Final Rule

- Published September 16, 2016
- Applies to all 17 provider and supplier types
- Implementation date November 15, 2017
- Compliance required for participation in Medicare
- Emergency Preparedness is one new CoP/CfC of many already required
- Appendix Z- State Operations Manual (updated in February 2019)
Four Provisions for All Provider Types

- Risk Assessment and Planning
- Policies and Procedures
- Emergency Preparedness Program
- Communication Plan
- Training and Testing
• Develop an emergency plan based on a risk assessment.

• Perform risk assessment using an “all-hazards” approach, focusing on capacities and capabilities.

• Update emergency plan at least annually.

(Note: CMS is not specifying a specific risk assessment to be used- i.e. HVA, Integrate EM System Risk Assessment)
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, including internal emergencies and a man-made emergency (or both) or natural disaster. This approach is specific to the location of the provider or supplier and considers the particular type of hazards most likely to occur in their areas. These may include, but are not limited to, care-related emergencies, equipment and power failures, interruptions in communications, including cyber-attacks, loss of a portion or all of a facility, and interruptions in the normal supply of essentials such as water and food.

2019 Update added “emerging infectious diseases” to the definition.
What do we mean by “Emerging Infectious Diseases”?  

• We are not specifying the type of infectious diseases to consider or care-related emergencies which are as a result of infectious diseases. Adding EID’s was specifically to ensure that facilities consider having infection prevention personnel at the table when it comes to planning and development of their emergency preparedness program.

• The proposed and final rule spoke to Ebola and H1N1 and subsequently we dealt with the Zika virus, therefore CMS found it prudent to ensure that EIDs are included in the definition of all-hazards.

• Some examples may include, but are not limited to:
  – Hazardous Waste
  – Bioterrorism
  – Pandemic Flu
  – Highly Communicable Diseases (such as Ebola)
Policies and Procedures

• Develop and implement policies and procedures based on the emergency plan and risk assessment.

• Policies and procedures must address a range of issues including subsistence needs, evacuation plans, procedures for sheltering in place, tracking patients and staff during an emergency.

• Review and update policies and procedures at least annually.
Communication Plan

• Develop a communication plan that complies with both Federal and State laws.

• Coordinate patient care within the facility, across health care providers, and with state and local public health departments and emergency management systems.

• Review and update plan annually.
Training and Testing Program

- Develop and maintain training and testing programs, including initial training in policies and procedures.

- Demonstrate knowledge of emergency procedures and provide training at least annually.

- Conduct drills and exercises to test the emergency plan.
1135 Waivers

- **SCOPE:** Federal Requirements only, not state licensure. Determine: Scope and severity of event with specific focus on health care infrastructure; Are there unmet needs for health care providers? Can these unmet needs be resolved within our current regulatory authority?

- **PURPOSE:** Allow reimbursement during an emergency or disaster even if providers can’t comply with certain requirements that would under normal circumstances bar Medicare, Medicaid or CHIP payment.

- **DURATION:** End no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.
1135 Waivers- DO NOT

• 1135 waivers are not a grant or financial assistance program
• Do not allow reimbursement for services otherwise not covered
• Do not allow individuals to be eligible for Medicare who otherwise would not be eligible
• Should NOT impact any response decisions, such as evacuations.
• Do not last forever. And appropriateness may fade as time goes on.
1135 Waivers- Examples

• Conditions of Participation: For instance, CAHs require 25-bed limit and Average Patient stays of less than 96-hours or SNFs- 3-day prior hospitalization for SNF Patients
• Licensure for Physicians or others to provide services in affected state
• Emergency Medical Treatment and Labor Act (EMTALA): For instance, Request to setup Alternate Screening Locations
• Stark Self-Referral Sanctions
• Medicare Advantage out of network providers
• HIPAA (Based on OCR determination)
1135 Waiver Review Process

- Within defined Emergency Area?
- Is there an actual need?
- Can this be resolved within current regulations?
- What is the expected duration?
- Will Regulatory relief requested actually address stated need?
- Should we consider individual or blanket waiver?
The Final Rule and 1135 Waivers

• To be compliant with the requirement under the Emergency Preparedness Final Rule, you’ll need to have a policy and procedure for addressing your facility’s awareness of the 1135 Waiver Process.

• There is no specific form or document template.

• Some elements that could be considered and reflected (but not limited to) in the policies and procedures.

• Having an 1135 waiver on file is NOT possible since 1135 waivers are event & geographically specific & time limited.

• For more information visit: Quality, Safety & Oversight Group 1135 Waiver Resource Website at:
What has been completed?

• In September, 2017, the surveyor training for emergency preparedness requirements was launched. Available at https://surveyortraining.cms.hhs.gov/

• Training through the Integrated Surveyor Training Website is available for providers/suppliers.

• Facilities started being surveyed after November 15th, 2017 in conjunction with scheduled surveys and survey cycles based on their provider types.
Where are we now? Upcoming Efforts

- Updated Appendix Z in February 2019 to include emerging infectious diseases; corrections to HHA citations; clarifications to portable use generators and alternate source power

- CMS will continue to review and analyze progress of compliance among providers suppliers affected

- CMS will engage with different partners related to the potential for additional resources in challenge areas of compliance

- Additional training as needed with surveyors
The Website

• Providers and Suppliers should refer to the resources on the CMS website for assistance in developing emergency preparedness plans.

• The website also provides important links to additional resources and organizations who can assist.

ASPR TRACIE was developed as a healthcare emergency preparedness information gateway to address the need for:

- Enhanced technical assistance
- Comprehensive, one-stop, national knowledge center for healthcare system preparedness
- Multiple ways to efficiently share and receive (push-pull) information between various entities, including peer-to-peer
- Leveraging and better integrating support (force multiplier)

- Self-service collection of audience-tailored materials
- Subject-specific, SME-reviewed “Topic Collections”
- Unpublished and SME peer-reviewed materials highlighting real-life tools and experiences

- Personalized support and responses to requests for information and technical assistance
  - Accessible by toll-free number (1844-5-TRACIE), email (askasprtracie@hhs.gov), or web form (ASPRtracie.hhs.gov)

- Area for password-protected discussion among vetted users in near real-time
  - Ability to support chats and the peer-to-peer exchange of user-developed templates, plans, and other materials
Email Addresses for CMS Regional Offices:

**ROATLHSQ@cms.hhs.gov**  (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee;

**RODALDSC@cms.hhs.gov**  (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas

**ROPHIDSC@cms.hhs.gov**  (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont

**ROCHISC@cms.hhs.gov**  (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, and Nebraska

Contact Information for CMS

• Regional Office and State Survey Agency Contact Lists: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/ContactInformation.html (We recommend seeking their input first).

• General Mailbox for Policy Inquiries: SCGEmergencyPrep@cms.hhs.gov

• CMS Website: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html
Thank you!

SCGEmergencyPrep@cms.hhs.gov