



A GUIDE FOR HEALTHCARE PROVIDERS

Temporary Suspension or Modification of Statutes and Regulations in New York State During Emergencies

A collaboration between



Healthcare Association
of New York State



IROQUOIS
Healthcare Association

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Acknowledgments

New York State Department of Health

- Office of Health Emergency Preparedness
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Associations

ADULT CARE



COMMUNITY HEALTH CARE



HOME CARE



HOSPITALS



NURSING HOMES



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Definitions

1135 WAIVERS

Waivers or modifications that the Secretary of the U.S. Department of Health and Human Services is authorized to make under Section 1135 of the Social Security Act during an emergency.

EXECUTIVE ORDER

An order issued by the Governor of the State of New York pursuant to his or her authority under Executive Law § 29-a, which may temporarily suspend specific provisions of state statute, local law, ordinance, rules, or regulations during a state disaster emergency.

FLEXIBILITY

A government agency policy or procedure that can be adjusted under existing authority.

PROVIDER

A facility, agency, or organization licensed or certified to administer healthcare or long-term residential care. Such facilities and organizations include hospitals, nursing homes, community health centers, adult care facilities, and home care agencies.

REGULATION

A rule or order having the force of law that is issued by an executive authority or regulatory agency of a government.

STATUTE

A written law passed by a legislative branch of a government.

SUSPENSION OR MODIFICATION

The Governor may, by Executive Order, temporarily suspend or modify provisions of state statute, rules, or regulations during a state disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster. This action is commonly referred to as “waiver.”

WAIVER

See “Suspension or Modification.”

Acronyms

CDCCenters for Disease Control and Prevention, U.S. Department of Health and Human Services

CMSCenters for Medicare and Medicaid Services, U.S. Department of Health and Human Services

EMTALAEmergency Medical Treatment and Labor Act

HANYSHealthcare Association of New York State

HCSHealth Commerce System

HERDSHealth Emergency Response Data System

HHSU.S. Department of Health and Human Services

NYSNew York State

NYSDOHNew York State Department of Health

OHEPOffice of Health Emergency Preparedness, New York State Department of Health

OPCHSMOffice of Primary Care and Health Systems Management, New York State Department of Health

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Background

After experiencing many events, including the 2009 H1N1 influenza pandemic, Hurricane Irene, Tropical Storm Lee, and Superstorm Sandy, the healthcare community expressed a need for guidance to overcome statutory and regulatory barriers when responding to disasters. In NYSDOH's After Action Reports and Improvement Plans for these major emergencies, recommendations were made to develop guidance on this subject and assemble a list of potential statutory or regulatory barriers.

In response, the Healthcare Association of New York State (HANYS) and Iroquois Healthcare Association, in collaboration with NYSDOH, convened a work group of associations representing a broad spectrum of healthcare providers to develop this guidance and assemble a list of potential statutory and regulatory barriers.

The work group, led by HANYS and Iroquois, assessed concerns related to regulatory barriers during emergencies, and reviewed Executive Orders issued during past events, statutes and regulations that might pose barriers during future emergencies, and the process to request a suspension or modification of legal requirements. HANYS and Iroquois Healthcare Association have summarized the work group's findings along with other key information in this reference guide.

An Overview of Temporary Suspension or Modification of Statutes or Regulations in New York State

In New York State, healthcare providers are required to comply with many standards mandated through statute or regulation by local, state, and federal government. These requirements range from licensure of healthcare professionals, to care of patients, to maintenance of building grounds. During an emergency, the conditions under which healthcare providers typically operate may change rapidly. In this altered environment, adherence to some laws or regulations may interfere with a provider's ability to deliver care.

To allow healthcare providers to cope with disaster, statutes and regulations may be temporarily suspended or modified. These temporary suspensions and modifications are often referred to as waivers. In most cases, an emergency declaration by the state or federal government must be made and a formal request process is followed. In other cases, language in a statute or regulation allows for suspension or modification under certain specified conditions with or without an emergency declaration.

If a healthcare provider encounters a statutory or regulatory barrier and there is no emergency declaration, the statute or regulation does not allow flexibility, or there is uncertainty, the provider should contact NYSDOH for guidance. *See Appendix A for contact information.*

Temporary Suspension or Modification of Statutes or Regulations Requiring a Declaration

Statutes and regulations affecting healthcare providers may be temporarily suspended or modified when there is an emergency declaration or proclamation by the local, state, or federal government. An emergency declaration is a mechanism written into law through which the government may exercise certain powers or provide resources only during times of disaster. Article 2-B of the New York State Executive Law defines disaster as the occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property. Examples of the types of statutes and regulations that have been suspended or modified during past emergencies and the corresponding declarations are provided in the following table.

Emergency Declarations for Local, State, and Federal Governments

LOCAL

Declaration	Emergency Proclamation NYS Exc. Law Article 2-B §24 (Appendix C.1)
Authority	Local Executive
Conditions Required	Occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property.
Powers	Issue local emergency orders to protect life and property.
Examples	2012 Superstorm Sandy: Residents were ordered to evacuate. Disaster Proclamation and Executive Order (Appendix C.2)

STATE

Declaration	Disaster or Emergency NYS Exc. Law Article 2-B §28 (Appendix C.3)
Authority	Governor
Conditions Required	Disaster has occurred or is imminent for which local governments are unable to respond adequately.
Powers	Temporarily suspend or modify certain state requirements (Appendix C.4) and provide supplemental state assistance (Appendix C.5).
Examples	2012 Superstorm Sandy: The number of physician assistants and nurse practitioners a physician may supervise was increased. Disaster Declaration Executive Order (Appendix C.6)

FEDERAL

Declaration	Major Disaster or Emergency Stafford Act (Appendix C.7)
Authority	President
Conditions Required	The severity and magnitude of a disaster exceeds state and local capabilities.
Powers	Provide supplemental federal assistance, primarily funding for individuals, state, and local governments, and certain non-profit organizations.
Examples	2012 Superstorm Sandy: \$2.4 billion + in federal funds were provided for public assistance. Major Disaster Declaration (Appendix C.8)

Declaration	National Emergency National Emergencies Act (Appendix C.9)
Authority	President
Conditions Required	A determination that an emergency exists warranting a declaration of a National Emergency.
Powers	Activate certain statutory authorities, including the authority to temporarily waive or modify certain federal requirements.
Examples	2009 H1N1 Influenza: The HHS Secretary was permitted to grant 1135 (CMS) waivers. National Emergency Declaration (Appendix C.10)

FEDERAL (CONTINUED)

Declaration	Public Health Emergency Public Health Service Act (Appendix C.11)
Authority	HHS Secretary
Conditions Required	A disease or disorder presents a public health emergency; or a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.
Powers	Authority to grant the following (not all inclusive): <ul style="list-style-type: none"> ● 1135 (CMS) waivers (Appendix C.12)—<i>Only if the President also declares a national emergency or major disaster;</i> ● access to public health emergency funds; ● issue emergency use authorizations for drugs; and ● grant extensions for submission of reports required under HHS laws.
Examples	2012 Superstorm Sandy: Requirements that physicians or other healthcare professionals hold licenses in the state in which they provide services were temporarily waived. Public Health Emergency Declaration and 1135 Waivers (Appendix C.13)

Request Process

When a disaster or emergency has been declared, the request for temporary suspension or modification of statutes and regulations is most often initiated by the leader of the enforcing government agency once it has been determined that compliance with such provisions would prevent, hinder, or delay action necessary to cope with disaster. This determination may be made by the enforcing agency in response to a request by a healthcare provider or made proactively without request from a healthcare provider.

If a healthcare provider encounters a statutory or regulatory barrier meeting the criteria described, the provider should first exercise prudent judgment to protect the safety of staff, patients, or residents in their care and then immediately contact NYSDOH for guidance (see the Steps for Requesting Temporary Suspension or Modification of Statutes and Regulations section).

It is important to note that suspensions and modifications can be made retroactively, but one should not anticipate that a statute or regulation will be suspended or modified until the Executive Order is issued. Further, although the same statute or regulation may be suspended or modified through several emergencies, a new request must be made every time due to the unique circumstances each disaster presents. **Suspension or modification of statutes and regulations cannot be pre-approved.**

Limitations

Statutes and regulations may be temporarily suspended or modified only if the change continues to safeguard the health and welfare of the public and provides for the minimum deviation from the original statute, law, ordinance, or regulation. Suspension and modification of the law is also subject to time limitations, which may be extended if necessary. In NYS, suspensions and modifications may not exceed 30 days; however, the Governor may extend such orders for subsequent periods of not more than 30 days each if the circumstances so require (see NYS Exc. Law § 29-a of Article 2-B). Lastly, once a request is made, the effect of the change on other entities will also be considered due to the complex relationships among different types of healthcare providers.

Regulatory Flexibility

Certain statutes or regulations include language allowing temporary suspension or modification of requirements under specified conditions which may or may not necessitate an emergency declaration. Once those conditions are met, the alterations described in the language of the statute or regulation may be made. The following are examples of regulatory flexibility during an emergency:

- **10 NYCRR 401.2:** During an emergency, a medical facility may temporarily exceed the bed capacity specified in the operating certificate. The regulation also allows for operation at an alternate or additional site approved by the Commissioner of Health on a temporary basis.
- **EMTALA:** If a hospital emergency department experiences a patient surge because of an outbreak of influenza-like illness, an Emergency Medical Treatment and Labor Act (EMTALA) waiver is not needed to set up another site for emergency medical screening on the same campus.

Steps for Requesting Temporary Suspension or Modification of Statutes and Regulations

When requesting suspension or modification of statutes and regulations, the following steps are necessary to ensure prompt and appropriate action:

- Prepare to provide the following information:
 - a description of the difficulty experienced (how the statute or regulation restricts the ability to perform critical patient/resident operations or maintain the life safety of patients/residents);
 - if known, the specific statute or regulation;
 - a description of the modification you are requesting and how it will help; and
 - if possible, an estimate for the duration of the current circumstances.
- Contact the NYSDOH Office of Primary Care and Health Systems Management (OPCHSM), Regional Office (RO) Program, or Central Office (CO) Program that oversees your type of facility. During weekends, holidays, and weekdays between 5 p.m. to 8 a.m., contact the NYSDOH Duty Officer. *See Appendix A for contact information.*
- Be prepared to provide additional information if necessary. NYSDOH OPCHSM Central Office Program and Executive staff will review the request and, if appropriate, communicate the request to the Governor's office or to CMS (Region Two). OPCHSM will inform the RO Program Director of relevant information regarding the request, or the need for additional information from you, and the RO Program Director will reach out as needed.
- Once a decision is made, it will usually be communicated to the requesting provider(s) by the RO Program Director. During a large-scale emergency event, when multiple providers request the same relief, a more general response to providers may be sent using the NYSDOH Health Commerce System (HCS) notification tool, notifying them of the response and any relevant details.

NOTE: Statutes or regulations cannot be pre-approved for suspension or modification. A new request must be made every time a disaster presents. NYSDOH will evaluate and respond to each request based on the unique circumstances emergencies present.

The requester should not anticipate that a statute or regulation will be suspended or modified until an Executive Order is issued.

APPENDIX A NYSDOH Contact Information

Division of Hospitals and Diagnostic & Treatment Centers (including Community Health Centers)

<u>REGION</u>	<u>TITLE</u>	<u>TELEPHONE NUMBER</u>
Capital	Regional Program Director	(518) 408-5329
Central	Regional Program Director	(315) 477-8592
Metropolitan	Regional Program Director	(212) 417-5990
Western	Regional Program Director	(716) 847-4357 (Buffalo) (585) 423-8141 (Rochester)
Central Office	Division Director	(518) 402-1004

Division of Nursing Homes and Intermediate Care Facilities/ Individuals with Intellectual Disabilities Surveillance

<u>REGION</u>	<u>TITLE</u>	<u>TELEPHONE NUMBER</u>
Capital	Regional Program Director	(518) 408-5372 or (518) 408-5433
Central	Regional Program Director	(315) 477-8417
Metropolitan	Regional Program Director	(212) 417-6197
Western	Regional Program Director	(716) 847-4348 (Buffalo) (585) 423-8019 (Rochester)
Central Office	Division Director	(518) 408-1267

Adult Care Facility and Assisted Living Surveillance Program

<u>REGION</u>	<u>TITLE</u>	<u>TELEPHONE NUMBER</u>
Capital	Regional Program Director	(518) 408-5287
Central	Regional Program Director	(315) 477-8472
Metropolitan	Regional Program Director	(212) 417-5814
Western	Regional Program Director	(585) 423-8185
Central Office	Division Director	(518) 408-1133

Division of Home and Community-Based Services

<u>REGION</u>	<u>TITLE</u>	<u>TELEPHONE NUMBER</u>
Capital	Regional Program Director	(518) 408-1128
Central	Regional Program Director	(315) 477-8422
Metropolitan	Regional Program Director	(212) 417-4970
Western	Regional Program Director	(716) 847-4655 (Buffalo) (585) 423-8142 (Rochester)
Central Office	Division Director	(518) 473-9871

OFF HOURS

(for all facilities and providers)
Weekdays 5 p.m. – 8 a.m.,
Weekends, and Holidays

Duty Officer (866) 881-2809

APPENDIX B

Sample List of Statutory and Regulatory Barriers Submitted by Associations

The following lists of potential statutory and regulatory barriers were collected by healthcare associations from their respective memberships in an effort to reduce the time and resources necessary to compile this information during an emergency. **These lists are not meant to be comprehensive. Statutes and regulations cannot be pre-approved for suspension or modification prior to an emergency due to the unique conditions each disaster presents.**

Adult Care Facilities

- Empire State Association of Assisted Living
- Leading Age New York
- New York State Center for Assisted Living

Community Health Centers

- Community Health Care Association of New York State

Home Health Agencies

- New York State Association of Health Care Providers
- Home Care Association of New York State

Hospitals

- Healthcare Association of New York State
- Iroquois Healthcare Association
- Rochester Regional Healthcare Association
- Suburban Alliance (Northern Metropolitan Hospital Association and Nassau-Suffolk Hospital Council)
- Western New York Healthcare Association

Nursing Homes

- Healthcare Association of New York State
- New York State Health Facilities Association
- LeadingAge New York

Statutes and regulations cannot be pre-approved for suspension or modification. A new request must be submitted for every disaster due to the unique circumstances each disaster presents.

APPENDIX B: ADULT CARE FACILITIES

485.5/1001.4: Operating Certificate

Imposition of civil penalties for operators that cease operations without prior approval and notification submission to NYSDOH.

Adult Care Facility (ACF) registered nurse (RN) and licensed practical nurse (LPN) staff are not allowed to provide nursing in the ACF setting. ACF certified personal care aide and certified home health aide staff are not allowed to provide paraprofessional services in the ACF setting.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Major physical damage, extensive casualties, etc., are some of the factors that may contribute to a decision to “cease operations” by evacuating or closing.

The availability of medical personnel may not be easily attainable or even available based on the emergent event.

Suggested Suspension or Modification

Relocated residents are deemed to have been transferred to the receiving location to assure their health, safety, and wellbeing. When time allows the ACF provider to notify NYSDOH of evacuation in advance, NYSDOH responds and approves in a timely manner. When time does not allow the ACF provider to first consult with NYSDOH, the ACF provider is required to notify NYSDOH as soon as possible.

The operator of the evacuated/transferring facility will cooperate with operators or representatives of receiving facility(ies) including, whenever possible, providing the receiving facility with staff, service provision, medications/medical equipment, financial support, records/information about resident medical and behavioral conditions as well as their service needs/care plans.

ACF licensed and certified personnel will be allowed to act within their scope of tasks or practice.

487.4/488.4/494.4/1001.7: Admission and Retention Standards

Operators shall admit, retain, and care for only those individuals who do not require services beyond those the operator is permitted by law and regulation to provide.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Often there are one or more residents who have been determined to exceed the ACF level of care and for which an appropriate alternate setting is being sought but has not yet been located or secured. The receiving ACF provider may be concerned with accepting such individuals.

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This also applies to the temporary retention of a resident requiring a higher level of care during shelter-in-place. During the emergency event, it may not be practical or viable to continue with persistent efforts as required in 487.4 (k)/488.4 (g).

Suggested Suspension or Modification

Transfers based on Admission/Retention Regulations should be flexible based on the time and type of event. ACF resident admission and retention standards shall be maintained except that residents needing a higher level of care may be retained until an appropriate placement may be obtained. The responsibility for transfer of residents will remain with the original evacuating facility operator. The evacuating facility operator should continue to make “persistent efforts” during the emergency if it is viable to do so; otherwise, the requirements under these regulations should be relaxed. In the interim, all care needs of those residents must be appropriately and effectively met by trained and qualified staff.

For these people, in those cases where the receiving facility is also a licensed ACF, the receiving ACF must be allowed to temporarily accept the resident until persistent efforts can be resumed and/or an appropriate alternate setting is secured. Likewise, an ACF that is sheltering-in-place should be required to continue to make “persistent efforts” during the emergency if it is viable to do so; otherwise, the requirements under these regulations should be relaxed.

487.5/488.5/1001.8: Resident Protections—Resident Rights and Admission Agreement Provisions

Operators will support all protections covered under resident rights. These are as follows: “a resident shall have the right to have private, written, and verbal communications with anyone of his/her choice, a resident shall have the right to privacy in his/her own room and in caring for personal needs, and a resident shall be permitted to leave and return to the facility and grounds at reasonable hours.”

Also under this section of the regulations, an ACF operator is obligated to give at least 30 days’ written notice to the resident, the resident’s next of kin, and the person designated in the admission agreement as the responsible party, specifying the grounds for termination of such agreement and date of discharge and advising that the resident has the right to object to, and contest, involuntary termination.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

During emergency situations, certain resident rights and/or provisions of the Admission Agreement may need to be temporarily suspended to best protect the safety of residents and/or their visitors. Unless certain aspects are clarified or relaxed, during an emergency where evacuation is required, the ACF provider could potentially be in violation of resident rights and/or Admission Agreement provisions such as giving 30-day written notice, as well as other rights such as privacy in a person’s room.

continued...

Suggested Suspension or Modification

Every effort shall be made to protect the rights of residents and to adhere to the provisions of the Admission Agreement. However, in some circumstances, provisions such as allowing residents to have visitors and/or be able to leave and return may in fact jeopardize their safety and wellbeing, and the requirement should be relaxed based on the good faith judgment of the operator after conferring with the resident(s). Also, providing 30-days notice for a resident should be suspended and the operator not held liable during an event. (The transfer would not mean that the evacuating operator is moving to terminate the Admission Agreement and, to the extent possible, the provisions would remain in full effect. Also, residents will be kept informed of the emergency and disaster conditions, recovery efforts, and the effect on continued residency in both the evacuated and receiving facilities).

Freedom of movement shall be assured except that reasonable limitations may be required to assure resident health and safety.

487.6/488.6/1001.9: Resident Funds and Valuables

The operator shall issue a receipt to residents for any funds received, and residents shall have access to personal allowance accounts at least four hours daily (Monday-Friday); residents shall have an opportunity to review accounts, and the operator shall reconcile accounts using the personal allowance summary DSS-2855.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Operators maintaining Personal Needs Allowance and Valuables should continue to be accountable for distribution of property to residents; however, in the event of evacuation, the funds/valuables may not arrive at the same time of the transfer, mandated forms may not be available, and hours/days to review accounts may not be in accordance based on emergent events.

Suggested Suspension or Modification

Flexibility will be available as to the timely transfer of funds to the resident and/or the receiving ACF operator. Receipts and an accounting would still be maintained, but may require a less detailed format until the emergent event is over. All critical information would be recorded, but not necessarily on the NYSDOH-mandated forms to be determined, based on the event.

487.7/488.7/494.5/1001.10: Resident Services

Certain events—death, suspected felony, and attempted suicide—require immediate reporting to NYSDOH and a follow-up Incident Report (DSS-3123) within 24 hours (as well as notification to family and physician). Other types of events also require completion and submission of the DSS-3123. This section contains comprehensive requirements pertaining to resident supervision, from maintaining knowledge of the general whereabouts of each resident, to monitoring for abrupt or progressive changes in health status, to ensuring adequate supervision during an evacuation.

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This section also lists the ACF provider’s obligations for the various ACF services that must be offered. In addition to supervision previously described, they are: personal care, medication assistance, case management, activities, food service, and housekeeping.

Assisted-living residences (ALRs) are required to create and adhere to an Individualized Service Plan (ISP).

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

During a catastrophic event, the evacuating and/or receiving facility may not always be able to meet reporting requirement timeframes and/or perform other supervision functions as required.

There are likely to be barriers to meeting all of the requirements in the various service categories. For instance, the provider may not always be able to ensure that each meal is “balanced,” they may not be able to perform the annual case management evaluation that is due at a 12-month period; or guarantee that the 1.5-hour window for medication assistance is honored if the medications are for some reason not available, or during the actual transfer of residents. These are just a few examples of the many provisions in this section that might not be achievable depending on the circumstances.

Suggested Suspension or Modification

While maintaining the spirit of the original regulations and providing for the basic needs and safety of residents, temporary flexibility to waive timeframes and mandatory deadlines as circumstances dictate based on resident needs and the emergent event will be allowed on a case-by-case basis. Allow for “reasonable” attempts to meet regulatory guidelines. Relaxed timeframes for completion of mandated DSS-3123 and other NYSDOH reports would be invoked during an emergent event.

Case management notes may be recorded on a pre-developed form/log that would document a date/time/issue/person reporting similar to a “communication log” used for resident care aides.

Care and service plans, including the ISP, will be followed to the fullest extent possible.

Incidents would also be recorded in a similar format, if necessary on a daily log. Operators will focus on the safety and wellbeing of all residents, which may occupy much of their time during the event, preventing the completion of such requirements. Priority would be given to notifying the family or resident representative and NYSDOH in the event of a death. Incident reporting may be documented in a notebook and later transferred to the mandated NYSDOH forms.

Priority would be given to accommodating minimal dietary restrictions based on the individual resident requirements. Meeting medication timeframes may not be attainable based on the event and if medication delivery is suspended by pharmacies.

A variety of group and individual activities will be provided, but may not meet the requirements pertaining to diversity of activity and/or times that the activities are provided, and/or including activities outside of the facility. Likewise, services such as housekeeping and laundry will be provided to keep residents safe and clean, but may not be provided at the frequency or level as is provided during the normal course of business.

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487.8/488.8/1001.10: Food Service

Operators shall provide meals that are balanced, nutritious, and adequate in amount and content to meet the daily dietary needs of residents.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Emergency food and water supplies maintained by the operator may be the only source of nutrition for a period of time during an emergency. While maintaining a focus on special dietary restrictions and nutrition will be followed to the maximum extent possible, the American Dietary Association's recommended guidelines relating to daily consumption may be unattainable.

Suggested Suspension or Modification

Reasonable modifications in menu preparation, substitutions, mealtimes, variety of foods, methods of preparation, food service systems, and use of disposables may be made based on the availability of food, staff, space, and equipment.

487.9/488.9/494.6/1001.11: Personnel

Operators shall provide staff sufficient in number and qualified by training and experience to render, at a minimum, those services mandated by statute or regulation. Operators shall conduct an initial program of orientation and training for all staff and volunteers. Operators shall maintain/obtain employee records, physicals, Purified Protein Derivative (PPD) testing, and documented training records. Minimum staffing times for various functions will be assigned (i.e., housekeeping, one hour).

ACF RN and LPN staff are not allowed to provide nursing in the ACF setting. ACF certified personal care aide and certified home health aide staff are not allowed to provide paraprofessional services in the ACF setting.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Regulation requirements may not be fulfilled based on many variables presented during an emergent event. The staffing ratio may vary based on ability to make it to work. Required documentation may be unavailable to retrieve from physicians. Required training may not transpire based on the variables of the event during the required timeframes.

The availability of medical personnel may not be easily attainable or even available based on the emergent event.

Suggested Suspension or Modification

To the extent possible, utilizing trained staff and volunteers already approved to work in the ACF up to and including family members, will be the pursued standard. However, based on the circumstances, flexibility to provide the minimum amount of training/orientation during an event, with focus on the immediate safety of residents, will be allowed.

Flexibility will be given to utilize other individuals in the event the regulation cannot be met in order to maintain a standard of care and safety for the residents affected.

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Required minimum staff hours may be relaxed based on availability of the staff and on the needs of each resident.

Training requirements for staff and volunteers will be relaxed; however, training that must be provided will include location and use of: fire extinguishers; emergency equipment; emergency shut-off valves for gas/electric/water; emergency food/water supplies; e-Finds equipment; all exits; emergency contact phone numbers; temporary tracking forms/logs to be utilized in the event required documentation/forms were not attainable or feasible to utilize during the event; and, to the extent that non ACF staff individuals would provide personal care services, instruction and then direct observation to determine competency, with regular supervision provided thereafter.

ACF licensed and certified personnel will be allowed to act within their scope of tasks or practice.

487.10/488.10/1001.12: Records and Reports

Maintenance of resident and facility records such as resident medical and mental health evaluations, personal allowance, staffing schedules, daily census, records of food purchases, menus, activity calendars, etc. This section also contains provisions regarding use of NYSDOH-mandated forms, reports to be submitted to NYSDOH, and the required length for records retention.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Blank copies of NYSDOH-mandated forms may not be available. Some records and documents may be destroyed or damaged, preventing the completion of required reporting per the timeframes specified and/or records retention obligations. The operator may not have access to the internet in order to submit NYSDOH-required reports via the Health Commerce System.

Suggested Suspension or Modification

Resident and facility recording will be maintained to the extent practicable including census, receipts, and accounting of all resident accounts and property, medical and mental health reports and evaluations, service provision including medication assistance and case management notes; however, NYSDOH forms and formats would not have to be utilized and required timeframes may be exceeded for the duration of the emergency. Operators would be required to complete reports as soon as possible based on the circumstances and the stabilization of the emergency event.

487.11/488.11/494.7/1001.13: Environmental Standards

The operator shall maintain the facility in a good state of repair and sanitation, and in conformance with applicable state and local laws, regulations, and ordinances. There shall be a minimum of one toilet and one lavatory for each six residents and a minimum of one tub/shower for each ten residents. No more than two residents may share a bedroom.

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Maintenance of an inside temperature of at least 68° in cold weather and taking measurements of air temperature inside the building when outside temperature is >85° to ensure comfort are required.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

There may be loss of power, no generator or no fuel for the generator, malfunctions in equipment, damage with the inability to repair or secure a vendor to complete the repair/service based on the event.

Temporary living arrangements may not meet the various square-foot size, maintenance, and repair requirements, and may result in more than two residents sharing a room. Minimum requirements for toilets/lavatory/tub/shower may be unattainable based on damage from the emergent event and/or what is available in the receiving facility.

There are many provisions within this section that, while required, may not be present in an emergent event.

Suggested Suspension or Modification

Suitable and adequate space that is a safe, clean, comfortable environment, in a good state of repair and sanitation with required smoke and fire protection will be maintained to the extent possible. However, physical plant certified capacity may be exceeded. Square-foot size and furnishing requirements do not have to be met, nor do other minimum standards that are not directly related to the immediate safety and comfort of the resident.

487.12/488.12/1001.14: Emergency Plans

Accessing the Health Commerce System (HCS) and developing and following emergency plans.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Access to HCS may not be available to the ACF provider during the emergent event, nor may staff with HCS access. Agreements with other service providers that are part of the emergency plan may not be met based on their availability and willingness and/or the circumstances of the event.

Suggested Suspension or Modification

If HCS is not accessible, there should be flexibility in when and how communication between NYSDOH and the ACF provider will be received/sent during the event. ACF providers will make every effort to carry out all provisions of the emergency plan; however, they will not be held responsible for the unavailability or unwillingness of other providers with whom they have agreements.

continued...

Part 80 Rules and Regulations on Controlled Substances in NYS (Statutory Authority: Public Health Law, Section 338, 3300, 3305, 3307, 3308, 3381, 3701(1),(6), Art. 33); General Provisions 80.2 Exemptions

The restriction of the possession of controlled drugs by anyone other than licensed/certified staff. Access to controlled substances shall be limited to minimum number of employees.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Licensed/certified personnel may not be available based on the numerous variables of an event, and controlled substances and other medications may need to be transported with evacuating residents to other entities by unlicensed staff.

Suggested Suspension or Modification

Part 80—Rules and Regulations on Controlled Substances in NYS, Section 80.2
EXEMPTIONS: (a) Pursuant to section 3305 of the Public Health Law, the provisions of this Part restricting the possession of controlled substances shall not apply to:
80.2(a)(3)—temporary incidental possession by employees or agents of individuals lawfully entitled to possession or by people whose possession is for the purpose of aiding public officers in performing their official duties.

continued...

Statutes and regulations cannot be pre-approved for suspension or modification. A new request must be submitted for every disaster due to the unique circumstances each disaster presents.

APPENDIX B Community Health Centers

Certificate of Need (CON)

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Complying with this regulation could limit the service area of the Federally Qualified Health Center (FQHC).

Suggested Suspension or Modification

A temporary expansion of the Certificate of Need into affected areas or areas declared to need medical services or to service an under-served population would allow for response flexibility and get outpatient care to affected areas.

Section 224 of the Public Health Service Act: FTCA Malpractice Coverage

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

FQHC providers are covered for liability under the Federal Tort Claims Act (FTCA). Ensuring that their coverage is extended outside their authorized area is critical for their use. Presently, a condition of coverage is that the FQHC follow its displaced medically under-served population to continue to serve them; and, in order to gain coverage outside the service area, the covered entity (FQHC) must demonstrate that the population has been displaced by the emergency and that other displaced medically under-served population may need their services as well.

Suggested Suspension or Modification

A suspension of required demonstration that population being served is either under-served or is the same population served by the covered entity. This will ensure that providers covered will continue to be covered in disaster areas regardless of the population served.

Education (Ed.) Law Article 133: Vaccination Provider Expansion

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Many FQHCs have dental departments and the suspension of this regulation can expand the pool of qualified vaccinators during disasters.

Suggested Suspension or Modification

Enable dentists and other qualified health professionals (podiatrists and paramedics) to administer tetanus vaccines under the supervision of a physician or nurse practitioner (NP) to people above the age of 18.

continued...

Ed. Law Section 6527(7): Physician Prescription Expansion

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Under the provision, physicians and NPs cannot order other health practitioners to give vaccines.

Suggested Suspension or Modification

Suspension of this rule would allow physicians to order the vaccination in a point-of-delivery or other mass immunization sequence.

Statutes and regulations cannot be pre-approved for suspension or modification. A new request must be submitted for every disaster due to the unique circumstances each disaster presents.

APPENDIX B Home Care Agencies

PHL Articles 28-E & 36; Ed. Law Article 139; Associated Regulations

Scope of Practice: RNs must be licensed in NYS.

Home health aides must be certified in NYS.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Home care patients may be unable to receive nursing or home health aide services in a timely manner due to short staffing.

Examples:

1. Patients requiring life-sustaining equipment or medications.
2. Those needing highly skilled wound care.
3. Unstable patients with no caregiver or informal (family) support to provide care.

Suggested Suspension or Modification

Provide for a rapid endorsement of out-of-state RNs and home health agencies to provide services supporting Home Health Agency Classification Levels.

10 NYCRR 766.5

RN must conduct supervisory visit for new home health aide/personal care aide/patient.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

RN unable to conduct supervisory visit in a timely manner due to staffing shortage or transportation issues.

Suggested Suspension or Modification

Waive time/requirement during the emergency event; eliminate Statements of Deficiency (SODs) post-event. Conduct phone orientations for new aides during event.

continued...

10 NYCRR 766.3

MD orders required for change in hours of service for HHAs.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

A reduction in level of services may be required due to short staffing, increased staffing demands, transportation issues, physical barriers, etc. An increase in level of services may be required due to absence of family member or change in patient condition/status. The home care agency may be unable to obtain change in MD orders in a timely manner to accommodate service needs during emergency situation.

Suggested Suspension or Modification

Modify requirement during the emergency event to permit RN authorization of change in service hours.

10 NYCRR 766.4; 10 NYCRR 763.7; 42 CFR 484.18

MD orders required to provide HHA services.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

The home care agency may be unable to secure timely MD orders for new admissions or for reauthorization of MD orders nearing expiration date. Possible communication delays will inhibit ability to provide timely services.

Suggested Suspension or Modification

Modify requirements during the emergency event to permit: authorization by an agency or an affiliated medical director; authorization by an NP or physician assistant (PA) functioning under NYS requirements for physician collaboration; extensions of MD orders past expiration date; extension for start of care orders.

10 NYCRR 766.6

Documentation: Patient care record.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Staffing shortages or timing issues may prohibit the ability to satisfy full documentation requirements within required timeframes.

Suggested Suspension or Modification

Waive requirement/extend timeframe during the emergency event; eliminate SODs post-event.

continued...

10 NYCRR 763.6; 10 NYCRR 766.3; 10 NYCRR 766.6

Documentation: Patient-specific plan of care.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Staffing shortages or timing issues may prohibit the ability to satisfy full documentation requirements within required timeframes.

Suggested Suspension or Modification

Modify requirements to provide flexibility to satisfy point-of-care documentation requirements during the emergency event; eliminate SODs post-event. Work with providers to create a template for an abbreviated/preliminary plan of care document for use in emergencies, to be subsequently reconciled to a full plan of care as soon as the emergency/recovery permits.

PHL Article 36; PHL Article 40; Associated Regulations: 10 NYCRR 762.2

Certified Home Health Agencies (CHHAs)/Long-Term Home Health Care Programs (LTHHCPs), hospices, and Licensed Home Care Services Agencies must be approved to operate in specific geographic service areas.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Because of this requirement, agencies/areas needing reinforcement from entities outside the service area are precluded from receiving their assistance. In turn, such outside entities (though willing and needed) lack authorization to serve patients in need of care in the emergency area. Agency/patient access needs, which may surge or radically shift due to emergency conditions, are thus constrained from receiving outside help due to the geographic service limitation.

Flexibility is also needed to ensure that patients under care can continue to receive services at a new location which may not be within the agency's approved CON area. For example, a patient who resides in Queens moves in with a family member in Nassau County and the agency is able to send the staff to provide care at the new location, but the location is not within the approved geographic boundaries.

Suggested Suspension or Modification

Suspend geographic limitations on home health agencies, hospices, and durable medical equipment suppliers; establish and implement temporary reciprocal agreements between states to allow for delivery of home health services where needed.

Allow home care staff emergency parking privileges whether in or outside of normal service areas during emergencies.

continued...

10 NYCRR 763.4; 10 NYCRR 766.5; 18 NYCRR 505.14

Scope of Practice: Supervisory personnel are required to conduct in-home supervision of home health aides/personal care aides after initial service visit.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Staffing shortages may prevent supervisory personnel (RN, LPN, and PT/OT) from completing supervisory responsibilities within required timeframes.

Suggested Suspension or Modification

Waive; maintain reasonable flexibility to accommodate emergency circumstances with the most practicable methodology.

10 NYCRR 763.5—Initial Service Visit

Documentation: Initial service visit required within 24 hours of referral.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Home health agencies may be unable to conduct the initial service visit within 24 hours due to severe weather, staffing shortages, travel restrictions, or limited resources.

Visit can be re-scheduled as soon as safe and practicable (given emergency conditions) after notifying the patient and the doctor.

Provider Example: “This was a significant problem for (our agency) during Sandy. We had capacity issues and needed an extended window of at least 72 hours to respond and get to patients already under care as well as new patients. We needed time to staff up.”

Suggested Suspension or Modification

Waive time/requirement during emergency event; maintain reasonable flexibility to accommodate emergency circumstances; eliminate SODs post-event.

Notification to facilities of such suspension would ease facility discharge traffic or patient/family expectation.

10 NYCRR 763.7; 10 NYCRR 766.4; 18 NYCRR 505.14; 18 NYCRR 505.28

Documentation: MD orders must be obtained/forwarded within 30 days of medical examination.

Associated requirements regarding verbal orders, orders for change in plan of care, renewal of orders.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Staffing shortages and limited resources may prevent MD orders from being completed and/or forwarded to the local department of social services within required timeframes.

continued...

During an extended emergency, it is often not possible to reach the physician to obtain orders signed within the mandated timeframe.

Potential delays in receipt of written orders and 60-day renewal of orders due to:

- Delay in medical practitioner response and signing of “routine” documents (medical practitioner re-prioritization of non-care related tasks).
- Power outages prevent timely receipt of MD email.
- Delays in receipt of paper documents (medical orders) from clinician due to staff safety/travel restrictions.
- Power outages preventing compliance of agency workflows relating to timely receipt and tracking of medical orders.
- Lack of ability to effectively maintain telephone/email communication with medical practitioners.

Overall, receipt of signed physician orders within the 30-day regulatory window and especially for change in plan of care is a tremendous burden during an emergency.

Verbal orders are also hard to obtain in emergencies, but all other orders have a tremendous impact during a disaster. It takes time to prepare and to recover from a disaster, so during recovery the essentials are the priority. Orders that need to be signed to meet protocol might not be the priority.

Suggested Suspension or Modification

Waive time/requirement during emergency event; maintain reasonable flexibility to accommodate emergency circumstances; eliminate SODs post-event.

The window for signatures on orders should be extended, depending on the incident.

Flexibility should be provided relative to requirements for receipt of verbal orders, signed copy of medical orders, ordered changes and renewals; and timeframes for receipt of initial signatures on orders should be extended, as needed, with flexibility for further extension depending upon the emergency situation.

During acute episodes and for new patients, agencies should be allowed to use their medical director or a physician other than the primary care physician (PCP) to authorize home care for that individual until the PCP can be contacted.

Temporarily suspend timeframe for verbal order receipt and also for transmission of documentation. Revisit scenario daily to assess and evaluate process. Revert to paper when appropriate.

Orders for change in plan of care are a tremendous burden during an emergency; documentation indicating that there was an emergency and that the plan of care was not necessarily adhered to or revised should suffice and keep the agency in compliance.

continued...

10 NYCRR 763.6—Patient Assessment and Plan of Care; Federal 42 CFR 484.55—Outcome and Assessment Information Set (OASIS) Requirements; Federal 42 CFR 424.22—Face to Face (F2F)

Patient Assessment:

- **Timetable for completing assessment, reassessment.**
- **Completion of Outcome and Assessment Information Set (OASIS) Face to Face documentation.**

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

During an emergency, it may not be possible to keep the timetable for completing the patient assessment and reassessment, nor for the Face to Face encounter with the community physician, who may not be accessible or if the patient cannot travel to see the physician.

Potential delays in timely completion due to:

- Clinical staff increased workloads.
- Travel and communication disruption.
- Diminished ability to perform comprehensive assessments/reassessments due to time limitations and need to re-prioritize caseloads and visits.
- Reassessments—need to adjust client visit priorities, e.g., focus on priority cases vs. routine assessments on clients whose needs are met and who are lower visit priorities.
- F2F—Lack of ability to effectively maintain telephone/email communication with medical practitioners; delay in medical practitioner response.
- Staff have challenges obtaining access to patients in affected areas and/or shelters. It would be challenging to complete necessary documentation in a timely manner.

During an emergency, as hospitals attempt to discharge patients, the number of admissions increases in the home health agencies, resulting in surge needs and in necessity for flexibility in usual required timeframes and documentation.

Suggested Suspension or Modification

Waive/modify/provide flexibility relative to regulations and timeframes for verbal orders, assessments, and related documentation.

Waiver/flexibility provisions in the November 12, 2012 NYSDOH “Dear Administrator” Letter (DAL), issued for Hurricane Sandy regulatory relief by Center for Health Care Quality and Surveillance Director Keith Servis, should serve as a basis for relief in future disasters, and be issued timely.

During emergencies, extend 30-day timeframe for the patient to see his community physician to have the mandated F2F encounter.

Permit F2F documentation to be done by an NP or NP in Psychiatry during a declared emergency.

continued...

During declared emergency, permit use of the abbreviated OASIS form without penalty.

Institute a reconciliation period for documentation and requirements during or following the recovery phase, taking into account workload, backlog, and financial implications.

10 NYCRR 763.6—Patient Assessment and Plan of Care; 10 NYCRR 763.4—Policies and Procedures of Service Delivery; Federal CFR 411.404(b) and (c), 411.408(d)(2)—CMS Home Health Change of Care Notice “HHCCN” Requirements (formerly “HHABN,” Advanced Beneficiary Notice)

- **Development of patient-specific plan of care.**
- **Change in plan of care—hours, services, etc. Home Health Advance Beneficiary Notice provided.**

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Emergency conditions may interfere with the development of a specific plan of care, and prior authorizations for a change in the plan of care may not be possible, practicable, or safe.

There is the need for provider flexibility in following the plan of care based on need to modify hours up or down, individual services, or personnel based on need and availability or lack of staff availability.

It might be difficult to reach physicians during a disaster, thus hindering development or change of the plan of care.

The delivery of the federally required HHCC/ABN prior to discharge may not be possible because of the emergency if the patient is not accessible and/or available.

Suggested Suspension or Modification

Extend the timeframes, amend/provide flexibility with requirements as needed to address aforementioned barriers.

Allow for an abbreviated Unified Assessment System (UAS) or other assessments, including abbreviated OASIS. Work with providers to create abbreviated UAS template.

Ensure provider flexibility in following the plan of care based on need to modify hours up or down, individual services, or personnel based on need and availability or lack of availability of staff.

Document attempts made to reach the physician and then follow up on the needed orders once the emergency has passed.

continued...

10 NYCRR 763.5—Patient Referral, Admission, and Discharge

Admission Requirements

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

See above issues with respect to challenges/adversity in strict regulatory/timetable compliance for services during emergency conditions.

Suggested Suspension or Modification

See above recommendations.

There should be flexibility for adherence to admission requirements during emergencies without penalties. There should be allowance for a triage process enabling agencies to prioritize cases and actions as necessary per patient need and emergency conditions.

Relax/modify requirements until **after** defined period of recovery, and provide alternate guidance for flexibility on admission including with regard to homebound status (as emergency conditions may warrant this waiver). Flexibility during recovery period may be lengthy as recovery flexibility not only includes activities directly related to service during and immediately post the emergency, but implications due to the loss of revenue, support of staff, and community impact.

10 NYCRR 763.4—Policies and Procedures of Service Delivery; 10 NYCRR 763.7—Clinical Records; 10 NYCRR 763.6—Patient Assessment and Plan of Care

- **Assignment of specific aide to specific patient.**
- **Written instructions for aide prepared by RN.**
- **Aide demonstration of competence to perform tasks for patient.**
- **Safety and appropriateness.**

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Assignment of specific aide and provision of written instruction may not be possible in given emergency situations where the patients are displaced and the needed personnel are not available.

During an emergency/disaster, home care agencies provide care based on acuity reporting, family/caregiver direct involvement, availability of staff, ease of movement within restricted areas, and access to transportation.

Suggested Suspension or Modification

Suspend/provide flexibility to these requirements during the emergency, commensurate with the conditions. Allow home care agencies flexibility to staff according to availability of staff and provide care based on need during these conditions.

Allow agency to bring on volunteer RN staff, credentialed provisionally based on the emergency with basic licensure checks and a simplified orientation.

continued...

10 NYCRR 763.11—Governing Authority

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Individual scenarios dictate modification to staffing schedules. All attempts are made to maintain compliance with regulations.

Suggested Suspension or Modification

In declared emergencies, the assignment of a specific aide to a specific patient with “special circumstance” needs should be modified or altogether waived.

Permit a home health aide with specific skill sets, training, and demonstrated competence, but who has not met the requirements of being supervised on a specific case, to assume care of patients requiring the special circumstance care.

Suspend home health aide supervision timetable and requirement. Resume as soon as practicable and reasonable following the emergency.

Provide flexibility as it relates to scheduling, increased hours, and tasks.

Coordination of care requirements must be contingent upon ability to communicate with patients, make referrals, and communicate with related disciplines and physicians.

Assignment of aides should be allowed to be prioritized.

Practicable requirements should be implemented and allowed relating to staff ID.

Regulation should allow for verbal instructions during an emergency.

There should be a modification for the demonstration of competent task performed by an aide during an emergency; if there is verbal communication, an assessment of the aide competence should take place.

10 NYCRR 763.4—Policies and Procedures of Service Delivery; 10 NYCRR 763.13—Personnel

Scope of Practice:

- **Personnel are assigned to the care of patients in accordance with their licensure, as appropriate, and their training, orientation, and demonstrated skills.**
- **Requirements for in-state licensure (i.e., as related to the ability of neighboring state agencies or practitioners to cross borders to assist in providing services in emergencies).**

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Emergency conditions limit staff availability and staff access to patients; the requisite level of professional or aide may not be available to the patient as needed. The situation is exacerbated by simultaneous surge in demand for care occurring during an emergency.

continued...

Staffing flexibility may be needed to ensure fulfillment of tasks for patients, and particularly to avoid potential vital gaps in care.

Suggested Suspension or Modification

Permit licensed, credentialed healthcare professionals from other states, with similar scope of practice rules, to practice in NYS to help fill needs in a declared emergency; also volunteers or temporary contract assistance from within the state.

Provide flexibility in regulatory qualifications for practice/fulfillment of tasks in home care on an emergency basis, as needed. Work with providers, practitioners, and State Education Department to create a template of permissible, acceptable tasks that, in an emergency, alternate practitioners/attendants can be directed to provide.

10 NYCRR 763.5—Patient Referral, Admission, and Discharge

Discharge: Standards for discharge.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

- Safety risks/hazards related to travel disruptions.
- Communication disruptions with clients, medical practitioners, and agency office.
- Home visit (HV) schedule overload without flexibility related to timely discharges (client visit re-prioritization with necessary adjustments).
- Some client discharges via telephone may be necessary, as client may not be in his or her own home (living out of area, with relatives, etc.).

Example of risk/negative impact to patients: Potential reduction in provision of quality care due to staff HV schedule overload.

Suggested Suspension or Modification

Suspend/grant flexibility in standards for discharge, until the emergency is declared over and recovery process permits appropriate resumption of standards.

Allow providers to prioritize patients and response to patients' needs; discharge visits and protocols must be allowed to be subordinate to those higher priorities.

continued...

18 NYCRR 540.6—Billing for Medical Assistance; CSC-EMEDNY FOD 7001— Exceptions for Submitting Claims Over 90 Days from Date of Service; Federal 42 CFR 424.44—Time Limits for Filing Medicare Fee-for-Service (Part A and Part B) Claims; Federal 42 CFR 424.22—Face to Face; Federal 42 CFR 424.516—PECOS Enrollment

Claims/Billing:

- **Timely filing of Medicaid/Medicare claims.**

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

The ability to bill, including timely billing within the Medicaid or Medicare window, can be impaired during emergencies, due to impairment of operations and billing systems, redirection of staff activities, and other.

Providers' ability to comply with additional procedures ordinarily mandated for payment, e.g., signed physician orders; face to face; use of only Medicare Provider Enrollment, Chain, and Ownership System (PECOS)-enrolled physicians (federal) or Medicaid-enrolled (state) physicians; and others are also likely to become impaired during emergencies, necessitating flexibility in order for providers to be able to be reimbursed.

In addition, agencies incur extraordinary costs for services and operations during emergencies that are not eligible for direct billing and that also are not recoverable through the agency's Administrative & General allocation. Agencies are impacted in cash flow, loss of eligible claim reimbursement, and unrecoverable funding for services faithfully provided.

Suggested Suspension or Modification

Suspend/extend Medicaid and Medicare timeframes for billing; provide for EmedNY exception code to Medicaid 90-day billing requirement.

Providers need flexibility regarding timeframes for claims and billing during declared emergencies; timeframes should be frozen during the entire time of the declared emergency as well as until after a defined period of recovery.

State and federal flexibility needs to be provided (through suspension or other easement of requirements) to permit reimbursement when emergency conditions impair compliance with prerequisites including face to face, signed orders, PECOS, and others.

continued...

Federal 42 CFR 484.20—Reporting of OASIS-derived Information; 10 NYCRR 86-1.13 Rates; 86-1.44; 86-5.2; 86-6.4; 763.14; 766.12

Reporting:

- **Agency reporting of OASIS information.**

DOH Statistical/Cost Reporting

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

All CHHAs and LTHHCPs are required to collect and report via internet OASIS-derived data.

Agencies impacted by emergencies must be allowed to prioritize patient care and agency operations related to care, management, and safety.

Given such patient care and safety priorities, the ability to timely report mandated OASIS information to the state and federal government and/or to fulfill other non-emergency reporting, is necessarily compromised during the emergency period. Therefore, easing of reporting requirements and timeframes is necessary for prioritization to ensure patient care and safety.

Suggested Suspension or Modification

Until the emergency is ended and the recovery sufficient, all non-emergency reporting requirements and deadlines should be waived.

continued...

Statutes and regulations cannot be pre-approved for suspension or modification. A new request must be submitted for every disaster due to the unique circumstances each disaster presents.

APPENDIX B Hospitals

Ed. Law Article 139

Nurses must be licensed in NYS to provide services to patients in NYS.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patients unable to receive services due to low staffing.

Suggested Suspension or Modification

Allow out-of-state licensed nurses to provide general nursing care.

10 NYCRR §400.9; 10 NYCRR §405.9 (f)(7)

Transferring a patient or resident from one facility to another requires certain provisions.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patients unable to receive care due to limited or no bed availability within the affected facility.

Suggested Suspension or Modification

Allow Article 28 facilities affected by the disaster/emergency to rapidly discharge, transfer, or receive patients, provided all reasonable measures to protect patient health and safety are taken.

10 NYCRR §400.11

Requires that hospitals shall have sufficient trained and qualified screener(s) and assessor(s) for assessment of long-term care patients.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patients unable to be accepted from an evacuating hospital due to a receiving hospital not having enough qualified screeners available.

Suggested Suspension or Modification

To permit Article 28 facilities receiving patients evacuated from other Article 28 facilities due to the disaster/emergency to complete patient review instruments as soon as practicable.

continued...

10 NYCRR §405.2(e)

Provides for appointment of medical staff and granting of professional privileges.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Hospital unable to complete usual appointment and privileging in a timely manner to provide patient care during an emergency.

Suggested Suspension or Modification

Permit hospitals to maintain adequate staffing.

10 NYCRR §405.3(b)

Establishes requirements of personnel policies and procedures including volunteers.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Performance of physical exam, verification, and other requirements may delay qualified medical volunteers from being able to provide patient care as needed in an emergency.

Suggested Suspension or Modification

Allow hospitals to use qualified volunteers or personnel affiliated with different hospitals, subject to terms and conditions established by the Commissioner of Health.

10 NYCRR §405.9(b)(12)

Every patient shall have a complete history and physical examination performed by an appropriately credentialed practitioner within 30 days before or 24 hours after admission.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patient care may be delayed due to time requirements and staff resources needed to complete required volunteer processing.

Suggested Suspension or Modification

Permit hospitals receiving patients transferred/evacuated as a result of the disaster/emergency to arrange for the performance of histories and physical examinations of the evacuated patients as soon as practicable following admission.

continued...

10 NYCRR §405.19(d)

Establishes requirements for emergency services physicians.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Surge in emergency services may exceed normal emergency services physician staffing.

Suggested Suspension or Modification

Allow hospitals affected by the disaster emergency to staff their emergency departments as needed.

10 NYCRR §405.28(a)

Requires that each patient be screened prior to or upon admission to determine the need for social services, and that such services be provided as the patient requires.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Such screening may delay or impede the provision of patient care due to lack of qualified staff and/or need to expedite treatment, discharge, or transfer.

Suggested Suspension or Modification

Permit hospitals receiving individuals affected by the disaster/emergency to provide social services screenings as soon as practicable following admission or to forego such screenings for individuals returned to facilities from which they were evacuated.

EMTALA

A Medical Screening Exam (MSE) must be provided by a Qualified Medical Provider.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patients with minor illnesses place burden upon qualified medical provider staff dealing with critically ill patients.

Suggested Suspension or Modification

In a public health emergency, an MSE on a patient who is triaged as a level 4 or 5 may have an MSE performed by a licensed/certified emergency department RN and referred elsewhere, if appropriate.

continued...

EMTALA

Provision of medical care occurs in a site-specific manner.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

If a site is badly damaged, it may not be able to render care.

Suggested Suspension or Modification

A medical director may use prudent judgment to temporarily relocate necessary medical supplies and diagnostic tools to a safe site for the provision of emergency care.

Public Health Law Article 28 S 2805-l; Section 405.8—10NYCRR Incident Reporting

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is an adverse event reporting system.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Patients not receiving adequate care due to decreased availability of staff time.

Suggested Suspension or Modification

Suspend NYPORTS reporting and other requirements similar in nature.

Statutes and regulations cannot be pre-approved for suspension or modification. A new request must be submitted for every disaster due to the unique circumstances each disaster presents.

APPENDIX B Nursing Homes

42 CFR §483.20 Resident Assessment

Requirements for completion/documentation/transmission of comprehensive assessments.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

This is a non-essential function, removes staff from providing essential care, and delays admissions to skilled nursing facilities (SNF).

Suggested Suspension or Modification

Waive requirements and deadlines during emergency event; allow delay of requirements until after emergency event and response has ended.

42 CFR §483.75 (e-h), (q) Administration

Requirements for credentialing and training of certified nurse assistants (CNAs), nurses, and feeding assistants.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policy would severely limit/delay SNF admissions and direct patient care.

Suggested Suspension or Modification

Waive procedural requirements during emergency event. Require ongoing supervision of “unchecked” credentials/training during event and until it can be completed following the event and response.

42 CFR §483.10, 483.12 Admission, Transfer, and Discharge

Outlines patient rights in discharge/transfer to nursing home.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policy would delay SNF admissions caused by time taken to inform about all patient rights immediately upon admission.

Suggested Suspension or Modification

Waive requirements and deadlines during emergency event; delay requirements to be completed for admissions until after emergency event and response has ended.

continued...

42 CFR §483.25(m) Scheduled Medication Administration

Timing of medication administration, intervals between administration, etc.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to administration deadlines would negatively impact essential resident care.

Suggested Suspension or Modification

Permit windows of administration times of routine medications during the event/response in impacted facilities.

Ed. Law Article 139

Nurses providing dialysis services must be licensed in NYS to provide services to patients in NYS.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policy would result in patients unable to receive life-saving dialysis services.

Suggested Suspension or Modification

Allow out-of-state licensed nurses to provide dialysis.

42 CFR §483.65 (b)(1)—Clinical/Infection Control

Regulation states, “When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.”

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policy would severely limit direct resident care, and resident relocations would detract from essential care activities.

Suggested Suspension or Modification

Permit cohorting of infected residents with caregivers following universal precautions.

PHL Article 36; PHL Article 40

Patients must be served within approved geographic locations.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Would severely limit SNF bed availability and transfer options during an emergency.

continued...

Suggested Suspension or Modification

Waive geographic/distance requirements for necessary transfers during the event. Permit relocations following the event.

42 CFR §483.35(f) Frequency of Meals

Interval requirements between meal times.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adhering to arbitrary time intervals between meals would detract staff from other essential care activities.

Suggested Suspension or Modification

Waive time requirements during an event. Permit frequent informal snacks and smaller meals as substitutes.

42 CFR §483.15 Activities/Quality of Life, Accommodation of Needs, Self-Determination and Participation, Housekeeping, and Maintenance Services

Requirements for assessment completion, scheduled programs, notification of room and roommate changes, assist with individual activities, addressing personal resident preferences, cleaning schedules and regimes.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policies would detract from more essential direct resident care maintenance of operations.

Suggested Suspension or Modification

Waive requirements. Permit deviations from activities, schedules, and plans of care.

10 NYCRR §400.9; 10 NYCRR §405.9 (f)(7)

Transferring a patient to another location requires certain provisions and processes.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to policies would detract from essential direct resident care and delay appropriate and necessary transfers during an emergency event.

Suggested Suspension or Modification

Waive requirements. Permit deviations from details.

continued...

42 CFR §483.25(a)(2) Clinical/Therapy

Requirements for five days of consecutive restorative rehabilitation.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Adherence to these requirements would detract from essential resident care activities.

Suggested Suspension or Modification

Waive the requirement for the duration of the event and eliminate any negative impact of the interruptions of the therapy schedule on Medicare eligibility.

42 CFR §483.45(a)(1)(2); 10 NYCRR 700.3; Pre-Admission Screening and Resident Review (PASRR); Patient Review Instrument (PRI)

Requirement for pre-admission screening for SNF placement.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

This is a non-essential function, removes staff from providing essential care, and delays admissions to SNFs.

Suggested Suspension or Modification

Suspend the PASRR/PRI assessment requirements during the event.

42 CFR §483.12(b) Notice of Bed-Hold Policy and Readmission

Requires timely notice of bedhold.

How Compliance May Prevent, Hinder, or Delay Action Necessary to Cope with a Disaster

Non-essential administrative function that detracts from essential resident care and facility operations.

Suggested Suspension or Modification

Waive requirement and eliminate negative payment consequences.

APPENDIX C:
Emergency Declaration
Definitions and Examples
*References from Emergency Declarations
for Local, State, and Federal Governments Table*

- C.1 Local Emergency Declaration
- C.2 Example of Local Disaster Proclamation and Executive Order
- C.3 State Emergency Declaration
- C.4 Suspension and Modification of State Requirements
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- C.11 Public Health Emergency Declaration
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- C.13 Example of Public Health Emergency Declaration and 1135 Waivers

APPENDIX C-1: Local Emergency Declaration

Executive

§ 24. Local state of emergency; local emergency orders by chief executive. 1. Notwithstanding any inconsistent provision of law, general or special, in the event of a disaster, rioting, catastrophe, or similar public emergency within the territorial limits of any county, city, town or village, or in the event of reasonable apprehension of immediate danger thereof, and upon a finding by the chief executive thereof that the public safety is imperiled thereby, such chief executive may proclaim a local state of emergency within any part or all of the territorial limits of such local government; provided, however, that in the event of a radiological accident as defined in section twenty-nine-c of this article, such chief executive may request of the governor a declaration of disaster emergency. Such proclamation shall remain in effect for a period not to exceed thirty days or until rescinded by the chief executive, whichever occurs first. The chief executive may issue additional proclamations to extend the state of emergency for additional periods not to exceed thirty days. Following such proclamation and during the continuance of such local state of emergency, the chief executive may promulgate local emergency orders to protect life and property or to bring the emergency situation under control. As illustration, such orders may, within any part or all of the territorial limits of such local government, provide for:

a. the establishment of a curfew and the prohibition and control of pedestrian and vehicular traffic, except essential emergency vehicles and personnel;

b. the designation of specific zones within which the occupancy and use of buildings and the ingress and egress of vehicles and persons may be prohibited or regulated;

c. the regulation and closing of places of amusement and assembly;

d. the suspension or limitation of the sale, dispensing, use or transportation of alcoholic beverages, firearms, explosives, and flammable materials and liquids;

e. the prohibition and control of the presence of persons on public streets and places;

f. the establishment or designation of emergency shelters, emergency medical shelters, and in consultation with the state commissioner of health, community based care centers;

g. the suspension within any part or all of its territorial limits of any of its local laws, ordinances or regulations, or parts thereof subject to federal and state constitutional, statutory and regulatory limitations, which may prevent, hinder, or delay necessary action in coping with a disaster or recovery therefrom whenever (1) a request has been made pursuant to subdivision seven of this section, or (2) whenever the governor has declared a state disaster emergency pursuant to section twenty-eight of this article. Suspension of any local law, ordinance or regulation pursuant to this paragraph shall be subject to the following standards and limits:

(i) no suspension shall be made for a period in excess of five days, provided, however, that upon reconsideration of all the relevant facts and circumstances, a suspension may be extended for additional periods not to exceed five days each during the pendency of the state of emergency;

(ii) no suspension shall be made which does not safeguard the health and welfare of the public and which is not reasonably necessary to the disaster effort;

(iii) any such suspension order shall specify the local law, ordinance or regulation, or part thereof suspended and the terms and conditions of the suspension;

(iv) the order may provide for such suspension only under particular circumstances, and may provide for the alteration or modification of the requirements of such local law, ordinance or regulation suspended, and may include other terms and conditions;

(v) any such suspension order shall provide for the minimum deviation from the requirements of the local law, ordinance or regulation suspended consistent with the disaster action deemed necessary; and

(vi) when practicable, specialists shall be assigned to assist with the related emergency actions to avoid adverse effects resulting from such suspension.

2. A local emergency order shall be effective from the time and in the manner prescribed in the order and shall be published as soon as practicable in a newspaper of general circulation in the area affected by such order and transmitted to the radio and television media for publication and broadcast. Such orders may be amended, modified and rescinded by the chief executive during the pendency or existence of the state of emergency. Such orders shall cease to be in effect five days after promulgation or upon declaration by the chief executive that the state of emergency no longer exists, whichever occurs sooner. The chief executive nevertheless, may extend such orders for additional periods not to exceed five days each during the pendency of the local state of emergency.

3. The proclamation of a local state of emergency and local emergency orders of a chief executive of a county shall be executed in quadruplicate and shall be filed within seventy-two hours or as soon thereafter as practicable in the office of the clerk of the governing board of the county, the office of the county clerk, the office of the secretary of state and the state office of emergency management within the division of homeland security and emergency services. The proclamation of a local state of emergency and local emergency orders of a chief executive of a city, town or village shall be executed in quadruplicate and shall be filed within seventy-two hours or as soon thereafter as practicable in the office of the clerk of such municipal corporation, the office of the county clerk, the office of the secretary of state and the state office of emergency management within the division of homeland security and emergency services.

4. Nothing in this section shall be deemed to limit the power of any local government to confer upon its chief executive any additional duties or responsibilities deemed appropriate.

5. Any person who knowingly violates any local emergency order of a chief executive promulgated pursuant to this section is guilty of a class B misdemeanor.

6. Whenever a local state of emergency is declared by the chief executive of a local government pursuant to this section, the chief executive of the county in which such local state of emergency is declared, or where a county is wholly contained within a city, the mayor of such city, may request the governor to remove all or any number of sentenced inmates from institutions maintained by such county in accordance with section ninety-three of the correction law.

7. Whenever a local state of emergency has been declared pursuant to this section, the chief executive of the county in which the local state of emergency has been declared, or where a county is wholly contained within a city, the chief executive of the city, may request the governor to provide assistance under this chapter, provided that such chief executive determines that the disaster is beyond the capacity of local government to meet adequately and state assistance is necessary to supplement local efforts to save lives and to protect property, public health and safety, or to avert or lessen the threat of a disaster.

8. The legislature may terminate by concurrent resolution, such emergency orders at any time.

APPENDIX C-2: Example of Local Disaster Proclamation and Executive Order



THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N. Y. 10007

EXECUTIVE ORDER NO. 163

PROCLAMATION OF A STATE OF EMERGENCY AND EVACUATION ORDER

October 28, 2012

WHEREAS, the National Weather Service is predicting that a hurricane or tropical storm may hit the City within hours; and

WHEREAS, the Governor has issued a Declaration of Emergency for the State of New York, including the City of New York and contiguous counties;

§ 1. Pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the Charter and Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency, I hereby declare a State of Emergency.

§ 2. This State of Emergency has been declared because anticipated weather conditions are likely to cause heavy flooding, power outages, and disruption of public transportation and other vital services, and these conditions imperil the public safety.

§ 3. The Office of Emergency Management, Police Department, Fire Department, Department of Health and Mental Hygiene, Health and Hospitals Corporation, Department of Sanitation, Department of Housing Preservation and Development, Department of

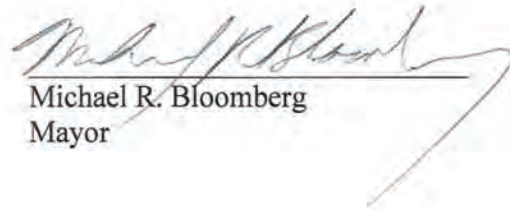
Sanitation, Department of Buildings, Department of Environmental Protection, Department of Transportation, New York City Housing Authority, Department of Housing Preservation and Development, Department of Design and Construction, Department of Homeless Services, Department of Correction, Department of Parks and Recreation, Department of Citywide Administrative Services, Office of Citywide Event Coordination and Management, Office of Labor Relations, School Construction Authority, Department of Education, Department of Information Technology and Telecommunications, Department for the Aging, Department of Small Business Services, Department of Consumer Affairs, Office of Media and Entertainment and Department of Cultural Affairs, Taxi and Limousine Commission, and other relevant departments and agencies, are directed, by and through themselves and others as needed, to undertake whatever activities and measures are needed, including revocation of street activity and other related event permits, to protect life and property or bring the emergency situation under control.

§ 4. All members of the public (other than authorized government personnel and essential emergency personnel, and patients and residents of hospitals, nursing homes and senior homes) are ordered to evacuate their homes and businesses if they are located in Zone A, as defined by the Office of Emergency Management. Members of the public are ordered to evacuate Zone A no later than 7:00 p.m. on Sunday, October 28, 2012.

§ 5. Following evacuation from Zone A, all members of the public (other than authorized government personnel and essential emergency personnel) shall remain outside of Zone A.

§ 6. Any person who knowingly violates any provision of this Order is guilty of a class B misdemeanor.

§ 7. This Order shall take effect immediately. It shall remain in effect for five (5) days unless it is terminated or modified at an earlier date.



Michael R. Bloomberg
Mayor

APPENDIX C-3: State Emergency Declaration

Executive

§ 28. State declaration of disaster emergency. 1. Whenever the governor, on his own initiative or pursuant to a request from one or more chief executives, finds that a disaster has occurred or may be imminent for which local governments are unable to respond adequately, he shall declare a disaster emergency by executive order.

2. Upon declaration of a disaster arising from a radiological accident, the governor or his designee, shall direct one or more chief executives and emergency services organizations to:

(a) notify the public that an emergency exists; and

(b) take appropriate protective actions pursuant to the radiological emergency preparedness plan approved pursuant to sections twenty-two and twenty-three of this article. The governor, or his designee, shall also have authority to direct that other actions be taken by such chief executives pursuant to their authority under section twenty-four of this article.

3. The executive order shall include a description of the disaster, and the affected area. Such order or orders shall remain in effect for a period not to exceed six months or until rescinded by the governor, whichever occurs first. The governor may issue additional orders to extend the state disaster emergency for additional periods not to exceed six months.

4. Whenever the governor shall find that a disaster is of such severity and magnitude that effective response is beyond the capabilities of the state and the affected jurisdictions, he shall make an appropriate request for federal assistance available under federal law, and may make available out of any funds provided under the governmental emergency fund or such other funds as may be available, sufficient funds to provide the required state share of grants made under any federal program for meeting disaster related expenses including those available to individuals and families.

APPENDIX C-4: Suspension and Modification of State Requirements

Executive

§ 29-a. Suspension of other laws. 1. Subject to the state constitution, the federal constitution and federal statutes and regulations, the governor may by executive order temporarily suspend specific provisions of any statute, local law, ordinance, or orders, rules or regulations, or parts thereof, of any agency during a state disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster.

2. Suspensions pursuant to subdivision one of this section shall be subject to the following standards and limits:

a. no suspension shall be made for a period in excess of thirty days, provided, however, that upon reconsideration of all of the relevant facts and circumstances, the governor may extend the suspension for additional periods not to exceed thirty days each;

b. no suspension shall be made which does not safeguard the health and welfare of the public and which is not reasonably necessary to the disaster effort;

c. any such suspension order shall specify the statute, local law, ordinance, order, rule or regulation or part thereof to be suspended and the terms and conditions of the suspension;

d. the order may provide for such suspension only under particular circumstances, and may provide for the alteration or modification of the requirements of such statute, local law, ordinance, order, rule or regulation suspended, and may include other terms and conditions;

e. any such suspension order shall provide for the minimum deviation from the requirements of the statute, local law, ordinance, order, rule or regulation suspended consistent with the disaster action deemed necessary; and

f. when practicable, specialists shall be assigned to assist with the related emergency actions to avoid needless adverse effects resulting from such suspension.

3. Such suspensions shall be effective from the time and in the manner prescribed in such orders and shall be published as soon as practicable in the state bulletin.

4. The legislature may terminate by concurrent resolution executive orders issued under this section at any time.

APPENDIX C-5: Supplemental State Assistance

Executive

§ 29-e. New York state emergency assistance program. 1. For purposes of this section the following terms shall have the following meanings:

(a) "Infrastructure" shall mean and include publicly owned storm and sanitary sewers, water supply systems, drainage systems, transportation systems, roads and bridges.

(b) "Municipality" shall mean any county, city, village, or town of the state.

(c) "Public facilities" shall mean and include publicly owned buildings, including traditional government buildings, such as courthouses, firehouses, police stations, parks, recreational facilities, and correctional facilities.

(d) "Fund" shall mean the state's contingency reserve fund established by law.

(e) "The office of emergency management" shall mean the office within the division of homeland security and emergency services.

2. The governor may, upon a finding that a municipality in the state has suffered substantial damage by an unanticipated natural disaster which has resulted in significant economic distress within such municipality, issue a declaration of significant economic distress in accordance with the provisions herein. In determining whether such significant economic distress exists, the governor shall consider whether the following criteria have been met:

(a) the municipality suffered a substantial loss of assessed value;

(b) substantial damage has occurred to municipal buildings, facilities and infrastructure;

(c) the cost incurred by the municipality for clean-up operations is significant;

(d) businesses within the municipality have experienced significant economic loss due to the inability to conduct normal business due to the disaster;

(e) a significant increase in unemployment claims filed by persons employed within the municipality has occurred; and

(f) the county or the county within which the municipality is located has been declared eligible by the United States small business administration for physical disaster and economic injury disaster loans. In addition, the governor shall also consider the extent that other financial resources, including federal assistance and insurance, are available to assist the municipality to repair damage caused by the disaster.

3. (a) Upon the issuance of a declaration of significant economic distress due to unanticipated natural disaster by the governor, a municipality recognized by the governor as being affected by such disaster which occurred on or after December first, nineteen hundred ninety-two, may apply to the division of homeland security and emergency services on a form prescribed by such office, for reimbursement from the state's contingency reserve fund for reimbursement of extraordinary and unanticipated costs associated with the reconstruction or repair of public buildings, facilities or infrastructure.

(b) Where the municipality applying for assistance authorized pursuant to this section is a city, and such application pertains to a county wholly contained within such city, such city may submit separate applications for such assistance for each such county.

(c) Such municipality shall be granted the assistance provided pursuant to this section, within the amounts made available by

appropriation from the fund, upon approval of such application, provided that such municipality agrees to have a local disaster preparedness plan pursuant to section twenty-three of this article in effect by December thirty-first, nineteen hundred ninety-three. On or after December thirty-first, nineteen hundred ninety-three, no municipality shall be eligible for reimbursement of such expenses unless such plan is in effect.

(d) Municipalities which have received assistance pursuant to this section shall, as soon thereafter as may be possible, amend their respective local disaster preparedness plans to include corrective measures that must be taken in order to avoid, to the extent possible, similar emergencies in the future.

(e) Municipalities applying for assistance pursuant to this section shall accurately describe the emergency conditions which necessitate the expenditure of funds for which reimbursement is being sought pursuant to this section.

(f) In providing assistance pursuant to this section, the division of homeland security and emergency services may give preference to applicants which demonstrate the greatest need or which document that such assistance will be utilized to bring the applicant into compliance with federal or state law.

(g) In the event that amounts appropriated are insufficient to provide for full reimbursement of all extraordinary and unanticipated costs incurred by such municipality approved for reimbursement pursuant to this section, the division of homeland security and emergency services is authorized to provide a pro rata share of the appropriations, appropriated herein, to such municipality.

4. (a) The commissioner of the division of homeland security and emergency services as defined in article twenty-six of this chapter with the advice and consent of the disaster preparedness commission created pursuant to this article, shall have the power to make such rules and regulations as may be necessary and proper to effectuate the purposes of this section.

(b) The commissioner of the division of homeland security and emergency services shall by March fifteenth of each year report to the governor and the legislature describing the activities and operation of the program authorized by this section. Such report shall set forth the number of reimbursement applications received and approved; the identities of the counties, cities, towns and villages receiving reimbursement together with the amount and purpose of the reimbursement.

APPENDIX C-6: Example of State Disaster Declaration

**Temporary Suspension And Modification of Health Statutes And Regulations During The State Disaster Emergency**

Printer-friendly version

WHEREAS, on October 26, 2012, I issued Executive Order Number 47, declaring a disaster emergency in all 62 counties in the State of New York; and

WHEREAS, on October 30, 2012, the President issued a major disaster declaration for the counties of Bronx, Kings, Nassau, New York, Queens, Richmond and Suffolk, and on November 2, 2012, extended such declaration to include Rockland and Westchester Counties; and

WHEREAS, Hurricane Sandy necessitated the evacuation of numerous health care facilities while simultaneously increasing the threat of injury and disease in the impacted areas, and resulted in power outages and shortages of fuel that have complicated the efforts of health care providers to serve their patients; and

WHEREAS, it is incumbent upon the State to ensure that the provision of health care services to New Yorkers continues with minimal disruption to the maximum extent feasible; and

WHEREAS, full compliance with certain statutory and regulatory requirements may delay or impede the ability of providers to furnish such services;

NOW, THEREFORE, I, ANDREW M. CUOMO, Governor of the State of New York, by virtue of the authority vested in me by Section 29-a of Article 2-B of the Executive Law to temporarily suspend or modify specific provisions of any statute, local law, ordinance, orders, rules or regulations, or parts thereof, of any agency during a State disaster emergency, if compliance with such provisions would prevent, hinder or delay action necessary to cope with the disaster emergency, hereby temporarily suspend or modify, as the case may be, during the period from the date that the disaster emergency was declared pursuant to Executive Order Number 47, issued on October 26, 2012, until further notice, the following:

Subdivision (2) of section 3320 of the Public Health Law, and any associated regulations, to the extent necessary to allow licensed facilities, including but not limited to hospitals, nursing homes, and institutional dispensers, to temporarily accept, store and administer those controlled substances lawfully prescribed to patients and residents affected by the disaster emergency, while maintaining appropriate patient specific record-keeping and diversion prevention practices, and subject to any terms and conditions that the Commissioner of Health may deem appropriate;

Subdivision (1) of section 3333 and subdivision (2) of section 3338 of the Public Health Law, and any associated regulations, to the extent necessary to allow a licensed pharmacist to dispense a controlled substance to a patient whose access to prescriptions or previously dispensed controlled substances has been directly affected by the disaster emergency, if the pharmacist, through the use of a shared database can verify the authenticity of the prescription and the prescription indicates authorized refills;

Subdivision (3) of section 3332, subdivision (1) of section 3333 and subdivision (3) of section 3339 of the Public Health Law, and any associated regulations, to the extent necessary to allow a licensed practitioner to prescribe and a licensed pharmacist to dispense a controlled substance more than seven days prior to the date the previously dispensed supply would have been exhausted if the patient's supply has been destroyed, made unusable or made inaccessible due to the disaster emergency;

Subpart 58-1 of Title 10 of the New York Codes, Rules and Regulations ("NYCRR"), to the extent necessary to permit the Commissioner of Health to issue provisional permits to laboratories or blood banks for the purpose of conducting permitted categories of tests at alternate locations or conducting categories of tests not listed in the laboratory's permit if, in the discretion of the Commissioner, the laboratory has provided sufficient information to show

that such testing can be conducted safely and accurately so as not to present an undue risk to patient health and fills a need for testing created by the disaster emergency to protect the public health and safety;

Section 400.9 and paragraph (7) of subdivision (f) of section 405.9 of Title 10 of the NYCRR, to the extent necessary to permit general hospitals and nursing homes licensed pursuant to Article 28 of the Public Health Law ("Article 28 facilities") and affected by the disaster emergency to rapidly discharge, transfer or receive patients, as authorized by the Commissioner of Health, provided that such facilities take all reasonable measures to protect the health and safety of patients and residents, including safe transfer and discharge practices, and comply with the Emergency Medical Treatment and Active Labor Act (42 U.S.C. § 1395dd) and any associated regulations;

Section 400.11 of Title 10 of the NYCRR, to the extent necessary to permit Article 28 facilities receiving patients evacuated from other Article 28 facilities due to the disaster emergency to complete patient review instruments as soon as practicable;

Section 400.12 of Title 10 of the NYCRR, to the extent necessary to allow patients affected by the disaster emergency to be transferred to receiving Article 28 facilities as authorized by the Commissioner of Health;

Subdivision (e) of section 405.2 of Title 10 of the NYCRR, to the extent necessary to permit general hospitals affected by the disaster emergency to maintain adequate staffing;

Subdivision (b) of section 405.3 of Title 10 of the NYCRR, to the extent necessary to allow general hospitals affected by the disaster emergency to use qualified volunteers or personnel affiliated with different hospitals, subject to terms and conditions established by the Commissioner of Health;

Paragraph (6) of subdivision (b) of section 405.4 of Title 10 of the NYCRR, to the extent necessary to allow general hospitals affected by the disaster emergency to assess the fitness of medical postgraduate trainees and attending physicians to continue working without a specific hourly limit;

Paragraph (1) of subdivision (e) of section 405.4 and subdivision (b) of section 707.3 of Title 10 of the NYCRR, to the extent necessary to permit physicians to supervise up to ten physician assistants and registered specialist assistants in general hospitals affected by the disaster emergency;

Paragraph (12) of subdivision (b) of section 405.9 of Title 10 of the NYCRR, to the extent necessary to permit general hospitals receiving patients transferred from Article 28 facilities evacuated as a result of the disaster emergency to arrange for the performance of histories and physical examinations of the evacuated patients as soon as practicable following admission;

Subdivision (d) of section 405.19 of Title 10 of NYCRR, to the extent necessary to allow general hospitals affected by the disaster emergency to staff their emergency departments as needed;

Subdivision (a) of section 405.28 of Title 10 of the NYCRR, to the extent necessary to permit general hospitals receiving individuals affected by the disaster emergency to provide social services screenings as soon as practicable following admission or to forego such screenings for individuals returned to facilities from which they were evacuated;

Section 415.11 of Title 10 of the NYCRR, to the extent necessary to permit nursing homes receiving individuals affected by the disaster emergency to perform comprehensive assessments of those residents temporarily evacuated to such nursing homes as soon as practicable following admission or to forego such assessments for individuals returned to facilities from which they were evacuated;

Subdivision (b) of section 415.15 of Title 10 of the NYCRR, to the extent necessary to permit nursing homes receiving individuals affected by the disaster emergency to obtain physician approvals for admission as soon as practicable following admission or to forego such approval for individuals returned to facilities from which they were evacuated;

Subdivision (i) of section 415.26 of Title 10 of the NYCRR, to the extent necessary to permit nursing homes receiving individuals affected by the disaster emergency to comply with admission procedures as soon as practicable following admission or to forego such procedures for individuals returned to facilities from which they were evacuated;

Paragraph (7) of subdivision (h) of section 763.4 and paragraph (1) of subdivision (d) of section 766.5 of Title 10 of the NYCRR, to the extent necessary to permit certified home health agencies, long term home health care programs, AIDS home care programs, and licensed home care services agencies serving individuals affected by the disaster emergency to conduct in-home supervision of home health aides and personal care aides as soon as practicable after the initial service visit;

Subdivision (a) of section 763.5 of Title 10 of the NYCRR, to the extent necessary to permit initial patient visits for certified home health agencies, long term home health care programs and AIDS home care programs serving individuals affected by the disaster emergency to be made within 48 hours of receipt and acceptance of a community referral or return home from institutional placement;

Paragraph (3) of subdivision (a) of section 763.7 and subdivision (d) of section 766.4 of Title 10 of the NYCRR, to the extent necessary to permit certified home health agencies, long term home health care programs, AIDS home care programs and licensed home care services agencies serving individuals affected by the disaster emergency to obtain medical orders signed by authorized practitioners within 60 days;

Paragraph (3) of subdivision (b) of section 505.14 and paragraph (1) of subdivision (d) of section 505.28 of Title 18 of the NYCRR, to the extent necessary to permit a physician's order to be completed and forwarded to the social services district within 60 days after the medical examination of a patient affected by the disaster emergency;

Subparagraph (ix) of paragraph (5) of subdivision (b) of section 505.14 and subdivision (f) of section 505.28 of Title 18 of the NYCRR, to the extent necessary to permit an additional 30 days for reauthorizations of personal care and consumer directed personal assistance program services for

individuals affected by the disaster emergency, where the authorized period of services otherwise would terminate during the period of the disaster emergency declared pursuant to Executive Order Number 47;

Subparagraph (ii) of paragraph (2) of subdivision (e) of section 505.14 of Title 18 of the NYCRR, to the extent necessary to permit training for personal care workers serving individuals affected by the disaster emergency to be held as soon as practicable after the conclusion of such period, where such training otherwise would be required during the period of the disaster emergency declared pursuant to Executive Order Number 47, provided that such workers have sufficient competence to provide such services; and

Paragraph (3) of subdivision (f) of section 505.14 of Title 18 of the NYCRR, to the extent necessary to permit nursing supervision visits for personal care services provided to individuals affected by the disaster emergency to be made as soon as practicable.

G I V E N under my hand and the Privy Seal of the State in the City of Albany this eleventh day of November in the year two thousand twelve.

BY THE GOVERNOR

Secretary to the Governor

APPENDIX C-7: Federal Disaster Declaration



Disaster Declaration Process Fact Sheet

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121-5207 (the Stafford Act) §401 states in part that: "All requests for a declaration by the President that a major disaster exists shall be made by the governor of the affected state." A state also includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. The Marshall Islands and the Federated States of Micronesia are also eligible to request a declaration and receive assistance.

Preliminary Disaster Assessment

The governor's request is made through the applicable FEMA Regional Office. State and federal officials conduct a joint federal, state, and local Preliminary Damage Assessment (PDA) to determine the extent of the disaster and its impact on individuals and public facilities. This information is included in the governor's request to show that the disaster is of such severity and magnitude that effective response is beyond the capabilities of the state and the local governments and that supplemental federal assistance is necessary. Normally, the PDA is completed prior to the submission of the governor's request. However, when an obviously severe or catastrophic event occurs, the governor's request may be submitted prior to the PDA.

State Resources Overwhelmed

As part of the request, the Governor must take appropriate action under State law and direct execution of the State's emergency plan. The Governor shall furnish information on the nature and amount of State and local resources that have been or will be committed to alleviating the results of the disaster, provide an estimate of the amount and severity of damage and the impact on the private and public sectors, and provide an estimate of the type and amount of assistance needed under the Stafford Act.

In addition, the Governor must certify that, for the current disaster, State and local government obligations and expenditures (of which State commitments must be a significant proportion) will comply with all applicable cost-sharing requirements.

Declaration Types

There are two types of disaster declarations provided for in the Stafford Act:

Emergency Declarations: An Emergency Declaration can be declared for any occasion or instance when the President determines federal assistance is needed. Emergency Declarations supplement State and local efforts in providing emergency services, such as the protection of lives, property, public health, and safety, or to lessen or avert the threat of a catastrophe in any part of the United States. The total amount of assistance provided for a single emergency may not exceed \$5 million. If this amount is exceeded, the President shall report to Congress.

Major Declaration: The President can declare a Major Disaster Declaration for any natural event, including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or, regardless of cause, fire, flood, or explosion, that the President believes has caused damage of such severity that it is beyond the combined capabilities of state and local governments to respond. A major disaster declaration provides a wide range of federal assistance programs for individuals and public infrastructure, including funds for both emergency and permanent work.

Assistance Available for Major Declarations

Not all programs, however, are activated for every disaster. The determination of which programs are authorized is based the types of assistance specified in the governor's request and on the needs identified during joint PDA and any subsequent PDAs. FEMA disaster assistance programs are as follows:

- **Individual Assistance** - Assistance to individuals and households;
- **Public Assistance** - Assistance to state and local governments and certain private nonprofit organizations for emergency work and the repair or replacement of disaster-damaged facilities; and
- **Hazard Mitigation Assistance** – Assistance to state and local governments and certain private nonprofit organizations for actions taken to prevent or reduce long term risk to life and property from natural hazards.

FEMA's mission is to support our citizens and first responders to ensure that as a nation we work together to build, sustain, and improve our capability to prepare for, protect against, respond to, recover from, and mitigate all hazards.

APPENDIX C-8: Example of Federal Disaster Declaration

**Date of Notice:**

Tuesday, October 30, 2012

Billing Code 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4085-DR]

Docket ID FEMA-2012-0002

New York; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New York (FEMA-4085-DR), dated October 30, 2012, and related determinations.

EFFECTIVE DATE: October 30, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW, Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 30, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of New York resulting from Hurricane Sandy beginning on October 27, 2012, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of New York.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and assistance for debris removal and emergency protective measures (Categories A and B), including direct Federal assistance, under the Public Assistance program in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance, Hazard Mitigation, and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of New York have been designated as adversely affected by this major disaster:

Bronx, Kings, Nassau, New York, Richmond, Suffolk, and Queens Counties for Individual Assistance.

Bronx, Kings, Nassau, New York, Richmond, Suffolk, and Queens Counties for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

All counties within the State of New York are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance - Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households - Other Needs; 97.036, Disaster Grants - Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

APPENDIX C-9: National Emergency Declaration

50 U.S.C.

United States Code, 2009 Edition

Title 50 - WAR AND NATIONAL DEFENSE

CHAPTER 34 - NATIONAL EMERGENCIES

From the U.S. Government Printing Office, www.gpo.gov**CHAPTER 34—NATIONAL EMERGENCIES****SUBCHAPTER I—TERMINATING EXISTING DECLARED EMERGENCIES**

Sec.

1601. Termination of existing declared emergencies.

SUBCHAPTER II—DECLARATIONS OF FUTURE NATIONAL EMERGENCIES

1621. Declaration of national emergency by President; publication in Federal Register; effect on other laws; superseding legislation.

1622. National emergencies.

SUBCHAPTER III—EXERCISE OF EMERGENCY POWERS AND AUTHORITIES

1631. Declaration of national emergency by Executive order; authority; publication in Federal Register; transmittal to Congress.

SUBCHAPTER IV—ACCOUNTABILITY AND REPORTING REQUIREMENTS OF PRESIDENT

1641. Accountability and reporting requirements of President.

SUBCHAPTER V—APPLICATION TO POWERS AND AUTHORITIES OF OTHER PROVISIONS OF LAW AND ACTIONS TAKEN THEREUNDER

1651. Other laws, powers and authorities conferred thereby, and actions taken thereunder; Congressional studies.

SUBCHAPTER I—TERMINATING EXISTING DECLARED EMERGENCIES**§1601. Termination of existing declared emergencies**

(a) All powers and authorities possessed by the President, any other officer or employee of the Federal Government, or any executive agency, as defined in section 105 of title 5, as a result of the existence of any declaration of national emergency in effect on September 14, 1976, are terminated two years from September 14, 1976. Such termination shall not affect—

- (1) any action taken or proceeding pending not finally concluded or determined on such date;
- (2) any action or proceeding based on any act committed prior to such date; or

(3) any rights or duties that matured or penalties that were incurred prior to such date.

(b) For the purpose of this section, the words “any national emergency in effect” means a general declaration of emergency made by the President.

(Pub. L. 94–412, title I, §101, Sept. 14, 1976, 90 Stat. 1255.)

SHORT TITLE

Section 1 of Pub. L. 94–412 provided: “That this Act [enacting this chapter, amending section 1481 of Title 8, Aliens and Nationality, and section 2667 of Title 10, Armed Forces, repealing section 249 of Title 12, Banks and Banking, section 831d of Title 16, Conservation, section 1383 of Title 18, Crimes and Criminal Procedure, section 211b of Title 42, The Public Health and Welfare, and section 1742 of the Appendix to this title, and enacting provisions set out below] may be cited as the ‘National Emergencies Act’.”

SAVINGS PROVISION

Section 501(h) of Pub. L. 94–412 provided that: “This section [amending section 1481 of Title 8, Aliens and Nationality and section 2667 of Title 10, Armed Forces, and repealing section 249 of Title 12, Banks and Banking, section 831d of Title 16, Conservation, section 1383 of Title 18, Crimes and Criminal Procedure, and section 211b of Title 42, The Public Health and Welfare] shall not affect—

“(1) any action taken or proceeding pending not finally concluded or determined at the time of repeal;

“(2) any action or proceeding based on any act committee prior to repeal; or

“(3) any rights or duties that matured or penalties that were incurred prior to repeal.”

SUBCHAPTER II—DECLARATIONS OF FUTURE NATIONAL EMERGENCIES

§1621. Declaration of national emergency by President; publication in Federal Register; effect on other laws; superseding legislation

(a) With respect to Acts of Congress authorizing the exercise, during the period of a national emergency, of any special or extraordinary power, the President is authorized to declare such national emergency. Such proclamation shall immediately be transmitted to the Congress and published in the Federal Register.

(b) Any provisions of law conferring powers and authorities to be exercised during a national emergency shall be effective and remain in effect (1) only when the President (in accordance with subsection (a) of this section), specifically declares a national emergency, and (2) only in accordance with this chapter. No law enacted after September 14, 1976, shall supersede this subchapter unless it does so in specific terms, referring to this subchapter, and declaring that the new law supersedes the provisions of this subchapter.

(Pub. L. 94–412, title II, §201, Sept. 14, 1976, 90 Stat. 1255.)

PROC. NO. 7463. DECLARATION OF NATIONAL EMERGENCY BY REASON OF CERTAIN TERRORIST ATTACKS

Proc. No. 7463, Sept. 14, 2001, 66 F.R. 48199, provided:

A national emergency exists by reason of the terrorist attacks at the World Trade Center, New York, New York, and the Pentagon, and the continuing and immediate threat of further attacks on the United States.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me as President by the Constitution and the laws of the United States, I hereby declare that the national emergency has existed since September 11, 2001, and, pursuant to the National Emergencies Act (50 U.S.C. 1601 *et seq.*), I intend to utilize the following statutes: sections 123, 123a, 527, 2201(c), 12006,

and 12302 of title 10, United States Code, and sections 331, 359, and 367 of title 14, United States Code.

This proclamation immediately shall be published in the Federal Register or disseminated through the Emergency Federal Register, and transmitted to the Congress.

This proclamation is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of September, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-sixth.

GEORGE W. BUSH.

CONTINUATION OF NATIONAL EMERGENCY DECLARED BY PROC. NO. 7463

Notice of President of the United States, dated Sept. 10, 2009, 74 F.R. 46883, provided:

Consistent with section 202(d) of the National Emergencies Act, 50 U.S.C. 1622(d), I am continuing for 1 year the national emergency declared on September 14, 2001, in Proclamation 7463, with respect to the terrorist attacks of September 11, 2001, and the continuing and immediate threat of further attacks on the United States.

Because the terrorist threat continues, the national emergency declared on September 14, 2001, and the powers and authorities adopted to deal with that emergency, must continue in effect beyond September 14, 2009. Therefore, I am continuing in effect for an additional year the national emergency the former President declared on September 14, 2001, with respect to the terrorist threat.

This notice shall be published in the Federal Register and transmitted to the Congress.

BARACK OBAMA.

Prior continuations of national emergency declared by Proc. No. 7463 were contained in the following:

Notice of President of the United States, dated Aug. 28, 2008, 73 F.R. 51211.

Notice of President of the United States, dated Sept. 12, 2007, 72 F.R. 52465.

Notice of President of the United States, dated Sept. 5, 2006, 71 F.R. 52733.

Notice of President of the United States, dated Sept. 8, 2005, 70 F.R. 54229.

Notice of President of the United States, dated Sept. 10, 2004, 69 F.R. 55313.

Notice of President of the United States, dated Sept. 10, 2003, 68 F.R. 53665.

Notice of President of the United States, dated Sept. 12, 2002, 67 F.R. 58317.

§1622. National emergencies

(a) Termination methods

Any national emergency declared by the President in accordance with this subchapter shall terminate if—

- (1) there is enacted into law a joint resolution terminating the emergency; or
- (2) the President issues a proclamation terminating the emergency.

Any national emergency declared by the President shall be terminated on the date specified in any joint resolution referred to in clause (1) or on the date specified in a proclamation by the President terminating the emergency as provided in clause (2) of this subsection, whichever date is earlier, and any powers or authorities exercised by reason of said emergency shall cease to be exercised after such specified date, except that such termination shall not affect—

- (A) any action taken or proceeding pending not finally concluded or determined on such date;
- (B) any action or proceeding based on any act committed prior to such date; or
- (C) any rights or duties that matured or penalties that were incurred prior to such date.

(b) Termination review of national emergencies by Congress

Not later than six months after a national emergency is declared, and not later than the end of each six-month period thereafter that such emergency continues, each House of Congress shall meet to consider a vote on a joint resolution to determine whether that emergency shall be terminated.

(c) Joint resolution; referral to Congressional committees; conference committee in event of disagreement; filing of report; termination procedure deemed part of rules of House and Senate

(1) A joint resolution to terminate a national emergency declared by the President shall be referred to the appropriate committee of the House of Representatives or the Senate, as the case may be. One such joint resolution shall be reported out by such committee together with its recommendations within fifteen calendar days after the day on which such resolution is referred to such committee, unless such House shall otherwise determine by the yeas and nays.

(2) Any joint resolution so reported shall become the pending business of the House in question (in the case of the Senate the time for debate shall be equally divided between the proponents and the opponents) and shall be voted on within three calendar days after the day on which such resolution is reported, unless such House shall otherwise determine by yeas and nays.

(3) Such a joint resolution passed by one House shall be referred to the appropriate committee of the other House and shall be reported out by such committee together with its recommendations within fifteen calendar days after the day on which such resolution is referred to such committee and shall thereupon become the pending business of such House and shall be voted upon within three calendar days after the day on which such resolution is reported, unless such House shall otherwise determine by yeas and nays.

(4) In the case of any disagreement between the two Houses of Congress with respect to a joint resolution passed by both Houses, conferees shall be promptly appointed and the committee of conference shall make and file a report with respect to such joint resolution within six calendar days after the day on which managers on the part of the Senate and the House have been appointed. Notwithstanding any rule in either House concerning the printing of conference reports or concerning any delay in the consideration of such reports, such report shall be acted on by both Houses not later than six calendar days after the conference report is filed in the House in which such report is filed first. In the event the conferees are unable to agree within forty-eight hours, they shall report back to their respective Houses in disagreement.

(5) Paragraphs (1)–(4) of this subsection, subsection (b) of this section, and section 1651(b) of this title are enacted by Congress—

(A) as an exercise of the rulemaking power of the Senate and the House of Representatives, respectively, and as such they are deemed a part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in the House in the case of resolutions described by this subsection; and they supersede other rules only to the extent that they are inconsistent therewith; and

(B) with full recognition of the constitutional right of either House to change the rules (so far as relating to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

(d) Automatic termination of national emergency; continuation notice from President to Congress; publication in Federal Register

Any national emergency declared by the President in accordance with this subchapter, and not otherwise previously terminated, shall terminate on the anniversary of the declaration of that emergency if, within the ninety-day period prior to each anniversary date, the President does not publish in the Federal Register and transmit to the Congress a notice stating that such emergency is to continue in effect after such anniversary.

(Pub. L. 94–412, title II, §202, Sept. 14, 1976, 90 Stat. 1255; Pub. L. 99–93, title VIII, §801, Aug. 16, 1985, 99 Stat. 448.)

AMENDMENTS

1985—Subsecs. (a) to (c). Pub. L. 99–93 substituted “there is enacted into law a joint resolution terminating the emergency” for “Congress terminates the emergency by concurrent resolution” in par. (1) of subsec. (a), and substituted “joint resolution” for “concurrent resolution” wherever appearing in second sentence of subsec. (a), subsec. (b), and pars. (1) to (4) of subsec. (c).

SUBCHAPTER III—EXERCISE OF EMERGENCY POWERS AND AUTHORITIES

§1631. Declaration of national emergency by Executive order; authority; publication in Federal Register; transmittal to Congress

When the President declares a national emergency, no powers or authorities made available by statute for use in the event of an emergency shall be exercised unless and until the President specifies the provisions of law under which he proposes that he, or other officers will act. Such specification may be made either in the declaration of a national emergency, or by one or more contemporaneous or subsequent Executive orders published in the Federal Register and transmitted to the Congress.

(Pub. L. 94–412, title III, §301, Sept. 14, 1976, 90 Stat. 1257.)

RELEASE OF AMERICAN HOSTAGES IN IRAN

For provisions relating to the release of the American hostages in Iran, see Ex. Ord. Nos. 12276 to 12285, Jan. 19, 1981, 46 F.R. 7913 to 7932, listed in a table under section 1701 of this title.

SUBCHAPTER IV—ACCOUNTABILITY AND REPORTING REQUIREMENTS OF PRESIDENT

§1641. Accountability and reporting requirements of President

(a) Maintenance of file and index of Presidential orders, rules and regulations during national emergency

When the President declares a national emergency, or Congress declares war, the President shall be responsible for maintaining a file and index of all significant orders of the President, including Executive orders and proclamations, and each Executive agency shall maintain a file and index of all rules and regulations, issued during such emergency or war issued pursuant to such declarations.

(b) Presidential orders, rules and regulations; transmittal to Congress

All such significant orders of the President, including Executive orders, and such rules and regulations shall be transmitted to the Congress promptly under means to assure confidentiality where appropriate.

(c) Expenditures during national emergency; Presidential reports to Congress

When the President declares a national emergency or Congress declares war, the President shall

transmit to Congress, within ninety days after the end of each six-month period after such declaration, a report on the total expenditures incurred by the United States Government during such six-month period which are directly attributable to the exercise of powers and authorities conferred by such declaration. Not later than ninety days after the termination of each such emergency or war, the President shall transmit a final report on all such expenditures.

(Pub. L. 94–412, title IV, §401, Sept. 14, 1976, 90 Stat. 1257.)

DELEGATION OF FUNCTIONS

Delegations of congressional reporting functions of President under subsec. (c) of this section were contained in the following:

Ex. Ord. No. 13441, §6, Aug. 1, 2007, 72 F.R. 43500.

Ex. Ord. No. 13396, §6, Feb. 7, 2006, 71 F.R. 7391, listed in a table under section 1701 of this title.

Ex. Ord. No. 13348, §7, July 22, 2004, 69 F.R. 44887, listed in a table under section 1701 of this title.

Ex. Ord. No. 13338, §12, May 11, 2004, 69 F.R. 26754, listed in a table under section 1701 of this title.

Ex. Ord. No. 13313, §1, July 31, 2003, 68 F.R. 46073, set out in a note under section 301 of Title 3, The President.

SUBCHAPTER V—APPLICATION TO POWERS AND AUTHORITIES OF OTHER PROVISIONS OF LAW AND ACTIONS TAKEN THEREUNDER

§1651. Other laws, powers and authorities conferred thereby, and actions taken thereunder; Congressional studies

(a) The provisions of this chapter shall not apply to the following provisions of law, the powers and authorities conferred thereby, and actions taken thereunder:

(1) Act of June 30, 1949 (41 U.S.C. 252);

(2) Section 3727(a)–(e)(1) of title 31;

(3) Section 3737 of the Revised Statutes, as amended (41 U.S.C. 15);

(4) Public Law 85–804 (Act of Aug. 28, 1958, 72 Stat. 972; 50 U.S.C. 1431 et seq.);

(5) Section 2304(a)(1) ¹ of title 10; ²

(b) Each committee of the House of Representatives and the Senate having jurisdiction with respect to any provision of law referred to in subsection (a) of this section shall make a complete study and investigation concerning that provision of law and make a report, including any recommendations and proposed revisions such committee may have, to its respective House of Congress within two hundred and seventy days after September 14, 1976.

(Pub. L. 94–412, title V, §502, Sept. 14, 1976, 90 Stat. 1258; Pub. L. 95–223, title I, §101(d), Dec. 28, 1977, 91 Stat. 1625; Pub. L. 96–513, title V, §507(b), Dec. 12, 1980, 94 Stat. 2919; Pub. L. 105–362, title IX, §901(r)(2), Nov. 10, 1998, 112 Stat. 3291; Pub. L. 107–314, div. A, title X, §1062(o)(1), Dec. 2, 2002, 116 Stat. 2652.)

REFERENCES IN TEXT

Act of June 30, 1949 (41 U.S.C. 252), referred to in subsec. (a)(1), is act June 30, 1949, ch. 288, 63 Stat. 377, as amended, known as the Federal Property and Administrative Services Act of 1949. Except for title III of the Act, which is classified generally to subchapter IV (§251 et seq.) of chapter 4 of Title 41, Public Contracts, the Act was repealed and reenacted by Pub. L. 107–217, §§1, 6(b), Aug. 21, 2002, 116 Stat. 1062, 1304, as chapters 1 to 11 of Title 40, Public Buildings, Property, and Works. Section 302 of the Act is

classified to section 252 of Title 41, Public Contracts.

Public Law 85-804, referred to in subsec. (a)(4), is Pub. L. 85-804, Aug. 28, 1958, 72 Stat. 972, as amended, which is classified generally to chapter 29 (§1431 et seq.) of this title. For complete classification of this Act to the Code, see Tables.

Section 2304(a)(1) of title 10, referred to in subsec. (a)(5), originally authorized purchases or contracts without formal advertising when necessary in the public interest during a national emergency declared by Congress or the President, and as amended generally by Pub. L. 98-369 now sets forth the competition requirements for procurement of property or services.

CODIFICATION

In subsec. (a)(2), “Section 3727(a)–(e)(1) of title 31” substituted for “Section 3477 of the Revised Statutes, as amended (31 U.S.C. 203)” on authority of Pub. L. 97-258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

AMENDMENTS

2002—Subsec. (a). Pub. L. 107-314 struck out par. (2), which read “Act of April 28, 1942 (40 U.S.C. 278b);”, and redesignated pars. (3) to (7) as (1) to (5), respectively.

1998—Subsec. (a)(6). Pub. L. 105-362 substituted “1431 et seq.” for “1431-1435”.

1980—Subsec. (a)(8). Pub. L. 96-513 struck out par. (8) which made reference to sections 3313, 6386(c), and 8313 of title 10.

1977—Subsec. (a)(1). Pub. L. 95-223 struck out par. (1) which read as follows: “Section 5(b) of the Act of October 6, 1917, as amended (12 U.S.C. 95a; 50 U.S.C. App. 5(b));”.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-513 effective Sept. 15, 1981, see section 701 of Pub. L. 96-513, set out as a note under section 101 of Title 10, Armed Forces.

APPENDIX C-10: Example of National Emergency Declaration

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 24, 2009

DECLARATION OF A NATIONAL EMERGENCY WITH RESPECT TO THE 2009 H1N1 INFLUENZA PANDEMIC

**BY THE PRESIDENT OF THE UNITED STATES OF AMERICA
A PROCLAMATION**

On April 26, 2009, the Secretary of Health and Human Services (the "Secretary") first declared a public health emergency under section 319 of the Public Health Service Act, 42 U.S.C. 247d, in response to the 2009 H1N1 influenza virus. The Secretary has renewed that declaration twice, on July 24, 2009, and October 1, 2009. In addition, by rapidly identifying the virus, implementing public health measures, providing guidance for health professionals and the general public, and developing an effective vaccine, we have taken proactive steps to reduce the impact of the pandemic and protect the health of our citizens. As a Nation, we have prepared at all levels of government, and as individuals and communities, taking unprecedented steps to counter the emerging pandemic. Nevertheless, the 2009 H1N1 pandemic continues to evolve. The rates of illness continue to rise rapidly within many communities across the Nation, and the potential exists for the pandemic to overburden health care resources in some localities. Thus, in recognition of the continuing progression of the pandemic, and in further preparation as a Nation, we are taking additional steps to facilitate our response.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), do hereby find and proclaim that, given that the rapid increase in illness across the Nation may overburden health care resources and that the temporary waiver of certain standard Federal requirements may be warranted in order to enable U.S. health care facilities to implement emergency operations plans, the 2009 H1N1 influenza pandemic in the United States constitutes a national emergency. Accordingly, I hereby declare that the Secretary may exercise the authority under section 1135 of the SSA to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the 2009 H1N1 influenza pandemic. In exercising this authority, the Secretary shall provide certification and advance written notice to the Congress as required by section 1135(d) of the SSA (42 U.S.C. 1320b-5(d)).

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of October, in the year of our Lord two thousand nine, and of the Independence of the United States of America the two hundred and thirty-fourth.

BARACK OBAMA

###

APPENDIX C-11: Public Health Emergency Declaration

Public Health Emergency Declaration

The Secretary of the Department of Health and Human Services (HHS) may, under section 319 of the Public Health Service (PHS) Act determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

Duration and Notification: The declaration lasts for the duration emergency or 90 days, but may be extended by the Secretary. Congress must be notified of the declaration within 48 hours, and relevant agencies, including the Department of Homeland Security, Department of Justice, and Federal Bureau of Investigation, must be kept informed. Prior to issuing the declaration, the Secretary should consult with public health officials as necessary.

Following a section 319 declaration, the Secretary can:

Take appropriate actions in response to the emergency, including: making grants; entering into contracts; and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder.

Access “no-year” funds appropriated to the Public Health Emergency Fund (when funds are so appropriated). The Secretary must report to Congress 90 days after the end of the fiscal year about any funds spent from the Public Health Emergency Fund, the emergency for which funds were spent, and activities undertaken with respect to the emergency. Public Health Emergency Funds supplement, and do not supplant, other Federal, State, and local funds provided for public health grants, awards, contracts, and investigations.

Grant extensions or waive sanctions relating to submission of data or reports required under laws administered by the Secretary, when the Secretary determines that, wholly or partially as a result of a public health emergency, individuals or public or private entities are unable to comply with deadlines for such data or reports. The Secretary must notify Congress and publish a Federal Register notice before or promptly after granting an extension or waiver.

Waive or modify certain Medicare, Medicaid, Children’s Health Insurance Program (CHIP) and Health Insurance Portability and Accountability Act (HIPAA) requirements. Under section 1135 of the Social Security Act (SSA), the Secretary may waive or modify certain requirements as necessary to ensure to the maximum extent feasible that, in an emergency area during an emergency period, sufficient health care items and services are available to meet the needs of individuals enrolled in SSA programs (including Medicare, Medicaid, and CHIP) and that providers of such services in good faith who are unable to comply with certain statutory requirements are reimbursed and exempted from sanctions for noncompliance, absent fraud or abuse. There must also be a Presidential declaration of an emergency or disaster in order to exercise this authority.

Adjust Medicare reimbursement for certain Part B drugs. Most Medicare Part B drugs are paid on the basis of the manufacturer’s average sales price (ASP), which manufacturers are required to report quarterly. The ASP-based payment allowance is updated prospectively each quarter, using the data manufacturers report. The statutory scheme results in a two-quarter lag between the date of the reported sale and the date that sale’s price is factored into the Medicare reimbursement rate. In the case of a public health emergency in which there is a documented inability to access drugs and biologicals and a concomitant increase in the price of a drug or biological that is not reflected in the manufacturer’s ASP for one or more quarters, the Secretary may use the wholesale acquisition cost or other reasonable measure of drug or biological price instead of the manufacturer’s ASP. The substituted price or measure may be used until the price of the drug or biological has stabilized and is substantially reflected in the manufacturer’s ASP. As of April 2013, CMS has not formally interpreted, nor exercised, this authority. However, in the event of a public health emergency in which this authority were triggered, the price change could be implemented without rulemaking. (See Section 1847A(c)(5)(C) of the Social Security Act, which states that notwithstanding any other provision of law, the Secretary may implement any of the provisions of Section 1847A by program instruction or otherwise.)

Make temporary (up to one year or the duration of the emergency) appointments of personnel to positions that directly respond to the public health emergency when the urgency of filling positions prohibits examining applicants through the competitive process.

Waive certain Ryan White HIV/AIDS program requirements (section 2683 of the PHS Act). Under this authority, up to five percent of the funds available under each of the Parts A and B base supplemental pools may be shifted to

ensure access to care during a public health emergency declared by the Secretary under section 319 of the PHS Act or an emergency or disaster declared by the President under the Stafford Act or the National Emergencies Act in the geographic area where the emergency, major disaster, or public health emergency exists. In addition, the Secretary may waive such requirements of title XXVI of the PHS Act to improve the health and safety of those receiving care under this title and the general public. This waiver authority is limited to the time period for which the emergency, major disaster, or public health emergency declaration exists.

Waive dual compensation (salary offset) for temporarily re-employed annuitants during a public health emergency declared by the Secretary or national emergency declared by the President (see above) involving a direct threat to life or property or other unusual circumstances.

Modify practice of telemedicine. The Ryan Haight Online Pharmacy Consumer Protection Act and implementing regulations allow the Secretary, with concurrence of the DEA Administrator, to designate patients and use of controlled substances during a public health emergency declared by the Secretary.

Allow State and local governments to access the General Services Administration (GSA) Federal supply schedule when using federal grant funds. GSA policy allows state, local, and tribal government grantees to use federal supply schedules to respond to public health emergencies declared by the Secretary.

Temporary reassignment of state and local personnel. The Secretary may authorize a requesting Governor of a state or tribal organization to temporarily reassign state and local public health department or agency personnel funded in whole or in part through programs authorized under the PHS Act to immediately address a public health emergency in the state or Indian tribe during the period of the emergency.

APPENDIX C-12: 1135 Waivers

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**PROVIDER SURVEY AND CERTIFICATION
FREQUENTLY ASKED QUESTIONS**

**DECLARED PUBLIC HEALTH EMERGENCIES - ALL HAZARDS
HEALTH STANDARDS AND QUALITY ISSUES**

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A. All PROVIDERS

- A-1. Affected States:** *Do the modifications and flexibilities described in these Q&As apply only to providers in the states in which the Secretary of Health and Human Services has declared a public health emergency? In other words, do the modifications and flexibilities described in these Q&As also apply to providers in states that receive evacuees, regardless of geographical location (e.g. an evacuee who relocates to a non-border-sharing state)?*

The waivers and modifications apply only to providers located in the declared “emergency area” (as defined in section 1135(g)(1) of the SSA) in which the Secretary has declared a public health emergency, and only to the extent that the provider in question has been affected by the disaster, or is treating evacuees. The CMS Regional Office(s) will review the provider’s request and make decisions on a case-by-case basis. The waivers do not apply to care that is delivered to an evacuee by a provider that is not located in one of the designated areas. Providers outside of the affected areas should operate under normal rules and regulations unless specifically notified otherwise.

- A-2. 1135 Waiver Duration:** *How long does an 1135 waiver last and why do some people believe it only lasts 60 days?*

The length of the waiver or modification is for the duration of the emergency period, unless terminated sooner. In general, a waiver or modification of a Medicare, Medicaid or State Children’s Health Insurance Program (SCHIP) requirement invoked by the Secretary as a result of a public health emergency, will end upon the termination of the Secretary’s declaration of the public health emergency pursuant to Section 319 of the Public Health Service Act.

Waivers of sanctions under the Emergency Medical Treatment and Labor Act (EMTALA) in the emergency area end 72 hours after implementation of the hospitals disaster plan. However, if a public health emergency involves pandemic infectious disease, the waiver of sanctions under EMTALA is extended until the termination of the applicable declaration of a public health emergency."

In addition, a waiver or modification granted under the 1135 authority may terminate prior to the end of the Secretary’s declaration of a public health emergency, if the waiver or modification is no longer necessary to accomplish the purposes set forth in Section 1135(a).

These waiver purposes are to ensure: (1) that sufficient health care items and services are available to meet the needs of Medicare, Medicaid and SCHIP beneficiaries; and (2) that health care providers (defined in this provision) that

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furnish such items and services in good faith, but are unable to comply with certain requirements (defined in this provision), may still be reimbursed for such items or services and exempted from sanction (absent fraud or abuse). For example, if a hospital regains its ability to comply with a waived requirement before the end of the declared emergency period, the waiver of that requirement would no longer apply to that hospital.

Section 1135(e)(1) provides three options to the Secretary for determining the duration of waivers or modifications under Section 1135. A waiver or modification terminates upon:

1. The termination of the declaration by the President of the emergency or disaster under the Robert T. Stafford Act or the National Emergencies Act (as applicable),
2. The termination of the declaration by the Secretary of the public health emergency, pursuant to section 319 of the Public Health Services Act, or
3. A period of 60 days from the date the waiver was published.

A-3. Waived Requirements: *What regulatory requirements can be waived under the 1135 waiver?*

When the Secretary invokes the 1135 waiver authority, CMS will take steps during each declared public health emergency to identify the specific requirements that will be waived or modified under the 1135 authority and to whom and under what circumstances such waivers or modifications will apply.

Some waivers may be "blanket waivers" and apply to all providers in the emergency area and during the emergency period, that would otherwise be required to comply with the particular cited requirement.

For example, to facilitate a smooth transition, CMS may determine that time-limited waivers under the Section 1135 authority are necessary to allow critical access hospitals to exceed the 25-bed limits in order to accept evacuees.

Other waivers CMS determines to be necessary under the Section 1135 authority may apply only to particular provider(s), requirements, or conditions of participation specified by CMS, and may apply only for a specified period of time -- that is, not for the full emergency period. Examples include: temporary suspension of a pending termination action or denial of payment sanction so as to enable a nursing home to accept evacuees.

Updated waiver information and other announcements will be communicated on the CMS S&C Emergency Preparedness Website, which can be accessed at: <http://www.cms.hhs.gov/SurveyCertEmergPrep/>. This information will also be reflected in the FAQs.

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- A-4. Services in Non-Emergency Area:** *In addition to those services provided in the emergency area, can the § 1135 waiver authority be used to include waivers regarding benefits and services provided for evacuees from emergency areas who are receiving those services in non-emergency areas?*

The § 1135 waiver authority does not extend beyond the "emergency area," which is defined as the area in which there has been both a Stafford Act or National Emergencies Act declaration and a public health emergency declaration. Medicare does allow for certain limited flexibilities outside the scope of the § 1135 waiver authority (as discussed in other Q&As), and some of these flexibilities may be extended to areas beyond the declared "emergency area."

- A-5. Provider Relocation:** *If a provider who has been adversely impacted by a declared public health emergency, is unable to restart full operations, can they maintain their existing Medicare or Medicaid provider agreement while the facility is closed? Can a provider relocate, and what are the procedures for program certification if relocation is necessary?*

Each Medicare and Medicaid certified provider in the declared emergency area(s) should contact their State Survey Agency (SA) regarding their status and future plans. CMS recognizes that there are times when a public health emergency may result in consequences beyond the provider's control. Therefore, some providers may never be able to reopen at their original location and others may reopen at their original location after some period of time. Some providers may not be able to reopen unless they relocate to a new site.

Participation as a Medicare and/or Medicaid certified provider is based on the ability of the provider to demonstrate they can furnish services in a manner that protects the health and safety of beneficiaries according to the specific regulations for each provider type. However, CMS will exercise discretion and flexibility on a case-by-case basis, when determining to deactivate a provider's Medicare or Medicaid provider agreement and number, when the cessation of business is due to a declared public health emergency.

If the provider/supplier plans to reopen in a new location, CMS will need to determine if this will be a relocation of the current provider under its existing Medicare certification or a cessation of business at the original location and subsequent establishment of a new business at another location, which would require another Medicare certification. To retain the current provider certification, the entity must demonstrate to the RO that it is functioning as essentially the same provider serving the same community. CMS will consider each request for relocation on a case-by-case basis and will typically use the following type of criteria:

- The provider remains in the same State and complies with the same State licensure requirements.

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- The provider remains the same type of Medicare provider after relocation.
- The provider maintains at least 75 percent of the same medical staff, nursing staff and other employees, and contracted personnel (contracted personnel who regularly work 20 or more hours a week at the provider).
- The provider retains the same governing body or person(s) legally responsible for the provider after the relocation.
- The provider maintains essentially the same Medical Staff bylaws, policies and procedures, as applicable.
- At least 75 percent of the services offered by the provider during the last year at the original location continue to be offered at the new location.
- The distance the provider moves from the original site.
- The provider continues to serve at least 75 percent of the original community at its new location.
- The provider complies with all Federal requirements, including CMS requirements and regulations at the new location.
- The provider maintains essentially the same policies and procedures such as nursing, infection control, pharmacy, patient care, etc.
- CMS may use any other necessary information to determine if a provider/supplier continues to be essentially the same provider, under the same provider agreement, after relocation.

A-6. New Provider Regulation: *Because States with evacuees may be overwhelmed, regulation of new facilities may be challenging and fraud is a risk, what type of regulation will there be for new providers, such as assisted living or home health providers, that developed as a result of increased need for services in a particular area by evacuees? What will be the Federal and State requirements?*

The Federal government does not regulate assisted living facilities. Assisted living is a service recognized under several States' Medicaid home and community-based services (HCBS) waivers. State governments have jurisdiction in regulating these facilities and will continue to oversee the compliance of assisted living facilities with State law. New home health providers will be held to the same program requirements, Federal law and regulations, which would have otherwise been applied if the public health emergency had not occurred. In other words, no new Federal requirements will be imposed on new facilities, as a result of the disaster.

B. Clinical Laboratory Improvement Amendment (CLIA)

B-1. Relocating Laboratories: *What should newly established laboratories that are providing emergency services (e.g., FEMA laboratories) and laboratories that are re-locating to continue existing services do to obtain or retain CLIA certification?*

All entities should work with the appropriate State Agency, if available, or the appropriate CMS Regional Office CLIA personnel.

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Newly established laboratories are approved to begin emergency testing as soon as they have completed the CLIA application and transmitted it to the aforementioned agencies. The application is available on the CMS CLIA Website at: <http://www.cms.hhs.gov/clia>. Contact information for the appropriate State Agencies and CMS Regional Offices can also be found there. The application can be faxed, or mailed. For FEMA laboratories and other laboratories providing emergency services, the number of certificates required is discretionary.

Existing laboratories that are re-locating just need to notify their State Agency or CMS regional office regarding their new or temporary location.

B-2. Laboratory Surveys: *When will laboratory surveys be conducted in the declared public health emergency area?*

During a declared public health emergency, surveys for both new and existing laboratories in the affected area will be completed as resources and time permit. CMS will work with its regional offices and State Survey Agencies to provide assistance to assure quality as needed.

B-3. Laboratory Inspection: *Will my laboratory be inspected?*

If a CMS certified laboratory is located in a declared public health emergency area and there are sufficient State Agency resources available, the laboratory will be inspected as timely as possible. We will consider complaints a priority followed by laboratories whose certificates are expiring and new laboratories requiring initial certification inspections.

If a laboratory is not in operation, the State Department of Health CLIA personnel should be contacted. If you are accredited by one of the six CMS-approved accrediting organizations, contact the applicable organization. You may contact these entities or the CMS Regional Offices for any other CLIA questions or the CMS regional offices.

CLIA reviews, follow up surveys, validation and FMS surveys will be conducted as resources are available in the relevant states. Full functionality will resume as recovery progresses.

B-4. Proficiency Testing: *Will laboratories residing in the public health emergency area be subject to proficiency testing (PT)?*

If your laboratory is in an area that has essentially lost its infrastructure or is not in operation, you can contact your PT program for further information or CMS. PT requirements will resume as soon as it is logistically possible.

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- B-5. Volunteer Personnel Qualifications:** *If I open an emergency services laboratory using volunteer laboratory personnel, how should they be qualified and their competency assessed?*

Volunteer testing personnel should have proof of their certification; i.e., medical technologists, medical laboratory technicians and individuals previously certified by the Department Health Education and Welfare (HEW). Personnel for moderate complexity testing should have to demonstrate their proficiency before performing testing. Persons who hold positions of responsibility in emergency laboratories (directors and supervisors) should develop a simple mechanism to provide training and assess personnel competency for all testing individuals prior to initiating testing.

Under CLIA, the laboratory director has the overall responsibility to assure the quality of the testing; therefore, the laboratory director must meet the qualifications specified in the regulations for that position based on the complexity of testing performed. The laboratory director should retain personnel with the minimum CLIA qualifications required or, as necessary, to complete testing accurately and timely.

- B-6. Laboratory Noncompliance Enforcement:** *Will enforcement actions be imposed against laboratories not in compliance?*

Circumstances where there is immediate jeopardy to patient health and safety will be first priority; however, CMS will exercise enforcement discretion during the recovery period as necessary in order to take into account unusual circumstances under which labs are operating.

- B-7. Special Assistance Coordination:** *Where can laboratories impacted by the public health emergency receive assistance with obtaining supplies or reagents, meeting critical staffing needs, transporting specimens, or communicating with their state or local public health laboratory?*

CDC has established a Help Line for clinical laboratories experiencing trouble obtaining supplies or reagents, meeting critical staffing needs, transporting specimens, or communicating with their state or local public health laboratory. Laboratories in need of assistance should contact the CDC Help Line at 1-800-232-4636 for appropriate coordination of needed aid. Callers will need to identify themselves as representing a clinical laboratory in need of assistance, because the hotline handles many inquiries.

C. Community Mental Health Center (CMHC)

- C-1. Certification Requirements:** *Will certification requirements be waived for CMHC applicants in the public health emergency area?*

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CMS may defer the on-site review requirement during a public health emergency. However, all other requirements must be met (i.e., core requirements, operational for at least one business quarter, etc.), at the time the Regional Office defers the on-site review. It should be understood that continued certification is dependent upon a satisfactory on-site visit by CMS staff, once travel to the affected area is feasible.

C-2. Operating for One Business Quarter: *Will CMS waive the requirement for a CMHC to be operational for one business quarter?*

No. The CMHC must show a history of providing services to be considered for the expedited certification process.

C-3. Relocating CMHCs: *Will CMS waive the restrictions on CMHCs relocating?*

The CMS Regional Office will allow affected CMHCs to temporarily relocate their practice on a case-by-case basis. Each relocation request will then be reviewed within six months to determine the continued need for the temporary site.

C-4. 24-Hour Emergency Phone Service: *Will new CMHC providers be required to meet the 24-hour emergency phone service criteria?*

This requirement may be waived if phone service is disrupted in the public health emergency area, and if all other core requirements are met by the new CMHC applicant. However, if the provider is found to be out of compliance with this requirement, once phone service has been restored, its certification will be terminated.

D. Critical Access Hospital (CAH)

D-1. 25 Inpatient Bed Rule: *Critical access hospitals (CAHs) are normally limited to 25 beds and to a length of stay of not more than 96 hours, but may need to press additional beds into service or extend lengths of stay to respond to the crisis. Will CMS enforce these limits?*

During a declared public health emergency, CMS will not count any bed use that exceeds the 25 inpatient bed or 96-hour average length of stay (LOS) limits, if this result is clearly identified as relating to the disaster. CAHs must clearly indicate in the medical record where an admission is made or length of stay extended to meet the demands of the crisis.

D-2. 96-Hour Rule: *Will critical access hospitals in affected states remain subject to the 25 inpatient bed and 96-hour length of stay rule?*

The 96 hour average annual length of stay (LOS) is calculated annually. Depending on the length of the declared public health emergency, there may be

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no adverse impact on a CAH's ability to achieve this annual average. However if a CAH located in the emergency area is found to have exceeded the 96-hour average in its next annual calculation, CMS will determine whether this resulted from the CAH's provision of services to evacuees during the public health emergency. CAHs should notify their State Survey Agency (SA) if they find that their patients are averaging a longer than 96 hour LOS during the public health emergency. They should also describe the measures that they are taking to ensure that there are adequate, qualified personnel, equipment and supplies to provide safe care for those patients who require a longer LOS. Generally CAHs are expected to transfer out patients who require longer admissions, to hospitals that are better equipped to provide specialized or complex services to patients who are more acutely ill.

E. Drugs

E-1. Contaminated Drugs: *How can health care facilities determine the appropriate use of contaminated and temperature sensitive drugs?*

For information regarding the use of potentially contaminated and temperature sensitive drugs during a disaster, please access the FDA's Website at <http://www.fda.gov/Drugs/EmergencyPreparedness/ucm085200.htm>. For questions about specific drug products, call the FDA general number: 1-888-INFO-FDA.

E-2. Redistribution of Drugs: *Does the 1135(b) waiver allow the redistribution of drugs marked for destruction in skilled nursing facilities (SNFs), nursing facilities (NFs), hospitals, etc., to aid a declared public health emergency relief effort?*

While Federal regulations do not directly address the issue of redistribution, it does speak about "including procedures that ensure the accurate acquiring, receiving, dispensing and distribution of all medications." Therefore, although the redistribution of drugs is a matter that is regulated by the State Boards of Pharmacy it is also addressed in Federal regulations with respect to the safety of the distribution system in practice. Each respective State Board of Pharmacy should be consulted regarding any proposed variance to State law to aid the relief effort (the Federal regulations also address compliance with applicable state laws).

E-3. Medications for Evacuated Patients & Residents: *Information regarding medications that patients and residents were receiving before being evacuated is important for facilities that now serve the evacuees. Can this information be accessed anywhere?*

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Providers may access the State's Medicaid recipients' clinical drug histories for up to four (4) months. Facilities that receive this information will need to comply with the requirements of the Privacy Act.

In addition, the Emergency Rx History was launched by the nation's pharmacies in April 2007, to provide individuals who have been displaced by disasters or other kinds of emergencies with faster, safer access to prescription medications. Emergency Rx History allows licensed prescribers and pharmacists anywhere in the country to securely access information containing the prescription history of a patient from the affected area. Emergency Rx History reduces the risk of medication errors by making prescription information available to licensed caregivers when they are where they are treating patients and residents. Emergency Rx History is a collaborative, public-service initiative made possible by the nation's community pharmacies and the Pharmacy Health Information Exchange, operated by SureScripts. For more information about Emergency Rx History, please access SureScripts' Website at: <http://www.surescripts.com/>

In addition, health care organizations involved in the manufacturing, distribution and dispensing of pharmaceutical products have come together to announce the creation of Rx Response – a program designed to help support the continued delivery of medicines during a severe public health emergency. The partnership includes the American Hospital Association, American Red Cross, Biotechnology Industry Organization, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association and the Pharmaceutical Research and Manufacturers of America. For more information regarding Rx Response, please see their website at: <http://www.rxresponse.org/>.

F. Emergency Evacuations

F-1. Policy of Emergency Evacuation: *What is CMS' policy to Medicare contractors regarding evacuations?*

Medicare policy provides contractors with leeway to determine Medicare reimbursement for services provided under unusual circumstances. While CMS recognizes it is in the patients' best interest to be evacuated as soon as possible during an emergency, contractors have the responsibility to determine if Medicare expenditures should be made for the evacuation.

In most cases, mass emergency evacuations billed to Part B are for nursing home patients from ambulance suppliers. Medicare skilled nursing facilities and Medicaid nursing facilities are required to have an emergency evacuation plan as a requirement for participation. Many will have insurance to cover these situations. If the facility has insurance that will cover the evacuations, Medicare is the secondary payer. If not, contractors should consider the following points prior to making payment:

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- Medicare's medical necessity requirements apply in all cases;
- Payment may be made only if the patient was transported to an approved destination; and,
- Multiple patient transport payment provisions apply in all cases.

G. Enforcement Activities

G-1. Survey Activities in Affected States: *Will State Survey Agencies change their activities during a declared public health emergency? What is the potential impact to survey activities?*

Based on a variety of factors, including State Survey Agency (SA) operational status, scope of the emergency, and impact on normal operations of providers, SAs may, at the CMS Regional Office or Central Office direction, modify or suspend certain survey activities.

Each pending action will be reviewed on a case-by-case basis to determine if there are activities that need to be completed by the CMS Regional Office in the interim, such as review any currently imposed denial of payment for new admissions (DPNAs) to determine the effect they may be having on facilities that take in additional patients from other homes.

G-2. DPNAs and Terminations: *What happens when a skilled nursing facility or a nursing facility (either an evacuated facility or one that has accepted evacuees) is on an enforcement track and its operations have been impacted by a declared public health emergency? For example, a denial of payment for new admissions sanction may be in effect for the "accepting" or receiving facility.*

For a facility that is located in an emergency area, enforcement actions such as denial of payments for new admissions (DPNAs) and termination actions may be deferred during the effective period of the 1135(b) waiver. Each pending enforcement action will be reviewed on a case-by-case basis. For facilities accepting evacuated residents, DPNA deferment will be based on a recommendation by the State Survey Agency and a review of vacancies in other facilities in the area. Further, deferral of DPNA for accepting facilities will only apply to new admissions that are evacuees from the affected states.

G-3. Civil Money Penalties: *How should the collection and accrual of civil money penalties be handled for affected facilities?*

State Survey Agencies can make recommendations regarding this issue to the Regional Office (RO). ROs have discretion in this regard after considering the specifics of any given situation. Facilities may be facing different challenges and CMS will take those differences into account, such as the following:

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- (a) For facilities directly impacted by the emergency, generally, civil money penalties (CMPs) will not be collected during the emergency period, and accrual of penalty amounts will temporarily cease, during the effective period of the section 1135(b) waiver.
- (b) For all facilities that have admitted evacuees where CMPs have also been imposed, the ROs will handle CMP issues on a case-by-case basis.
- (c) For other facilities that may be affected by the inability of the SAs to conduct revisit surveys, which affects the accrual of CMPs, the ROs should be contacted for a case-by-case determination.

G-4. Civil Money Penalties in Affected Area: *Will CMS consider suspending the collection of a CMP for a skilled nursing facility in a declared public health emergency area while they care for additional evacuees they have taken into their facility?*

Based on the 1135(b) waiver, CMS will generally suspend collection of a CMP for skilled nursing facilities located in an emergency area that are providing care for evacuees. The suspension will remain in effect during the time period of the 1135(b) waiver. Subsequently, CMS will request a financial impact statement from the specific facilities where CMPs are due and payable, and will conduct a case-by-case review to determine if any adjustments should be made. Suspension of a CMP collection for any other skilled nursing facility admitting evacuees will be handled on a case-by-case basis.

G-5. Plans of Correction: *Is a plan of correction still required from affected skilled nursing facilities (SNFs) that would otherwise have needed to submit one?*

State Survey Agencies and the CMS Regional Office will address this issue on a case-by-case basis since the answer depends on the extent to which the provider is affected. For seriously affected SNFs in the public emergency area, a plan of correction will generally be deferred during the effective period of the section 1135(b) waiver.

H. End Stage Renal Disease (ESRD)

H-1. ESRD Facility Status: *How do I find out information about the status of dialysis facilities during a disaster?*

The Kidney Community Emergency Response (KCER) group monitors weather-related and other disasters, and maintains information about dialysis services. KCER makes it easy to keep abreast of dialysis services during disasters. To view open / closed status of dialysis facilities please see KCER's link at: <http://www.dialysisunits.com>.

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Providers should notify their local End-Stage Renal Disease Network if there are any changes in status. To access information on ESRD Networks and Coalition activities, and available tools and resources, please see the KCER Website at: <http://www.KCERCoalition.com>

- H-2. Certification:** *In an emergency environment, how might capable providers who are not currently certified to provide ESRD outpatient services, become certified to receive Medicare reimbursement for delivered dialysis services?*

The Medicare program has a special classification for facilities that provide dialysis treatment services during emergencies. This classification is entitled "special purpose dialysis facilities." The certification for a "special purpose dialysis facility" may last for up to eight months. A special purpose dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility. A special purpose dialysis facility should consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's care plan.

Certification for a special purpose dialysis facility can be immediate. For this certification, a provider should contact either the State Agency where the facility would be located, or the CMS Regional Office.

- H-3. Recertification:** *How will recertification be handled for those Medicare-certified dialysis facilities with CMS Certification Numbers that have to close due to damage?*

Medicare-certified dialysis facilities with CMS Certification Numbers that need to rebuild or relocate following the public health emergency, should notify either the State Survey Agency or the Regional Office of their intention. Once the dialysis facility is operational and in compliance with Medicare's health and safety requirements, the facility may resume billing under their current CMS Certification Number. Relocated and rebuilt ESRD facilities will be surveyed to assure compliance with basic health and safety requirements when recovery efforts and resources at the State level permit.

- H-4. Water Treatment Precautions:** *The CDC states that dialysis centers that are operating in the area need to pay special attention to water treatment and especially carbon tank maintenance because of the assumption that extra chlorine may be dumped into the water system by water treatment plants. More frequent disinfection of the water treatment and dialysis equipment may be needed. Is additional information available about special precautions?*

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have set up Websites about infection control and water treatment issues and medical devices for natural disasters. The CDC has

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provided multiple sets of guidelines, available at <http://www.bt.cdc.gov/disasters/hurricanes/index.asp>. These include guidelines of particular interest to health-care providers, relief workers, and shelter operators. *Hurricane-Related Information for Health-Care Professionals* (<http://www.bt.cdc.gov/disasters/hurricanes/hcp.asp>) includes guidelines for managing acute diarrhea and guidance related to immunizations and vaccine storage. *Worker Safety During Hurricane Cleanup* (<http://www.bt.cdc.gov/disasters/hurricanes/workers.asp>) includes health recommendations for relief workers and guidance on worker safety during a power outage. In addition, a new compilation, *Natural Disasters*, has been added to the *M Guide Online Knowledge Centers* at the *MMWR Website* (<http://www.cdc.gov/mmwr>). The *M Guide* provides Internet links to previously published *MMWR* reports regarding assessment of health needs and surveillance of morbidity and mortality after hurricanes, floods, and the December 26, 2004 tsunami.

The FDA Website at <http://www.fda.gov/EmergencyPreparedness/default.htm> covers general safety, power outage (warning about potential carbon monoxide problems when using generators), water contamination, sterility, reuse, heat and humidity (information about using blood glucose meters), and treating snakebites. The FDA has a main site for health and safety <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064572.htm>.

H-5. Restoring Operations: *What considerations need to be taken into account when restoring a dialysis facility to operational status in the recovery phase following a public health emergency?*

The CDC, FDA, and the Association for the Advancement of Medical Instrumentation (AAMI) have prepared recommendations about reopening dialysis facilities following a disaster. These directions are for use if the building has not been flooded, and after utilities have been restored, the physical facility is in operational condition, and adequate water flow and pressure is available, although source water may be subject to a “boil water alert.” If the facility was flooded, please see the CDC guidelines for recovery of a flooded building at <http://www.bt.cdc.gov/disasters/floods/>

Water Treatment System:

- Flush all pretreatment equipment to drain for at least 30 minutes to remove the stagnant water from the system.
- Test the level of free chlorine and chloramine in your source water (expect it to be higher than normal).
- Test chlorine and chloramine after the primary carbon tank to verify that the water is <0.5 ppm free chlorine, or <0.1 ppm chloramine.
- If chlorine or chloramines after the primary carbon tank ≥ 0.5 ppm or ≥ 0.1 ppm, respectively, promptly change the primary carbon tank, or for

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systems with a secondary carbon tank, test the levels after the secondary carbon tank.

- If chlorine and chloramine are below these levels (0.5 ppm or 0.1 ppm), turn on the Reverse Osmosis (RO) machine.
- Flush the distribution system (to drain if possible).
- Disinfect the RO and the distribution system and rinse. Test for residual disinfectant levels to ensure proper rinsing.
- Replace all cartridge filters.
- Compare your product water quality readings to your historical data. A significant difference could mean that your RO membranes are damaged, or the quality of the incoming water has drastically decreased. (see note below) If the total dissolved solids (TDS) are greater than 20% higher than your historical readings you may need to use deionization (DI) tanks as a polisher on the product water, followed by an ultrafilter to minimize microbial contamination.
- Increase your frequency of monitoring:
 - Check chlorine/chloramine hourly
 - Verify hourly that your product water quality is acceptable.
 - Monitor water cultures and endotoxin at least weekly. If you have the capability to test for endotoxin on site, test daily.
- Draw representative water cultures and endotoxin tests as soon as possible. If you have the capability of testing for endotoxin on site, do this before you run patients; report the results to your Medical Director.
- Anticipate an increased level of particulate matter in the water. Monitor the pressure drop across pretreatment components and backflush as necessary.
- Plan on re-bedding your carbon tanks as soon as possible.
- Send a sample of product water for an AAMI analysis as soon as is practical.
- Clean the RO membranes as soon as is practical.

Dialysis Machines:

- Chemically disinfect the dialysis machines and rinse. Test for residual disinfectant levels to ensure proper rinsing.
- Bring up the conductivity and “self test” the machines to verify proper working condition. If a machine fails the “self test,” perform needed repairs prior to using that machine.

Note: If the product water TDS is high and the percent rejection is in line with historical performance, then the RO membranes are most likely good, but the feed water may have a higher than usual level of contaminants. DI polishing will help cope with the extra burden in the feed water.

If the product water TDS is high and the percent rejection is lower than historical values, then the RO membranes are probably bad and should be replaced

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promptly. DI polishing may or may not be needed once the RO membranes are replaced.

Hemodialysis Water Treatment References:

Association for the Advancement of Medical Instrumentation, Recommended Practices for Dialysis Water Treatment Systems (RD 52 and RD 62)
<http://aami.org/publications/standards/dialysis.html>

Other Resources:

Notice: *Guidance for Dialysis Care Providers: What to do when your municipal water supplier issues a "boil water advisory"*
<http://www.cdc.gov/dialysis/guidelines/boil-water-advisory.html>

Water Related Emergencies

<http://www.bt.cdc.gov/disasters/watersystemrepair.asp>

Tips about Medical Devices and Hurricane Disasters

<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm055987.htm>

Medical Devices that Have Been Exposed to Heat and Humidity

<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm056086.htm>

Medical Devices Requiring Refrigeration

<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm056075.htm>

Fact Sheet: Flood Cleanup - Avoiding Indoor Air Quality Problems

<http://www.epa.gov/mold/flood/index.html>

NIOSH Response: Storm and Flood Cleanup

<http://www.cdc.gov/niosh/topics/emres/flood.html>

American Institute of Architects: Procedures for Cleaning Out a House or Building Following a Flood

<http://www.aia.org/about/initiatives/AIAS075276?dvid=&recspec=AIAS07527>

- H.6. Relocated Transplant Patients:** *Some transplant patients or patient candidates may be relocated due to a public health emergency. How will their wait-list time be calculated if they transfer to other transplant centers? How can they receive information about open transplant centers?*

The Organ Procurement Transplantation Network (OPTN), which operates the nation's organ transplant and allocation system can assist relocated transplant patients in finding alternative transplant centers. In past public health emergencies, OPTN has provided specific information to address relocated transplant candidates on its website, <http://optn.transplant.hrsa.gov/>, including information about other available transplant centers within each state. We would encourage any transplant candidate seeking information about transferring to

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another transplant center to refer to this website or contact the toll-free Patient Services line at 1-888-894-6361. Transplant candidates and recipients are encouraged to call between 8:30 a.m. to 5:00 p.m. EST Monday through Friday for assistance with questions and resources.

Relocated transplant candidates who need to list at a different center can transfer their accumulated waiting time without losing any allocation priority.

I. Home Health Agency (HHA)

I-1. Home Health Services at Alternative Sites: *Can the “residence” component of the homebound requirements be suspended by allowing the delivery of home health services at an alternative site of temporary residence during the crisis?*

The Social Security Act stipulates that beneficiaries must be confined to the home in order to be eligible to receive home health services. A beneficiary’s home is any place in which a beneficiary resides that is not a hospital, skilled nursing facility (SNF), or nursing facility as defined in § 1861(e)(2), § 1819(a)(1), or § 1919(a)(1) of the Social Security Act, respectively. During the emergency period, the place of residence can include services provided at a temporary alternative site, such as a family member’s home, a shelter, a community facility, a church, or a hotel. A hospital, SNF, or nursing facility as defined above would not be considered a temporary residence.

I-2. OASIS Assessment Requirements: *What adjustments or flexibility is allowed related to Medicare requirements for completion of the OASIS assessment process?*

In the time period indicated in the statutory waiver invoked by the HHS Secretary under § 1135 of the Social Security Act, CMS may modify certain timeframe and completion requirements for OASIS. In this emergency situation, an abbreviated assessment can be completed to assure the patient is receiving proper treatment and to facilitate appropriate payment.

For those Medicare approved HHAs serving qualified home health patients in the public health emergency areas determined by the Secretary, the following modifications to the comprehensive assessment regulation at 42 CFR § 484.55 may be made. These minimal requirements will support reimbursement when billing is resumed and help ensure appropriate care is provided.

- The Start of Care assessment (RFA 1) may be abbreviated to include the Patient Tracking Sheet and the 24 payment items.
- The Resumption of Care assessment (RFA 3) and the Recertification assessment (RFA 4) may be abbreviated to the 24 payment items.
- The Discharge assessment (RFA 8 or RFA 9) and the Transfer assessment (RFA 6, RFA 7) are suspended during the waiver period.

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HHAs should maintain adequate documentation to support provision of care and payment.

- I-3. Abbreviated OASIS:** *Are HHAs permitted to do abbreviated OASIS data collection at start of care, i.e., limit collection to the OASIS items required for billing (as long as they use some tool to assess patient's clinical status)?*

For HHAs that are located in the emergency area(s) that serve evacuees, the Start of Care assessment (RFA 1) may be abbreviated to include the Patient Tracking Sheet and the payment items. HHAs should maintain adequate documentation to support provision of care and payment.

- I-4. Time Limits for OASIS:** *During a public health emergency, must HHAs comply with the 5-day OASIS completion window? Must they comply with the 7-day lock date? Must they transmit data within the required time frame?*

HHAs that are operating under the time limited statutory waiver in the affected disaster areas may complete an abbreviated assessment. This abbreviated assessment does not have to meet the 5-day completion date or the 7-day lock date. In addition, the OASIS transmission requirements at 42 CFR 484.20 are suspended for those Medicare approved HHAs that are serving qualified home health patients/evacuees in the affected areas.

HHAs are expected to use this policy only as needed, and to return to business as usual as soon as possible.

- I-5. Resuming Care:** *May HHAs omit transfer and resumption of care assessments?*

The Resumption of Care assessment (RFA 3) and the Recertification assessment (RFA 4) may be abbreviated during a public health emergency to the 24 payment items as discussed above.

The OASIS Discharge assessment (RFA 8 or RFA 9) and the Transfer assessment (RFA 6, RFA 7) are suspended during the waiver period.

- I-6. OASIS Alternatives:** *Will home health agencies be given any special consideration for OASIS if their vendor is located in an emergency area and has been impacted by the disaster?*

HHAs do have other options as far as software to use. We suggest they use HAVEN for the interim. If they need assistance with importing their vendor's data into HAVEN, they should contact the HAVEN Help Desk at 1-877-201-4721.

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- I-7. Facility Relocation:** *Several of my home health agency physical locations have been destroyed by the disaster. May I relocate and continue furnishing services?*

Contact your CMS Regional Office. The Regional Office will review requests on a case-by-case basis, and limited exceptions to the physical location requirements may be allowed. In addition, please refer to the State's specific licensure and certification requirements during an emergency. For example, during Hurricane Katrina, Louisiana Gov. Kathleen Blanco declared a public health state of emergency and temporarily waived certain licensure requirements.

If the facility will not be operating in the original location for several months (approximately four months after the disaster), CMS will revisit the situation and determine if voluntary deactivation is best. The original certification was for services to a designated service area and may not be used to expand or relocate services, but is for temporary emergency service delivery.

- 1-8. Home Health Services:** *If there is an increased demand for home health or other services, how will those needs be met in the long run?*

CMS does not limit the number of patients that can be cared for by a home health agency. The agency must meet all federal participation requirements and have appropriately qualified staff to care for the patients and adequate supervision of the staff. However, State law may place limitations on the number of agencies or the relocation of agencies.

J. Hospitals

- J-1. Acute Care Patients:** *Can a bed in a psychiatric unit be used for acute care patients admitted during a public health emergency?*

Yes, for hospitals located in the emergency area, beds in a psychiatric unit may be used for acute care; however, it should be fully documented in hospital records. In addition, the acute portion of the hospital should bill for all Medicare-covered services; the psychiatric unit should record the services/charges as non-Medicare.

- J-2. Hospital Certification:** *Could the State certify a hospital to provide Skilled Nursing Services?*

A hospital could apply for certification of portions of its facility as a Nursing Facility. A hospital with less than 100 beds and located in a nonurbanized area may apply for swing bed status and receive payment for skilled nursing facility services by applying with the CMS RO. A survey by the SA would be required.

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J-3. EMTALA Waiver: *Does a hospital need to submit a request to the State Survey Agency for the general EMTALA waiver?*

Requests for waiver of sanctions under the Emergency Medical Treatment and Active Labor Act (EMTALA) are not required for hospitals or CAHs located in the emergency area that have activated their disaster plans and operate under the general EMTALA waiver. Such waivers are limited to a 72 hour period beginning with the hospital's activation of its hospital disaster protocol and are not effective for actions that discriminate among individuals on the basis of their source of payment or ability to pay. Hospitals that activate their hospitals disaster plan and are invoking the permitted EMTALA waiver of sanctions must provide notice to their State Survey Agency, who will forward the information to their CMS Regional office.

J-4. EMTALA Requirements: *Would it be considered an EMTALA violation if the hospital did not have any medical records available because of the disaster?*

During a declared public health emergency, CMS would take a liberal view of the situation. However, as in physician attestations, the new medical record would have to reflect the lack of prior documentation.

J-5. EMTALA Compliance during a Public Health Emergency: Are hospitals required to comply with all of the requirements of EMTALA during the public health emergency period in the emergency area?

Generally, yes. However, CMS has the authority not to impose sanctions on a hospital located in the emergency area during the emergency period if the hospital redirects or relocates an individual to another location to receive a medical screening examination pursuant to either a state emergency preparedness plan or transfers an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency. Such waivers are limited to 72 hours from the beginning of the implementation of the hospital's disaster protocol. This waiver, however, is not effective with respect to any action taken that discriminates among individuals on the basis of their health status, source of payment or their ability to pay.

J-6. EMTALA Medical Screening: *Evacuees from states affected by the public health emergency may arrive at hospital emergency departments merely to obtain refills of prescriptions that they lost when they evacuated during a disaster or public health emergency. Must these individuals be given an EMTALA medical screening examination when they come to the emergency department?*

Even under non-emergency circumstances, the Emergency Medical Treatment and Active Labor Act (EMTALA) regulations make it clear that individuals seeking only prescription refills need not be given a complete medical screening examination, but rather, one that is appropriate for the request that they make.

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Hospitals may wish to develop specific protocols that include a streamlined screening examination for patients seeking prescription refills, consistent with the regulation cited above.

- J-7. Emergency Department Shut-Down:** *If a hospital remains open during a disaster and is operating at or in excess of its normal operating capacity and cannot get sufficient staff, may the hospital shut down its emergency department (ED) without violating EMTALA?*

Under these circumstances, EMTALA would not prohibit the hospital from closing its ED to new patients if it no longer had the capacity to screen and treat individuals (in effect, going on diversion). The hospital should follow any applicable State and local notice requirements and its own previously established plan for public notification when it goes on diversionary status. The hospital would continue to have an EMTALA obligation to individuals undergoing examination or treatment in its ED at the time it stops accepting new emergency patients. In addition, in spite of the “closure” if an individual comes to such a hospital and requests examination or treatment for an emergency medical condition, the hospital would be obligated by EMTALA to act within its capabilities to provide screening and, if necessary, stabilization.

- J-8. Inpatient Rehabilitation Rule:** *As a result of the disaster or public health emergency, some hospitals may use any available bed to care for patients that have been transferred from the affected areas, or to treat the large number of people requiring hospital care. Will CMS enforce the 60 percent rule for inpatient rehabilitation facilities that admit patients outside of the 13 conditions in order to meet the demands of this crisis?*

CMS recognizes that some facilities in the emergency area may take a higher number of admissions outside of the 13 conditions to meet the demands of the crisis during the emergency period. Facilities should clearly indicate in the medical record where an admission is made to meet the demands of the crisis. These cases will not be counted toward compliance with the 60 percent rule.

- J-9. Inpatient Rehabilitation Facility – 60 Percent Rule:** *The disruption to the hospital system caused by the flooding and its aftermath may require some hospitals to use any available bed to care for patients that have been transferred from the affected areas, or to treat the large number of people requiring hospital care. If an inpatient rehabilitation facility (IRF) admits a patient solely in order to meet the demands of this crisis, will the patient be included in the hospital’s or unit’s inpatient population for purposes of calculating the applicable compliance thresholds in 42 Code of Federal Regulations (CFR) § 412.23(b)(2) (“the 60 percent rule”)?*

In order to meet the demands of the crisis, CMS will modify enforcement of the requirements specified in 42 CFR § 412.23(b)(2), which is the regulation

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commonly referred to as the “60 percent rule.” If an IRF admits a patient solely to respond to the crisis and the patient’s medical record properly identifies the patient as such, the patient will not be included in the hospital’s or unit’s inpatient population for purposes of calculating the applicable compliance thresholds outlined in § 412.23(b)(2). In the case of an admission that is made solely to meet the demands of the crisis, a facility should clearly identify in the inpatient’s medical record by describing why the patient is being admitted solely to meet the demands of the crisis. In addition, during the applicable waiver time period, the exception described in this answer would also apply to facilities not yet classified as IRFs, but that are attempting to attain classification as an IRF.

An institutional provider would use the “CR” (catastrophic/disaster related) modifier to designate any service line item on the claim that is disaster related. If all of the services on the claim is disaster related, the institutional provider should use the “DR” (disaster related) condition code to indicate that the entire claim is disaster related.

- J-10. Inpatient Rehabilitation 3-Hour rule:** *In addition to suspending the “60 percent rule” during the flood, will the Medicare admission criteria for inpatient rehabilitation found (IRF) in Section 110 of the Medicare Benefits Policy Manual, such as the 3-hour rule, also be temporarily suspended?*

CMS recognizes that it may become necessary for patients who are not rehabilitation candidates to be admitted to IRFs due to the flood. In these instances, CMS would not apply the IRF specific criteria (e.g., the 3-hour rule) to any review of claims. IRFs should clearly document in the patient’s medical record that the patient was admitted solely to meet the demands of the crisis.

- J-11. 25-Day Average Length of Stay:** *Long term care hospitals (LTCHs), which normally require a 25-day average length of stay, may need to use beds for less than this time when responding to the crisis. Will CMS enforce this average length of stay requirement?*

During the public health emergency, CMS will not count evacuees in calculating whether patients from this emergency meet the 25-day average length of stay requirement during the emergency period. LTCHs must clearly indicate in the medical record where an admission is made to meet the demands of the crisis.

- J-12. Converting Exempt Beds:** *Can exempt beds in the emergency area be converted to acute beds if a shortage of acute beds occurs due to victims of the disaster? In the past, such requests were handled on a case-by-case basis. Should we continue to send such requests to the State Survey Agency for conversion?*

CMS will handle each request to convert exempt beds to acute care beds to accommodate the needs of disaster victims on a case-by-case basis. The

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State's input in reviewing the provider's request and determining whether or not there really is a need for the proposed beds is critical to helping ensure that beneficiaries receive the high quality care they need.

It is important to realize that any change in bed type would be approved only if there was an established need for the care to be provided, if the care can be provided safely and only for a very short period of time. Basically the change in bed type would only be approved for a brief emergency situation. Beneficiaries must be transferred to the appropriate provider type as soon as their condition permits.

J-13. Temporary Certification to Perform Organ Transplants: *May a hospital in a public health emergency area that is covered by the 1135(b) waiver authority be given temporary certification to perform organ transplants as a transplant center?*

A hospital in a public health emergency area that is covered by the 1135(b) waiver may be given temporary certification to perform organ transplants as a transplant center under special circumstances. Waiver of the standard certification and survey process will be considered on a case-by-case (i.e., center-by-center) basis. Any approved waiver will be effective for only so long as the emergency period exists, as determined by the President and the Secretary of HHS, or (with State and/or Regional Office approval) until the transplant center is ready to relocate from a temporary location to a permanent location.

In considering whether to grant a waiver of the standard certification and survey process for a temporary certification, a transplant center must have an experienced and credentialed transplant team, offer a full range of transplant services, provide the required administrative and support services, ensure that the temporary hospital setting has all of the needed support services, and have a relationship with the Organ Procurement Transplant Network (OPTN) and an Organ Procurement Organization.

In order to ensure safe and adequate care, the following areas must be addressed prior to the granting of a temporary relocation of a transplant center:

- The transplant team needs to include the full component of experienced transplant staff, including the director, transplant surgeons and physicians, nurses, transplant coordinator, social worker, and dietitian.
- The full-range of services need to be provided, including pre- and post-transplant care.
- The hospital that will temporarily house the renal transplant center must have the administrative operations, physical capacity, and necessary support services for transplantation. This includes a governing body that acknowledges and assumes responsibility for the transplant program, full pharmaceutical services, access to a certified histocompatibility laboratory,

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dialysis facilities (for renal transplant centers), and social and dietary services that can meet the needs of a renal transplant program.

- The temporary facility must show that there will be a working relationship with the OPTN.
- The temporary facility must have the capacity to meet Medicare's quality standards for renal transplantation, 42 CFR 482.68 through 482.104.

Before such approval, there must be evidence that the interest of Medicare beneficiaries would be better served by receiving transplant services in the temporary facility rather than in existing certified transplant centers. To request approval of the temporary certification of a transplant center, in those States where the survey and certification process is handled by the State Survey Agency, contact either the respective State Survey Agency or Regional Office. In those states, where the survey and certification process is handled by CMS' contractors, contact the Regional Office.

K. Nursing Home PROVIDERS

- K-1. 3-Day Hospital Stay:** *Will skilled nursing facilities (SNFs) in the declared public health emergency area still be requiring residents to have a 3-day hospital stay prior to their admission?*

During the emergency period, CMS will temporarily provide SNF benefits in the absence of the 3-day prior hospital qualifying stay for those SNF residents affected by the declared public health emergency to facilitate a smooth transition for skilled nursing facility (SNF) residents that will fit their individual care needs. This policy applies to any Medicare beneficiary who:

- was evacuated from a nursing home provider in the emergency area;
- was discharged from a hospital (in the emergency or receiving locations) in order to provide care to more seriously ill patients; or
- needs SNF care as a result of the emergency, regardless of whether that individual was in a hospital or SNF prior to the disaster.

Providers must document in the medical record both the medical need for the SNF admission and how the admission was related to the crisis created by the declared public health emergency and its aftermath.

- K-2. Voluntary Recertification:** *If a skilled nursing facility has sustained moderate to severe damage and physical plant assessments indicate re-occupancy may be delayed for several months, what are the particulars of assigning voluntary deactivation status to those facilities?*

Providers in the emergency area will be reviewed on a case-by-case basis. If the facility will not be back in business for several months (approximately four months after the disaster), CMS may ask for their voluntary termination of their

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provider agreement and will be flexible about bringing them back into the program.

- K-3. Tracking Residents:** *How will residents be tracked so they can get in touch with their families, especially residents with Alzheimer's or dementia who may not be able to identify themselves or provide much other information?*

CMS recommends that State Agencies collaborate with health care facilities and their public and private partners to develop a method for tracking patients and residents in the event of a public health emergency.

- K-4. MDS Medical Record Information:** *How can providers that accept residents evacuated from a skilled nursing facility obtain MDS information?*

Skilled nursing facility residents in the public health emergency area may be evacuated to other nursing homes without their medical history. The Minimum Data Set (MDS) may be the primary source of medical record information for many of these residents. Providers accepting such residents may submit requests for consideration to obtain information available on the residents' MDS record by contacting the QIES Help Desk at 888-477-7876.

- K-5. MDS Assessment Requirements:** *What are the requirements for filling out an MDS assessment?*

Under normal circumstances, or absent implementation of an 1135 waiver, a nursing facility or skilled nursing facility (NF/SNF) provider must complete an OBRA-required Comprehensive Resident Assessment Instrument (RAI), that is the Minimum Data Set (MDS) required under §1819 and 1919 of the Act and 42 C.F.R. §483.20, as well as the Care Area Assessments (CAAs), for each resident within 14 days of admission to the facility (excluding readmissions in which there is no significant change in the resident's physical or mental condition), annually, when there has been a significant change in the resident's condition, or when a significant error in prior comprehensive assessment is identified. A non-comprehensive Quarterly assessment must be completed at least every 92 days following the previous OBRA-required assessment of any type as well as when a significant error in a prior Quarterly Assessment is detected. Additionally, Entry Tracking Records, Discharge Assessments, and Death in Facility Tracking Records are required to track residents when they enter or leave a facility. MDS assessments are also required to determine payment for each resident whose stay is covered by Medicare Part A. Details of these assessments can be found in the *Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0*, October 2010. If the Secretary has authorized waivers under 1135, the guidance below will apply during the 1135 waiver period as needed.

In the case of evacuations, the evacuating facility should determine by day 15 of the evacuation, whether or not residents will be able to return to the evacuating facility within 30 days from the date of the evacuation. This determination must be documented

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according to the facility's policy and the evacuating facility must immediately notify all residents and/or their responsible parties, receiving facilities, the State Survey Agency (SA) and the State Medicaid Agency of its' determination. The evacuating facility must confirm and document that all parties noted above have received their determination and notice. These notices may be made via a phone call, delivered in person, mailed via Certified US Mail, sent via fax or e-mail or other method that allows confirmation of receipt of the notice.

- If the residents return to the evacuating facility within 30 days from the evacuation date, the MDS cycle will continue as though the residents were never transferred/discharged. In determining if the resident returned to the facility within 30 days, the day of evacuation from the facility is not counted in the 30 days. For example, a resident who is evacuated on December 1 would need to return to the evacuating facility by December 31 to meet the "within 30 day" grace period. This places minimal disruption on the staff's daily routine in caring for all residents. The evacuating facility would then complete the MDS according to the *Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0*, October 2010 once the residents return to its facility. If an OBRA-required resident assessment was due during the time the resident was evacuated from the facility, the facility will have 14 days from the resident's return (that is date of return + 13 days) to complete the assessment. If Prospective Payment System (PPS)-required assessments (under §413.343(b)) were due while the resident was evacuated, the facility should seek guidance from the Fiscal Intermediary (FI)/Medicare Administrative Contractor (MAC) regarding the appropriate course of action.
- When the evacuating facility determines that the residents will not be able to return to the facility within the 30-day time frame, the evacuating facility should discharge the resident by completing a discharge assessment within the 30-day time frame. The receiving facility may then admit the resident if this is the resident's choice or must work with the resident and/or their responsible party to offer alternative choices of other available facilities or locations that meets the resident's choice and needs. Once admitted, the receiving facility will complete an Entry Tracking Record indicating the resident is an "Admission". If the resident's stay is covered by Medicare Part A, a PPS 5-day MDS will be completed as per §413.343(b). The MDS cycle will begin as of the admission date. The discharge/admission date must occur within the previously mentioned 30-day time frame.

If the resident returns to the evacuating facility after the 30-day time frame, the receiving facility will discharge the resident and complete a discharge assessment. The evacuating facility will then consider the resident as an "Admission" (i.e., not a "Re-entry") for MDS purposes. The MDS cycle will be established based on the Admission Date and will begin with an Entry Tracking Form followed by an Admission Assessment which will determine the scheduling of future OBRA-required assessments. Additionally, if the resident is on Medicare Part A, a PPS 5-day MDS will be completed.

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When residents are transferred to the receiving facility with an anticipated return to the evacuating facility within the 30-day time frame, the evacuating facility may bill Medicare for the services that were provided at the receiving facility. The evacuating facility is responsible for payment to the receiving facility for the services that the receiving facility provides to the evacuated residents. In these cases, the FI/MAC will process these claims using the evacuating facility's provider number as if the residents had not been transferred (i.e., are being provided services "under arrangement"). Specific methods for transfer of funds from one facility to another are not determined by the Centers for Medicare & Medicaid Services (CMS) or the FI/MAC; these financial arrangements should be made between the facilities themselves.

When a provider has a problem meeting the requirements for RAI/MDS scheduling, completion, and/or submission in the event of an emergency, it should contact its SA to discuss the situation and receive guidance about any extensions in meeting the OBRA-required RAI/MDS assessment requirements.

The 1135 waiver also provides authority to extend the deadline for facilities to designate the Assessment Reference Date (ARD) for scheduled and unscheduled PPS assessments. However, a facility is still required to set the ARD for these assessments **for** a day that falls within a strict ARD window for each assessment and is still required to complete all required PPS assessments.

It is essential to distinguish between the date that the ARD is set **for** (that is, the day the facility designates as the ARD for that assessment) and the date that the ARD is set **on** (that is, the day when designation of the ARD occurs). For example, under normal circumstances, a 14-day PPS assessment (which is a scheduled PPS assessment) must have an ARD set **for** a day within Days 13 through 18 of a SNF stay (the allowable ARD window, including grace days, for a 14-day PPS assessment). The ARD for this assessment must be set **on** a day that is within the ARD window (including grace days) for that assessment. This means that the ARD for this 14-day assessment must be set **on** a day no later than Day 18; otherwise, the assessment would have been considered out of compliance. However, under the 1135 waiver, facilities may now set the ARD **on** a day which falls beyond the prescribed timeframe that would otherwise apply for setting the ARD in the absence of the 1135 waiver. In the case of the 14-day PPS assessment, facilities would be able to set the ARD **on** a day following Day 18 of the stay. To offer an example of an unscheduled PPS assessment, under normal circumstances, if a resident's last day of therapy was Day 7 of a stay, the ARD of an End of Therapy (EOT) Other Medicare Required Assessment (OMRA) must be set **for** either Day 8, Day 9, or Day 10 of that stay and the ARD must be set **on** a day no later than Day 12; otherwise, the assessment would be considered out of compliance. However, under the 1135 waiver, the facility may now set the ARD **on** a day which falls beyond the prescribed timeframe that would otherwise apply for setting the ARD in the absence of the 1135 waiver. In the EOT OMRA example above, the facility would be able to set the ARD **on** a

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day following Day 12. This extension applies to PPS assessments for residents who are in the SNF, as well as for patients who have been discharged from the SNF during the 1135 waiver period.

The 1135 waiver authority does not change the requirement that a PPS assessment must still have an ARD set **for** a day that falls within the allowable ARD window, and that any assessment with an ARD that is not set **for** a day within the allowable window will be considered out of compliance.

When a provider is having a problem meeting the deadline to designate the ARD for an assessment, they should contact their FI/MAC to discuss the situation and receive guidance about any extensions in meeting the required MDS assessment time frames.

- K-6. Electronic Submission of MDS:** *During a disaster, the electronic MDS submission may not be possible from the evacuated facilities (e.g., server is down or equipment has water damage).*

If the MDS database is lost or destroyed, facilities may contact the QIES Help Desk at 888-477-7876 for assistance. Note: CMS is unable to restore data unless the provider previously submitted the data to the Federal data submission system.

- K-7. Bed Capacity:** *Can a skilled nursing facility (SNF) in declared public health emergency area exceed their licensed and certified bed capacity to accommodate additional patients?*

The SNF should contact their SA, who will review the request and make a case-by-case determination and consult with their Regional Office as appropriate. While CMS may allow providers to exceed their certified census to meet a short-term need [which is 30 days or less from the date of evacuation], continued housing of residents over a facility's State licensed capacity will require review and evaluation by the SA and CMS Regional Office, to ensure that staffing levels, Life Safety Code and other services are sufficient to meet the needs of all residents, as well as ensure the ability to safeguard residents.

- K-8. Accepting Evacuated Residents in Non-Affected States:** *Can nursing home providers in a state not affected by the emergency exceed their licensed and Medicare certified bed capacity in order to accept residents from another facility (e.g., corporate sister facility) in an affected area?*

Evacuating and receiving nursing home provider should contact their CMS Regional Office (RO) and their SA, who will review the request and make a case-by-case decision. If receiving facilities involve more than one CMS RO or State all CMS ROs and States should be involved in this decision. While CMS may allow providers to exceed their certified resident census to meet a short-term need [which is 30 days or less from the date of evacuation], continued housing of

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residents over a facility's State licensed capacity will require review and evaluation by the SA. CMS will not make decisions regarding the placement of residents from one facility into another. This decision is left up to the local State officials to best meet the needs of residents and the emergency situation at hand. In making case-by-case determinations regarding a receiving provider's acceptance of residents that places it over its licensed and certified capacity, CMS will not make it a priority to place displaced/evacuated residents from one facility into another facility owned by the same owner.

- K-9. MDS Requirements for Transfers:** *What will be the requirements for MDS completion if a resident is discharged from an evacuating facility within the 30 days? Will another admission MDS be required?*

See K-5 (above).

- K-10. PASRR Level I Screening:** *What should a Medicaid-certified nursing facility do if an individual is transferred without record of PASRR Level I Screen?*

Transfers are not subject to the requirement for Preadmission Screening and Resident Review (PASRR) Level I prior to admission, but are subject to Resident Review (RR) upon a change of condition. Therefore, payment will not be denied based on the absence of a Level I screen. Nevertheless, Medicaid nursing facilities (NFs), and state Medicaid agencies are responsible to identify possible mental illness/mental retardation (MI/MR) in NF residents.

CMS suggests that the NF, or other entity specified by the state, accomplish this requirement by performing a Level I Screen as part of the intake procedure. The NF is responsible to see that the screen is performed, to complete the resident's record, and to ensure that the resident receives a Level II evaluation if needed. If there is insufficient data to do so, document the situation, then be alert with these residents for any signs of MI/MR, which will trigger a change in condition and if needed a Resident Review (RR).

- K-11. PASRR Level II Evaluation & Determination:** *What should a Medicaid certified NF do if they receive a transfer of an individual with indication that PASRR Level II Evaluation and Determination is needed, but no record is available?*

Inter-facility transfers are subject to Resident Review (RR), not preadmission screening (PAS) pursuant to 42 CFR 483.106(b)(4). Therefore, there is no risk to the NF that federal financial participation (FFP) will be denied for lack of a PAS. NFs may admit residents, under the emergency Categorical Determination if possible, and begin the Level II evaluation process.

CMS will not consider the NF or the state out of compliance if documentation shows that due to evacuation, a resident's possible need for RR is known at admission, is initiated not later than the initial resident assessment and MDS

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process, and the evaluation/determination is performed as soon thereafter as resources are available.

K-12. Person's Previous PASRR Status Unclear: *What should a Medicaid certified NF do if they receive a displaced resident/evacuee for admission who is not a transfer from a Medicaid-certified NF, or the person's previous status is not clear?*

The NF, or other entity specified by the State, should perform a Level I Screen. CMS will not consider the NF or the State out of compliance or withhold FFP if documentation shows that due to the evacuation from declared public health emergency, a Level I Screen was performed upon admission, or within 2 days of admission, and Level II Evaluation is initiated per state procedures if indicated.

K-13. Displaced Residents from Specialty Facility: *What should a Medicare certified NF do if they receive a displaced resident/evacuee from an ICF/MR, hospital, or other specialized facility?*

Level of care (LOC) determinations are state medical necessity requirements and CMS has no authority to suspend such requirements. Emergency guidance from the State Survey Agency and from the CMS Survey and Certification Group should control admitting practices regarding LOC. However, because PASRR determination of need for NF is connected to LOC, the following information may be useful:

- a) To the extent that a NF admits individuals from a higher LOC, the NF would be required to provide all needed services until the individual can be discharged to a facility that would provide the appropriate LOC. MI/MR needs at the hospital or the ICF/MR LOC are unlikely to be met at a NF.
- b) CMS is aware that some evacuees will lack records, and that pre-evacuation LOC may be inaccurate due to the effects of the emergency on the individual.
- c) To the extent that a NF admits evacuees who do not meet the paying state's LOC requirements, the state may deny Medicaid payment for those individuals.

CMS would not consider this a Medicaid-reimbursable admission. A receiving state should make available appropriate facilities for direct admission of displaced persons, rather than compromise the well-being of the person, other residents, and staff by admitting individuals the facility is not equipped to serve.

K-14. No Inter-state PASRR Agreement: *What will happen when there is no inter-state PASRR agreement between the evacuating and receiving states?*

The state of residence normally has responsibility to pay for PASRR functions, or have a reciprocal agreement with the receiving state. Depending on the number

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of evacuated Medicaid NF residents, and the length of stay, states may wish to make retroactive inter-state PASRR agreements.

CMS will not require inter-state agreements unless states are adjacent (and should already have agreements) or PASRR requirements are not being met due to lack of inter-state cooperation.

K-15. *What will happen when a resident is transferred from another state and has PASRR Level II documentation in their record that is sufficient for planning care?*

The receiving Medicaid NF should determine whether the evacuee's PASRR documentation would be sufficient under the receiving state's PASRR's rules. The receiving state may allow NFs to accept the existing Level II data on a case-by-case basis. CMS will not expect a new evaluation if the documentation shows

that for a resident evacuated due to declared public health emergency, the PASRR data received with the out-of-state resident can be used by a care planning team as sufficient and in lieu of an in-state PASRR Evaluation and Determination.

K-16. *What will happen when a resident is transferred from another state that has PASRR Level II documentation in their record, but the information is not meaningful in the receiving state (e.g., differing terminology, level of detail, or definitions of Specialized Services)?*

If the NF decides to admit the evacuating individual as a transfer, proceed as with a resident requiring RR and ensure the individual receives a Level II screening that can be used in care planning. CMS will not consider the NF or the state out of compliance or withhold FFP if documentation shows that due to the evacuation from the declared public health emergency, a transferred resident lacked a valid Level II Determination that NF is appropriate, and RR is initiated not later than the initial resident assessment and MDS process, and the evaluation/determination is performed as soon thereafter as resources are available to do so.

K-17. *What will happen if an evacuated resident transferred from another state, with MI/MR, is considered appropriate for Medicaid NF placement in the state of origin, but documentation or examination shows the individual is not appropriate according to the PASRR criteria in the receiving state?*

The decision is up to the receiving State and the NF's prerogative to admit only residents whose needs it can meet. CMS suggests admitting under emergency Categorical Determination, while seeking appropriate alternative placement. But if the well-being of the transferred resident and/or other residents are compromised, the transferred resident should be immediately placed in another facility per the standards of the receiving State.

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CMS will not consider the NF or the State out of compliance or withhold FFP if documentation shows that due to the evacuation, an individual is admitted to a NF under the sending state's PASRR Determination, and the receiving state's emergency Categorical Determination for a period no longer than the period normally specified by the state for this category.

- K-18. Specialized Services:** *What will happen if the evacuating State defines Specialized Services as services provided in the Medicaid NF to augment NF services, while the receiving state defines Specialized Services as hospitalization or other placement not in a NF?*

If this circumstance exists, contact your CMS Regional Office for guidance.

L. Staffing

- L-1. Licensed Health Professional Volunteers:** *I would like to volunteer my medical services, but do not have a license to practice in a state affected by the declared public health emergency. Can I still treat patients in the state?*

Check with your State Agency and the appropriate health care professional board. Each State should be making plans to address potential staffing shortages and licensing procedures, such as establishing reciprocity with other states and recruiting volunteers during nonemergency periods and/or emergency periods.

In addition, the U.S. Department of Health and Human Services requires every state that receives Hospital and Healthcare Facilities Partnership Preparedness Program grant funds to develop an Emergency System for Advance Registration of Volunteer Health Professions (ESAR-VHP) system, that allows advance registration and credentialing of clinicians and health volunteers to effectively respond to surge capacity needs. The State ESAR-VHP System will:

- Register health professional volunteers
- Apply emergency credentialing standards to registered volunteers
- Allow verification of the identity, credentials, and qualifications of registered volunteers during an emergency

By registering in ESAR-VHP, the volunteer agrees to provide health services during an emergency and authorizes the State to collect the necessary information to determine the individual's credential status and emergency credentialing level.

- L-2. Nurse Aide Screening:** *Nurse aides may relocate from a state in a public health emergency area, into another state, as some corporate skilled nursing facilities (SNFs) may transfer resident evacuees and staff to sister facilities in other states*

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during an emergency. Some SNFs in the affected states may be unable to conduct criminal background checks, check references, or search the status of the Nurse Aide Registry. What should these SNFs do to assure that they do not employ nurse aides with a conviction and/or substantiated finding of abuse, neglect or misappropriation of resident property?

During a declared public health emergency, nursing home providers must do the best they can to ensure that only nurse aides in good standing who have relocated from an affected area, are hired to work in the nursing home. At a minimum, CMS expects that nursing home providers that employ nurse aides relocating from an affected state will search any nurse aide registry that the nursing home believes is likely to contain information on the nurse aide.

The Office of Inspector General (OIG) Exclusion List is also a useful tool for nursing homes and other health providers to obtain information about nurse aides and other health care workers with relevant convictions, such as offenses of abuse and neglect.

(Federal regulations do not require that nursing homes conduct a criminal background check before hiring a nurse aide; however, the criminal background check may be a state requirement.)

- L-3. Employing Persons to Provide Direct Care:** *Additional nurse aides may be needed by nursing homes that have admitted residents displaced by a disaster. May those SNFs use persons who are currently not included on the State's nurse aide registry to help with duties normally performed by nurse aides?*

Under current law, nursing homes may employ individuals who are enrolled in an approved nurse aide training program, who have demonstrated proficiency, but have not yet passed the competency evaluation program. These persons must be under the supervision of a registered nurse. There is a 4-month period that facilities may employ persons enrolled in a nurse aide training program, but whose names are not yet included on the state nurse aide registry. SNFs must employ individuals who are competent to function as nurse aides to provide direct care to residents, as determined by regulation.

If a SNF wishes to use volunteers to provide services, they are free to do so. However, volunteers are not employees of the facility and generally will be limited in the types of duties they can perform.

- L-4. Licensure Verification Requirements:** *We have had several questions related to licensure verification of health professional including physicians, nurses, and social workers. What should a prospective employer do if he/she cannot verify licensure with the appropriate professional board during a declared public health emergency?*

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The 1135(b) waiver allows for some flexibility that would be applicable for the declared public health emergency areas. We would expect providers to exercise due diligence, access whatever information is available through alternate resources, and ensure that the individual properly attests to their qualifications. The employer may contact past employers that may have verified the license, request verification, and document the efforts. Also, the employer may obtain a signed affidavit from the prospective employee attesting that he or she is licensed. The affidavit should be maintained while awaiting the professional board to resume operations.

- L-5. Medication Administration:** *Skilled Nursing Facilities located in declared public health emergency areas may be having problems with delivering medication to residents. Some states will only allow a nurse to administer medications. Can nurse aides administer medication in this emergency? Are there any Federal statutes or regulations that would affect these issues, or are they only affected by state laws and regulations?*

With regard to the administration of medications by anyone other than a nurse in a declared public health emergency area, SNFs would need to seek guidance from the State, as this is an issue of State law.

M. CMS & State Survey Agency Role & Responsibilities

- M-1.** *What is the role of CMS Central Office during an emergency?*

During a declared public health emergency, the primary role of the CMS Survey and Certification (S&C) Central Office (CO) is to provide a national, centralized point of contact for gathering and disseminating essential information, to respond to questions and requests for information, and to promptly make critical health care provider policy and procedure decisions. The CO's essential functions include the following:

- Maintaining a current, centralized list of State Survey Agency (SA) designated emergency points of contact, as well as appropriate stakeholders and partners (e.g., accreditation organizations, provider associations, advocate associations, etc.), to ensure effective communication regarding key information.
- Assisting to disseminate information regarding a declared public health emergency to SAs and other appropriate partners and stakeholders.
- Establishing a point of contact (and back-up) who is responsible for tracking all submitted emergency preparedness questions, and posting approved Questions and Answers on the CMS Frequently Asked Questions (FAQ) Website, on a prompt and timely basis.

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- Responding promptly to S&C health care provider policy and procedure questions, and/or regulatory waiver/suspension of Conditions of Participation (CoP) issues that have been submitted by Congress, other Department of Health and Human Services (HHS) operating divisions, Regional Offices (ROs), SAs, health care providers, media, and other stakeholders. Legal issues shall be referred to the HHS Office of General Counsel, as needed.
- Creating centralized health care provider data reports, as appropriate, to assist ROs, SAs, and other HHS operative divisions, as necessary (health care providers in possible path of storm, hospitals with emergency departments, status of affected health care providers, etc.).

M-2. *What is the role of CMS Regional Office during an emergency?*

During a disruptive event, the Regional Office's (RO) primary role is to provide guidance to affected SAs regarding health care providers' CoP and potential altered care decisions, while ensuring the health and safety of patients and residents. The RO's essential functions include the following:

- Establishing an emergency point of contact (and back-up) who is responsible for promptly responding to questions and concerns submitted from affected SAs and health care providers in their jurisdiction.
- Ensuring communication links with affected SA's designated emergency point of contact in their jurisdiction, utilizing back-up contingencies/strategies (cell phones, radios, Internet, etc.), if telephone and/or electrical power is inoperable.
- Responding promptly to requests for 1135(b) waiver or suspension of Medicare/Medicaid CoP requirements from affected SA and/or health care providers.
- Referring questions and waiver/suspension of regulation requests to CO, as needed.
- Requesting status reports from the SA regarding affected health care providers, as well as forwarding the reports, alerting and keeping the CO and other appropriate parties apprised about key developments.
- Assisting affected SAs to provide essential monitoring and enforcement activities, should the SA be overwhelmed and unable to meet their S&C obligations.

M-3. *What is the role of the State Survey Agencies during an emergency?*

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Under section 1864 of the Social Security Act, CMS has established agreements with the State Survey Agencies (SAs) to carry out the Federal survey and certification obligations to ensure Medicare/Medicaid certified health care facilities and suppliers meet their CoP and are providing quality care. During a disruptive event these survey and certification responsibilities continue; however, CMS recognizes that certain actions may need to be adjusted and increased flexibility may be necessary during an emergency situation. For example, the State's Incident Command may order the SA's clinical staff to care for at-risk populations in special need shelter, reducing resources for standard survey and certification activities.

The SA is a part of a larger State emergency management system, which frequently operates under the Incident Command System (ICS), and may be led by another agency or department. The SA may be designated as the responsible agency for carrying out the State's Essential Support Function (ESF) # 8 – Medical and Public Health Response. (Note: The U.S. Department of Health and Human Services is the Federal ESF Coordinator for the ESF #8).

CMS expects the SAs to have the following emergency preparedness functions in place no later than July 1, 2008:

Emergency Planning

- Each year the SA must complete a coordinated emergency Continuity of Operations Plan (COOP) which is submitted to the CMS RO on an annual basis. The completed COOP needs to address the following components:
 - Determination of essential S&C business functions
 - Designation of an SA S&C emergency point of contact (and back-up), responsible for maintaining communication with CMS, or with a designated person within the State Incident Command System (ICS), who has been clearly assigned to communicate with CMS and provide data for S&C functions.
 - Identification of strategies to ensure protection of S&C critical data.
 - Completion of exercises to be executed no later than September 30, 2008, to ensure State, Regional, Tribal and Federal coordination, effectiveness, and mutual support.

Essential Functions

- The SA determines their essential S&C functions, which must include plans for:
 - Providing prompt responses to complaints regarding patients/residents who are in immediate jeopardy.

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- Providing monitoring and enforcement of health care providers. Even in widespread disasters where reduced S&C activities may occur, key activities (such as complaint investigations) will still need to occur in order to ensure the health and safety of patients and residents.
- Conducting timely surveys or re-surveys following the aftermath of a disaster and prior to the re-opening of a health care facility.

Communication & Coordination

- The designated S&C emergency point(s) of contact is available 24 hours per day, 7 days per week to the CMS RO, during a State declared widespread disaster. The contact is responsible for:
 - Coordinating the State S&C activities with CMS
 - Addressing questions and concerns regarding S&C essential functions
 - Providing status reports to the RO
 - Ensuring effective communication of Federal S&C policy to local constituencies (see details below)
- These functions may be fulfilled by a person within the State Incident Command System (ICS) who has been clearly assigned to communicate with CMS and provide data for S&C functions.
- The SA maintains capability for prompt dissemination of CMS policy and procedures to surveyors, providers, and affected stakeholders. During a disaster, the capability is operative 24/7. The SA capability includes back-up communication strategies, such as Websites, hot lines, and emergency capability that enable functional communication during power outages.
- A designated person is available for responding to health care providers' emergency preparedness questions and concerns related to survey and certification.

Exercises

- The SA will conduct a program of COOP exercises, at least annually, by designated staff, to ensure State, Regional, Tribal and Federal coordination, responsiveness, effectiveness and mutual support.

Recovery Functions

- Recovery functions will be determined on a case-by-case basis between the SA and the CMS Regional Office. In the context of survey and certification,

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recovery functions represent those activities that are required to establish that a provider has re-established the environment and systems of care necessary to comply with Federal certification requirements.

Information and Status Reports

- The SA or the State ICS maintains capability and operational protocols to provide the CMS RO:
 - State policy actions (such as a Governor's declaration or waiver of licensure requirements)
 - An electronic provider tracking report, upon request, regarding the current status of health care providers affected by the disaster. The report capabilities must include the following:
 - Provider's name
 - Provider's Identification Number
 - CLIA number, if applicable
 - Provider type
 - Address (Street, City, ZIP Code, County)
 - Current emergency contact name
 - Telephone number and alternate (e.g., cell phone)
 - Provider status (evacuated, closed, damaged)
 - Provider census
 - Available beds
 - Emergency department contact information (name, telephone number, FAX number) if different than provider contact information
 - Emergency department status (if applicable)
 - Loss of power and/or provider unable to be reached
 - Estimated date operational
 - Source of information
 - Date of information

While many States have well developed systems that far exceed the data elements that are described above, some States will need additional time to establish capability for the electronic provider tracking and reporting capacity. Therefore, SAs will be permitted to have established capability for this function no later than July 1, 2009.

N. Emergency Preparedness Resource Information

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- N-1. Applying For FEMA Assistance:** *Hospitals, skilled nursing facilities (SNFs), nursing facilities (NFs), home health agencies and other providers affected by a public health emergency are concerned about reimbursement for uncompensated care delivered to evacuees that are not covered by Medicare, Medicaid, or insurance. How does a provider go about applying for assistance from FEMA? Is there a point of contact within FEMA for providers who are searching for answers to questions about qualification for federal reimbursement?*

The following Website: <http://www.fema.gov/government/grant/pa/index.shtm> provides information about how States, local governments, and certain non-profit organizations can apply for assistance through FEMA to alleviate suffering and hardship resulting from major disasters or emergencies. Please note the payment source will depend upon whether or not the patient was eligible for Medicaid, Medicare and/or had private insurance and the type of services provided.

- N-2. Emergency Preparedness Planning Resources:** *Where can I get additional information about the resources for emergency preparedness planning?*

Federal emergency planning resources are listed below:

- HHS Disasters & Emergencies: Requests for Information on Aspects of Emergency Preparedness, Response, and Recovery: <http://www.hhs.gov/emergency/rfi/>
- U.S. Government - Avian and Pandemic Flu Website (managed by HHS): <http://pandemicflu.gov/>
- Centers for Disease Control & Prevention: Healthcare Preparation & Planning: <http://www.bt.cdc.gov/planning/#healthcare>
- Centers for Disease Control & Prevention: Emergency Preparedness & Response: <http://www.bt.cdc.gov/>
- Centers for Disease Control & Prevention: Emergency Preparedness—Training & Education: <http://www.bt.cdc.gov/training/>
- Agency for Healthcare Research & Quality (AHRQ): Public Health Emergency Preparedness: <http://www.ahrq.gov/prep/>
- Department of Homeland Security: <http://www.dhs.gov/>
- Department of Homeland Security Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities: <http://www.dhs.gov/interagency-coordinating-council-emergency-preparedness-and-individuals-disabilities>
- Federal Emergency Management Administration (FEMA): Emergency Preparedness: <http://www.fema.gov/plan/index.shtm>
- FEMA: Continuity of Operations (COOP) Programs: <http://www.fema.gov/continuity-operations-continuity-capabilities>
- U.S. Fire Administration (USFA): <http://www.usfa.dhs.gov/index.shtm>
- National Disaster Medical System (NDMS): <http://ndms.dhhs.gov/>

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- National Fire Protection Association:
<http://www.nfpa.org/index.asp?cookie%5Ftest=1>
- Veterans Affairs Emergency Management Strategic Healthcare Group:
<http://www.va.gov/VHAEMERGENCYMANAGEMENT/index.asp>
- National Renal Administrators Association, Kidney Community Emergency Response Coalition: <http://www.nraa.org/index.php/disaster-preparedness>
- U.S. Department of Labor, Occupational Safety & Health Administration, Emergency Preparedness & Response:
<http://www.osha.gov/SLTC/emergencypreparedness/>
- Centers for Medicare & Medicaid (CMS) Survey and Certification Emergency Preparedness Website: <http://www.cms.hhs.gov/SurveyCertEmergPrep/>

Hemodialysis Water Treatment References:

- Association for the Advancement of Medical Instrumentation, Recommended Practices for Dialysis Water Treatment Systems (RD 52 and RD 62)
<http://aami.org/publications/standards/dialysis.html>

Other Resources:

- Guidelines for Dialysis Care Providers on Boil Water Advisories:
<http://www.cdc.gov/dialysis/guidelines/boil-water-advisory.html>
- Water Related Emergencies:
<http://www.bt.cdc.gov/disasters/watersystemrepair.asp>
- Tips about Medical Devices and Hurricane Disasters:
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm055987.htm>
- Medical Devices that Have Been Exposed to Heat and Humidity:
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm056086.htm>
- Medical Devices Requiring Refrigeration
<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm056075.htm>
- Fact Sheet: Flood Cleanup - Avoiding Indoor Air Quality Problems:
<http://www.epa.gov/mold/flood/index.html>
- NIOSH Declared public health emergency Response: Storm and Flood Cleanup:
<http://www.cdc.gov/niosh/topics/emres/flood.html>
- American Institute of Architects: Procedures for Cleaning Out a House or Building Following a Flood:
<http://www.aia.org/about/initiatives/AIAS075276?dvid=&recspec=AIAS075276>
- American Red Cross: <http://www.redcross.org/>
- Salvation Army: http://www.salvationarmyusa.org/usn/www_usn_2.nsf

APPENDIX C-13: Example of Public Health Emergency Declaration and 1135 Waivers



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

OCT 31 2012

The Honorable Harry Reid
Majority Leader
United States Senate
S-221 United States Capitol
Washington, D.C. 20510

Re: Declaration of a Public Health Emergency and Waiver and/or Modification of Certain HIPAA, Medicare, Medicaid, and Children's Health Insurance Program Requirements

Dear Majority Leader Reid:

I am writing to notify you that, as a consequence of Hurricane Sandy in New York, and pursuant to the authority vested in me under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, I determined that a public health emergency exists and has existed since October 27, 2012 in the State of New York. In addition, as required under Section 1135(d) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I hereby notify you that, on November 2, 2012, I intend to waive or modify certain HIPAA and Medicare, Medicaid, and Children's Health Insurance Program requirements as indicated on the attached document. I certify that these waivers and/or modifications are necessary to carry out the purposes of Section 1135 of the Act.

Sincerely,

Kathleen Sebelius
Secretary

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

OCT 31 2012

The Honorable John Boehner
Speaker of the House
United States House of Representatives
H-232 United States Capitol
Washington, D.C. 20515

Re: Declaration of a Public Health Emergency and Waiver and/or Modification of Certain HIPAA, and Medicare, Medicaid, and Children's Health Insurance Program Requirements

Dear Mr. Speaker:

I am writing to notify you that, as a consequence of Hurricane Sandy in New York, and pursuant to the authority vested in me under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, I determined that a public health emergency exists and has existed since October 27, 2012 in the State of New York. In addition, as required under Section 1135(d) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I hereby notify you that, on November 2, 2012, I intend to waive or modify certain HIPAA and Medicare, Medicaid, and Children's Health Insurance Program requirements as indicated on the attached document. I certify that these waivers and/or modifications are necessary to carry out the purposes of Section 1135 of the Act.

Sincerely,

A handwritten signature in black ink, which appears to read "Kathleen Sebelius", is positioned above the printed name and title.

Kathleen Sebelius
Secretary

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a consequence of Hurricane Sandy in the State of New York, on this date and after consultation with public health officials as necessary, I, Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since October 27, 2012 in the State of New York.

October 31, 2012
Date

Kathleen Sebelius
Kathleen Sebelius

**WAIVER OR MODIFICATION OF REQUIREMENTS
UNDER SECTION 1135 OF THE SOCIAL SECURITY ACT**

October 31, 2012

- I. Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I hereby waive or modify the following requirements of titles XVIII, XIX, and XXI of the Act and regulations thereunder, and the following requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, and XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of Hurricane Sandy, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse:
 - a. Certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services, and pre-approval requirements.
 - b. Requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area).
 - c. Sanctions under section 1867 of the Act (the Emergency Medical Treatment and Labor Act, or EMTALA) for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or a state pandemic preparedness plan or for the transfer of an individual who has not been

stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for Hurricane Sandy.

- d. Sanctions under section 1877(g) (relating to limitations on physician referral) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.
 - e. Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.
2. Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.
 3. Pursuant to Section 1135(b)(5), I also hereby modify deadlines and timetables and for the performance of required activities, but only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of Hurricane Sandy, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

These waivers and modifications will become effective at 12:00 P.M. Eastern Standard Time on November 2, 2012, but will have retroactive effect to October 27, 2012 in the State of New York, and continue through the period described in Section 1135(e). Notwithstanding the foregoing, the waivers described in paragraphs 1(c) and 2 above are in effect for a period of time not to exceed 72 hours from implementation of a hospital disaster protocol but not beyond the period described in Section 1135(e), and such waivers are not effective with respect to any action taken thereunder that discriminates among individuals on the basis of their source of payment or their ability to pay.

The waivers and modifications described herein apply in the geographic area covered by the President's declaration, pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act, of a major disaster as a result of Hurricane Sandy on October

30, 2012 in the State of New York; and my October 31, 2012 determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency exists and has existed as a result of Hurricane Sandy since October 27, 2012 in the State of New York.

October 31, 2012
Date

Kathleen Sebelius
Kathleen Sebelius

Thank You

Healthcare Association of New York State

- Sarah DuVall, M.P.H.
Director, Emergency Preparedness and Response and Trauma Initiatives

Iroquois Healthcare Association

- Andrew Jewett
Director, Hospital Preparedness Program

New York State Department of Health

- **Bureau of House Counsel, Division of Legal Affairs**
Holly M. Dellenbaugh, J.D.
- **Office of Health Emergency Preparedness**
Michael G. Perillo, D.C., M.P.H., Manager, Healthcare Facilities Preparedness
M. Katharine Logan, R.N., Non-Acute Coordinator
Patricia Anders, M.S., Manager, Health Emergency Preparedness Exercises
Dennis J. White, M.S., Ph.D., Planning Chief, Healthcare Facilities Preparedness
- **Office of Health Systems Management**
Debra L. Sottolano, Ph.D., M.B.A., Liaison, Public Health Emergency Preparedness