

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,

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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 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.

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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.

- 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

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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.
- 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?*

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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.

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: 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.

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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.

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.

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- 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?*

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.

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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 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 www.fda.gov/cder/emergency. 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?*

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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?*

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 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.com/>.

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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:

- 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.*

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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:

- (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?*

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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: www.dialysisunits.com.

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: 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

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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 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 www.fda.gov/cdrh/emergency/hurricane.html 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/oc/opacom/hottopics/hurricane.html>.

- 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?*

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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 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.

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

Hemodialysis Water Treatment References:

Northwest Renal Network document *Monitoring Your Dialysis Water Treatment System*

<http://www.nwrenalnetwork.org/watermanual.pdf>

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/ncidod/dhqp/dpac_dialysis_boilwater.html

Water Related Emergencies

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

Tips about Medical Devices and Hurricane Disasters

<http://www.fda.gov/cdrh/emergency/hurricane.html>

Medical Devices that Have Been Exposed to Heat and Humidity

<http://www.fda.gov/cdrh/emergency/heathumidity.html>

Medical Devices Requiring Refrigeration

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<http://www.fda.gov/cdrh/emergency/refrigeration.html>

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/flood/>

OSHA Fact Sheet

http://www.osha.gov/OshDoc/data_Hurricane_Facts/Bulletin3.pdf

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

http://www.aia.org/liv_disaster_floodproc

- 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, www.optn.org, including information about other available transplant centers within each state. We would encourage any transplant candidate seeking information about transferring to 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

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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.

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

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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.

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.

I-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?*

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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.

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.

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- 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. 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.

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- 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 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?*

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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 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

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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, 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?*

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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 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: *Skilled nursing facility residents in the public health emergency area may be evacuated to other nursing homes without their medical history. The national Minimum Data Set (MDS) may be the primary source of medical record information for many of these residents. What can providers that accept such residents do to obtain information available on the residents' MDS record to assure appropriate care of those residents? In some cases the States affected by the disaster are unable to provide this information.*

CMS will compile a list of all skilled nursing facilities and nursing facilities that are reported as being evacuated, and will compile a file of critical clinical information obtained from the MDS records of the residents in those Medicare certified

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nursing facilities in an Excel spreadsheet. Any nursing provider that has received evacuees may request access to this file(s).

To obtain this information, the receiving nursing home should contact the IFMC Help Desk at 1-888-477-7876. When the request is received, the Iowa Foundation for Medical Care (IFMC) will place the file in the receiving nursing home provider's shared MDS folder. The report will stay in the receiving nursing home provider's file for about 30 days.

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

Under normal circumstances, a provider is required to complete a Minimum Data Set (MDS) assessment of a resident within 14 days of admission to the facility or when there has been a significant change in the resident's condition. In order to facilitate nursing home provider responses during a declared emergency, the guidance below will apply during the 1135(b) waiver period.

In the case of evacuations, the evacuating facility should determine by day 15 whether or not residents will be able to return to the evacuating facility within 30 days from the date of the evacuation. In the case that the evacuating facility is unavailable to make this determination, the receiving facility makes this determination.

If and when the residents return to the evacuating facility within 30 days, the MDS cycle will continue as though the residents were never transferred. This decision places minimal disruption on the staffs' daily routine in caring for all residents. The evacuating facility would then complete the MDSs according to the *Long-Term Care Facility Resident Assessment Instrument User's Manual* once the residents return to its facility.

When the evacuating and/or receiving facility determines that the residents will not return to the evacuating facility within the 30-day time frame, the evacuating facility should discharge the resident by completing a discharge tracking form whenever possible. The receiving facility will admit the residents and complete an admission MDS (and/or a 5-day MDS) as per the federal participation requirements. 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 and when the resident returns to the evacuating facility after the 30-day time frame, the receiving facility will discharge the resident and complete a discharge tracking form. The evacuating facility will re-admit the resident. The MDS cycle will be established based on the reentry tracking form.

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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's provider number. The evacuating facility is responsible for payment to the receiving facility for the services that facility provides to the evacuated residents. In these cases, the fiscal intermediary will process these claims using the evacuating facility's provider number as if the patients had not been transferred.

When a provider is having a problem meeting these requirements, they should contact their State Agency 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 local MDS database is unavailable (destroyed or lost), CMS can help the evacuating facility restore previously submitted MDS data once a working computer is obtained. They should call the MDS Help Desk at 1-888-477-7876.

Note: CMS can not help 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 CMS Regional Office, who will review the request and make a case-by-case determination. While providers may exceed their census to meet a short-term need, continued housing of residents over a facility's capacity will require review and evaluation by the State Survey Agency, to ensure that staffing levels are sufficient, 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?*

The nursing home provider should contact their CMS Regional Office (RO) who will review the request and make a case-by-case decision. While providers may exceed their resident census to meet a short-term need, continued housing of residents over a facility's capacity will require review and evaluation by the State Survey Agency. In making case-by-case determinations regarding a receiving provider's acceptance of residents that places it over its licensed and certified

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capacity, CMS will not make it a priority to place displaced/evacuated residents from one facility into another facility 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 with the 30 days? Will another admission MDS be required?*

The evacuating facility should determine by day 15 whether or not residents will be able to return to the originating facility within 30 days or not. If the resident returns to the originating facility with the 30-day time limit the MDS cycle will continue as though the resident was never transferred.

The receiving facility should determine by day 15 whether or not residents will be able to return to the evacuating facility within 30 days or not. If the resident returns to the evacuating facility with the 30-day time limit, the MDS cycle will continue as though the resident was never transferred.

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.

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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 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?*

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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 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

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compromised, the transferred resident should be immediately placed in another facility per the standards of the receiving State.

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.

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- 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 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. The OIG Exclusion List of Excluded Individuals/Entities may be located at: <http://oig.hhs.gov/fraud/exclusions/listofexcluded.html>

(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. For more information about the declared public health emergency volunteer efforts, please see the following Website: <https://volunteer.ccrf.hhs.gov/>

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- 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?*

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.

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- 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.
- 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.

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- 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?*

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.

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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.
 - 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.

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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, 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

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- 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

- 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/>

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- Agency for Healthcare Research & Quality (AHRQ): Public Health Emergency Preparedness: <http://www.ahrq.gov/prep/>
- Department of Homeland Security: <http://www.ready.gov/>
- Department of Homeland Security Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities: <http://www.disabilitypreparedness.gov/>
- Federal Emergency Management Administration (FEMA): Emergency Preparedness: <http://www.fema.gov/plan/index.shtm>
- FEMA: Continuity of Operations (COOP) Programs: <http://www.fema.gov/government/coop/index.shtm>
- U.S. Fire Administration (USFA): <http://www.usfa.dhs.gov/index.shtm>
- National Disaster Medical System (NDMS): <http://ndms.dhhs.gov/>
- National Fire Protection Association: <http://www.nfpa.org/index.asp?cookie%5Ftest=1>
- Veterans Affairs Emergency Management Strategic Healthcare Group: <http://www1.va.gov/emshg/>
- National Renal Administrators Association, Kidney Community Emergency Response Coalition: http://www.nraa.org/Disaster_Prep.php
- U.S. Department of Labor, Occupational Safety & Health Administration, Emergency Preparedness & Response: http://www.osha.gov/SLTC/emergencypreparedness/osha_support.html
- Centers for Medicare & Medicaid (CMS) Survey and Certification Emergency Preparedness Website: <http://www.cms.hhs.gov/SurveyCertEmergPrep/>

Hemodialysis Water Treatment References:

- Northwest Renal Network document Monitoring Your Dialysis Water Treatment System: <http://www.nwrenalnetwork.org/watermanual.pdf>
- 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/ncidod/hip/dialysis/boilwater_advisory.htm
- Water Related Emergencies: <http://www.bt.cdc.gov/disasters/watersystemrepair.asp>
- Tips about Medical Devices and Hurricane Disasters: <http://www.fda.gov/cdrh/emergency/hurricane.html>
- Medical Devices that Have Been Exposed to Heat and Humidity: <http://www.fda.gov/cdrh/emergency/heathumidity.html>
- Medical Devices Requiring Refrigeration <http://www.fda.gov/cdrh/emergency/refrigeration.html>
- 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/flood/>
- OSHA Fact Sheet:

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- http://www.osha.gov/OshDoc/data_Hurricane_Facts/Bulletin3.pdf
- American Institute of Architects: Procedures for Cleaning Out a House or Building Following a Flood:
http://www.aia.org/liv_disaster_floodproc
- American Red Cross: <http://www.redcross.org/>
- Salvation Army: http://www.salvationarmyusa.org/usn/www_usn.nsf