AHA Rural Advocacy Alliance

CMS Proposed Rule on Emergency Preparedness

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Key Dates and Facts

- CMS released proposed rule Dec. 20; published in *Federal Register* Dec. 27
- AHA *Special Bulletin* issued Dec. 23; a more detailed AHA *Regulatory Advisory* will be issued shortly
- Proposed rule establishes emergency preparedness requirements for 17 types of Medicare/Medicaid providers and suppliers
- Revises the Medicare/Medicaid Conditions of Participation (CoPs) for providers and Conditions of Coverage (CfC) for suppliers
  - CoPs and CfCs are intended to protect public health and safety and ensure high quality care to all persons.
    - Must comply with these requirements to participate in Medicare/Medicaid.
- Comments due on or before Feb. 25

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Categories of Providers and Suppliers

1. Hospitals
2. Critical Access Hospitals (CAHs)
3. Rural Health Clinics (RHCs) & FQHCs
4. Long-Term Care Facilities (Skilled Nursing Facilities (SNF))
5. Home Health Agencies (HHAs)
6. Ambulatory Surgical Centers (ASCs)
7. Hospice
8. Inpatient Psychiatric Residential Treatment Facilities (PRTFs)
9. Programs of All-Inclusive Care for the Elderly (PACE)
10. Transplant Centers
11. Religious Nonmedical Health Care Institutions (RNHCIs)
12. Intermed. Care Facilities for Indiv. with Intellectual Disabilities (ICF/IID)
13. Clinics, Rehab. Agencies, & Public Health Agencies as Providers of Outpatient Physical Therapy & Speech Language Pathology Services
14. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
15. Community Mental Health Centers (CMHCs)
16. Organ Procurement Organizations (OPOs)
17. End-Stage Renal Disease (ESRD) Facilities

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Background and Purpose

- Challenges faced from natural and man-made disasters since 9/11 terrorist attacks.

- Definition of “emergency” or “disaster”: 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 reviewed a variety of emergency preparedness (EP) guidance from federal agencies, states, accrediting bodies and standard setting bodies.
  - Many key resources listed in proposed rule.
  - AHA will be posting these as well.

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Justification

- CMS also reviewed its existing EP regs
  - Conclusion: not comprehensive enough
    - Doesn't address communication, coordination, contingency planning or training
- CMS concludes: Existing law, guidelines, accrediting organization EP standards, fall short of what is needed for healthcare to be adequately prepared for a disaster
- Thus, proposed EP regs intended to establish:
  - "a comprehensive, consistent, flexible, and dynamic regulatory approach to EP and response that incorporates the lessons learned from the past, combined with the proven best practices of the present."
  - Regs would encourage providers and suppliers to coordinate efforts in communities and across state lines.

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Summary of Major Provisions

- 4 core elements to effective and comprehensive framework. These provide framework for the proposed rules for all provider/supplier categories
  - Risk assessment and planning
  - Policies and procedures
  - Communication plan
  - Training and testing

- Emergency and standby power systems regulations proposed only for inpatient providers
  - Hospitals, CAHs, LTC/SNFs.

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Proposed Hospital Regs Act as "Template" for Other Providers/Suppliers

- Other provider/supplier regulations based on proposed comprehensive requirements for hospitals.
  - Hospitals as "focal points" for health care in community
    - EMTALA / Discharge evaluation and planning
  - Hospitals in best position to coordinate EP planning with others providers and to care for disaster victims
- Proposed rule: Hospital regs are "template" for proposed rules for others, except some modification/ tailoring to reflect unique needs of other provider/ supplier types.
- In general:
  - Inpatient provider proposed regs (e.g. CAH, SNF, LTC) similar to hospital standards.
  - Outpatient providers: can close, cancel appointments, but still may need to shelter or evacuate.
  - CMS expects implementation to be different based on category or provider – CAH vs large PPS hospital

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Proposed Hospital/CAH Regulation

- Hospital and CAH proposed requirements almost identical
  - I use “hospital” in slides, but unless the slide points out difference, the CAH regs are identical.

- As outpatient providers, Rural Health Clinics (RHCs) proposed requirements have some differences
  - I’ll address those after hospital/CAH discussion

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Hospital/CAH Reg: Emergency Program

The hospital must comply with all applicable Federal and State emergency preparedness requirements.

The hospital must develop and maintain a <u>comprehensive emergency preparedness program</u> that meets the requirements of this section, <u>utilizing an all-hazards approach</u>

- "All-hazards approach": An integrated approach to emergency preparedness planning.
  - NOT managing separate planning initiatives for a multitude of threat scenarios
  - INSTEAD, focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters.

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Hospital/CAH Reg: Framework

The emergency preparedness program must include, but not be limited to, the following elements:

- Emergency Plan:
- Policies and Procedures
- Communications Plan
- Training and Testing
- *Emergency and Standby Power Systems (for inpatient providers only)*

CMS would require all these program elements to:

- be developed and maintained by the hospital/CAH
- reviewed an updated at least annually

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Hospital/CAH Reg: Emergency Plan

EMERGENCY PLAN.

- ***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.***

- Facility-based risk assessment: contained within actual facility and carried out by facility.
- Community-based risk assessment: carried out outside the organization, within its defined community.

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Hospital/CAH Reg: Emergency Plan

To meet this "all-hazards risk assessment" requirement, CMS expects hospitals to consider:

- identification of essential business functions that should be continued in an emergency;
- identification of all risks or emergencies that the hospital my reasonably expect to confront;
- identification of all contingencies for which the hospital should plan;
- consideration of the hospital's locations, 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

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Hospital/CAH Reg: Emergency Plan

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

- CMS expects strategies to include consideration of collaboration with hospitals and suppliers across state lines

(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.

- Persons at risk include: infants/children, senior citizens, pregnant women, persons who have physical or mental disabilities, who live in institutionalized settings, from diverse cultures, have limited English proficiency, lack transportation, have chronic medical disorders, or have pharmacological dependency.

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Hospital/CAH Reg: Emergency Plan

(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.

- CMS references ASPR's Hospital Preparedness Program (HPP) and its support for robust community healthcare coalitions (HCCs)
  - Engaging critical partners such as other hospitals, emergency management, public health, mental health etc.
  - HCCs used for collaboration/coordination in planning.
- If EP officials opt not to collaborate with providers, providers can document their efforts to reach out to officials.

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Hospital/CAH Reg: Policies and Procedures

POLICIES AND PROCEDURES

(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

(A) Temperatures to protect patient health and safety and for safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

- CMS is soliciting public comment on this proposed requirement.

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Hospital/CAH Reg: Policies and Procedures

(2) A system to track the location of staff and patients in the hospital's care both during and after the emergency.

- CMS does not propose a specific type of tracking system, but says the information should be:
  - readily available, accurate, and shareable among officials within emergency response system.

- CMS proposes this requirement for providers and suppliers who provide ongoing care for inpatients or outpatients.
  - Eg. Hospitals, CAHs, HHA, ESRD, LTC would have this req; RHCs would not.

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Hospital/CAH Reg: Policies and Procedures

(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.

- Policies should consider whether building would survive disaster and proactive steps to facilitate sheltering or transferring patients to alternate settings.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.

- Policies must be HIPAA privacy and security compliant

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Hospital/CAH Reg: Policies and Procedures

(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.

- CMS cites helpful volunteer programs such as Medical Reserve Corps (MRC); federal Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP)

(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.

- Proposed only for providers and suppliers that provide continuous care and services for individual patients
  - Hospitals, CAHs, etc. but not RHCs

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Hospital/CAH Reg: Policies and Procedures

(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."

- CMS intends this to encourage collaboration with emergency officials in proactive planning in the event that services are severely disrupted.
- Section 1135 of the *Social Security Act* provides the Secretary with authority to temporarily waive or modify certain Medicare, Medicaid and Children's Health Insurance Program requirements
  - E.g. waiver of CoPs, Emergency Medical Treatment and Labor Act (EMTALA) requirements, HIPAA, etc.

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Hospital/CAH Reg: Communication Plan

COMMUNICATION PLAN.

Must include:

(1) Names and contact information: staff; entities under arrangement; physicians; other hospitals; volunteers.

(2) Contact information: Federal, State, tribal, regional, and local EP staff.

(3) Primary and alternate means for communicating with the following: hospital's staff; Federal, State, tribal, regional, and local emergency management agencies.

- Alternate communications: e.g. mobile phones, HAM radio, satellite phones.
- CMS recognizes difficulties with communications systems in remote areas; expects hospitals to address challenges in emergency communication systems.

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Hospital/CAH Reg: Communication Plan

(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.

- CMS expects system of communication that:
  - Ensures comprehensive patient care information could be disseminated across providers and suppliers in timely manner.
  - Ensures 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
  - Electronic information backed up both within and outside the hospital's geographic location.

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Hospital/CAH Reg: Communication Plan

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510

- System that can generate timely, accurate information that could be disseminated, as permitted by HIPAA privacy regulations, to family members and others
- Not required for RHCs

(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)

- HIPAA privacy ''Use and disclosures for disaster relief purposes''; e.g. American Red Cross

(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

- Hospitals/CAHs engaging in HCCs in their area can effectively meet this requirement.

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Hospital/CAH Reg: Training and Testing

TRAINING AND TESTING.

Training Program.

(i) Initial training in EP policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers.

(ii) Provide EP training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.

- Only CAH difference from hospital regs, reflects current rules:
  - Requires specific training in extinguishing of fires, protection, and evacuation of patients, personnel, and guests, fire prevention and cooperation with fire-fighting and disaster authorities.
- CMS: Small and rural hospitals may find state/local gov't resources helpful here; notes value of participation in HCCs in planning and conducting exercises

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Hospital/CAH Reg: Training and Testing

(2) Testing. The hospital must conduct drills and exercises to test the emergency plan.

(i) Participate in a community mock disaster drill at least annually. If not available, individual, facility-based mock disaster drill at least annually.

(ii) If hospital experiences an actual natural or man-made emergency that requires activation of emergency plan, this exempts hospital from requirements for 1 year following.

(iii) Conduct paper-based, tabletop exercise at least annually.

(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.

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Hospital/CAH Reg: Emergency and Standby Power Systems

EMERGENCY AND STANDBY POWER SYSTEMS.

(1) Emergency generator location. Must in accordance requirements 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 and NFPA 110:

> ***(i) At least once every 12 months, test each emergency generator for minimum of 4 continuous hrs. Test load must be 100% of load hospital anticipates it will require during an emergency.***
>
> ***(ii) Maintain written record 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 duration of emergency or until likely resupply.

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RHC/FQHC Reg: Policies and Procedures

CMS proposes to apply proposed hospital requirements with following exceptions:

Policies and Procedures

- RHCs *not required* to have following policies/procedures:
  - To meet subsistence needs of patients and staff
  - Tracking the location of patients and staff
  - Arrangements with other providers
  - Plans for an alternative site of care
- RHCs *would have additional policy/procedure* (based on current RHC emergency procedures)
  - In proposal for safe evacuation, plans for evacuation must include appropriate placement of exit signs, staff responsibilities, and needs of patients.

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RHC/FQHC Reg: Communications Plan

Communications Plan

CMS *does not propose to include* requirements related to:

- Methods for sharing information with other health care providers,
- The release of patient information in event of an evacuation
- The provision of information related to occupancy.

Emergency and Standby Power Systems

- Not included in RHC/FQHC proposed rule

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Paperwork and Regulatory Impact Analysis

- *Paperwork Reduction Act* requires CMS to review burden associated with information collection requirements (ICRs). The provisions for which CMS estimates ICRs include:
  - risk assessment,
  - emergency preparedness plan,
  - emergency preparedness policies and procedures,
  - emergency preparedness communication plan and
  - emergency preparedness training and testing program.
- CMS also must calculate a regulatory impact analysis (RIA) for major rules. This incorporates estimated costs for two other elements of the proposed rule:
  - annual testing req. for disaster drills and tabletop exercises
  - annual generator testing req. for hospitals, CAHs, and LTC
- CMS requests comments on these impact numbers.

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Burden and Cost Estimate: Hospitals

Requirement	Respondents	Burden Hours Per Respondent	Total Cost	Cost per Respondent
Risk assessment ICR (Non TJC accred)	1,518	36	$4,437,114	$2,923
EP plan ICR (Non TJC accred)	1,518	62	$7,719,030	$5,085
EP policies/ procedures ICR (TJC accred)	3,410	17	$4,852,430	$1,423
EP policies/procedures ICR (Non TJC accred)	1,518	33	$3,981,714	$2,623
Agreements with other hospitals ICR	4,928	8	$3,543,232	$719
EP communication plan ICR (Non TJC accred)	1,518	10	$1,149,126	$757
EP training/ testing ICR (Non TJC accred)	1,518	40	$3,178,692	$2,094
EP drills/exercises ICR (Non TJC accred)	1,518	9	$793,914	$523
EP drills/exercises econ. impact (Non TJC accred)	1,518	48	$5,100,480	$3,360
Generator testing (Accred)	4,059		$3,413,619	$841
Generator testing (Non accred)	869		$1,096,243	$1,261
TOTAL			**$39,265,594**	**$7,968**

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Burden and Cost Estimate: CAHs

Requirement	Respondents	Burden Hours Per Respondent	Total Cost	Cost per Respondent
Risk assessment ICR (Non TJC accred)	952	15	$903,448	$949
EP plan ICR (Non TJC accred)	952	26	$1,542,240	$1,620
EP policies/ procedures ICR (TJC or AOA accred)	402	10	$327,228	$814
EP policies/procedures ICR (Non accred)	920	14	$791,200	$860
EP communication plan ICR	1322	9	$686,118	$519
EP training/testing ICR	1322	14	$1,102548	$834
EP drills/exercise ICR (Non accred)	920	8	$448,960	$488
EP drills/exercises economic impact (Non accred)	920	20	$1,041,440	$1,132
EP Generator testing economic impact (Non accred)	915		$1,154,273	$1,261
Generator testing economic impact (Accred)	407		$342,287	$841
TOTAL			**$8,339,742**	**$6,308**

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Burden and Cost Estimate: RHC

Requirement	Respondents	Burden Hours Per Respondent	Total Cost	Cost per Respondent
Risk assessment ICR	4,013	10	$2,857,256	$712
EP plan ICR	4,013	14	$3.808,337	$949
EP policies/ procedures ICR	4,013	12	$3,884,584	$968
EP communication plan ICR	4,013	10	$3,443,154	$734
EP training/testing ICR	4,013	10	$2,110,838	$526
EP drills/exercise ICR	4,013	5	$1,107,558	$276
EP drills/exercise economic impact	4,013	8	$1,813,876	$452
TOTAL			**$19,025,603**	**$4,740**

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CMS Request for Comments on Alternative Approaches to Implementation

CMS requests comments on the following issues.

1. Targeted approaches to emergency preparedness: Should CMS cover one or a subset of provider classes to learn from implementation prior to extending the rule to all groups?

2. A phase in approach: Should CMS implement the requirements over a longer time horizon, or differential time horizons for the respective provider classes? CMS proposes to implement all of the requirements 1 year after the final rule is published.

3. Variations of the primary requirements: E.g., CMS has proposed requiring two annual training exercises. Should both should be required annually, semiannually, or should training be an annual or semiannual requirement?

4. Integration with current requirements: How can the proposed requirements be integrated with, or satisfied by, existing policies and procedures which regulated entities may have already adopted?

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Discussion Questions

- How closely do these proposed requirements align with what you are already doing? If these proposed regulations are implemented, would you already be mostly in compliance, somewhat in compliance, or barely in compliance? What are the most stark differences?

- What specific concerns do you have about the proposed requirements for developing an emergency plan, including addressing the needs of persons at risk and collaborating with authorities?

- What specific concerns do you have about the proposed requirements for implementing emergency preparedness policies and procedures, such as ensuring for subsistence needs, alternate sources of energy, the tracking of patients and more?

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Discussion Questions

- What specific concerns do you have about the proposed requirement to develop and implement a communication plan?
- What specific concerns do you have about the proposed requirements for training and testing?
- What specific concerns do you have about the proposed requirements for emergency and standby power systems?

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