declared by the Secretary, in accordance with

section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The ASC must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other ASCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) ASC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of

patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction the Incident Command Center, or designee.

(d) Training and testing. The ASC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The ASC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The ASC must conduct exercises to test the emergency plan. The ASC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge

an emergency plan.

(iv) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

PART 418-- HOSPICE CARE

7. The authority citation for Part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

§ 418.110 [Amended]

8. Amend § 418.110 by removing paragraph (c)(1)(ii) and by removing the paragraph designation (i) from paragraph (c)(1)(i).

9. Add § 418.113 to subpart D to read as follows:

§ 418.113 Condition of participation: Emergency preparedness.

The hospice must comply with all applicable Federal and State emergency preparedness requirements. The hospice must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other

emergencies that would affect the hospice's ability to provide care.

(3) Address patient population, including, but not limited to, the type of services the hospice has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospice's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of hospice employees and patients in the hospice's care both during and after the emergency.

(2) Procedures to inform State and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health

care professionals to address surge needs during an emergency.

(5) The development of arrangements with other hospices and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospice patients.

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s). and primary and alternate means of communication with external sources of assistance.

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(A) Food, water, and medical supplies.

(B) Alternate sources of energy to maintain the following:

(1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(2) Emergency lighting.

(3) Fire detection, extinguishing, and alarm systems.

(C) Sewage and waste disposal.

(iv) The role of the hospice under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The hospice must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Hospice employees.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospices.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospice's employees.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospice's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command

Center, or designee.

(d) Training and testing. The hospice must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The hospice must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.

(ii) Ensure that hospice employees can demonstrate knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least annually.

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(2) Testing. The hospice must conduct exercises to test the emergency plan. The hospice must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a

group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospice's emergency plan, as needed.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

10. The authority citation for Part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

11. Add § 441.184 to subpart D to read as follows:

§ 441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal and State emergency preparedness requirements. The PRTF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PRTF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the PRTF's care both during and after the emergency.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s);

and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The PRTF must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other PRTFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PRTF's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The PRTF must develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually.

(1) Training program. The PRTF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training at least annually.

(iii) Ensure that staff can demonstrate knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(2) Testing. The PRTF must conduct exercises to test the emergency plan. The PRTF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv)(A) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events.

(B) Revise the PRTF's emergency plan, as needed.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

12. The authority citation for part 460 continues to read as follows:

Authority: Secs: 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f)).

§ 460.72 [Amended]

13. Amend § 460.72 by removing paragraph (c).

14. Add § 460.84 to subpart E to read as follows:

§ 460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal and State emergency preparedness requirements. The PACE organization must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the PACE's efforts to contact such officials and, when applicable, of its participation in organization's collaborative and cooperative planning efforts.

(b) Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the

communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and participants under the PACE center(s) care both during and after the emergency.

(2) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric conditions and home environment.

(4) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves participant information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PACE organizations, PACE centers, or

other providers to receive participants in the event of limitations or cessation of operations to ensure the continuity of services to PACE participants.

(8) The role of the PACE organization under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(9)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) Communication plan. The PACE organization must 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 communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) PACE organization's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PACE organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The PACE organization must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The PACE organization must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Ensure that staff demonstrate a knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(2) Testing. The PACE organization must conduct exercises to test the emergency plan. The PACE organization must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the PACE organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE organization is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

15. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

16. Add § 482.15 to subpart B to read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

The hospital must comply with all applicable Federal and State emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the

following elements:

(a) Emergency plan. The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the hospital's care both during and after the emergency.

(3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients.

(8) The role of the hospital under a waiver declared by the Secretary , in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified

by emergency management officials.

(c) Communication plan. The hospital must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospitals

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospital's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The hospital must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The hospital must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The hospital must conduct drills and exercises to test the emergency plan. The hospital must do all of the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge

an emergency plan.

(iv) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

(e) Emergency and standby power systems. The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(2)(i) and (ii) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99, NFPA 101, and NFPA 110.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99 – Health Care Facilities and NFPA 110 – Standard for Emergency and Standby Power systems, as referenced by NFPA 101 – Life Safety Code (as required by 42 CFR 482.41(b)), the hospital must:

(i) At least once every 12 months, test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the hospital anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

17. Add § 482.78 to subpart E to read as follows:

§ 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must have policies and procedures that address emergency

preparedness.

(a) Standard: Agreement with at least one Medicare approved transplant center. A transplant center or the hospital in which it operates must have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. The agreement must address the following, at a minimum:

(1) Circumstances under which the agreement will be activated.

(2) Types of services that will be provided during an emergency.

(b) Standard: Agreement with the Organ Procurement Organization (OPO) designated by the Secretary. The transplant center must ensure that the written agreement required under § 482.100 addresses the duties and responsibilities of the hospital and the OPO during an emergency.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

18. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

19. Add § 483.73 to subpart B to read as follows:

§ 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal and State emergency preparedness requirements. The LTC facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk

assessment, utilizing an all-hazards approach, including missing residents;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems, and;

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the LTC facility's care both during and after the emergency.

(3) Safe evacuation from the LTC facility, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to ensure the continuity of services to LTC residents.

(8) The role of the LTC facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The LTC facility must 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 communication plan must include all of the

following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other LTC facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) LTC facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the LTC facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the LTC facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command

Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives.

(d) Training and testing. The LTC facility must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The LTC facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The LTC facility must conduct drills and exercises to test the emergency plan, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a

group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

(e) Emergency and standby power systems. The LTC facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99 – Health Care Facilities and NFPA 110 – Standard for Emergency and Standby Power Systems, as referenced by NFPA 101 – Life Safety Code as required under paragraph (a) of this section, the LTC facility must do the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the LTC facility anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.

(3) Emergency generator fuel. LTC facilities that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency

power for the duration of the emergency or until likely resupply.

§ 483.75 [Amended]

20. Amend § 483.75 by removing and reserving paragraph (m).

§ 483.470 [Amended]

21. Amend § 483.470 by--

A. Removing paragraph (h).

B. Redesignating paragraphs (i) through (l) as paragraphs (h) through (k), respectively.

C. Newly redesginated paragraph (h)(3) is amended by removing the reference "paragraphs (i)(1) and (2)" and adding in its place the reference "paragraphs (h)(1) and (2)".

22. Add § 483.475 to subpart I to read as follows:

§ 483.475 Condition of participation: Emergency preparedness.

The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal and State emergency preparedness requirements. The ICF/IID must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the ICF/IID efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of staff and residents in the ICF/IID's care both during and after the emergency.

(3) Safe evacuation from the ICF/IID, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The ICF/IID must 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 communication plan must include the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other ICF/IIDs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives.

(d) Training and testing. The ICF/IID must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(h).

(1) Training program. The ICF/IID must do all the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The ICF/IID must conduct exercises to test the emergency plan. The ICF/IID must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

PART 484--HOME HEALTH SERVICES

23. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

24. Add § 484.22 to subpart B to read as follows:

§ 484.22 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal and State emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts

to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at § 484.55.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system to track the location of staff and patients in the HHA's care both during and after the emergency.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other HHAs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to HHA patients.

(c) Communication plan. The HHA must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other HHAs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4)..

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) Training and testing. The HHA must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The HHA must conduct drills and exercises to test the emergency plan. The HHA must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

25. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.64 [Removed]

26. Remove § 485.64.

27. Add § 485.68 to subpart B to read as follows:

§ 485.68 Condition of participation: Emergency preparedness.

The Comprehensive Outpatient Rehabilitation Facility (CORF) must comply with all applicable Federal and State emergency preparedness requirements. The CORF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the CORF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CORF's

efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts;

(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) Policies and procedures. The CORF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the CORF, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) Communication plan. The CORF must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CORFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the CORF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CORF's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the CORF's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CORF must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The CORF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The CORF must ensure that staff can demonstrate knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and fire fighting equipment.

(2) Testing. The CORF must conduct drills and exercises to test the emergency plan. The CORF must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

§ 485.623 [Amended]

28. Amend § 485.623 by removing paragraph (c) and redesignating paragraph (d) as paragraph (c).

29. Add § 485.625 to subpart F to read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

The Critical Access Hospital (CAH) must comply with all applicable Federal and State emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CAH's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to:

(i) Food, water, and medical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of staff and patients in the CAH's care both during and after the emergency.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The CAH must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CAH must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with fire fighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The CAH must conduct exercises to test the emergency plan. The CAH must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99 and NFPA 100.

(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99 – Health Care Facilities and NFPA 110 – Standard for Emergency and Standby Power Systems, as referenced by NFPA 101 – Life Safety Code (as required by 42 CFR 485.623(d)), the CAH must do all of the following:

(i) At least once every 12 months test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the CAH anticipates it will require during an emergency.

(ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation, and repairs.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.

30. Revise § 485.727 to read as follows:

§ 485.727 Condition of participation: Emergency preparedness.

The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must comply with all applicable Federal and State emergency preparedness requirements. The Organizations must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the Organizations have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

(5) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation.

(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) Policies and procedures. The Organizations must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the Organizations, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) Communication plan. The Organizations must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other Organizations.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Organizations' staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the Organizations' care, as necessary, with other health care providers to ensure continuity of care.

(5) A means of providing information about the Organizations' needs, and their ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The Organizations must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The Organizations must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The Organizations must ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The Organizations must conduct drills and exercises to test the emergency plan. The Organizations must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, they are exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

31. Section 485.920 is added to Subpart J (as added on October 29, 2013, at 78 FR 64630 and effective on October 29, 2014) to read as follows::

§485.920 Condition of participation: Emergency preparedness.

The Community Mental Health Center (CMHC) must comply with all applicable federal and state emergency preparedness requirements. The CMHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address client population, including, but not limited to, the type of services the CMHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the CMHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The CMHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at

paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and clients in the CMHC's care both during and after the emergency.

(2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves client information, protects confidentiality of client information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other CMHCs or other providers to receive clients in the event of limitations or cessation of operations to ensure the continuity of services to CMHC clients.

(7) The role of the CMHC under a waiver declared by the Secretary of Health and Human Services, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The CMHC must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other CMHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CMHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the CMHC's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CMHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CMHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training. The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must ensure that staff can demonstrate knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.

(2) Testing. The CMHC must conduct drills and exercises to test the emergency plan. The CMHC must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

PART 486--CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

32. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

33. Add § 486.360 to subpart G to read as follows:

§ 486.360 Condition of participation: Emergency preparedness.

The Organ Procurement Organization (OPO) must comply with all applicable Federal and State emergency preparedness requirements. The OPO must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the OPO's efforts

to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The OPO must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff during and after an emergency.

(2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

(c) Communication plan. The OPO must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Volunteers.

(iv) Other OPOs.

(v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) OPO's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(d) Training and testing. The OPO must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training. The OPO must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) The OPO must ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

(e) Agreements with other OPOs and hospitals. Each OPO must have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's Donation Service Area in the event that the OPO cannot provide such services due to an emergency. Each OPO must include within the hospital agreements required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

PART 491--CERTIFICATION OF CERTAIN HEALTH FACILITIES

34. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 491.6 [Amended]

35. Amend § 491.6 by removing paragraph (c).

36. Add § 491.12 to read as follows:

§ 491.12 Condition of participation: Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal and State emergency preparedness requirements. The RHC/FQHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) Policies and procedures. The RHC/FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) Communication plan. The RHC/FQHC must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other RHCs/FQHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RHC/FQHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) Training program. The RHC/FQHC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) Testing. The RHC/FQHC must conduct exercises to test the emergency plan. The RHC/FQHC must do the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario,

and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

PART 494--CONDITIONS FOR COVERAGE FOR END–STAGE RENAL DISEASE FACILITIES

37. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

§ 494.60 [Amended]

38. Amend § 494.60 by--

A. Removing paragraph (d).

B. Redesignating paragraph (e) is as paragraph (d).

39. Add § 494.62 to subpart B to read as follows:

§ 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal and State emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least annually. The plan must:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach;

(2) Include strategies for addressing emergency events identified by the risk assessment;

(3) Address patient population, including, but not limited to, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the dialysis facility's care both during and after the emergency.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(8) A process to ensure that emergency medical system assistance can be obtained when needed.

(9) A process ensuring that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) Communication plan. The dialysis facility must 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 communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other dialysis facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Dialysis facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to ensure continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that must be evaluated and updated at least annually.

(1) Training program. The dialysis facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually. Staff training must:

(A) Ensure that staff can demonstrate knowledge of emergency procedures, including informing patients of--

(*1*) What to do;

(*2*) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(*3*) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(*4*) How to disconnect themselves from the dialysis machine if an emergency occurs.

(B) Ensure that, at a minimum, patient care staff maintain current CPR certification; and

(C) Ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(D) Maintain documentation of the training.

(2) Testing. The dialysis facility must conduct drills and exercises to test the emergency plan. The dialysis facility must:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the dialysis facility is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

(3) Patient orientation. Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

CMS-3178-P

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 28, 2013

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Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: December 12, 2013

_____

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

NOTE: The following appendix will not appear in the Code of Federal Regulations

APPENDIX--Emergency Preparedness Resource Documents and Sites

Presidential Directives:

- Homeland Security Presidential Directive (HSPD-5): "Management of Domestic Incidents" authorized the Department of Homeland Security to develop and administer the National Incident Management System (NIMS). NIMS consists of federal, state, local, tribal governments, private-sector and nongovernmental organizations to work together to prevent, respond to and recover from domestic incidents. The directive can be found at http://www.gpo.gov/fdsys/pkg/PPP-2003-book1/pdf/PPP-2003-book1-doc-pg229.pdf

- The elements of NIMS can be found at http://www.fema.gov/emergency/nims/index.shtm

- The National Response Framework (NRF) is a guide to how the nation should conduct all-hazards responses. Further information can be found at http://www.fema.gov/NRF

- The National Strategy for Pandemic Influenza and Implementation Plan is a comprehensive approach to addressing the threat of pandemic influenza and can be found at http://www.flu.gov/professional/federal/pandemic-influenza.pdf

- The World Health Organization (WHO) maintains a relatively up-to-date human case count of reported cases and death related to pandemic influenzas. The document can be found at http://www.who.int/csr/disease/avian_influenza/country/en/index.html

- The National Strategy for Pandemic Influenza Implementation Plan was established to ensure that the Federal government's efforts and resources would occur in a coordinated manner, the Federal government's response, international efforts, transportation and borders, protecting human and animal health, law enforcement, public safety, and security, protection of personnel

and insurance of continuity of operations. This document can be found at http://www.fao.org/docs/eims/upload/221561/national_plan_ai_usa_en.pdf

- Homeland Security Presidential Directive (HSPD-21) addresses public health and medical preparedness. It establishes a National Strategy for Public Health and Medical Preparedness. The key principles are: preparedness for all potential catastrophic health events, vertical and horizontal coordination across levels of government, regional approach to health preparedness, engagement of the private sector, academia and other non-governmental entities, and the roles of individual families and communities. It discusses integrated biosurveillance capability, countermeasure stockpiling and rapid distribution of medical countermeasures, mass casualty care in coordinating existing resources, and community resilience with oversight of this effort led by ASPR. The directive can be found at http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm

- "National Preparedness Guidelines" adopt an all-hazards and risk-based approach to preparedness. It provides a set of national planning scenarios that represent a range of threats that warrant national attention. For further information, this document can be found at http://www.dhs.gov/xlibrary/assets/National_Preparedness_Guidelines.pdf

- Presidential Directive (PPD-8): National Preparedness. It is aimed at facilitating an integrated, all-of-nation, flexible, capabilities-based approach to preparedness. It requires the development of a National Preparedness Goal, a national system description, a national planning system that features the 5 integrated national planning frameworks for prevention, protection, response, recovery and mitigation and federal interagency operational plans (FIOPS). This directive can be found at http://www.dhs.gov/presidential-policy-directive-8-national-preparedness and at http://www.phe.gov/Preparedness/legal/policies/Pages/ppd8.aspx

Office of Inspector General (OIG), Government Accountability Office (GAO) and additional reports and their recommendations:

- OIG study entitled, "Nursing Home Emergency Preparedness and Responses During Recent Hurricanes" (OEI-06-06-00020) conducted in response to a request from the U. S. Senate Special Committee on Aging asking for an examination of nursing home emergency preparedness. Based on the study, the OIG had two recommendations for CMS: (1) strengthen federal certification standards for nursing home emergency plans; and (2) encourage communication and collaboration between State and local emergency entities and nursing homes. As a result of the OIG's recommendations, the Secretary initiated an emergency preparedness improvement effort coordinated across all HHS agencies. This study can be found at http://oig.hhs.gov/oei/reports/oei-06-06-00020.pdf

- The National Hurricane Center report entitled, "Tropical Cyclone Report, Hurricane Katrina, 23-30 August 2005" provided data on the effect that the 2005 hurricanes had on the community. This report can be found at http://www.nhc.noaa.gov/pdf/TCR-AL122005_Katrina.pdf

- GAO report entitled, "Disaster Preparedness: Preliminary Observations on the Evacuation of Hospitals and Nursing Homes Due to Hurricanes" (GAO-06-443R) discusses the GAO's findings regarding (1) responsibility for the decision to evacuate hospitals and nursing homes; (2) issues administrators consider when deciding to evacuate hospitals and nursing homes; and (3) the federal response capabilities that support evacuation of hospitals and nursing homes. This can be found at http://www.gao.gov/new.items/d06443r.pdf

- GAO report entitled, "Disaster Preparedness: Limitations in Federal Evacuation Assistance for Health Facilities Should be Addressed" (GAO-06-826) supports the findings

noted in the first GAO report. In addition, the GAO noted that the evacuation issues that facilities faced during and after the hurricanes occurred due to their inability to secure transportation when needed. This report can be found at www.gao.gov/cgi-bin/getrpt?GAO-06-826.

- GAO report, an after-event analysis, entitled, "Hurricane Katrina: Status of Hospital Inpatient and Emergency Departments in the Greater New Orleans Area" (GAO-06-1003) revealed that: (1) emergency departments were experiencing overcrowding and (2) the number of staffed inpatient beds per 1,000 population was greater than that of the national average and expected to increase further and the number of staffed inpatient beds was not available in psychiatric care settings. While this study focused specifically on patient care issues in the New Orleans area, the same issues are common to hospitals in any major metropolitan area. This report can be found at http://www.gao.gov/docdblite/details.php?rptno=GAO-06-1003

- GAO report, an after-event analysis entitled, "Disaster Recovery: Past Experiences Offer Recovery Lessons for Hurricane Ike and Gustav and Future Disasters" (GAO-09-437T) concluded that recovery from major disasters involves the combined efforts of federal, state and local governments. This report can be found at http://www.gao.gov/products/GAO-09-437T

- OIG study entitled, "Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010, OEI-06-09-00270. The report noted 6 areas of concern that nursing homes did not include in their plans but could affect residents during an emergency which are: staffing, resident care, resident identification, information and tracking, sheltering in place, evacuation and communication and collaboration.

GAO Recommendations for Response to Influenza Pandemics:

- GAO report entitled, "Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to be Addressed" (GAO-09-909T July 29,2009 expressed concern that many gaps in pandemic planning and preparedness still existed in the presence of a potential pandemic influenza outbreak. This report can be located at http://www.gao.gov/new.items/d09909t.pdf

- GAO report entitled, "Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement" (GAO-10-73). The GAO assessed the progress of the responsible federal agencies in implementing the plans 342 action items set forth in the "National Strategy for Pandemic Influenza: Implementation Plan. These reports can be found at http://www.gao.gov/new.items/d1073.pdf and http://georgewbush-whitehouse.archives.gov/homeland/pandemic-influenza-implementation.htm.

Resources for Healthcare Providers and Suppliers for Responding to Pandemic Influenza:

- "One-step access to U. S. Government h1N1, Avian, and Pandemic Flu Information" website provides links to influenza guidance and information from federal agencies. This can be found at www.flu.gov More information can be found at http://www.flu.gov/professional/index.html that provides information for hospitals, long term care facilities, outpatient facilities, home health agencies, other health care providers and clinicians.

- "HHS Pandemic Influenza Plan Supplement 3: Healthcare Planning" provides planning guidance for the provision of care in hospitals. This can be located at http://www.hhs.gov/pandemicflu/plan/sup3.html

- "Best Practices in Preparing for Pandemic Influenza: A Primer for Governors and Senior State Officials (2006) written by the National Governors Association (NGA) provides

both current and historical perspective on potential disease outbreaks in communities. This report can be found at http://www.nga.org/Files/pdf/0607PANDEMICPRIMER.PDF

- The Public Readiness and Preparedness Act of 2005 establishes liability protections for program planners and qualified persons who prescribe, administer, or dispense covered counter measures in the event of a credible risk of a future public health emergency. Additional information can be found at: https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx

Public Health Emergency Preparedness:

- HRSA Policy Information notice entitled, "Health Center Emergency Management Program Expectations" (Document No. 2007-15 dated August 22, 2007, can be found at http://www.hsdl.org/?view&did=478559 describes the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of the Department of Health and Human Services or the President of the United States.
- CDC report describes natural disasters and man-made disasters. To access this list, go to http://emergency.cdc.gov/disasters/ under "emergency preparedness and response" and click on "specific hazards".
- RAND Corporation 2006 report stated that since 2001, the challenge has been the need to define public health emergency preparedness and the key elements that characterize a well-prepared community. This report can be found at http://www.rand.org/publications/randreview/issues/summer2006/pubhealth.html

The RAND Corporation convened a diverse panel of experts to propose a public health emergency preparedness definition. According to this expert panel, in an article by Nelson, Lurie, Wasserman and Zakowski, titled "Conceptualizing and Defining Public Health Emergency Preparedness", published in the American Journal of Public Health, Supplement 1,

2007, Volume 97, No S9-S11 defined public health emergency preparedness as the capability of the public health and health care systems, communities, and individuals to prevent, protect against, quickly respond to and recover from health emergencies. This report can be found at http://ajph.aphapublications.org/doi/full/10.

2105/AJPH.2007.114496

- Trust for America's Health (TFAH) report published in December 2012 entitled, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism". This report can be found at http://www.healthyamericans.org/report/101/.

- The HHS, 2011 Hospital Preparedness Program (HPP) report, entitled "From Hospitals to Healthcare Coalitions: Transforming Health Preparedness and Response in Our Communities", describes how the HPP has become a critical component of community resilience and enhancing the healthcare system's response capabilities, preparedness measures, and best practices across the country. The report can be found at: http://www.phe.gov/Preparedness/planning/hpp/Documents/hpp-healthcare-coalitions.pdf.

- A 2008 ASPR published document entitled, "Pandemic and All-Hazards Preparedness Act: Progress Report on the Implementation of Provisions Addressing At Risk Individuals," describes the activities undertaken since the passage of the PAPHA to address needs of at-risk populations and describes some of the activities planned to work toward preparedness for at-risk populations. The report can be found at: http://www.phe.gov/Preparedness/legal/pahpa/Documents/pahpa-at-risk-report0901.pdf.

- An August 30, 2005 article in the *Health Affairs* publication by Dausey, D., Lurie, N., and Diamond, A, entitled, "Public Health Response to Urgent Case Reports," evaluated the ability of local public health agencies (LPHAs) to adequately meet "a preparedness standard" set

by the CDC. The standard was for the LPHAs to receive and respond to urgent case reports of communicable diseases 24 hours a day, 7 days a week. The goal of the test was to contact an "action officer" (that is, physician, nurse, epidemiologist, bioterrorism coordinator, or infection control practitioner) responsible for responding to urgent case reports.

- A June 2004 article published by Lurie, N., Wasserman, J., Stoto, M., Myers, S., Namkung, P., Fielding, J., and Valdez, R. B., entitled, "Local Variations in Public Health Preparedness: Lessons from California", provides information on performance measures that were developed based on identified essential public health services. The article can be found at: http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.341/DC1.

Development of Plans and Responses:

- Distributed nationally in FY 2012, ASPR's publication (distributed nationally in FY 2012), "Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness", takes an innovative capability approach to assist state and territory grant awardee planning that focuses on a jurisdiction's capacity to take a course of action. Additional information can be found at:

http://www.phe.gov/preparedness/responders/ndms/Pages/default.aspx.

A different ASFR guidance provides information, guidance and resources to support planners in preparing for mass casualty incidents and medical surges. The document includes a total of (8) healthcare preparedness capabilities that are: (1) healthcare system preparedness (for example. information regarding healthcare coalitions); (2) healthcare system recovery; (3) emergency operations coordination, (4) fatality management; (5) information sharing; (6) medical surge; (7) responder safety and health; and (8) volunteer management. This information can be found at: http://www.phe.gov/Preparedness/planning/hpp/reports/Documents/capabilities.pdf.

- Center for Health Policy, Columbia University School of Nursing, policy paper, March 2008 entitled, "Adapting Standards of Care Under Extreme Conditions: Guidance for Professionals During Disasters, Pandemics, and Other Extreme Emergencies". This paper, aimed at the nursing population, discusses the challenges to meeting the usual standards of care during natural or man-made disasters and makes recommendations for effectively providing care during emergency events. The paper can be found at: http://www.nursingworld.org/MainMenuCategories/HealthcareandPolicyIssues/DPR/TheLawEthicsofDisasterResponse/AdaptingStandardsofCare.aspx.

- Institute of Medicine (IOM) September 2009 report to the HHS entitled, "Guidelines for Establishing Crisis Standards of Care for Use in Disaster Situations. The report provides guidance for State and local health agencies and health care facilities regarding the standards of care that should apply during disaster situations. This report covers guidance on conserving, substituting, adapting, and doing without resources. Further information on this report can be found at http://www.nap.edu/catalog.php?record_id=12749#.

- CMS published two guidance documents dated September 30, 2007 and October 24, 2007. The first document entitled, "Provider Survey and Certification Frequently Asked Questions: Declared Public Health Emergencies – All Hazards, Health Standards and Quality Issues", answers questions for all providers and suppliers regarding the lessons that were learned during and after the 2005 hurricanes and can be found at: http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf. The second document entitled, “Survey and Certification Emergency Preparedness Initiative: Provider Survey & Certification Declared Public Health Emergency FAQs – All Hazards," provides web address for emergency preparedness information. It provides links to various resources and to

other federal emergency preparedness websites and can be found at:

(http://www.nhha.org/WhatsNewFiles/S&C-08-01.01.AllHazardsFAQsmemo.pdf). In addition,

the website entitled, "Emergency Preparedness for Every Emergency," can be found at

http://www.cms.HHS.gov/SurveyCertEmergPrep/.

Emergency Preparedness Related to People with Disabilities

The National Council on Disability's website has a page entitled, "Emergency Management," that can be found at http://www.ncd.gov/policy/emergency_management. There are various reports/papers that contain specific information on emergency planning for people with disabilities and on how important it is to include people with disabilities in emergency planning, such as:

- Effective Emergency Management: Making Improvements for Communities and People with Disabilities (2009)
- The Impact of Hurricanes Katrina and Rita on People with Disabilities: A Look Back and Remaining Challenges (2006)
- Saving Lives: Including People with Disabilities in Emergency Planning (2005)

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