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Emergency Preparedness Rule Proposed for Health Care Providers

The U.S. Department of Health and Human Services (DHHS) has proposed new regulations to expand national emergency preparedness requirements for Medicare and Medicaid providers and suppliers (MMPSs). This rule is proposed under legal authorities applicable to 17 wide-ranging health care sectors that include hospitals, ambulatory surgical centers, hospices, community mental health centers, and home health agencies.[1] These requirements would become enforceable Conditions of Participation for providers and Conditions for Coverage for suppliers.

The DHHS determined that current emergency preparedness requirements for Medicare providers and suppliers are not "comprehensive enough to address the complexities of actual emergencies." The DHHS concluded that current requirements do not address the need for communication to coordinate with other systems of care within local jurisdictions or states, contingency planning, and training of personnel. In part, the DHHS is concerned that in the event of a disaster, health care providers and suppliers would not have the necessary emergency planning and preparations in place to adequately protect the health and safety of their patients. There is also concern that the current system of federal, state, and local laws and guidelines, along with the varied accrediting agency emergency preparedness standards, is not comprehensive enough to ensure that health care providers and suppliers are adequately prepared for a disaster.

In developing the proposed rule, the DHHS reviewed a wide range of existing emergency planning requirements, including those established by presidential directives, guidance issued by the Centers for Disease Control and Prevention, and state and local experiences. The agency also considered several reports and studies analyzing a variety of natural and manmade incidents, from the Three Mile Island nuclear incident to Hurricanes Katrina and Sandy.

Under the proposed regulation, new emergency preparedness standards are tailored to the requirements of each of the 17 identified health care sectors. These standards incorporate the "all hazards" approach adopted from other programs for disaster and emergency management. The DHHS has identified four core elements believed to be central to an effective and comprehensive framework of an emergency preparedness program for MMPSs. These elements are risk assessment and planning, policies and procedures, a communication plan, and training and testing.

The proposed rule requires hospitals to have both an emergency preparedness program and an emergency preparedness plan. The intent of the program component is to provide for a continuous building of a comprehensive system of health care responses to a natural or manmade emergency. The plan component has to conform to federal and state standards as well as incorporate the "all hazards" risk assessment and response measures. The plan also takes into account an evaluation of the facility patient population and available resources, incorporates authority delegation and succession practices during emergencies, and is subject to annual or more frequent internal review.

The DHHS has also requested that commenters address several specific issues, including the following:

- whether the requirements should be implemented on a staggered basis
- whether a more limited number of provider classes should be targeted

- whether the policy and procedure reviews should be more or less frequent
- the provision of emergency subsistence needs for staff and patients, including food, water, medical supplies, and alternate energy to maintain heating and cooling systems, fire detection, extinguishing and alarm systems, and sanitary waste management
- the feasibility of outpatient tracking during emergencies
- how the proposed rule would be integrated with or satisfied by existing policies and procedures
- the burden of the information collection requirements

The DHHS must receive comments on the proposed rule no later than February 25, 2014. Comment filing procedures are set forth in the Federal Register Notice (78 FR 79082, December 27, 2013).

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[1]The 17 provider and supplier entities are Religious Nonmedical Health Care Institutions, Ambulatory Surgical Centers, Hospices, Inpatient Psychiatric Service for Individuals Under Age 21 in Psychiatric Facilities or Programs, Programs of All-Inclusive Care for the Elderly, Hospitals, Long-Term Care Facilities – Skilled Nursing and Nursing Facilities, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Home Health Agencies, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, "Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services," Community Mental Health Centers, Organ Procurement Organizations, Rural Health Clinics, and End-Stage Renal Disease Facilities.

For more information on these proposed new regulations, please contact a member of Robinson & Cole's Health Law Practice Group:

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