

January 31, 2013

Medicare Fee-For-Service

**Additional Emergency and Disaster-Related Policies and Procedures
That May Be Implemented Only With a § 1135 Waiver**

NOTE: The following Q&As address matters that, in the event of a disaster or emergency, could potentially be the subject of or be affected by a waiver or modification of certain requirements of the Social Security Act (the Act). Section 1135 of the Act authorizes the Secretary of the Department of Health and Human Services to waive or modify certain Medicare, Medicaid, CHIP, and HIPAA requirements. However, two prerequisites must be met before the Secretary may invoke the § 1135 waiver authority. First, the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act. Second, the Secretary must have declared a Public Health Emergency under Section 319 of the Public Health Service Act. Then, with respect to the geographic area(s) and time periods provided for in those declarations, the Secretary may elect to authorize waivers/modifications of one or more of the requirements described in Section 1135(b). The implementation of such waivers or modifications is typically delegated to the Administrator of CMS who, in turn, determines whether and the extent to which sufficient grounds exist for waiving such requirements with respect to a particular provider, or to a group or class of providers, or to a geographic area.

In the following Q&As, CMS identifies policies and procedures that may be available when the section 1135 waiver authority is invoked. However, the decisions to grant specific waivers or modifications will be made during or after each emergency or disaster (if a specific waiver or modification is granted after the emergency or disaster, it may be retroactive to the beginning of the emergency or disaster). Moreover, as noted previously, implementation of such waivers or modifications may apply to a particular provider, or a group or class of providers, or to a geographic area and may require additional fact-finding to ensure that sufficient grounds exist for waiving or modifying requirements in a particular circumstance. See the Q&As in *Section B – Waiver of Certain Medicare Requirements* for information concerning making requests for waivers or modifications under the Section 1135 authority.

Current/Recent Emergencies

- Section 1 – 2009/2010 – National: H1N1 Influenza Pandemic (10-23-09 – 6-23-10)
- Section 2 – 2010 – North Dakota: Floods (2-26-10 – 6-15-10)
- Section 3 – 2011 – North Dakota: Floods (4-5-11 – 8-24-11)
- Section 4 – 2011 – Missouri: Severe Storms and Tornadoes (5-22-11 – 5-14-12)
- Section 5 – 2011 – New York: Tropical Storm *Lee* (9-24-11 – 3-12-12)
- Section 6 – 2012 – Hurricane *Sandy*: New York and New Jersey (10-27-12 –)

All Emergencies

- Section A - Flexibilities Available in the Event of an Emergency or Disaster
- Section B - Waiver of Certain Medicare Requirements
- Section C - General Payment Policies
- Section D - General Billing Procedures
- Section E - Physician Services
- Section F - Ambulance Services
- Section G - Laboratory & Other Diagnostic Services
- Section H - Drugs & Vaccines Payable Under Part B
- Section I - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
- Section J - End Stage Renal Disease (ESRD) Facility Services
- Section K - Home Health Services
- Section L - Hospice Services
- Section M - Hospital Services – General
- Section N - Hospital Services – EMTALA
- Section O - Hospital Services – Acute Care
- Section P - Hospital Services – Critical Access Hospitals (CAH)
- Section Q - Hospital Services – Inpatient Rehabilitation Facilities (IRF)
- Section R - Hospital Services – Long Term Care Hospitals (LTCH)
- Section S - Hospital Services – Mobile Emergency Hospitals
- Section T - Skilled Nursing Facility (SNF) Services
- Section U - Mental Health Counseling
- Section V - Rural Health Clinics / Federally Qualified Health Clinics
- Section W - Fee-for-Service Administration
- Section X - Financial Management Policies

Control #	Question and Answer
1	<p style="text-align: center;">2009 – 2010 – National: H1N1 Influenza Pandemic</p> <p>On October 23, 2009, President Obama declared a national emergency with respect to the H1N1 influenza pandemic. On April 26, 2009, Acting Secretary Charles Johnson declared a public health emergency in response to the H1N1 virus. Secretary Sebelius renewed that declaration on July 24, 2009, again on October 1, 2009, again on December 28, 2009, and again on March 26, 2010. The Secretary allowed the H1N1 public health emergency determination to expire on June 23, 2010.</p> <p>Note 1: The policies, procedures, and guidance expressed in this section are specific to the 2009/2010 H1N1 influenza pandemic. However, the Medicare fee-for-service policies, procedures, and guidance specified in the following sections (other than the Midwest Floods section), which apply to emergencies or disasters generally, may also apply to the H1N1 emergency. See the other sections of these Q&As for these other potentially relevant policies.</p> <p>Note 2: The timely filing period for H1N1-related fee-for-service claims closed on June 22, 2011.</p>

1135-1-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the H1N1 influenza pandemic emergency?</p> <p>Answer: Yes. On October 23, 2009, President Obama declared a national emergency with respect to the H1N1 influenza pandemic. On April 26, 2009, Acting Secretary Charles Johnson declared a public health emergency in response to the H1N1 virus. Secretary Sebelius renewed that declaration on July 24, 2009, again on October 1, 2009, again on December 28, 2009, and again on March 26, 2010. Secretary Sebelius authorized 1135 waivers on October 29, 2009, with a retroactive effect to October 23, 2009. The Secretary allowed the public health emergency determination to expire on June 23, 2010 and, therefore, the 1135 waiver authority for the H1N1 pandemic also terminated as of that date.</p>
1135-1-2	<p>Question: When and to what entities does the HIPAA 1135 waiver granted in response to the 2009 H1N1 influenza pandemic apply?</p> <p>Answer: The HIPAA waiver applied nationwide, but only to hospitals that instituted a disaster protocol during the time period from October 23, 2009 through June 23, 2010, for up to 72 hours from the time that the hospital implemented its disaster protocol. HIPAA waivers are effective only if actions taken thereunder do not discriminate among individuals on the basis of their source of payment or their ability to pay.</p> <p>Regardless of whether HIPAA waivers under section 1135 are available, the HIPAA Privacy Rule permits disclosures for treatment purposes and certain disclosures to disaster relief organizations. For instance, the Privacy Rule allows covered entities to share patient information with the American Red Cross so it can notify family members of the patient's location. See 45 CFR 164.510(b)(4).</p> <p>Learn More: * Visit the weblink below for information on sharing information in emergency situations. http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/katrinahipaa.pdf</p>
1135-1-3	<p>Question: When and where are the H1N1 1135 waivers (not related to HIPAA) in effect?</p> <p>Answer: The Secretary may issue specific waivers or modifications under section 1135 only to the extent they ensure that sufficient health care items and services are available to meet the needs of Medicare, Medicaid, and CHIP beneficiaries in the emergency area during the emergency period. The "emergency area" and the "emergency period" are the geographic area, in which, and the time period, during which, the dual declarations exist. For the H1N1 event, the emergency area was nationwide and the emergency period began on October 23, 2009 and ended on June 23, 2010.</p>
1135-1-4	<p>Question: Is there a specific process for requesting 1135 waivers?</p> <p>Answer: See Section B, below – in particular Q&As 1135B-9, B-10, B-11, B-12, B-13, B-15, B-16, and B-18. Further information on the 1135 waiver process during the H1N1 pandemic emergency can be found at: http://www.cms.hhs.gov/H1N1/.</p> <p>Questions regarding 1135 waivers for the H1N1 pandemic emergency that are not addressed at the above website can be sent to the following mailbox: Pandemic@cms.hhs.gov.</p>
1135-1-5	<p>Question: How will we receive the H1N1 declaration or expect to receive it from (Federal, State or local)?</p> <p>Answer: HHS released all H1N1-related declaration information on www.flu.gov and additionally at http://www.cms.hhs.gov/H1N1/. Facilities that requested specific waivers of Medicare, Medicaid, CHIP requirements or EMTALA sanctions in order to respond to the H1N1 pandemic, received a written response from CMS, transmitted via e-mail or otherwise.</p>
2	2010 – North Dakota: Floods
1135-2-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the 2010 North Dakota flooding emergency?</p> <p>Answer: Yes. On March 14, 2010, President Obama declared an emergency under the Stafford Act for the State of North Dakota. On March 18, 2010, HHS Secretary Sebelius declared a public health emergency – retroactive to February 26, 2010 – and authorized waivers under § 1135 of the Social Security Act. The Secretary allowed the public health emergency determination to expire on June 15, 2010 and, therefore, the 1135 waiver authority also terminated as of that date.</p>

3	2011 – North Dakota: Floods
1135-3-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the 2011 North Dakota flooding emergency?</p> <p>Answer: Yes. On April 7, 2011, President Obama declared an emergency under the Stafford Act for the State of North Dakota. On April 8, 2011, HHS Secretary Sebelius declared a public health emergency – retroactive to April 5, 2011 – and authorized waivers under § 1135 of the Social Security Act. On July 1, 2011, Secretary Sebelius renewed her declaration, for an additional 90 days, that a public health emergency continued to exist in North Dakota. Therefore, the 1135 waiver authority also remained in effect through the end of September 2011. However, waivers were no longer needed when the last facility needing waivers repatriated on August 24, 2011.</p>
4	2011 – Missouri: Severe Storms and Tornadoes
1135-4-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the Missouri severe storms and tornadoes emergency?</p> <p>Answer: Yes. On May 9, 2011, President Obama declared a major disaster under the Stafford Act for the State of Missouri. On May 23, 2011, HHS Secretary Sebelius declared a public health emergency in the State of Missouri – retroactive to May 22, 2011 – and authorized waivers under § 1135 of the Social Security Act. Secretary Sebelius renewed her Missouri public health emergency declaration several times and the 1135 waiver authority also remained in effect until the last extension expired on May 14, 2012.</p>
1135-4-2	<p>Question: Technical Direction Letter (TDL)-11345, dated June 2, 2011, which provides direction regarding the use of the CR/DR modifier/condition code, specifically refers to "items and services furnished to Medicare beneficiaries within the State of Missouri." Many patients were moved for outpatient or inpatient care to other States such as Kansas. Does a provider still use the CR/DR modifier/condition code when the provider is in a State other than Missouri?</p> <p>Answer: Agency policy concerning the use of the DR condition code and the CR modifier is established by Change Request 6451 (Transmittal 1784, issued July 31, 2009). This Change Request provides that the DR condition code and the CR modifier are required when: 1) a § 1135 waiver necessitates the use of the condition code or modifier, 2) CMS mandates their use, or 3) a claims administration contractor mandates their use. See Change Request 6451 for a more precise statement of the policy. TDL-11345, dated June 2, 2011, clarifies that the use of the DR condition code and the CR modifier on a claim with respect to an item or service furnished under a "formal waiver," i.e., the first of the three possibilities discussed in Change Request 6451, is effective only in Missouri and no sooner than May 22, 2011. This is consistent with the scope of the § 1135 waiver authority granted by the Secretary of the Department of Health and Human Services for this particular emergency. CMS has not, for the Missouri emergency, mandated the use of the condition code or modifier in other circumstances, i.e., the second of the three possibilities discussed in Change Request 6451. Finally, under Change Request 6451, claims administration contractors continue to be authorized – but not required – to mandate or authorize the use of the DR condition code or the CR modifier on claims related to the Missouri emergency, including claims from providers and suppliers furnishing items and services in States other than Missouri when the effects of the Missouri emergency affect the delivery of such items and services in other States. This is the third of the three possibilities discussed in Change Request 6451. Note, however, that the requirement or authorization to the use the DR condition code or the CR modifier on a claim does not, itself, constitute a waiver of a Medicare requirement, but rather reflects that a waiver or other special condition may apply to the furnishing of an item or service in a Federally-declared emergency situation.</p>
5	2011 – New York: Remnants of Tropical Storm Lee

1135-5-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the emergency in New York resulting from the remnants of Tropical Storm <i>Lee</i>?</p> <p>Answer: Yes. On September 8 and 13, 2011, President Obama declared under the Stafford Act that an emergency and a major disaster exist in the State of New York as a result of the remnants of Tropical Storm <i>Lee</i>. On September 24, 2011, HHS Secretary Sebelius declared a public health emergency in the State of New York and authorized waivers under § 1135 of the Social Security Act for the State of New York. Secretary Sebelius renewed her New York public health emergency declaration several times and the 1135 waiver authority also remained in effect until the last extension expired on March 12, 2012.</p>
6	<p style="text-align: center;">2012 – Hurricane <i>Sandy</i>: New York & New Jersey</p>
1135-6-1	<p>Question: Has the Secretary of HHS authorized waivers or modifications under § 1135 of the Social Security Act regarding the emergency resulting from Hurricane <i>Sandy</i>?</p> <p>Answer: Yes. For New York: On October 30, 2012, President Obama declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act that a major disaster exists in the State of New York as a result of Hurricane <i>Sandy</i>. The President’s declaration is retroactive to October 27, 2012. On October 31, 2012, HHS Secretary Sebelius declared a public health emergency, and authorized waivers and modifications under § 1135 of the Social Security Act, for the State of New York, retroactive to October 27, 2012. The Secretary approved an extension of the Public Health Emergency for New York related to Hurricane Sandy on 1/25/13 for an additional 90 days. The 1135 waiver authorizations remain in effect.</p> <p>For New Jersey: On October 30, 2012, President Obama declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act that a major disaster exists in the State of New Jersey as a result of Hurricane <i>Sandy</i>. The President’s declaration is retroactive to October 26, 2012. On November 1, 2012, HHS Secretary Sebelius declared a public health emergency, and authorized waivers and modifications under § 1135 of the Social Security Act, for the State of New Jersey, retroactive to October 26, 2012. The New Jersey Hurricane Sandy Public Health Emergency was not renewed (per information from the State that there was not a continued need) and therefore the 1135 waivers approved for NJ have expired.</p>
1135-6-2	<p>Question: Has CMS issued blanket waivers for providers adversely affected by Hurricane Sandy in the impacted area of New York and New Jersey.</p> <p>Answer: Yes, CMS has issued blanket waivers in the impacted area of New York and New Jersey. Individual facilities do not need to apply for the blanket waivers. Additional information on blanket waivers for New York and New Jersey can be found at: http://www.cms.gov/About-CMS/Agency-Information/Emergency/.</p>
1135-6-3	<p>Question: Can Medicare coverage be continued for patients/residents in medical, long term care and rehabilitation facilities who are ready to be discharged and cannot return home due to lack of power or flooding from Hurricane Sandy?</p> <p>Answer: No, Medicare cannot pay providers to retain individuals who are medically able to be discharged, but are unable to return home due to damage caused by a disaster.</p> <p>Individuals or providers should consider contacting their State Department of Health to discuss options to transfer individuals to appropriate settings:</p> <ul style="list-style-type: none"> • New York State Department of Health’s special emergency hotline at 1-866-544-1303 • New Jersey State Department of Health’s special emergency hotline at 1-866-234-0964. <p>Additionally, FEMA and the Red Cross are operating shelters which may be able accommodate them. To locate a shelter please access the following link http://www.fema.gov/sandy . FEMA provides housing assistance at http://www.fema.gov/how-do-i-find-place-stay</p> <p>For those who have longer-term housing needs, FEMA offers several types of assistance, including services and grants to help people repair their homes and find replacement housing.</p>

1135-6-4	<p>Question: I received notice regarding the 1135 waiver. During this emergency period are we requesting the waiver on a case by case basis, on discharge or on admission?</p> <p>Answer: Whether CMS issues a blanket waiver or considers waivers on a case-by-case basis depends on the nature of the particular emergency. CMS has generally granted waivers on a case-by-case basis. However, for the Hurricane Sandy emergency, CMS issued certain blanket waivers for New York and New Jersey. A summary of these blanket waivers appears here: http://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Hurricane_Sandy_1135BlanketWaiversApprovedNYNJ.pdf</p>
1135-6-5	<p>Question: I am looking to process a 1135 waiver in light of the recent Hurricane on the northeast coast. Can you please provide the information on how to do so and the forms needed?</p> <p>Answer: There are no forms to request a waiver. Providers that believe they need waiver flexibility should contact Bill Roberson from the CMS Regional Office at William.roberson@cms.hhs.gov. Please provide information about the flexibility requested, the need for the flexibility, and how long you believe the flexibility will be necessary.</p>

ALL EMERGENCIES

A	Flexibilities Available in the Event of an Emergency or Disaster
1135A-1	<p>Question: What is the difference between a “flexibility” and a “waiver”?</p> <p>Answer: A “flexibility” is an agency policy or procedure that can be adjusted under current authority – and generally speaking, can be adjusted without reprogramming CMS’s systems. As used in these FAQs, the terms “waiver or a modification” refer to a waiver or modification of a statutory requirement of the Social Security Act (Act) or its implementing regulations that may be waived or modified under the authority of § 1135 of the Act or § 1812(f) if the Act, as the case may be.</p>
1135A-2	<p>Question: In the event of an emergency or disaster, is assistance available to health care providers and suppliers for capital expenditures?</p> <p>Answer: Health care providers and supplier located in declared disaster areas may be eligible for the following disaster assistance for capital expenditures.</p> <p>Federal Emergency Management Agency (FEMA) Public Assistance Program The FEMA Public Assistance Program provides grants to certain private non-profit (PNP) entities including hospital, outpatient facility, rehabilitation facility, long-term care facility, etc. to assist them with the response to and recovery from disasters. Specifically, the program provides assistance for debris removal, emergency protective measures, and permanent restoration of infrastructure. Generally, private, non-profit entities must first apply to the Small Business Administration (SBA) for a disaster loan (see below). If the PNP is declined for a SBA loan or the loan does not cover all eligible damages, the applicant may reapply for FEMA assistance. PNPs that provide "critical services" (power, water - including water provided by an irrigation organization or facility, sewer, wastewater treatment, communications and emergency medical care) may apply directly to FEMA for a disaster grant. For more information, go to http://www.fema.gov/public-assistance-local-state-tribal-and-non-profit</p> <p>Small Business Administration (SBA) Disaster Assistance Loans Following disasters, the U.S. Small Business Administration (SBA) plays a major role. SBA’s disaster loans are the primary form of federal assistance for nonfarm, private sector disaster losses. Disaster loans from SBA help businesses of all sizes and nonprofit organizations (including many in health care providers and organizations) fund rebuilding. SBA’s disaster loans are a critical source of economic stimulation in disaster ravaged communities, helping to spur employment and stabilize tax bases. Disaster assistance loans make recovery possible when private, non-profit entities need to borrow capital to repair uninsured damages caused by a disaster. They are low-interest long-terms loans that are repaid directly to the Treasury.</p> <p>The SBA is authorized by the Small Business Act to make two types of disaster loans: Physical disaster loans are a primary source of funding for permanent rebuilding and replacement of uninsured or underinsured disaster damages to privately-owned real and/or personal property. SBA’s physical disaster loans are available to homeowners, renters, businesses of all sizes and</p>

	<p>nonprofit organizations.</p> <p>Economic injury disaster loans provide necessary working capital until normal operations resume after a physical disaster. The law restricts economic injury disaster loans to small businesses, small agricultural cooperatives, small businesses engaged in aquaculture and most private, non-profit organizations of all sizes.</p> <p>For more information, contact SBA's Disaster Customer Service Center by calling (800) 659-2955, emailing disastercustomerservice@sba.gov , or visiting SBA's Web site at www.sba.gov .</p> <p>Medicare Fee-for-Service (FFS) Once these, and other available resources (such as insurance), are exhausted, Medicare FFS assistance may be available to a limited extent. See Qs&As M-2, M-15, and M-16 at: http://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_QsAs.pdf.</p>
<p>B</p>	<p>Waiver of Certain Medicare Requirements</p>
<p>1135B-1</p>	<p>Question: Can Medicare rules be waived in a disaster or emergency?</p> <p>Answer: In general, Medicare coverage or payment rules cannot be waived, even in a disaster or emergency. However, subject to certain pre-conditions being met, the Secretary of the Department of Health and Human Services may authorize the waiver or modification of certain requirements that relate to the Medicare, Medicaid, and the Children's Health Insurance Programs under the authority of § 1135 of the Social Security Act (Act), and some of these waivers or modifications may have an indirect effect on the application of Medicare fee-for-service coverage or payment rules in an emergency or disaster.</p> <p>The preconditions that must be met before the Secretary can invoke the authority to waive or requirements under the § 1135 authority are that:</p> <ol style="list-style-type: none"> 1. the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act, and 2. the Secretary must have declared a Public Health Emergency under Section 319 of the Public Health Service Act. <p>Then, with respect to the geographic area(s) and time periods to which both of those declarations apply, the Secretary may elect to authorize waivers/modifications of one or more of the requirements described in Section 1135(b).</p> <p>The implementation of such waivers or modifications is largely handled by CMS which determines whether and the extent to which sufficient grounds exist for waiving or modifying such requirements with respect to a particular provider, or to a group or class of providers, or to a geographic area within the emergency area.</p>
<p>1135B-2</p>	<p>Question: What rules can be waived under § 1135?</p> <p>Answer: Very few rules can be waived or modified under current law, even in a disaster or emergency. Section 1135 of the Act authorizes the Secretary of the Department of Health and Human Services to waive, or some cases modify, certain requirements that relate to the Medicare, Medicaid, and the Children's Health Insurance Programs. The requirements that the Secretary may waive or modify, in an emergency area and during an emergency period, are, in summary:</p> <ol style="list-style-type: none"> 1. <ol style="list-style-type: none"> a. conditions of participation or other certification requirements for an individual health care provider or types of providers; b. program participation and similar requirements for an individual health care provider or types of providers; and c. pre-approval requirements. 2. requirements that physicians and other health professional be licensed in the State in which they provide services, if they provide equivalent services in another State and are not affirmatively excluded from practice in that State or in any state a part of which is included in the emergency area. 3. actions under EMTALA rules (per § 1867 of the Act) regarding: <ol style="list-style-type: none"> a. the transfer of an individual who has not been stabilized (if the transfer arises out of the circumstances of the emergency) ; and b. the direction or relocation of an individual to receive medical screening at an alternative location in accordance with an appropriate (and applicable) State preparedness plan. 4. sanctions for violations of Stark rules (physician self-referral under § 1877 of the Act). 5. deadlines and timetables for performance of required activities (may be modified but not waived). 6. limitations on the ability to make direct payments to providers for services provided to Medicare

	<p>Advantage enrollees.</p> <p>7. sanctions and penalties for noncompliance with certain patient privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).</p> <p>Note that HIPAA and EMTALA waivers are subject to special time limitations.</p> <p>In addition to these § 1135-based waivers or modifications, in situations where the use of 1135 authority is appropriate, CMS may consider exercising authority under § 1812(f) to waive the 3-day prior hospital stay requirement for coverage of a SNF stay.</p> <p>Q&As in the following sections discuss the application of these waivers and modifications in the context of Medicare fee-for-service, in greater detail.</p>
1135B-3	<p>Question: How does the President’s National Emergency declaration under the National Emergencies Act differ from a Stafford Act declaration? How does the request process for assistance under the Stafford Act differ from the request process for 1135 waivers?</p> <p>Answer: Presidential proclamation of a national emergency under the National Emergencies Act and a Presidential declaration of an emergency or major disaster under the Stafford Act are distinct and separate declarations.</p> <p>The National Emergencies Act allows the President to issue a proclamation to invoke particular emergency authorities as needed. The President’s proclamation under the National Emergencies Act does not trigger a Stafford Act declaration or provide financial or other resources.</p> <p>In general, when an incident overwhelms or is anticipated to overwhelm State resources, the Governor may request Federal assistance, including assistance under the Stafford Act. The Stafford Act authorizes the President to provide financial and other assistance to State and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or major disaster declarations under the Stafford Act. The Stafford Act is triggered by a Presidential declaration of a major disaster or emergency under that Act, when an event causes damages of sufficient severity and magnitude to warrant Federal disaster assistance to supplement the efforts and available resources of States, local governments, and the disaster relief organizations in alleviating the damage, loss, hardship, or suffering.</p> <p>Most incidents are not of sufficient magnitude to warrant a Presidential declaration. However, if State and local resources are insufficient, a Governor may ask the President to make such a declaration. Ordinarily only a Governor can initiate a request for a Presidential emergency or major disaster declaration. In extraordinary circumstances, the President may unilaterally declare a major disaster or emergency. In order to assist States in assessing impacts and evaluating the need for Federal assistance in an emergency or disaster, FEMA may develop a fact sheet for requesting Stafford Act assistance from the Federal government. For example, FEMA developed such a fact sheet for the H1N1 influenza pandemic, which may be viewed at: http://www.fema.gov/pdf/emergency/pandemic_influenza_fact_sheet.pdf.</p>
1135B-4	<p>Question: Specifically, what will a National Emergencies Act Declaration enable? What will 1135 waivers allow hospitals to do if a waiver is requested and granted?</p> <p>Answer: For purposes of section 1135 waivers or modifications, the President’s declaration of a national emergency fulfills one of the two conditions required for the Secretary of HHS to be able to invoke the 1135 waiver authority. The other condition is that the Secretary has determined that a public health emergency exists in the same geographic area and time frame. If both conditions are met and the Secretary has invoked the 1135 waiver authority, then healthcare facilities that receive specific waivers or modifications under section 1135 will be able to continue to be reimbursed for covered services even if they are out of compliance with certain Medicare, Medicaid and CHIP requirements.</p>
1135B-5	<p>Question: Do 1135 waivers affect State laws or regulations?</p> <p>Answer: Under section 1135, only certain Federal requirements relating to Medicare, Medicaid, CHIP, and HIPAA may be waived or modified. An 1135 waiver does not affect State laws or regulations.</p>
1135B-6	<p>Question: Has the authority to grant 1135 waivers been exercised before?</p> <p>Answer: Yes, there are several instances where 1135 waiver authority has been invoked to help healthcare facilities cope with large patient burdens. Recent examples include Hurricane Katrina (2005), Hurricanes Ike and Gustav (2008), and the North Dakota flooding (2009 & 2010) and the H1N1 pandemic (2009 – 2010).</p>

	<p>The Secretary was also prepared and able to invoke the 1135 waiver authority in connection with the 56th Presidential Inauguration (2009) in the event that 1135 waivers became necessary.</p>
<p>1135B-7</p>	<p>Question: Is the HIPAA Privacy Rule suspended during a national or public health emergency?</p> <p>Answer: No. The HIPAA Privacy Rule is not suspended during a national or public health emergency. However, the Secretary of HHS may waive certain sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule under section 1135(b)(7) of the Social Security Act.</p> <p>Specifically, the Secretary of HHS may waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule: (1) the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care (45 CFR 164.510(b)); (2) the requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a)); (3) the requirement to distribute a notice of privacy practices (45 CFR 164.520); (4) the patient's right to request privacy restrictions (45 CFR 164.522(a)); and (5) the patient's right to request confidential communications (45 CFR 164.522(b)). These waivers are subject to special time limits.</p> <p>The HHS Office for Civil Rights (OCR) enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. Additional information concerning these matters can be accessed at the OCR website: http://www.hhs.gov/ocr/privacy/index.html.</p>
<p>1135B-8</p>	<p>Question: When and where are 1135 waivers (not related to HIPAA) in effect?</p> <p>Answer: The Secretary may issue specific waivers or modifications under section 1135 only to the extent they ensure that sufficient health care items and services are available to meet the needs of Medicare, Medicaid, and CHIP beneficiaries in the emergency area during the emergency period. The "emergency area" and the "emergency period" are the geographic area, in which, and the time period, during which, the dual declarations exist.</p>
<p>1135B-9</p>	<p>Question: What are practical implementation steps States and individual healthcare providers need to consider when seeking a waiver or modification of requirements during an emergency or disaster?</p> <p>Answer:</p> <p><u>Determining if Waivers Are Necessary</u></p> <p>In determining whether to recommend that the Secretary invoke the 1135 waiver authority (once the conditions precedent to the authority's exercise have been met), the Assistant Secretary for Preparedness and Response (ASPR), with input from relevant HHS Operating Divisions, will determine the need and scope for such modifications. Information considered includes requests from Governors' offices, feedback from individual healthcare providers and associations, and requests to regional or field offices for assistance. If the Secretary invokes the waiver authority, then 1135 waivers and modifications are authorized.</p> <p><u>How States or Individual Healthcare Providers Can Ask for Assistance or a Waiver</u></p> <p>Once the 1135 waiver authority is invoked, health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority to either the State Survey Agency or CMS Regional Office. Requests can be made by sending an email to the CMS Regional Office in their service area, or by calling the State or CMS Regional Office. Email addresses are listed below. The requesting entity should furnish all pertinent facts concerning its particular situation and how it would operate under the particular waiver it is seeking.</p> <p><u>Review of 1135 Waiver requests</u></p> <p>A cross-regional CMS Waiver Validation Team will review waiver requests to ensure they are justified and supportable.</p> <p><u>Implementation of 1135 Waiver Authority</u></p> <p>Providers must resume compliance with normal Medicare fee-for-service rules and regulations as soon as</p>

	<p>they are able to do so and, in any event, the waivers or modifications a provider was operating under are no longer available after the termination of the emergency period. Note that HIPAA and EMTALA waivers are subject to special time limits, as discussed elsewhere in these FAQs.</p> <p>All Medicare-enrolled providers must operate under normal Medicare fee-for-service rules and regulations, unless they have sought and have been granted waivers or modifications under the 1135 waiver authority of specific requirements.</p> <p><u>Email Addresses for CMS Regional Offices</u></p> <p>ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee</p> <p>RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas</p> <p>ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont</p> <p>ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska</p> <p>ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.</p>
1135B-10	<p>Question: Approximately how long will the process take for approving/denying a waiver request?</p> <p>Answer: CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The cross-regional Waiver Validation Team will review waiver requests to ensure they are justified and supportable. HHS anticipates that requests to operate under 1135 Waiver flexibilities should be responded to within three business days of receipt.</p>
1135B-11	<p>Question: Can a healthcare system apply for a waiver of regulations at all or some of its hospitals, or can only a hospital apply?</p> <p>Answer: HHS anticipates that healthcare systems or corporations may make requests on behalf of their facilities. However, they should include the information necessary to allow the CMS regional office to appropriately justify the flexibility requested for each facility.</p>
1135B-12	<p>Question: Can a county health department apply on behalf of several hospitals in its county or must each hospital apply individually?</p> <p>Answer: A county may apply on behalf of facilities in its county, but the county should supply all pertinent facts concerning each facility's particular situation, and how the facility would operate under the particular waiver it is seeking, in order to enable the CMS regional office to appropriately justify the waiver or modification requested for each facility.</p>
1135B-13	<p>Question: Can a State petition the Federal government for a waiver covering all Critical Access Hospitals (CAH) and if so, to whom?</p> <p>Answer: Health care providers can submit requests to operate under that authority (or for other relief that may be possible under other authority) to either the State Survey Agency or CMS Regional Office. Requests can be made by sending an email to the CMS Regional Office in their service area, or by calling the State or CMS Regional Office. Information on your facility and justification for requesting the waiver or modification will be required.</p>
1135B-14	<p>Question: Can the 72-hour waiver time frame for HIPAA and EMTALA waivers under the section 1135 authority be extended if the disaster plan is still in effect?</p> <p>Answer: No. These waivers, when applicable, are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol, except in the case of a public health emergency involving a pandemic infectious disease – for these emergencies EMTALA waivers may be effective until the termination of the emergency period.</p>

1135B-15	<p>Question: Are there mechanics for requesting a waiver or modification under section 1135 proactively?</p> <p>Answer: Health care providers in the emergency area are asked to submit supported and justifiable requests reflecting actual need for a waiver or modification of applicable requirements as the need arises (i.e., rather than in anticipation of a need). The requesting entity should furnish all pertinent facts concerning its particular situation, and how it would operate under the particular waiver it is seeking, to ensure that the Waiver Validation Team can validate the request quickly. Requested waivers or modifications can be approved effective retroactively to the beginning of the emergency period.</p>
1135B-16	<p>Question: To whom and in what form should a hospital “petition” for an 1135 waiver?</p> <p>Answer: Health care providers can submit requests to operate under that authority (or for other relief that may be possible under other authority) to either the State Survey Agency or CMS Regional Office. Requests can be made by sending an email to the CMS Regional Office in their service area, or by calling the State or CMS Regional Office. Email addresses are listed below. Information on your facility and justification for requesting the waiver or modification will be required.</p> <p>ROATLHSO@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee</p> <p>RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas</p> <p>ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont</p> <p>ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska</p> <p>ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.</p>
1135B-17	<p>Question: Must a State or locality declare its own public health emergency (PHE) before it may request that an 1135 be put into place for one or more of its healthcare facilities? If so, is it possible for a hospital in a State that has not declared a PHE to petition directly to HHS for an 1135 waiver? If so, what is the process?</p> <p>Answer: A state or locality’s declaration of an emergency has no bearing on the Secretary’s authority to invoke the section 1135 waiver authority. Rather, so long as the Secretary has declared a public health emergency and the President has declared an emergency or disaster under the Stafford Act or National Emergencies Act for the relevant geographic area, the Secretary may invoke the 1135 authority and authorize waivers or modifications of certain Medicare, Medicaid, CHIP and HIPAA requirements in the geographic area during the period when the declarations are in effect. However, the fact that a State or locality has declared an emergency or requested federal assistance in response to an emergency may be relevant to the Secretary’s consideration of whether a public health emergency exists or an 1135 waiver should be authorized. The process for requesting a waiver or modification under section 1135 once such waivers or modifications are authorized is addressed in other FAQs.</p>
1135B-18	<p>Question: Is there a mechanism for submitting 1135 waiver questions that have not been addressed on the CMS website?</p> <p>Answer: Additional Questions regarding 1135 waivers can be sent to the CMS Regional Office in your service area, or by calling the State or CMS Regional Office. Email addresses are listed below.</p> <p>ROATLHSO@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee</p> <p>RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas</p> <p>ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont</p> <p>ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska</p> <p>ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah,</p>

	Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.
1135B-19	<p>Question: Do waivers and modifications in response to an emergency apply to providers located only in States in which the Secretary of Health and Human Services (HHS) has declared a public health emergency and FEMA or the president has made a declaration under the Stafford Act or National Emergencies Act?</p> <p>Answer: Waivers and modifications granted under § 1135 of the Act apply only to providers in the areas in which the President has made a declaration of an emergency or disaster under either the Stafford Act or the National Emergencies Act, in which the Secretary has declared a public health emergency, in which the Secretary has authorized one or more waivers under § 1135 of the Act, and for which a determination has been made that the waiver or modification is necessary for a provider or group or type of providers.</p>
1135B-20	<p>Question: What is the duration of the waivers/modifications granted by the HHS Secretary under § 1135?</p> <p>Answer: In general, the length of a waiver under § 1135 is limited by the duration of the declared emergency/disaster period, unless sooner terminated, as described in § 1135(e).</p> <p>However, because requirements are waived or modified only to the extent such waivers are necessary the duration of applicability of a waiver or modification to any particular provider may be shorter if the provider can operate without benefit of a particular waiver. For example, it's possible that if a particular hospital were to regain its ability to comply with a waived requirement before the end of the declared emergency period, then the waiver of that requirement would no longer be available to that hospital. In general, however, recent practice has been that waivers, when granted, apply to all similarly situated providers within the declared area for the duration of the emergency. Exceptions to that practice in the future would be addressed in a general or specific informal notice.</p> <p>Note, too, that if a waiver of certain Emergency Medical Treatment and Labor Act (EMTALA) or Health Insurance Portability and Accountability Act (HIPAA) sanctions is granted, such a waiver is subject to special limits on duration (see the Q&As in Section N below for more information).</p>
1135B-21	<p>Question: 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?</p> <p>Answer: No. 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 under Section 319 of the Public Health Service Act. Medicare does allow for certain limited flexibilities under other authority, as discussed in other Q&As. Some of these flexibilities may be extended to areas beyond the declared "emergency area."</p>
1135B-22	<p>Question: Could CMS provide examples of requests for waivers of the physician self-referral prohibition ("Stark law") sanctions that would be considered under the Secretary's Section 1135 waiver authority?</p> <p>Answer: The physician self-referral law prohibits a physician from referring a Medicare patient for certain designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship, unless an exception applies. The primary sanction for a Stark violation is denial of payment for claims that were the subject of a prohibited referral. A waiver of Stark sanctions under Section 1135 of the Social Security Act (42 U.S.C. § 1320b-5) may be granted in order to ensure the sufficiency of health care service delivery in an area where there is <i>both</i> a declaration of a public health emergency (PHE) under Section 319 of the Public Health Service Act and a declaration of an emergency or disaster under the Stafford Act or National Emergencies Act. Waivers are generally granted only on a case-by-case basis. Based on the specific facts provided by the requestor, CMS will make a determination to approve or deny the request. For example, a waiver of Stark sanctions might be granted if a hospital in an emergency area needs additional physicians to treat patients immediately and exigent circumstances prevent the parties from executing a written agreement setting forth their arrangement (as required by many Stark exceptions). Unless a determination is made approving a waiver of sanctions, parties must comply with all Stark rules.</p>
1135B-23	<p>Question: Can waivers of sanctions for violations of the physician self-referral prohibition (the "Stark law") be authorized?</p> <p>Answer: In instances where the Secretary has authorized waivers of sanctions for violations of the Stark law under the § 1135 authority and delegated implementation of such waivers to CMS, sanctions for violations of the Stark law may be waived in such circumstances as CMS determines necessary and</p>

	appropriate. In these instances, CMS will consider waiver requests on a case-by-case basis and/or through future guidance posted on the CMS website.
1135B-24	<p>Question: What is the process for requesting and receiving a Stark waiver (i.e., a waiver of sanctions under section 1877(g) of the Act)?</p> <p>Answer: The process described above in Q&A 1135B-9 is also the process to be followed to request waiver of sanctions for violations of the Stark law. See also Q&A 1135B-15. In past emergencies, such waivers were granted only upon request and on a case-by-case basis and required specific details concerning the actual or proposed financial relationship between the referring physician(s) and the referred-to entity. Unless and until a "Stark waiver" is granted to the requesting party(ies), such party(ies) must comply with all physician self-referral (Stark) rules.</p>
C	General Payment Policies
1135C-1	<p>Question: LTC providers are trying to learn how to be reimbursed for their services furnished during an emergency/disaster. Evacuation-related billing is quite complex and both the evacuating and receiving facilities incur costs. It would be helpful if there was a simplified and consistent process for billing during emergency/disaster-related situations. A Medicare Part A default rate for residents taken in temporarily would be extremely helpful. The additional cost of admitting and discharging residents on a short term basis and the additional challenges to facilities who willingly assist in an emergency/disaster should not be overlooked, and reasonable reimbursement mechanisms should be made available to them.</p> <p>Answer: There is currently no statutory authority that would permit Medicare to pay for evacuation costs. Moreover, even in the circumstance where the HHS Secretary invokes the waivers authorized by § 1135 of the Social Security Act, evacuation costs would not be covered under Medicare by such waivers. However, depending on particular circumstances, an ambulance transport to the nearest appropriate facility equipped to treat the beneficiary may be covered by Medicare Part B if transport of the beneficiary by ambulance was medically necessary and all other Medicare coverage requirements were met (i.e., the vehicle must meet certain requirements, the crew must be certified as required, the transport must be from an eligible origin to an eligible destination, certain billing and reporting requirements must be met, and Medicare Part A payment is not made directly or indirectly for the services). The local claims processing contractor would evaluate such transports on a case-by-case basis.</p>
D	General Billing Procedures
1135D-1	<p>Question: Regarding the use of the disaster-related condition code "DR", should this code be used for all billing situations relating to a declared emergency/disaster (i.e., SNF, ESRD, or Hospitals)?</p> <p>Answer: Yes, the "DR" condition code should be used by institutional providers (but not by non-institutional providers such as physicians and other suppliers) in all billing situations related to a declared emergency/disaster. The "DR" condition code is intended for use by providers (but not by physicians and other suppliers) in billing situations related to a declared emergency/disaster. However, use of the DR condition code, which previously was left to the provider's or supplier's discretion, is now to be used only in certain circumstances. Effective August 31, 2009, use of the DR condition code is mandatory for any claim for which Medicare payment is conditioned on the presence of a "formal waiver" (as defined in the CMS Internet Only Manual, Publication 100-04, Chapter 38, § 10). Also, the DR condition code may be required in certain circumstances relating to a particular disaster or emergency to facilitate efficient processing of claims. Medicare claims processing contractors will advise providers when and under what circumstance such ad hoc use of the DR condition code will be required. (Note: Non-institutional providers do not use the DR condition code. Instead, non-institutional providers must use the CR modifier for applicable HCPCS codes on any claim for which Medicare Part B payment is conditioned on the presence of a "formal waiver". The CR modifier also may be required for any HCPCS code for which, at the Medicare claims processing contractor's discretion or as directed by CMS in a particular disaster or emergency, the use of the CR modifier is needed to efficiently and effectively process claims or to otherwise administer the Medicare fee-for-service program.)</p>

1135D-2	<p>Question: Please provide direction regarding the use of the CR/DR modifier/condition code on claims for services furnished to patients that were moved to other areas, including other States outside the emergency area. Does a provider still use the CR/DR modifier/condition code when the provider is in a State other than the State where the emergency has been declared?</p> <p>Answer: Agency policy concerning the use of the DR condition code and the CR modifier is established by Change Request 6451 (Transmittal 1784, issued July 31, 2009). This Change Request provides that the DR condition code and the CR modifier are required in any one of three circumstances as follows: 1) a § 1135 waiver granted to a provider or supplier necessitates the use of the condition code or modifier, 2) CMS mandates their use, or 3) a claims administration contractor mandates their use. See Change Request 6451 for a more precise statement of the policy. When the President declares an emergency and the Secretary of the Department of Health and Human Services has also declared a public health emergency, CMS advises its contractors that use of the DR condition code or the CR modifier is required on a claim for an item or service furnished under a “formal waiver,” i.e., the first of the three possibilities discussed in Change Request 6451, and will also specify the emergency area and the beginning effective date. If CMS were to mandate the use of the condition code or modifier in other circumstances, i.e., the second of the three possibilities discussed in Change Request 6451, that decision would also be communicated to our contractors. Finally, under Change Request 6451, claims administration contractors are authorized – but not required – to mandate or authorize the use of the DR condition code or the CR modifier on claims related to a particular emergency, including claims from providers and suppliers furnishing items and services in States other than the State in which the emergency exists when the effects of the emergency affect the delivery of such items and services in other States. This is the third of the three possibilities discussed in Change Request 6451. Note, however, that the requirement or authorization to the use the DR condition code or the CR modifier on a claim does not, itself, constitute a waiver of a Medicare requirement, but rather reflects that a waiver or other special condition may apply to the furnishing of an item or service in a Federally-declared emergency situation. In each case where the DR condition code or the CR modifier is required, our contractors will notify providers and suppliers of the particulars regarding such use.</p>
E	<p>Physician Services</p>
1135E-1	<p>Question: Can Medicare fee-for-service rules regarding physician State licensure be waived in an emergency?</p> <p>Answer: Yes, in some cases. If the HHS Secretary has authorized 1135 waivers, then CMS may waive, on an individual basis, the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing. However, the 1135 waiver is not available unless all of the following four conditions are met: 1) the physician or non-physician practitioner must be enrolled as such in the Medicare program, 2) the physician or non-physician practitioner must possess a valid license to practice in the State which relates to his or her Medicare enrollment, 3) the physician or non-physician practitioner has traveled to the State in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and 4) the physician or non-physician practitioner is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area. In particular circumstances, CMS may require that additional conditions apply.</p> <p>An 1135-based licensure waiver expires as of: a) the termination or expiration of the Federally-declared emergency, b) the termination or expiration of the Secretary’s declaration of a public health emergency, or c) the Secretary’s withdrawal of authority to CMS to grant 1135 waivers. Further, an 1135-based licensure waiver is <u>not</u> available for a physician or non-physician practitioner who leaves the emergency area and travels to another State (which is not within, or comprises, an emergency area), even when the purpose of leaving the emergency area is to contribute to relief efforts in his or her professional capacity.</p> <p>In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving State or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the State. Therefore, for all practical purposes, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the State also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home State.</p>
1135E-2	<p>Question: How does a physician or non-physician practitioner apply for an 1135 waiver of licensure requirements for Medicare purposes?</p> <p>Answer: Physicians and non-physician practitioners can request an 1135 waiver of licensure requirements in the same manner as requestors for other 1135 waivers. For information concerning the process for</p>

	obtaining an 1135 waiver of licensure requirements for Medicare purposes, see the Qs&As in section 1135B, above – particularly Q&A 1135B-9.
1135E-3	<p>Question: Can the “Stark rules” against physician self-referral be waived in an emergency?</p> <p>Answer: Yes, Stark rules can be waived in particular circumstances when 1135 waivers are authorized for the emergency area. See Qs&As 1135B-22, 1135B-23, and 1135B-24, above for additional information regarding Stark waivers.</p>
1135E-4	<p>Question: Under an 1135 waiver, a physician may render services to Medicare beneficiaries outside of the physician’s normal service area, as long as certain licensure requirements are met. In these situations, who does the physician bill, his/her Medicare claims administration contractor with which he/she is enrolled or the contractor with jurisdiction over the area in which the service was performed? If the latter, must the physician first enroll with that contractor?</p> <p>Answer: For a full statement of the 1135-based licensure waiver, see Q&A 1135E-1 above. With respect to the issue of billing, the physician rendering services outside of his/her normal service area should bill the Medicare claims administration contractor that has jurisdiction over the area where the service was performed. Before billing, the physician must enroll with the Medicare contractor, but the enrollment process should be streamlined due to the extreme circumstances.</p>
F	Ambulance Services
1135F-1	<p>Question: We are a large company that bills for ambulance transport: most are municipal 9-1-1 responders. Do we call our regional jurisdiction and get a waiver prior to billing claims? What is the process? Will there be a modifier to use on billing out claims?</p> <p>Answer: The waiver authority under § 1135 does not authorize a waiver of the ambulance payment and coverage requirements, and thus there are no ambulance claims modifiers to indicate that a § 1135 waiver is in place. However, 1135 waivers granted to institutional providers can indirectly affect Medicare payment for ambulance transports in certain circumstances.</p>
1135F-2	<p>Question: In emergency/disaster situations how does CMS define an “approved destination” for ambulance transports and would it include alternate care sites, field hospitals and other facilities set up to provide patient care in response to the emergency/disaster?</p> <p>Answer: CMS defines “approved destination” in the Code of Federal Regulations (CFR), 42 CFR § 410.40(e), Origin and Destination requirements. Medicare can only pay for ambulance transportation when it meets the Origin and Destination Requirements and all other coverage requirements in Medicare regulations and manuals. These requirements specify that an appropriate destination is one of the following:</p> <ul style="list-style-type: none"> · Hospital; · Critical Access Hospital (CAH); · Skilled Nursing Facility (SNF); · Beneficiary’s home; · Dialysis facility for ESRD patient who requires dialysis. <p>Beneficiaries residing in a SNF who are receiving Part B benefits only are eligible for ambulance transport to one additional “approved destination”: From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident. For SNF residents receiving Medicare Part A benefits, this type of ambulance service is subject to SNF consolidated billing.</p> <p>A physician’s office is not a covered destination. However, under certain circumstances an ambulance transport may temporarily stop at a physician’s office without affecting the coverage status of the transport.</p> <p>In some emergencies/disasters, the availability of hospital or other facility services may be adversely affected. In such cases, should a facility which would normally be the nearest appropriate facility be unavailable during the emergency/disaster, Medicare may pay for transportation to another facility so long as that facility meets all Medicare requirements and is still the nearest facility that is available and equipped to provide the needed care for the illness or injury involved.</p> <p>42 CFR 410.40 allows Medicare to pay for an ambulance transport (provided that transportation by any other means is contraindicated by the patient’s condition and all other Medicare requirements are met) from any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level</p>

	<p>and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.</p> <p>The waiver authority under § 1135 does not authorize a waiver of the ambulance payment and coverage requirements, such as the approved destination requirements described above. However, Medicare payment for an ambulance transport to an alternative care site may be available if the alternative care site is granted approval by CMS to function as an extension of an institutional provider (hospital, CAH or SNF) that is an approved destination for an ambulance transport under 42 CFR § 410.40 (whether under a § 1135 waiver or existing rules).</p>
1135F-3	<p>Question: If a Medicare beneficiary is transported by ambulance to a local skilled nursing facility (SNF) because the ambulance was unable to transport the beneficiary to the hospital located in another community for factors such as weather, would Medicare payment be available under either of the following two scenarios?</p> <ol style="list-style-type: none"> 1. The ambulance service would use space in the SNF that was not used by patients and would provide the care for the patient under the direction of the ambulance medical director. 2. The staff from the SNF would help provide care for the patients, freeing the ambulance service staff to take other calls. <p>Answer: These scenarios implicate both payment policy and conditions of participation and the permissibility of either scenario may depend on whether a waiver under § 1135 of the Social Security Act has been granted to the SNF in question. First, in the absence of an 1135 waiver, if the patient needs a hospital level of care and not a SNF level of care, the SNF cannot be considered a hospital alternative care site. Therefore, the ambulance transport of the patient to the SNF would not be payable under Medicare because the SNF would not be the nearest appropriate facility that is capable of furnishing the required level and type of care for the beneficiary's illness or injury (see 42 CFR § 410.40(e) for destination requirements under Medicare fee-for-service). In addition, because the SNF cannot be considered a hospital alternative care site for furnishing a hospital level of care, no Medicare payment would be available for any services furnished to the patient while a resident of the SNF.</p> <p>Even if 1135 waivers were generally available for a particular emergency, because SNFs are not equipped to provide a hospital level of care, and because neither of the described scenarios entail a hospital working with a SNF to create an alternate hospital care site at the SNF, with the hospital providing additional staffing, CMS would likely have strong reservations about approving such a waiver request, regardless of whether or not the ambulance service would be providing personnel to monitor the patient(s) at the SNF. However, CMS would review the particular circumstances of the actual situation to make a determination under an 1135 waiver as to what practices would be permitted, along with whether Medicare could pay for any covered services and under which benefit the services would be paid.</p>
G	<p>Laboratory & Other Diagnostic Services (Reserved)</p>
H	<p>Drugs & Vaccines Under Part B (Reserved)</p>
I	<p>Durable Medical Equipment, Prosthetics, Orthotics, and Supplies</p>
1135I-1	<p>Question: How can people with Medicare who have been displaced and who are without access to their usual suppliers get access to durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) such as wheelchairs and therapeutic shoes?</p> <p>Answer: Beneficiaries who have access to a telephone may contact 1-800-Medicare for information regarding suppliers serving their current location. Alternatively, if beneficiaries have access to the Internet, they go to the following medicare.gov website to obtain a directory listing suppliers by geography, proximity and name: http://www.medicare.gov/supplier/home.asp.</p>
1135I-2	<p>Question: Can the face-to-face requirement for certain DMEPOS be waived in an emergency?</p> <p>Answer: Absent an 1135 waiver, no. In the event that 1135 waivers are authorized for a particular emergency, specific waivers could be granted to waive the face-to-face requirement. Each request for such a waiver would be evaluated to determine if the particular circumstances warranted such a waiver.</p>

J	End Stage Renal Disease (ESRD) Facility Services (Reserved)
K	Home Health Services
1135K-1	<p>Question: Under the State licensure authority, waivers have been given to receiving facilities concerning the procedures for admitting persons displaced by a declared emergency. What adjustments to Medicare requirements can be made for the completion of the assessment process?</p> <p>Answer: Consistent with the time period indicated in a 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.</p> <p>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.</p> <ul style="list-style-type: none"> ▪ The Start of Care assessment (RFA 1) may be abbreviated to include the Patient Tracking Sheet and the twenty-four (24) payment items. ▪ The Resumption of Care assessment (RFA 3) and the Recertification assessment (RFA 4) may be abbreviated to the twenty-four (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. <p>HHAs should maintain adequate documentation to support provision of care and payment.</p>
1135K-2	<p>Question: Our office has been destroyed by flood waters. Although we have electronic medical records, some paper documents including signed Face-to-Face Encounter Forms and Physician Plans of Care have been destroyed. What recourse do we have related to billing for the services that have been provided to these clients?</p> <p>Answer: Instructions for how to handle situations where documentation to support payment has been lost or destroyed can be found in CMS' Program Integrity Internet Only Manual in Publication 100-08, Chapter 3, § 3.8 entitled "Administrative Relief from MR During a Disaster" at the following link: http://www.cms.gov/manuals/downloads/pim83c03.pdf. A note should be entered (and dated) in the medical record that the documentation of "XYZ" was destroyed in the hurricane.</p>
1135K-3	<p>Question: What documentation does a provider need to have on file to submit as proof of the destruction of medical records for future ADRs, CERTs, RACs, etc.?</p> <p>Answer: Instructions for how to handle situations where documentation to support payment has been lost or destroyed can be found in CMS' Program Integrity Internet Only Manual in Publication 100-08, Chapter 3, § 3.8 entitled "Administrative Relief from MR During a Disaster" at the following link: http://www.cms.gov/manuals/downloads/pim83c03.pdf. A note should be entered (and dated) in the medical record that the documentation of XYZ was destroyed in the hurricane.</p>
1135K-4	<p>Question: Can the home health requirements for a face-to-face encounter be waived under Section 1135 of the Act?</p> <p>Answer: No. Home health requirements for a face-to face encounter are considered to be conditions for payment. A face-to-face encounter must occur no more than 90 days prior to the start of care or within 30 days after the start of care. (see section 30.5.5.1 in Chapter 7 of the Medicare Benefit Policy Manual (Pub. 100-02)). As such, the home health face-to-face requirements cannot be waived under Section 1135 of the Act. If conditions related to the emergency cause a provider to expect to be unable to meet these timeframes, that provider should contact the CMS RO to allow for tracking and completion of this encounter as soon as conditions allow.</p>

1135K-5	<p>Question: For a Home Health Agency (HHA) that is adversely affected by a disaster or emergency, can an extension be granted to for the submission of OASIS data?</p> <p>Answer: In 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.</p> <ul style="list-style-type: none"> · 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. <p>HHAs should maintain adequate documentation to support provision of care and payment. Subject to the public health emergency declarations under section 1135, 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. This abbreviated assessment does not have to meet the 5-day completion date or the 7-day lock date. In addition, the OASIS transmission requirements at 42 CFR 484.20 are suspended for those Medicare approved HHAs that are serving qualified home health patients/evacuees in the affected areas. HHAs are expected to use this policy only as needed, and to return to business as usual as soon as possible.</p> <p>For additional information, see the answers set out in Section I in the Survey & Certification FAQs at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf</p> <p>For the areas covered by the public health emergency (PHE) declaration for Hurricane <i>Sandy</i>, CMS has granted a blanket waiver for HHAs regarding the above, for the time period covered by the PHE declaration.</p>
L	Hospice Services
1135L-1	<p>Question: Can the hospice requirements for a face-to-face encounter be waived under Section 1135 of the Act?</p> <p>Answer: No. Hospice requirements for a face-to face encounter are considered to be conditions for payment. A face-to-face encounter must occur no more than 30 days prior to the start of the third benefit period and 30 days prior to any subsequent benefit periods thereafter (see section 20.1 in chapter 9 of the Medicare Benefit Policy Manual (Pub. 100-02)). As such, the hospice face-to-face requirements cannot be waived under Section 1135 of the Act. If conditions related to the emergency cause a provider to expect to be unable to meet these timeframes, that provider should contact the CMS RO to allow for tracking and completion of this encounter as soon as conditions allow.</p>
M	Hospital Services – General
1135M-1	<p>Question: A physician wants to assist in the emergency room of a hospital for which he/she does not have privileges to practice. The physician is licensed to practice in the same state in which the hospital is located. May the hospital permit this and may the physician bill Medicare for the services rendered?</p> <p>Answer: No. The Medicare hospital Conditions of Participation (CoPs) require that the hospital's governing body must grant privileges to each physician before he/she may practice in the hospital. Before the governing body can act, the hospital's medical staff has to review each physician's credentials and other factors and make a recommendation to the governing body about privileges. However, should an 1135 waiver of the Governing Body CoP be in place and applied to that particular hospital, then the physician (as well as nurse practitioners and physician assistants) may provide care in the hospital and bill Medicare. Even under an 1135 waiver, the hospital would be expected to take reasonable steps, considering the emergency circumstances, to verify that the volunteer is currently licensed.</p>

1135M-2	<p>Question: Can exempt beds in the declared emergency area be converted to acute beds if, because we are providing services to more patients than usual due to the disaster or emergency, a shortage of acute beds occurs? 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?</p> <p>Answer: If by “exempt beds” the question concerns beds in a hospital Inpatient Prospective Payment System (IPPS) excluded unit, then a section 1135 waiver would be required in order for the hospital to use those beds to provide short-term acute care services. As a condition of the waiver, we require that appropriate care would have to be provided, and careful consideration must be given to the appropriateness of placing the acute inpatients in the excluded unit. For example, placement of a medical/surgical inpatient in a locked, involuntary psychiatric unit would not be appropriate.</p>
1135M-3	<p>Question: Can a hospital that does not have either a hospital-based SNF or a swing bed unit use its acute care beds to provide SNF level care?</p> <p>Answer: Absent an 1135 waiver, no. If an 1135 waiver is in effect, the hospital must apply to CMS for application of the waiver, providing justification for its need for a waiver to use acute care beds for SNF-level services.</p>
1135M-4	<p>Question: During an emergency, will Medicare fee-for-service allow payment for care provided at a site not considered part of the facility (which are informally termed “alternative care sites” (ACSs)) for patients who are not critically ill? For example, if local hospitals are almost at capacity during an emergency and the few beds remaining must be reserved for patients needing ventilators and critical care, will Medicare fee-for-service pay for non-critical care provided at an ACS, such as a school gymnasium?</p> <p>Answer: In the absence of an 1135 waiver, a hospital may add a remote location that provides inpatient services to the hospital’s Medicare certified beds under its existing provider agreement, provided that the remote location satisfies the requirements to be provider-based to the hospital’s main campus (including being located within 35 miles pursuant to 42 CFR 413.65(e)(3)). The remote location must satisfy all provider-based requirements including being compliant with the hospital Conditions of Participation (CoPs). The hospital would be expected to file an amended Form CMS 855A with its Medicare Administrative Contractor or legacy Fiscal Intermediary as soon as possible adding an additional location. CMS generally requires a survey of compliance with all CoPs at all new inpatient locations, but also has discretion to waive the onsite survey in this area.</p> <p>However, for an “alternative care site” (ACS) that is not part of the hospital under existing rules; reimbursement may be permitted if the ACS is the subject of an applicable 1135 waiver. As specified at section 1135 of the Social Security Act, when certain conditions are met, the Secretary may temporarily waive or modify certain requirements, such as Medicare conditions of participation, for health care providers in an emergency area (or portion of such an area) during any portion of an emergency period. If the Secretary invokes the section 1135 authority and issues a waiver, and a Medicare-participating hospital located in the emergency area (or portion of the emergency area) covered by the waiver provides necessary acute care consistent with the waiver to eligible Medicare beneficiaries during the emergency period at an ACS, Medicare will pay for reasonable and necessary covered services as if the ACS was a part of the hospital.</p>
N	Hospital Services – Emergency Medical Treatment and Labor Act (EMTALA)
1135N-1	<p>Question: What is HHS’s process for approving and issuing Emergency Medical Treatment and Labor Act (EMTALA) waivers in response to an emergency (aside from both a public health emergency (PHE) being declared by the HHS Secretary and an emergency/disaster being declared by the President)?</p> <p>Answer: There are 5 prerequisites to a waiver of EMTALA sanctions under § 1135 of the Social Security Act. They are:</p> <ol style="list-style-type: none"> (1) The President declares an emergency or disaster under the Stafford Act or the National Emergencies Act, (2) The Secretary of HHS declares a Public Health Emergency (PHE) under § 319 of the Public Health Service Act, (3) The Secretary of HHS authorizes waivers under § 1135 of the Social Security Act and has delegated to CMS the specific authority to waive sanctions for certain EMTALA violations that arise as a result of the circumstances of the emergency, (4) The hospital in the affected area has implemented its hospital disaster protocol, and (5) CMS has determined that sufficient grounds exist for waiving EMTALA sanctions with respect to a particular hospital or geographic area.

1135N-2	<p>Question: What is the time frame for the EMTALA waiver of sanctions?</p> <p>Answer: Waivers of sanctions under the Emergency Medical Treatment and Labor Act (EMTALA) in the emergency area end 72 hours after implementation of the hospital's disaster plan. (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.)</p>
1135N-3	<p>Question: Can the 72-hour waiver time frame be extended if the disaster plan is still in effect?</p> <p>Answer: No. Waivers for EMTALA (for public health emergencies that do not involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic-related public health emergency.</p>
1135N-4	<p>Question: Are hospitals required to comply with all of the requirements of EMTALA during the public health emergency period in the emergency area?</p> <p>Answer: Generally, yes. However, under the Section 1135 waiver authority, the Secretary has the authority to waive sanctions if a hospital in the emergency area during the emergency period directs or relocates an individual to receive medical screening in an alternate location pursuant to either a state emergency preparedness plan or a state pandemic preparedness plan or transfers an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency. These waivers are limited to a 72-hour period beginning upon implementation of a hospital's emergency or disaster protocol (unless the emergency involves a pandemic infectious disease) and are not effective with respect to any action taken that discriminates among individuals on the basis of their source of payment or their ability to pay.</p>
1135N-5	<p>Question: Would it be possible for the HHS Secretary to waive all of EMTALA's provisions, or only some of them?</p> <p>Answer: There are only two EMTALA provisions for which the sanctions can be waived under a § 1135 waiver. Under the §1135 authority, CMS can be authorized to waive the following sanctions:</p> <ol style="list-style-type: none"> (1) For an inappropriate transfer (if the transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period), and (2) For the relocation or direction of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan. <p>However, the Secretary must first invoke the section 1135 waiver authority to authorize the waiver of these sanctions, and then each hospital must implement its disaster protocol in order for either of the waivers to apply to that hospital. Moreover, the statute provides that the waiver is applicable only if the hospital's actions do not discriminate among individuals based on their source of payment or ability to pay.</p>
1135N-6	<p>Question: It was my understanding that only the HHS Secretary had the authority to issue § 1135 waivers but a 12/7/07 CMS memo (Waiver of Emergency Medical Treatment and Labor Act (EMTALA) Sanctions in Hospitals Located in Areas Covered by a Public Health Emergency Declaration) indicates that the Regional Office (RO) "may issue an advisory notice that hospitals with dedicated emergency departments in the emergency area will not, during the emergency period, be subject to" certain EMTALA sanctions, if both the President and Secretary declare emergencies. Does the issuance of an advisory notice by the RO carry the same weight as a § 1135 waiver?</p> <p>Answer: No. The December 7, 2007 CMS memorandum referenced in the question is part of the standard operating procedure describing how CMS will implement the EMTALA provisions of a § 1135 waiver issued by the Secretary. The RO's issuance of an "advisory notice" occurs only <u>after</u> the Secretary has invoked his or her § 1135 waiver authority to authorize the waiver of EMTALA sanctions and CMS has determined that the waiver of certain EMTALA sanctions is necessary for the hospital(s) in the emergency area (or portion of the emergency area) with dedicated emergency departments that have implemented their hospital disaster protocol. Furthermore, in a refinement to the process described in the cited memorandum, hospitals in the emergency area (or portion of the emergency area) are required to notify the appropriate State Survey Agency when they implement a hospital disaster protocol.</p>
1135N-7	<p>Question: Would it be considered an EMTALA violation if the hospital did not have any medical records available because of the disaster?</p> <p>Answer: The waiver of EMTALA sanctions in § 1135 pertains to sanctions for either a transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency or the direction or relocation of an individual to receive medical screening at an alternate location</p>

	<p>pursuant to an appropriate state emergency or pandemic preparedness plan. Section 1135 does not authorize a waiver of the EMTALA requirement on hospitals to maintain medical and other records of individuals transferred from the hospital. While we would still expect hospitals to make every effort to transfer essential information with individuals so that the receiving hospital could treat them safely, when the Secretary has invoked her waiver authority under section 1135 of the Social Security Act, the Secretary may waive any sanctions applicable under EMTALA for a transfer of an individual who has not been stabilized, including the failure to send available medical records to the receiving hospital.</p>
1135N-8	<p>Question: 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?</p> <p>Answer: Hospitals are not required under the Medicare Conditions of Participation to operate emergency departments, and thus always have the option of closing this service, so long as there is no State law requirement for the hospital to maintain an ED, and so long as the hospital employs an orderly closure process. Once the hospital no longer has a dedicated emergency department, it no longer has an EMTALA obligation to provide screening and stabilization to individuals who come to the hospital.</p> <p>However, if the question is about whether an ED may temporarily refuse to see all new patients, due to capacity problems, such refusal may not be permitted under EMTALA in certain circumstances. The EMTALA regulations do permit hospitals to place themselves on “diversionary” status when they lack the staff or facilities to accept additional emergency patients, i.e., they may, by phone or other electronic communications system, advise non-hospital-owned ambulances to go to another hospital. Again, while they are permitted to do this under EMTALA, their actions must also be consistent with State or local requirements governing ambulances and hospital diversionary status. However, even in this circumstance, if the ambulance nevertheless brings an individual onto the property of the hospital on diversion, then the hospital has an EMTALA obligation to provide an appropriate medical screening examination and, if the individual has an emergency medical condition, to provide stabilizing treatment.</p> <p>Furthermore, if a hospital with a dedicated emergency department is operating under a section 1135 waiver, which includes a waiver under section 1135(b)(3) of the Act, sanctions for the direction or relocation of an individual to receive medical screening at an alternate location do not apply so long as the direction or relocation is pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan and the hospital does not discriminate on the individual’s source of payment or ability to pay.</p>
O	<p style="text-align: center;">Hospital Services – Acute Care</p>
1135O-1	<p>Question: During an emergency situation, if acute care beds are all in use, can a hospital use its hospital-based skilled nursing facility (SNF) beds to help relieve overcrowding within the hospital itself?</p> <p>Answer: It is important to clarify whether the SNF will be used to provide hospital-level acute care, or SNF-level care. If the hospital is seeking to provide inpatient acute care in a SNF bed, then this is not possible, unless an applicable 1135 waiver has been issued. Regardless of whether the SNF is hospital-based or not, it is a separately certified Medicare facility and cannot be used to provide inpatient hospital care, absent an applicable 1135 waiver.</p> <p><u>Providing SNF-level care</u></p> <p>Conditions of Participation (CoP) Requirements: There is no prohibition under the Hospital Conditions of Participation against a hospital identifying patients who could be safely discharged to a SNF earlier than usual, in order to free up inpatient hospital capacity. A hospital does not require a Section 1135 waiver in order to do this.</p> <p>Medicare Payment Requirements: For Medicare beneficiaries, if a section 1812(f) waiver is issued in response to an emergency, the 3-day prior hospital stay requirement for coverage of a SNF stay can be temporarily relaxed under the circumstances described below, and a Medicare beneficiary’s care would be reimbursed at the appropriate SNF PPS rate. This may help to relieve overcrowding in hospitals in the event there is an influx of patients requiring care. Section 1812(f) of the Act allows Medicare to pay for SNF services without a preceding 3-day qualifying hospital stay if the Secretary of HHS finds that doing so will not increase total payments made under the Medicare program or change the essential acute-care nature of the SNF benefit. In past emergencies (such as hurricanes or major flooding), this policy has applied to Medicare beneficiaries who were evacuated from the emergency area. In the event that a section 1812(f) waiver is issued in response to a particular emergency, it would apply when a hospital that is operating under a section 1135 waiver takes one of the following actions in order to prevent exposure of beneficiaries to a</p>

	<p>communicable disease or other adverse circumstance or to ensure that the hospital can provide needed care to more seriously ill patients during the emergency:</p> <p>1) Discharges its inpatient to a SNF before completing the full course of hospital treatment; or 2) Diverts a beneficiary directly to a SNF rather than admitting the beneficiary as an inpatient, thus bypassing hospital admission altogether due to the emergency.</p> <p>Note that in past emergencies where we have determined that a waiver under section 1812(f) is appropriate, we generally have applied the waiver of the requirement for a 3-day hospital stay to the geographic areas and timeframes specified in the Secretary’s waiver or modification of requirements under section 1135 of the Act. However, unlike the policies implemented directly under the section 1135 waiver authority itself, those implemented under authority of section 1812(f) need not be limited to those disaster-related relocations that occur <i>within</i> the designated emergency areas. Instead, the policies implemented under the authority of section 1812(f) would apply to all beneficiaries who are evacuated from an emergency area as a result of the disaster, regardless of where the “host” SNF providing post-disaster care is located.</p> <p><u>Providing Hospital Care in a SNF</u></p> <p>CoP Requirements: When the Secretary has authorized appropriate waivers under section 1135 of the Act, and there has been a determination that such waivers are necessary, a hospital that also has a hospital-based SNF on its campus potentially could expand its inpatient bed capacity by placing some hospital patients into its hospital-based SNF. Although the availability of 1135 waivers would depend upon the facts and circumstances of the emergency, in past emergencies, under the section 1135 waiver authority, we have allowed such an increase in inpatient bed capacity for up to the duration of the waiver period. We expect the hospital to document that those patients admitted to the hospital-based SNF continue to need hospital inpatient care, and that the hospital provided adequate RN staffing in the SNF to make sure that every patient requiring hospital inpatient care has immediate RN availability at the bedside as needed. However, even under such a waiver, high acuity hospital patients or patients who need special equipment or special treatments should not be placed in the SNF. Further, care must also be taken not to place hospital patients into the SNF if those patients would place the existing SNF patients at risk (e.g., as a result of behavior problems, communicable infections, etc.).</p> <p>Medicare Payment Requirements: When an appropriate section 1135 waiver has been in place for this purpose, the hospital has been permitted to bill at the IPPS rate for the stay of hospital patients temporarily located in the SNF beds. Should a hospital receive such a waiver, the hospital would need to keep good records for billing and for cost reporting reasons. Since the hospital and its hospital-based SNF share a cost report, costs would need to be appropriately attributed.</p>
11350-2	<p>Question: If we move some of our emergency patients to another location in the hospital because of the emergency – would we still be able to bill for Type A Emergency room charges? What if by virtue of an 1135 waiver we are operating an organized alternate care site which is provider-based to a hospital, could we bill Type A ED services?</p> <p>Answer: In addition to meeting all other applicable requirements, a provider-based Type A emergency department (ED) of a hospital must meet at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department and open 24 hours a day, 7 days a week; or (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment and open 24 hours a day, 7 days a week.</p>
P	<p>Hospital Services – Critical Access Hospitals (CAHs)</p>
1135P-1	<p>Question: Critical access hospitals (CAHs), which are normally limited to 25 beds and to a length of stay of not more than 96 hours, may need to press additional beds into service or extend lengths of stay to respond to the emergency. Will CMS enforce these limits?</p> <p>Answer: During the public health emergency period, and depending upon specific circumstances, CMS may waive both the limit of 25 inpatient beds and the 96-hour length of stay (LOS) limitation. If a waiver is made, then evacuees to a CAH operating under such waiver would not be counted toward the determination of the 25-bed limit or considered for the 96-hour average length of stay limit if this result is clearly identified as relating to the emergency. CAHs must clearly indicate in the medical record where an admission is made or length of stay extended to meet the demands of the emergency and must also annotate all Medicare fee-for-service claims for such admissions or length-of-stay extensions with the “DR” condition code or the “CR” modifier, as applicable, for the period that the CAH remains affected by the emergency.</p>

1135P-2	<p>Question: Critical Access Hospitals (CAH) anticipate that they will exceed their licensed bed capability using the 1135 waiver. Is there a source available to address how an 1135 waiver is applied for and what the process is?</p> <p>Answer: HHS is unable to implement specific 1135 waivers in anticipation of an actual need. Rather, once the need arises, a waiver may be granted. The waiver can be retroactive to the date the need actually arose (i.e., back to the beginning of the waiver period).</p>
Q	Hospital Services – Inpatient Rehabilitation Facilities (IRFs)
1135Q-1	<p>Question: The disruption to the hospital system caused by the emergency 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 emergency, 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")?</p> <p>Answer: In order to meet the demands of the emergency, when an applicable 1135 waiver is in effect, CMS can 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 emergency 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 emergency, 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 emergency. 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.</p> <p>An institutional provider that has been granted a § 1135 waiver would use the "CR" (catastrophic/disaster related) modifier to designate any service line item on the claim that is disaster/emergency related. If all of the services on the claim are disaster/emergency related, the institutional provider with a § 1135 waiver would use the "DR" (disaster related) condition code to indicate that the entire claim is disaster/emergency related. The IRF granted a § 1135 waiver must annotate all Medicare fee-for-service claims affected by the emergency with the "DR" condition code or the "CR" modifier, as applicable, for the period that the IRF is granted the waiver.</p>
1135Q-2	<p>Question: In addition to suspending the "60 percent rule" during the emergency or disaster, 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?</p> <p>Answer: CMS recognizes that it may become necessary for patients who are not rehabilitation candidates to be admitted to IRFs due to an emergency. In these instances, CMS would not apply the IRF-specific criteria (e.g., the 3-hour rule) to any review of claims submitted by an IRF that has been granted a § 1135 waiver. IRFs granted such a waiver should clearly document in the patient's medical record that the patient was admitted solely to meet the demands of the emergency/disaster and must annotate all Medicare fee-for-service claims for such patients with the "DR" condition code or the "CR" modifier, as applicable, for the period that the IRF is operating under the waiver.</p>
R	Hospital Services – Long Term Care Hospitals (LTCHs)
1135R-1	<p>Question: Generally, a hospital must have an average Medicare inpatient length of stay of greater than 25 days in order to be classified as a long-term care hospital (LTCH). If a long-term care hospital (LTCH) admits a patient solely to meet the demands of the emergency, will the patient's stay be counted towards the greater than 25-day average Medicare inpatient length of stay calculation in 42 CFR § 412.23(e)(3)(i)?</p> <p>Answer: If a long-term care hospital (LTCH) admits a patient solely in order to meet the demands of the emergency, and there is an applicable 1135 waiver, the patient's stay will not be included for purposes of the average length of stay calculation in § 412.23 (e)(3)(i). The LTCH must clearly indicate in the medical record where an admission is made to meet the demands of the emergency and must annotate all Medicare fee-for-service claims related to such admissions with the "DR" condition code or the "CR" modifier, as applicable, for the period that the LTCH remains affected by the emergency.</p>

S	Hospital Services – Mobile Emergency Hospitals (Reserved)
T	Skilled Nursing Facilities
1135T-1	<p>Question: Can CMS waive the skilled nursing facility (SNF) benefit's 3-day qualifying hospital stay requirement for those beneficiaries affected by the emergency situation?</p> <p>Answer: Yes. Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to grant SNF coverage in the absence of a qualifying hospital stay, as long as this action does not increase total program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).</p> <p>Under this authority, CMS can issue a temporary waiver of the SNF benefit's qualifying hospital stay requirement for those beneficiaries who are evacuated or transferred as a result of the emergency situation. In this way, beneficiaries who may have been discharged from a hospital early to make room for more seriously ill patients will be eligible for Medicare Part A SNF benefits. In addition, beneficiaries who had not been in a hospital or SNF prior to being evacuated, but who need skilled nursing care as a result of the emergency, will be eligible for Medicare Part A SNF coverage without having to meet the 3-day qualifying hospital stay requirement.</p> <p>CMS's waiver of the requirement for a 3-day hospital stay generally is limited to the time period during which the Secretary's Waiver or Modification of Requirements under § 1135 of the Social Security Act remains in effect.</p>
1135T-2	<p>Question: Can CMS temporarily relax the requirements for establishing a new spell of illness for beneficiaries who have a renewed need for skilled nursing facility (SNF) services as a direct result of the dislocations and trauma related to an emergency situation?</p> <p>Answer: If an applicable § 1812(f) waiver is in effect, a new SNF Part A benefit period can be made available to any beneficiary recently discharged from a nursing home who has not had the time to establish a new benefit period. The Part A SNF coverage would be available to any such beneficiary who was evacuated from a non-institutional setting in an emergency area and who requires skilled care in connection with an emergency, regardless of the location of the SNF that provides the post emergency/disaster care. Therefore, in this situation, the admitting SNF does not need to be located in the emergency area. Part A coverage would be available as long as the beneficiary requires skilled care, up to 100 days. Full coverage would be available for the first 20 days. The daily Medicare coinsurance will be applied from days 21-100.</p> <p>CMS's policy to provide a new benefit period in an emergency or disaster would apply only if the Secretary waives or modifies requirements under § 1135 of the Social Security Act and then only for the time period during which the § 1812(f) waiver remains in effect.</p>
1135T-3	<p>Question: A provider has residents who are returning to an evacuated facility. If a resident previously exhausted the 100 day benefit period and was not discharged, but was evacuated for a few days and now is back in the facility still requiring skilled care, does that Medicare beneficiary receive any additional days?</p> <p>Answer: No. The intent of the section 1812(f) waiver was to provide additional SNF benefits for a beneficiary who, at the time of the disaster, had exhausted the 100 days of SNF benefits available in the current benefit period and was in the process of establishing a new benefit period. A new benefit period is established after a period of 60 consecutive days elapses during which the beneficiary is not receiving skilled care in a SNF or inpatient hospital care. In the situation described above, because the beneficiary at the time of the disaster is still receiving skilled care in the SNF after exhausting the 100 days of SNF benefits, he or she would not be in the process of establishing a new benefit period at that point and, consequently, would not qualify for additional SNF coverage under the section 1812(f) waiver.</p>

1135T-4	<p>Question: How should situations, in which the 3-day qualifying hospital stay normally required for a covered Medicare admission to the SNF is waived, be reported on the UB-04 claim form?</p> <p>Answer: Providers that receive beneficiaries without a 3-day qualifying stay (and for whom the requirement was waived under section 1812(f)) should report condition codes "58" and "DR" (disaster related) on their claim. Based on the presence of these codes, Medicare systems will bypass the 3-day stay requirement and occurrence span code "70" (qualifying stay dates) need not be reported. In addition, providers should include remarks indicating "declared emergency/disaster" on their remarks page for tracking/verification purposes. (Condition code "58" is typically used only to bypass the 3-day stay requirement for managed care dis-enrollments, but in this case it is being adapted temporarily to bypass the requirement to assist the relief effort.)</p>
1135T-5	<p>Question: During an emergency situation, if acute care beds are all in use, can a hospital use its hospital-based skilled nursing facility (SNF) beds to help relieve overcrowding within the hospital itself?</p> <p>Answer: See Q&A 1135O-1, above.</p>
1135T-6	<p>Question: If a Medicare beneficiary is transported by ambulance to a local skilled nursing facility (SNF) because the ambulance was unable to transport the beneficiary to the hospital located in another community for factors such as weather, would Medicare payment be available under either of the following two scenarios?</p> <ol style="list-style-type: none"> 1. The ambulance service would use space in the SNF that was not used by patients and would provide the care for the patient under the direction of the ambulance medical director. 2. The staff from the SNF would help provide care for the patients, freeing the ambulance service staff to take other calls. <p>Answer: These scenarios implicate both payment policy and conditions of participation and the permissibility of either scenario may depend on whether a waiver under § 1135 of the Social Security Act has been granted to the SNF in question. First, in the absence of an 1135 waiver, if the patient needs a hospital level of care and not a SNF level of care, the SNF cannot be considered a hospital alternative care site. Therefore, the ambulance transport of the patient to the SNF would not be payable under Medicare because the SNF would not be the nearest appropriate facility that is capable of furnishing the required level and type of care for the beneficiary's illness or injury (see 42 CFR § 410.40(e) for destination requirements under Medicare fee-for-service). In addition, because the SNF cannot be considered a hospital alternative care site for furnishing a hospital level of care, no Medicare payment would be available for any services furnished to the patient while a resident of the SNF.</p> <p>Even if 1135 waivers were generally available for a particular emergency, because SNFs are not equipped to provide a hospital level of care, and because neither of the described scenarios entail a hospital working with a SNF to create an alternate hospital care site at the SNF, with the hospital providing additional staffing, CMS would likely have strong reservations about approving such a waiver request, regardless of whether or not the ambulance service would be providing personnel to monitor the patient(s) at the SNF. However, CMS would review the particular circumstances of the actual situation to make a determination under an 1135 waiver as to what practices would be permitted, along with whether Medicare could pay for any covered services and under which benefit the services would be paid.</p>
1135T-7	<p>Question: Will an 1135 waiver cover a SNF Part A stay for a beneficiary who was receiving Medicare-covered home health services and who was admitted directly to the SNF from the community? The beneficiary requires medical care and needed to evacuate due to the weather. Or would coverage for this patient be private pay?</p> <p>Answer: A §1812(f) (not §1135) waiver would permit a beneficiary to receive SNF coverage without meeting the requirement that would normally apply for a qualifying 3-day hospital stay. A blanket § 1812(f) waiver has been issued for the affected areas of New York and New Jersey. For additional information, see Q&A 1135T-1 above</p>
1135T-8	<p>Question: Although the intention of the 1812(f) waiver is for the hospital to be able to discharge the patient to a SNF without waiting 3 nights, is the waiver also applicable to a readmission of a SNF resident to our facility after two nights away from the facility due to an evacuation?</p> <p>Answer: Yes, in certain circumstances, under the 1812(f) authority, SNF care without a 3-day inpatient hospital stay will be covered for beneficiaries who: (1) are evacuated from a nursing home in the emergency area, (2) are discharged from a hospital (in the emergency or receiving locations) in order to provide care to more seriously ill patients, or (3) need SNF care as a result of the emergency, regardless of whether that individual was in a hospital or nursing home prior to the disaster. See Medicare fee-for-service Q&A 1135 T-1.</p>

1135T-9	<p>Question: We understand that 1135 waivers are valid for 60 days. Is this also true for an 1812(f) waiver? Does either waiver authority affect how long the facility can keep a patient who actually needs skilled care but has utilized their 100 days of Medicare coverage?</p> <p>Answer: Neither the § 1812(f) authority, nor the 1135 waiver authority, alter the medical necessity requirement for coverage of skilled nursing facility care, or the 100-day limitation on SNF benefits during a benefit period. However, in certain circumstances, under the § 1812(f) authority, a beneficiary recently discharged from a skilled nursing facility – after utilizing all of his/her available SNF benefit days – may be eligible to receive additional SNF benefits despite not establishing a new benefit period. This policy applies only for those beneficiaries who: (1) were evacuated from a non-institutional setting in an emergency area (as specified in the waiver(s) issued under Section 1135 of the Act in connection with Hurricane Sandy in the States of New York and New Jersey), (2) need SNF care as a direct result of Hurricane Sandy in the States of New York and New Jersey, and (3) were in the process of “breaking the spell of illness” for a prior SNF Part A stay, and would not normally be eligible for additional SNF Part A benefits. See Medicare fee-for-service Q&A 1135 T-2, above. Waivers granted under § 1812(f) are generally limited to the timeframes specified in waivers issued under § 1135. See Q&A 1135T-1 (last paragraph). Also, for information about the duration of 1135 waivers, see Q&A 1135B-20.</p>
1135T-10	<p>Question: Do we need to request an 1812(f) waiver for each patient and, if so, does it have to be upon admission, during their stay, or at discharge?</p> <p>Answer: Providers do not need to request a waiver for each patient under the § 1812(f) authority. Providers that receive beneficiaries without a 3-day qualifying stay (and for whom this requirement was waived under section 1812(f)) should report condition codes “58” and “DR” (disaster related) on their claim. Based on the presence of these codes, Medicare systems will bypass the 3-day stay requirement and occurrence span code “70” (qualifying stay dates) need not be reported. In addition, providers should include remarks indicating “declared emergency/disaster” on their remarks page for tracking/verification purposes. (Condition code “58” is typically used only to bypass the 3-day stay requirement for managed care dis-enrollments, but in this case it is being adapted temporarily to bypass the requirement to assist the relief effort.). See Medicare fee-for-service Q&A 1135 T-3.</p>
1135T-11	<p>Question: Is there an end date to this, i.e., waivers for SNF admissions? When will be the last date that we will be able to admit such a resident?</p> <p>Answer: We assume this question is referring to the waiver of the 3-day inpatient hospital stay requirement under the §1812(f) authority. Waivers granted under § 1812(f) are generally limited to the timeframes specified in waivers issued under § 1135. See Q&A 1135T-1 (last paragraph). Unless the 1812(f) waiver is terminated sooner, the last date to admit a resident under an §1812(f) waiver would generally be the date the § 1135 waiver is terminated. SNFs that are operating under a waiver, including an §1812(f) waiver, should contact the CMS RO for confirmation of the end date of such waivers.</p>
1135T-12	<p>Question: If an individual is unable to go home from the skilled nursing facility (SNF) after the 100 days is over due to the emergency, will Medicare pay after the 100 days that ended during the emergency period? If so, what type of minimum data set (MDS) needs to be done and how would the SNF bill Medicare?</p> <p>Answer: It should be noted that the <i>only</i> payment provisions that can be waived under §1812(f) relate to the SNF benefit’s qualifying hospital stay requirement, and to the renewal of exhausted SNF benefits for a beneficiary who was in the process of ending a benefit period at the time of the disaster. All other SNF coverage and payment requirements, including those relating to the required SNF level of care, remain in effect in situations where a SNF resident is unable to be discharged to his or her own home due to the disaster. Accordingly, the difficulty in securing a safe post-discharge environment in this situation cannot, in itself, serve as a basis for continued Part A coverage of the SNF stay. While Medicare coverage would remain available for certain individual medical and other health services under Part B, Medicare cannot pay under Part A <i>for the continued SNF stay itself</i> if the resident no longer requires an SNF level of care at that point or if the resident’s available benefit days are exhausted during the emergency period. Nevertheless, as noted in Medicare Learning Network (MLN) Matters article #SE1247 (available online at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1247.pdf), the Federal Emergency Management Agency (FEMA) website at www.fema.gov/sandy contains information on special disaster assistance, including the availability of emergency shelters for those who are unable to remain in or return to their homes due to the disaster.</p>

1135T-13	<p>Question: Is there any guidance concerning skilled nursing facility (SNF) consolidated billing during the emergency (say if a patient was getting a computed tomography (CT) scan in the hospital but due to the hospital's overcrowding or lack of staff or services, the patient is re-routed to a free-standing provider), would the SNF be responsible for payment?</p> <p>Answer: As explained more fully in other Qs&As in this section, the <i>only</i> payment provisions that can be waived under §1812(f) relate to the SNF benefit's qualifying hospital stay requirement, and to the renewal of exhausted SNF benefits for a beneficiary who was in the process of ending a benefit period at the time of the disaster. All other SNF coverage and payment requirements remain in effect, including the consolidated billing rules under which certain designated high-intensity outpatient services (such as CT scans) are separately payable under Part B <i>only</i> when furnished in the <i>hospital</i> setting. Thus, the SNF itself would remain responsible for a CT scan performed in a <i>nonhospital</i> setting, even if the use of the nonhospital setting is caused by a disaster-related dislocation.</p>
U	Mental Health Counseling (Reserved)
V	Rural Health Clinics / Federally Qualified Health Clinics (Reserved)
W	Fee-for-Service Administration (Reserved)
X	Financial Management Policies (Reserved)