

**Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule
CMS-3178-P; RIN 0938-AO91**

Summary, January 8, 2013

On December 27, 2013, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 *FR* 79082; it can be downloaded at <http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30724.pdf>). The proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers. **Comments are due no later than February 25, 2014.**

The proposed rule would amend the appropriate regulatory Conditions of Participation (CoPs) for each category of provider or Conditions for Coverage (CfCs) for suppliers in Title 42 of the Code of Federal Regulations. CMS identifies 17 Medicaid and Medicare providers and suppliers for which it proposes regulatory changes to CoPs or CfCs. It notes that it considered proposing the changes for each provider and supplier individually, as it updates their rules over time, but believes instead that the most prudent course of action is to publish emergency preparedness requirements in a single proposed rule.

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I. Overview

CMS reviews the challenges arising from natural and man-made disasters since the terrorist attacks on September 11, 2001. For purposes of this proposed rule, CMS defines “emergency” or “disaster” 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.

CMS notes that it reviewed guidance prepared by the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) as well as a number of other sources. It includes in the Appendix to the proposed rule at 78 *FR* 79198 an overview of “Emergency Preparedness Resource Documents and Sites,” including links to each relevant website, and encourages providers and suppliers to use these resources.

CMS identifies three key essentials to ensure that health care is available during emergencies: safeguarding human resources, ensuring business continuity, and protecting physical resources. Based on its review, CMS concluded 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.”

CMS proposes four core elements that it defines as central to a comprehensive framework of emergency preparedness requirements:

- Risk assessment and planning, based on an “all hazards” approach (which is described below);
- Policies and procedures based on the risk assessment and planning;
- Communications plan; and
- Training and testing.

CMS seeks comments on when the proposed standards should be implemented.

CMS describes (at pages 79085-79090) the current state of emergency preparedness at the federal, state and local and hospital level, including:

- Relevant Presidential Directives. There are three relevant Presidential directives: Homeland Security Presidential Directive (HSPD-5); Presidential Policy Directive (PPD-8); and Homeland Security Presidential Directive/HSPD-21, which addresses public health and medical preparedness (http://www.dhs.gov/xabout/laws/gc_129263961449.shtm).
- Policies and programs of the Assistant Secretary for Preparedness and Response (ASPR), which has the delegated leadership role within the Department of Health and Human Services. ASPR operates the National Disaster Medical System (NDMS) (<http://www.phe.gov/preparedness/responders/ndms/Pages/default.aspx>), which augments state and local capabilities with a single, integrated national medical response capability.

ASPR also operates the Hospital Preparedness Program (HPP) which operates through agreements with states, territories and municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

- Centers for Disease Control and Prevention (CDC), Office of Public Health Preparedness and Response (OPHPR), which leads CDC efforts as well as supports and coordinates across local, state, tribal, national, territorial and public health partners. The Public Health Emergency Preparedness Cooperative Agreement is a source of funding for preparedness activities; the Strategic National Stockpile is a stockpile of pharmaceuticals and medical supplies; the Cities Readiness Initiative is a pilot program to help cities increase their capacities to deliver medicines and medical supplies within 48 hours of a public health emergency.
- Studies of state and local preparedness efforts, including a December, 2012 report by the Trust for America's Health, "Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism" (<http://www.healthyamericans.org/report/101/>), as well as selected research reports.
- Studies of hospital preparedness, which CMS describes as the focal points for health care in their respective communities. CMS "...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." CMS cites several reports related to hospital capacity: Center for Biosecurity of the University of Pittsburgh Medical Center, "Hospitals Rising to the Challenge: The First Five Years of the U.S. Hospital preparedness Program and Priorities Going Forward;" "ASPR Health Care Preparedness Capabilities: National Guidance for Healthcare System Preparedness (2012)"; "CDC Public Health Preparedness Capabilities: National Standards for State and Local Planning" (March 2011); and an Institute of Medicine report by its Forum on Medical and Public Health Preparedness for Catastrophic Events, "Medical Surge Capacity" (2010).
- Office of the Inspector General (OIG) and Government Accountability Office (GAO) reports on nursing home and hospital preparedness as well as responses to hurricanes Katrina, Ike and Gustav and to influenza pandemics.

II. Provisions of the Proposed Regulations

CMS describes its challenge as developing core regulatory components that can be used across provider and supplier types, while tailoring requirements for individual provider types to their specific needs and circumstances, as well as the needs and circumstances of their patients, residents, clients and participants (CMS uses the term "patients" to cover all of these descriptors). It notes that its requirements ensure continued provision of necessary care or, if needed, the evacuation and transfer of patients to a locale that can supply necessary care.

As noted above, there are four core elements of the regulatory proposal:

- Emergency planning based on risk assessment;
- Policies and procedures based on the risk assessment and planning;
- Communications plan; and
- Training and testing.

CMS proposes a set of regulatory requirements for hospitals, and uses those requirements as a “template” for other providers and suppliers, but with specific requirements modified and tailored to each providers’ and suppliers’ unique needs. In general, CMS notes that other inpatient facilities have standards similar to those for hospitals because they have greater responsibility than outpatient facilities during an emergency for ensuring the health and safety of patients, employees and volunteers.

In contrast, in the event of a disaster, providers and suppliers of outpatient services may not open their facilities, or may close them, sending patients and staff home or to a place where they may shelter in place. Such facilities may find it necessary to shelter patients until they can be evacuated, or may be called on to provide some level of care for community residents in the event of an emergency. Finally, CMS notes that hospice facilities may provide inpatient and outpatient services, and transplant centers and organ procurement organizations (OPOs) are unique as well, so the proposed rule is more tailored to specifically address their circumstances.

CMS notes that it expects implementation of certain proposed requirements would be different based on the category of provider or supplier. For example, a small rural hospital’s implementation of the requirement to have policies and procedures in place to provide subsistence needs for patients and staff during an emergency would be different than that of a large hospital’s implementation. CMS specifically requests comment on the proposed requirement that all of the inpatient facilities meet various subsistence needs: should this be a requirement, and in what quantities and for what time period? CMS expects each facility would determine how to implement such a requirement based on a number of variables.

CMS believes it important 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 an emergency event.

CMS first reviews the hospital requirements in detail, and then presents each of the other provider and supplier groups in comparison with the hospital requirements. For each provider and supplier, CMS reviews briefly any existing regulatory requirements related to emergency preparedness (it generally incorporates or replaces such requirements with the requirements in the new proposed rules), presents the proposed rule and identifies resources available to providers.

A. Emergency Preparedness Regulations for Hospitals (§482.15)

Current hospital CoPs are at 42 CFR 482.1 – 482.66. CMS proposes in a new §482.15 that a hospital must comply with all applicable Federal and State requirements. Its emergency preparedness program must include the following elements.

a. Emergency Plan (§482.15(a)) (pages 79092-79095)

CMS identifies fifteen all-hazards “National Planning Scenarios”: 1) nuclear detonation-improvised nuclear device; 2) biological attack-aerosol anthrax; 3) biological disease outbreak-pandemic influenza; 4) biological attack – plague; 5) chemical attack- blister agent; 6) chemical

attack – toxic industrial chemicals; 7) chemical attack – nerve agent; 8) chemical attack-chlorine tank explosion; 9) natural disaster-major earthquake; 10) natural disaster - major hurricane; 11) radiological attack-radiological dispersal devices; 12) explosive attack-bombing using improvised explosive device; 13) biological attack – food contamination; 14) biological attack – foreign animal disease (foot and mouth disease) and 15) cyber-attack.

CMS reviews at pages 79092 and 79093 a number of resources available to providers in developing their plans.

CMS proposes at §482.15(a) that a hospital must develop and maintain an emergency preparedness plan that must be reviewed and updated annually. The plan must:

- (1) Be based on a facility-based and community-based risk assessment, using an all-hazards approach.

CMS describes an all-hazards approach as an integrated approach to emergency preparedness planning. “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.” CMS reviews a set of guides available to hospitals.

CMS expects hospitals to consider, among other things:

- Identification of essential business functions that should be continued in an emergency;
- Identification of all risks or emergencies that the hospital may reasonably expect to confront;
- Identification of all contingencies for which the hospital should plan;
- Consideration of the hospital’s location, including patient services and business operations;
- Assessment of the extent to which emergencies may cause the hospital to cease or limit operations; and
- Determination of whether arrangements with other hospitals or entities might be needed to ensure the provision of essential services

- (2) Include strategies for addressing events identified by the risk assessment.

CMS provides examples and notes that it expects strategies to include consideration of collaboration with hospitals and suppliers across state lines, if applicable.

- (3) Address the patient population, including 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 planning.

CMS notes that, in addition to individuals specifically identified as at risk in statute (children, senior citizens, and pregnant women), it proposes 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, and goes on to note the definition includes the elderly, persons in hospitals or nursing homes, people with physical and mental disabilities, infants and children.

(4) Include a process for ensuring cooperation and collaboration

CMS proposes that the emergency plan include a process for ensuring cooperation and collaboration with local, tribal, regional, state, or federal emergency preparedness officials, in order to ensure an integrated response. CMS notes that planning with officials in advance of an emergency will foster a smoother, more effective and more efficient response during a disaster. While responsibility for ensuring a coordinated response lies with state and local authorities, the hospital would need to document its efforts to contact these officials. CMS recognizes that officials may opt not to collaborate with some providers or suppliers due to their limited size and role (such as an RNHCI), and such providers need only document their efforts.

CMS notes and discusses the role of ASPR's Hospital Preparedness Program (HPP) and community Health Care Coalitions (HCCs). While CMS is not requiring that providers participate in HCCs, it recognizes and supports their value.

b. Policies and Procedures (§482.15(b)) (pages 79095-79099)

CMS proposes that the hospital develop and implement policies and procedures, based on the emergency plan and risk assessment and the communications plan under (c) (below), that are reviewed and updated at least annually. CMS solicits comments on the timing of the updates. The policies and procedures would have to address the following:

(1) Subsistence needs for staff and patients

CMS proposes that the policies and procedures address subsistence needs for staff and patients, whether evacuated or sheltered in place, including food, water, and medical supplies. CMS notes that hospitals should keep in mind that volunteers, visitors and individuals from the community may also arrive to provide assistance or seek shelter. CMS also proposes that the policies and procedures address alternative sources of energy that address temperature level, emergency lighting, and fire detection, extinguishing and alarm systems, as well as sewage and waste disposal.

(2) Tracking the location of staff and patients

CMS proposes that the policies and procedures address the need to track the location of staff and patients during and after an emergency, including evacuees. CMS notes that this requirement is proposed for providers and suppliers who provide ongoing care for inpatients or outpatients, including RNHCIs, hospices, PRTFs, PACE organizations, LTC facilities, ICFs/IID, HHAs, CAHs and ESRD facilities. ASCs would be required to maintain responsibility for staff and patients if patients were in the facility.

Other outpatient providers, such as CORFs, FQHCs and clinics have the flexibility to cancel appointments during an emergency, and CMS notes that they do not need to assume responsibility for patients. It is also not being proposed for organizations that are providers of physical therapy and speech-language pathology services, transplant centers or organ procurement organizations (OPOs), whose potential donors would be in hospitals. CMS solicits comments on the feasibility of this requirement for any outpatient facilities.

(3) Safe evacuation from the hospital

CMS proposes that the policies and procedures address a means to ensure safe evacuation, including consideration of care and treatment needs, staff responsibilities, transportation, evacuation locations, and primary and alternative means of communication.

(4) Means to shelter in place

CMS proposes that the policies and procedures address a means to shelter in place for patients, staff and volunteers, and CMS expects that would include criteria for selecting patients and staff that would shelter in place and the means to ensure their safety.

(5) System of medical documentation

CMS proposes that the policies and procedures would require a system of medical documentation that would preserve patient information, protect its confidentiality, and ensure that patient records are secure and readily available in an emergency. Such policies would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) requirements.

(6) Use of volunteers and other emergency staffing

CMS proposes that the policies and procedures address the use of volunteers and other emergency staffing strategies, including integration of state or federally designated health care professionals to address surge needs.

(7) Arrangements with other hospitals and providers

CMS proposes that the policies and procedures address arrangements with other hospitals and providers to receive patients in the event of limitations or cessations of operations.

(8) Role under a section 1135 emergency waiver

CMS proposes that the policies and procedures address the role of the hospital under a waiver declared by the Secretary under section 1135 of the Social Security Act (SSA) in the provision of care and treatment at an alternate care site (ACS) designated by emergency management officials. CMS notes that this requirement is intended to encourage providers to collaborate with emergency officials in proactive planning in the event that services are severely disrupted. CMS provides background on the section 1135 waiver authority. The Secretary is authorized to temporarily waive or modify certain Medicare, Medicaid and Children's Health Insurance

Program requirements for providers in an emergency area. That can include waiver of conditions of participation, and Emergency Medical Treatment and Labor Act (EMTALA) requirements. CMS reviews the section 1135 process and resources available, and notes ASPR's recommendation that existing buildings and infrastructure could serve as ASCs as the most practical solution if a surge medical care facility is needed. CMS notes that providers must resume compliance with normal rules and regulations as soon as they are able, and that the section 1135 waivers and modifications are no longer available after termination of the emergency period.

c. Communications Plan (§482.15(c)) (pages 79099-79100)

CMS proposes that hospitals be required develop and maintain an emergency preparedness communication plan, and that it be reviewed and updated annually. The plan would include:

(1) Name and contact information

The communications plan would have to include name and contact information for staff, entities providing services under arrangements, patient's physicians, other hospitals and volunteers.

(2) Contact information

The communications plan would also have to have contact information for federal, state, tribal, regional or local emergency preparedness staff and other sources of assistance. CMS notes that it supports hospitals engaging in coalitions in their area in effectively meeting this requirement.

(3) Primary and alternative means of communication

CMS proposes that hospitals have primary and alternative means of communications with the above, because in an emergency landline telephone systems may not operate, and notes a range of options. CMS recognizes that some hospitals, especially in remote areas, have difficulty using some current communications systems, and expects such hospitals to address these challenges in their emergency communications system. CMS reviews options and resources available to hospitals, such as the National Communication System.

(4) Method for sharing information and medical documentation with other providers

CMS proposes that hospitals have a method of sharing information and medical documentation with other health care providers to ensure continuity of care, and notes that it expects that the information would be disseminated across providers and suppliers in a timely manner.

(5) Means to release patient information in the event of an evacuation

CMS proposes that hospitals have a means to release patient information, as permitted under HIPAA, in the event of an evacuation. This proposed requirement would not apply to transplant centers, CORFs, OPOs, clinics, rehabilitation agencies and public health agencies as providers of outpatient physical therapy and speech-language pathology services, or to FQHCs/RHCs.

- (6) Means of providing information about the general condition and location of patients under the facility's care

CMS proposes that hospitals have a means of providing information about the general condition and location of patients under the facility's care, as permitted under HIPAA.

- (7) Means of providing information about the hospital's occupancy needs and its ability to provide assistance

CMS proposes that a hospital have a means of providing information about its occupancy, needs, and ability to provide assistance to the authority having jurisdiction or to the incident command center, and notes again that hospitals and other providers engaging in coalitions in their area can effectively meet this requirement.

d. Training and Testing (§482.15(d)) (pages 79100-79101)

CMS proposes that hospitals develop and maintain an emergency preparedness training and testing program that is reviewed and updated at least annually.

(1) Training

The training program would be provided to all new and existing staff, including individuals providing services under arrangement, and volunteers, and document such training. The hospital would ensure that staff can demonstrate knowledge of emergency procedures. The hospital would have to provide this training at least annually. CMS notes that small and rural hospitals may find it helpful to use the resources of their state and local governments in meeting this requirement, and again notes the value of participation in coalitions in the area in planning and conducting exercises.

(2) Testing

Hospitals would be required to conduct drills and exercises to test the emergency plan. Hospitals would have to participate in a community mock disaster drill at least annually, and if a community drill is not available, conduct an individual, facility-based drill. If a hospital experienced an actual emergency that required activation of its emergency plan, the hospital would be exempt from the requirement to conduct a drill for one year.

Hospitals would be required to conduct paper-based, table top exercise at least annually, which would be defined 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. Finally, hospitals would be required to analyze the response to the drills, exercises and actual emergency events and revise the emergency plan, as needed.

CMS expects that hospitals would conduct mock disaster drills and tabletop exercises using various emergency scenarios, based on their risk analyses, and reviews approaches and an extensive set of resources available.

e. Emergency and standby power systems (§482.15(e)) (page 79101)

CMS proposes that hospitals must implement emergency and standby power systems based on the plan and policies and procedures set out.

(1) Emergency generator location

The emergency generator would have to be located as required by the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). CMS notes that it intends to require compliance with future updates as may be adopted by the agency.

(2) Inspection and testing

At least once every 12 months, hospitals would have to test each emergency generator for a minimum of 4 continuous hours at a test load that is 100 percent of the load anticipated during an emergency. Hospitals would have to maintain written records of generator inspections, testing, operations and repairs, which would be available upon request.

CMS notes that it is proposing the same requirements for CAHs and LTC facilities and requests information on how it might better estimate costs in light of existing Life Safety Code and other state and federal requirements.

Additional providers and suppliers

As noted above, CMS reviews each additional provider and supplier requirement by noting the differences from the hospital requirements.

In general, if a proposed hospital requirement is NOT mentioned in this summary, it means that the hospital requirement is proposed for adoption for that provider or supplier. There is one exception: the proposed hospital standards for emergency and standby power systems apply only to hospitals, LTC facilities and CAHs and the summaries for the other providers and suppliers do not note that they are not included.

This summary notes policy in four proposed regulatory areas identified for hospitals:

- *Emergency plan;*
- *Policies and procedures;*
- *Communications plan; and*
- *Training and testing.*

B. Religious Nonmedical Health Care Institutions (RHNHCIs) (§403.748) (pages 79104-79105)

CMS notes that RHNHCIs are facilities that furnish only non-medical items and services on a 24 hour basis to beneficiaries who choose to rely solely upon a religious method of healing. There are 16 such institutions. CMS proposes replacing existing requirements at §403.742(a)(1), (4), and (5) and proposes new §403.748 generally requiring RHNHCIs to meet the proposed hospital requirements with several exceptions.

- In general, there are changes from the proposed hospital requirements relating to the type of services, changing terms such as “medical” and “non-medical” as well as “health” and “physician” to the appropriate terminology for the unique services provided by RHNHCIs.
- Communications plan: CMS proposes that the election form made by beneficiaries about their opposition to non-excepted medical treatment be shared with other care providers to preserve continuity of care.
- Training and testing: CMS proposes to modify the testing requirement to require only a tabletop exercise annually.

C. Ambulatory Surgical Centers (ASCs) (§416.54) (pages 79105-79106)

CMS proposes replacing existing requirements at §416.41(c) and proposes new §416.54 requiring ASCs to meet the requirements proposed for hospitals, with two exceptions.

- Policies and procedures: CMS is not proposing that ASCs provide for subsistence needs for their patients and staff.
- Communications plan: CMS is not proposing that ASCs communicate occupancy information, as that usually refers to bed occupancy.

CMS notes that small or rural ASCs may find it more challenging to meet the proposed requirements, but believes the requirements are important and that such ASCs would be able to develop the appropriate plan and meet the requirements with the assistance of resources in their state and local community guidance.

D. Hospices (§418.113) (pages 79106-79107)

CMS notes that some hospices have inpatient facilities and others do not, so it reorganizes the proposed requirements somewhat to accommodate that difference. CMS proposes replacing existing requirements at §418.110(c)(1)(ii) and proposes new §418.113 adopting the proposed hospital requirements for hospices, with several exceptions, especially in the case of those without inpatient capacities.

- Emergency plan, for all hospices: in developing strategies for addressing events identified by the risk assessment, CMS proposes to specifically identify management of the consequences of power failures, natural disasters, and other emergencies.
- Policies and procedures: CMS proposes policies and procedures for all hospices, and then additional policies and procedures applicable to those with inpatient facilities:

- For all hospices, including those without inpatient facilities, CMS proposes policies and procedures that adopt several of the proposed hospital requirements: a system to track the location of staff and patients, a system of medical documentation, and the development of arrangements with other providers. CMS proposes a modification in one hospital requirement by specifying the need for policies and procedures regarding the use of hospice employees (rather than volunteers) and other emergency staffing. Finally, CMS proposes that hospices have policies and 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 (CMS also proposes this for HHA and PACE patients).
- For hospices with inpatient facilities, CMS proposes policies and procedures for the remaining items included in the hospital requirements: policies and procedures related to meeting subsistence needs, safe evacuation, a means to shelter in place, and the role of a hospice in the event of a section 1135 waiver.
- Communications plan: CMS proposes to limit to inpatient facilities the requirement to provide information about the hospice's occupancy, needs and its ability to provide assistance.

E. Inpatient Psychiatric Residential Treatment Facilities (PRTFs) (§441.184) (page 79107)

CMS proposes that PRTFs meet the same requirements proposed for hospitals.

F. Programs for All-Inclusive Care for the Elderly (PACE) (§460.84) (pages 79107-79108)

CMS proposes replacing existing requirements at §460.72 (1) – (5) and proposes new §460.84 requiring that PACE organizations meet the same requirements proposed for hospitals, with several exceptions:

- Policies and procedures: CMS is not proposing that PACE organizations provide for subsistence needs for their patients and staff. CMS proposes two additional requirements for PACE organizations. First, they have 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 HIPAA. CMS notes that this requirement recognizes that many of the frail PACE patients may be unable to evacuate from their homes without assistance during an emergency. Second, CMS proposes that the policies and procedures address emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs; staff who know how to use the equipment must be on the premises at all times and be immediately available; and a documented plan to obtain emergency medical assistance from outside sources when needed.
- Communications: CMS is not proposing that PACE organizations communicate occupancy information.

G. Transplant Centers (§482.78) (pages 79108-79109)

CMS notes that the proposed requirements for hospitals would apply to transplant centers since they are located within hospitals, and proposes two additional emergency prepared requirements for transplant centers:

- CMS proposes an additional requirement 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 in an emergency. CMS notes that, ideally, this would be a center that performs the same type of organ transplant, but recognizes that this may not always be feasible. The agreement would have to address (1) the circumstances under which the agreement would be activated, and (2) the types of services that would be provided during an emergency.
- CMS proposes an additional requirement related to the existing required written agreement between the hospital in which the transplant center operates and the designated OPO. CMS proposes that transplant centers ensure that the written agreement also addresses the duties and responsibilities of the hospital and the OPO in an emergency.

H. Long-Term Care (LTC) Facilities (§483.73) (pages 70109-79110)

CMS proposes replacing existing requirements at §483.75(m)(1) and (2) and proposes new §483.73 requiring that LTC facilities meet the same requirements proposed for hospitals, with two exceptions:

- Emergency plan: CMS proposes that the all-hazards risk assessment include a directive to account for missing residents.
- Communications plan: CMS proposes that LTC facilities have a method, determined appropriate by the facility, for sharing information from the emergency plan with residents and their families or representatives.

CMS believes that the proposed requirement for a risk assessment, and the proposed requirement that the LTC facility address its patient population and continuity of operations, encompasses consideration of individual resident's power needs, such as for a motorized wheelchair or other supportive technology. However, CMS solicits comments on whether there should be a specific regulatory requirement for consideration of residents' power needs.

The proposed requirements for emergency and standby power systems would apply to LTC facilities.

I. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) (§483.475) (pages 79110-79111)

CMS proposes to replace existing requirements at §483.470(h)(1) and (2) and proposes new §483.475 requiring that ICFs/IID meet the same requirements proposed for hospitals, with several exceptions.

- Emergency plan: CMS proposes that the all-hazards risk assessment include a directive to account for missing residents (as it does for LTC facilities). CMS proposes that the provision for addressing the patient population would require that ICFs/IID "...address the special needs of its client population..." CMS notes that this revision is made because all patients in ICFs/IID have special needs. As with LTC facilities, CMS believes that as part of the consideration for addressing special needs that the facility would need to consider individual residents' power needs, but solicits comments on whether there should be a specific regulatory requirement for consideration of residents' power needs.
- Communications plan: CMS proposes that ICFs/IID have a method, determined appropriate by the facility, for sharing information from the emergency plan with clients and their families or representatives (as it does for LTC facilities).

CMS also cross-references in the training and testing section existing regulatory requirements for disaster drills (current §483.470(i)(1) and (2), which is designated as §483.470(h)(1) and (2)).

J. Home Health Agencies (HHAs) (§484.22) (pages 79111-79112)

CMS proposes that HHAs meet the requirements for hospitals with several exceptions, including additional requirements that would apply to HHAs.

- Policies and procedures: CMS proposes that HHAs have an individual emergency preparedness plan for each patient as part of the comprehensive patient assessment currently required at §484.55, and that HHAs have policies and procedures to inform state and local 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 conditions and home environment (as it proposes for PACE patients). CMS is not proposing that HHAs have provisions to meet the subsistence needs of patients and staff, safe evacuation plans, plans for sheltering patients or staff, or plans for an alternate care site in the case of a declared section 1135 emergency.
- Communications plan: CMS is not proposing that HHAs have a means to release patient information in the case of an evacuation, and would delete the reference to providing information about occupancy.

CMS notes that it expects an HHA to consider whether it would accept new referrals during an emergency, and would urge HHAs to include a method for providing information to all new patients and their families about the role the HHA would plan in an emergency.

K. Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§485.68) (pages 79112-79113)

CMS proposes to replace existing regulatory requirements at §485.64 for CORFs and proposes new §485.68 requiring CORFs to meet the proposed hospital requirements with several exceptions and additions.

- Emergency plan: CMS proposes to require that CORFs develop and maintain the plan with assistance from fire, safety and other appropriate experts (a current requirement under §485.64).
- Policies and procedures: CMS is not proposing that that CORF policies and procedures address basic subsistence needs for staff and patients; a system for tracking of staff and patients, arrangements with other providers, or plans for an alternate care site in the event of a section 1135 emergency. CMS proposes a more limited evacuation requirement, requiring that CORFs have policies and procedures for evacuation, including staff responsibilities and the needs of patients.
- Communications plan: CMS is not proposing to require a means to release patient information in the event of an evacuation, or a means for sharing information about the general condition and location of patients under care, or information about occupancy.
- Training and testing: CMS proposes to relocate more stringent existing requirements (at 485.64) to the proposed rule, requiring that all new personnel be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday, and that the training program include instruction in the location and use of alarm systems and signals and fire-fighting equipment.

L. Critical Access Hospitals (CAHs) (§485.625) (page 79113)

CMS proposes to replace current CAH requirements at §485.623(c) and proposes new §485.625 requiring CAHs to meet the proposed hospital standards, with one modification that reflects the current rules. In the training and testing section, CMS proposes to include specific training in extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention and cooperation with fire-fighting and disaster authorities. The proposed requirements for emergency and standby power systems would apply to CAHs.

M. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) (§485.727) (pages 79113-79114)

CMS refers to this collection of providers as “Organizations” and proposes to revise existing §485.727 requirements to adopt the proposed hospital requirements with several exceptions and additions.

- Emergency planning: CMS proposes to include requirements that the Organizations address the location and use of alarm systems and signals and methods of containing fire, and develop and maintain the plan with assistance from fire, safety, and other appropriate experts.
- Policies and procedures: CMS is not proposing that that the Organizations’ policies and procedures address basic subsistence needs for staff and patients; a system for tracking of staff and patients, arrangements with other providers, or plans for an alternate care site in the event of a section 1135 emergency. CMS proposes a more limited evacuation requirement, requiring that the Organizations have policies and procedures for evacuation, including staff responsibilities and the needs of patients.

- Communications plan: CMS is not proposing to require a means to release patient information in the event of an evacuation, or a means for sharing information about the general condition and location of patients under care, or information about occupancy.

N. Community Mental Health Centers (§485.920) (pages 79114-79115)

CMS notes that it will soon finalize the first health and safety CoPs for CMHCs, and proposes that CMHCs comply with the hospital requirements for emergency preparedness with several exceptions.

- Policies and procedures: CMS is not proposing that CMHCs have policies and procedures to address basic subsistence needs for staff and patients.
- Communications: CMS is not proposing that CMHCs release information about occupancy.

O. Organ Procurement Organizations (OPOs) (§486.360) (page 79115)

CMS proposes a more limited set of requirements for OPOs than for hospitals.

- Emergency plan: instead of addressing the patient population, as proposed for hospitals, CMS proposes that the plan address the type of hospitals with which the OPO has agreements, since potential donors are generally located in hospitals.
- Policies and procedures: CMS proposes to include only two of the requirements applicable for hospitals: a system to track the location of staff during and after an emergency, and a system of medical documentation related to donors and potential donors. CMS does not propose policies and procedures that it sees as more relevant for the hospitals the OPOs work with, related to meeting subsistence needs, safe evacuation, sheltering in place, the use of volunteers, arrangements with other providers (although it does include a separate section, below, on such arrangements), or plans for an alternative site of care in the event of a section 1135 emergency.
- Communications plan: CMS proposes to include just the requirements related to the maintenance of names and contact information, and primary and alternative means of communications. CMS does not propose any of the other communications requirements, which it sees as more relevant for the hospitals OPOs work with, including methods of sharing information with other providers, a means to release patient information in the event of an evacuation, a means of providing information about the general condition of patients under care, or a means of providing information about the OPOs capacity and ability to provide assistance.
- Training and testing: CMS proposes that OPOs meet the training requirements as proposed for hospitals, but proposes to require only the paper-based, tabletop testing exercise annually. CMS does not propose to require the annual community mock drill.
- CMS proposes a final section requiring that each OPO have agreements with one or more other OPOs to provide essential organ procurement services if the OPO cannot provide those services during an emergency. Further, each OPO must include within its agreements with hospitals and transplant programs a specification of the duties and

responsibilities of the hospital, transplant program, and OPO in the event of an emergency.

P. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§491.12) (pages 79115-79116)

CMS proposes to replace current requirements at §491.6(c) and proposes new §491.12 requiring RHCs and FQHCs to meet the proposed hospital requirements with the following exceptions.

- Policies and procedures: CMS does not propose to include requirements related to meeting subsistence needs of patients and staff, tracking the location of patients and staff, arrangements with other providers, or plans for an alternative site of care in the event of a section 1135 emergency. In the proposal for a safe evacuation, CMS proposes to specify that the plans for evacuation include appropriate placement of exit signs.
- Communications plan: CMS does not propose to include requirements related to methods for sharing information with other health care providers, or the release of patient information in the event of an evacuation, or the provision of information related to occupancy.

Q. End-Stage Renal Disease (ESRD) Facilities (§494.62) (pages 79116-79117)

CMS proposes to incorporate current emergency preparedness requirements at §494.62(d) into proposed new §494.62, and to adopt the proposed requirements for hospitals with the following exceptions. These additions to the proposed hospital requirements would incorporate existing and more specific language from §494.64(d) into the proposed rule.

- Emergency plan: CMS proposes, in addition to the hospital requirement for ensuring cooperation and collaboration with emergency preparedness officials, that 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 .
- Policies and procedures: CMS proposes to specify that the emergencies that an ESRD facility must prepare for include fire, equipment or power failures, care-related emergencies, water supply interruption and natural disasters likely to occur in the facility's geographic area. CMS does not propose that ESRD facilities provide basic sustenance needs. CMS proposes a modified evacuation requirement, requiring simply that ESRD facilities provide for safe evacuation, which includes staff responsibilities and the needs of the patients. CMS also notes and emphasizes, in commenting on the requirement for arrangements with other providers, the need for a robust system for back-up care at various dialysis centers. CMS proposes two additional requirements: (1) that the policies and procedures address a process to ensure that emergency medical system assistance can be obtained when needed, and (2) that they address 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 are immediately available.
- Communications plan: CMS does not propose that ESRD facilities provide information about occupancy.

- Training and testing: CMS proposes to incorporate additional specification into the proposed training requirement that staff demonstrate knowledge of emergency procedures. That would include informing patients of: what to do, where to go, including instructions if the geographic area of the ESRD facility must be evacuated, and whom to contact if an emergency occurs, including an alternate emergency phone number for the facility when the facility is unable to receive phone calls due to an emergency situation, unless the facility has the ability to forward calls to a working number in such conditions, and how to disconnect themselves from a dialysis machine in the event of an emergency. CMS also proposes that, at a minimum, patient care staff maintain current CPR certification and that nursing staff are properly trained in the use of emergency equipment and emergency drugs. CMS also proposes to include a requirement for patient orientation, requiring appropriate emergency preparedness orientation and training for patients.

III. Information Collection Requirements (ICR) and Regulatory Impact Analysis (RIA)

CMS presents ICRs for each relevant provision for each of the provider and supplier categories (see pages 79117-79169). The summary of the costs for each category is provided in column 3 of the summary table that follows.

CMS presents an RIA (see pages 79180). The RIA incorporates the ICRs and estimates costs for two other elements of the proposed rule:

- The annual testing requirements for disaster drills and tabletop drills
- The annual generator testing requirement for hospitals, LTC facilities and CAHs. CMS solicits information on how it might better estimate costs for this provision.

The estimated RIA costs are presented in columns 4, 5, and 6 of the following table.

Total Estimated Cost from ICR and RIA to Comply with Proposed Rule. (ICRs are from Tables 2-17; RIA from Table 18; and Total Cost and Year 2 Costs from Table 19)					
(1)	Number of providers (2)	Costs in year 1			Costs, year 2 and thereafter (6)
		Information Collection Requirements (ICR) (3)	Regulatory Impact Analysis (RIA) 1/ (4)	Total (5)	
Hospitals	4,928	\$29,655,252	\$9,769,771	\$39,265,594	\$9,769,771
RNHCI	16	\$18,928	\$5,280	\$24,208	\$5,280
Ambulatory surgical centers	5,354	\$12,564,036	\$2,677,000	\$15,241,036	\$2,677,000
Hospices 2/	3,773	\$10,444,148	\$1,463,924	\$10,076,910	\$1,463,924
PRTFs	387	\$932,670	\$139,320	\$1,071,990	\$139,320
PACE organizations	91	\$334,698	\$8,190	\$342,888	\$8,190
Transplant centers	770	\$1,399,104	\$0	\$1,399,104	\$0
LTC facilities	15,157	0	\$19,128,134	\$19,128,134	\$19,128,134
ICF/IIDs	6,442	\$15,538,104	\$0	\$15,538,140	\$0
Home health agencies	12,349	\$48,725,629	\$2,897,895	\$51,623,524	\$2,897,895
CORFs	272	\$828,784	\$0	\$828,784	\$0
CAHs	1,322	\$5,801,742	\$2,541,639	\$8,339,742	\$2,541,639
Organizations 3/	2,256	\$6,939,456	\$0	\$6,939,456	\$0
CMHCs	207	\$588,915	\$85,905	\$674,820	\$85,905
OPOs	58	\$606,970	\$6,206	\$613,176	\$6,206
RHCs and FQHCs	9,547	\$31,948,799	\$1,813,876	\$33,762,675	\$1,813,876
ESRD facilities	5,923	\$19,581,438	\$817,374	\$20,398,812	\$817,374
<p>1/ RIA estimates are for the annual cost to participate in disaster drills and to test generators</p> <p>2/ It is not clear why the total year 1 cost for hospices is less than the sum of the ICR and RIA costs.</p> <p>3/ “Organizations” refers to Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services</p>					