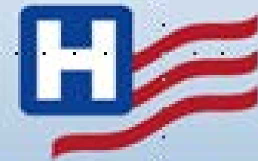
CMS Proposed Emergency Preparedness Rule



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Dedicated to optimizing the health care physical environment

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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Key Dates and Facts

- CMS released proposed rule Dec. 20; published in *Federal Register* Dec. 27
- 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

- **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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Comment Submission

Submit comments in one of four ways:

1. Electronically at http://www.regulations.gov

Follow the "Submit a comment" instructions.

2. By regular mail 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.

Comments due on or before Feb. 25

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Comment Submission

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.

Comments due on or before Feb. 25

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Comment Submission

4. By hand or courier to the following addresses:

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

For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For hand or courier deliveries see the proposed ruling for additional information

Comments due on or before Feb. 25

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Summary of Major Provisions

- 5 core elements
  - Emergency Preparedness Program & Plan
    - Based on Risk Assessment
  - Policies and Procedures
  - Communication Plan
  - Training and Testing of Program/Plan
  - Emergency Power Systems
    - 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

- 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 Hospital
- Hospital and CAH proposed requirements almost identical

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Hospital/CAH Reg: Framework

Emergency Preparedness Program :

- 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 and updated at least annually

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Hospital/CAH Proposals
Emergency Management Program and Plan

Emergency Management Plan:

- "All-hazards approach"
- Based on Risk Assessment
- Include Strategies Addressing Emergency Events
  - As Defined in Risk Assessment
- Address Patient Population & Persons at Risk
- List Types of Services Provided in Emergency
- Delegation & Succession Plan
- Process to Ensure Cooperation & Collaboration
  - Local, Tribal, Regional, State, & Federal
- Process to Develop Arraignments with Alternate Care Sites

- Review and Update Annually

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Hospital/CAH Proposals
Emergency Management Program and Plan

Policies and Procedures:

- Develop & Implement Based on:
  - EP Plan, Risk Assessment & Communication Plan
- Address Subsistence Needs
  - Patients & Staff Sheltered in Place or Evacuated
- Address Alternate Source of Energy for:
  - Temperature, Emergency Lighting, Fire Detection & Alarm
- Address Provision of Sewage & Waste Disposal
- System to Track Location of Staff & Patients
- Ensure Safe Evacuation
- Address Shelter in Place
- System of Medical Documentation
- Ensure Preservation & Protection
- Address Use of Volunteers
- Address Role under Waiver in Accordance with Section 1135
  - Alternate Care Site

- Review and Update Annually

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Hospital/CAH Proposals
Emergency Management Program and Plan

Communication Plan:

- Provide Contact Information for F, S, T, R & L EM Authorities
- Primary & Alternate Means of Communication
  - Staff & F, S, T, R & L EM Authorities
- Means to Share Medical Documents
- Means to Release Patient Information
- Means to Provide General Condition & Location of Patients
- Means to Provide Occupancy, Needs & Abilities

- Review and Update Annually

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Hospital/CAH Proposals
Emergency Management Program and Plan

Training and Testing Program:

- Provide Training to All New & Existing Staff
  - Maintain Documentation
  - Provide Annually
- Participate in a Community Mock Drill Annually
  - If not Available – Annual Facility Drill
- If Event Experienced Exempt for 1 Year
- Conduct Paper-Based Drill Annually
- Analyze Response and Maintain Documentation
  - Revise Plan as Needed

- Review and Update Annually

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Hospital/CAH Proposals
Emergency Management Program and Plan

Emergency Power Proposals:

- Hospital Store Emergency Fuel per 2000 LSC
- Test Emergency Power System 4 Hours Annually
  - 100% Anticipated Emergency Load
- Same for CAH's & LTC Facilities

Additional Recommendations:

- Recommend Subsistence for Volunteers, Visitors & Local Community
- Consider Secondary Source for Electronic Records
- Emergency Power System Located to Protect From Disasters

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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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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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Major Points of Concern

1. Current Codes: Use consensus codes and amended as necessary

2. All-Hazards Approach: Use of existing HVA Risk Based Approach.

3. Sewage and Waste Disposal: Establishment of individual waste treatment over burdensome

4. Increased Generator Testing

5. Generator location: For new and replacement not existing

6. Interpretations of Proposed Rules and Recommendations

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Questions?

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