

November 13, 2009

Medicare Fee-For-Service

**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.

These pre-conditions have been met with respect to the H1N1 influenza pandemic. 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, and Secretary Sebelius renewed that declaration on July 24, 2009 and again on October 1, 2009. Secretary Sebelius invoked the 1135 waiver authority on October 29, 2009, with a retroactive effect to October 23, 2009.

In the following Q&As, CMS identifies policies and procedures that are available when 1135 waivers or modifications are invoked. However, the application of specific waivers or modifications is pending at this time. 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 requirements in a particular circumstance. See the Q&As in *Section B – Waiver of certain Medicare Requirements* for information concerning making requests for waivers.

Section 1 – Urgent Preparedness Initiative: The H1N1 Influenza Pandemic

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Control #	Question and Answer
1	Urgent Preparedness Initiative: The H1N1 Influenza Pandemic – Vaccination and Related Issues (Reserved)
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 either a sub-regulatory policy or procedure or a policy or procedure that can be amended under the terms of the implementing statute or regulation and that, in either case, CMS can amend at will without reprogramming its systems. A waiver or a modification is generally thought of as a waiver or modification of a statutory requirement of the Social Security Act (Act) that may be waived or modified under the authority of § 1135 of the Act.</p>
B	Waiver of Certain Medicare Requirements
1135B-1	<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 that the 2009 H1N1 influenza pandemic constitutes a national emergency fulfills the second of the two conditions required for the Secretary of HHS to be able to grant 1135 waivers. The President’s proclamation coupled to the HHS Secretary’s prior public health emergency declaration for 2009 H1N1 influenza enables the HHS Secretary to issue waivers or modifications under section 1135 of the Social Security Act for certain Medicare, Medicaid, CHIP, and HIPAA requirements as discussed above. The President’s proclamation 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</p>

	<p>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 a pandemic influenza, FEMA has developed a fact sheet for requesting Stafford Act assistance from the Federal government: http://www.fema.gov/pdf/emergency/pandemic_influenza_fact_sheet.pdf.</p> <p>As noted above, the H1N1 epidemic is moving rapidly. By the time regions or healthcare systems recognize they are becoming overburdened, they need to implement disaster plans quickly. The President's proclamation of a national emergency under the National Emergencies Act, coupled to the HHS Secretary's prior public health emergency declaration for 2009 H1N1 influenza will allow the Secretary of HHS maximum flexibility to issue waivers or modifications under section 1135 of the Social Security Act nationwide as needed. The process for requesting specific waivers or modifications under section 1135 is discussed below. As the 2009 H1N1 pandemic evolves, if State and local resources become insufficient, then states may request assistance under the Stafford Act through the usual Stafford Act process.</p>
1135B-2	<p>Question: Specifically, what will this National Emergency Act (NEA) Declaration enable? What will 1135 waivers allow hospitals to do if a waiver is requested and granted?</p> <p>Answer: An NEA Declaration fulfills the second of the two conditions required for the Secretary of HHS to be able to grant 1135 waivers. Healthcare facilities that receive specific waivers or modifications under section 1135 will be able to continue to provide care even if they are out of compliance with certain Medicare, Medicaid and CHIP requirements.</p>
1135B-3	<p>Question: Why declare a National Emergency for the 2009 H1N1 pandemic now; why can't we wait until a hospital or region needs these 1135 Waivers?</p> <p>Answer: The H1N1 epidemic is moving rapidly. By the time regions or healthcare systems recognize they are becoming overburdened, they need to implement disaster plans quickly. When the Secretary of HHS invokes section 1135, HHS has in past practice accepted requests from affected healthcare facilities, providers, and/or States for specific waivers or modifications. HHS will be requiring such requests in connection with this emergency and will need to process such requests quickly. Adding a potential delay by requiring HHS to wait for a National Emergency Declaration before it could issue necessary 1135 waivers is not in the best interest of the public, particularly if this step can be done proactively as the President has done.</p>
1135B-4	<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 as listed in section 1135. An 1135 waiver does not affect State laws or regulations.</p>
1135B-5	<p>Question: Has the authority to grant 1135 waivers been granted before?</p> <p>Answer: Yes, there are several instances where 1135 Waiver authority has been granted under the Stafford Disaster Relief and Emergency Assistance Act (as opposed to the National Emergencies Act) 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). 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>
1135B-6	<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 sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule under the Project Bioshield Act of 2004 (PL 108-276) and 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)).</p>

1135B-7	<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 only applies to hospitals nationwide that have instituted a disaster response plan and for up to 72 hours from the time the hospital implements its disaster response plan. In addition, hospitals may only operate under such a HIPAA waiver during the emergency period beginning on October 23, 2009 through the duration of the HHS Secretary's public health emergency declaration for 2009 H1N1 influenza.</p> <p>When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours has not elapsed since implementation of its disaster protocol. HIPAA waivers are only effective if taken in a manner that does not discriminate among individuals on the basis of their source of payment or their ability to pay.</p> <p>Regardless of the activation of an emergency waiver, 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/katrinanhipaa.pdf</p>
1135B-8	<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. For this event, the emergency area is nationwide and the emergency period begins on October 23, 2009, and will last through duration of the declared Public Health Emergency for 2009 H1N1 influenza. HIPAA waivers are subject to special time limits as discussed above.</p>
1135B-9	<p>Question: What are practical implementation steps States and Individual Healthcare Providers need to consider?</p> <p><u>Determining if Waivers Are Necessary</u></p> <p>In determining whether to invoke an 1135 waiver (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.</p> <p><u>How States or Individual Healthcare Providers Can Ask for Assistance or a Waiver</u></p> <p>Once an 1135 Waiver is authorized, 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. Information on your facility and justification for requesting the waiver will be required.</p> <p><u>Review of 1135 Waiver requests</u></p> <p>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.</p> <p><u>Implementation of 1135 Waiver Authority</u></p> <p>Providers must resume compliance with normal rules and regulations as soon as 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.</p> <p>Federally certified/approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.</p> <p><u>Frequently Asked Questions</u></p> <p>Further information on the 1135 Waiver process can be found at: http://www.cms.hhs.gov/H1N1/</p> <p>Questions regarding 1135 that are not addressed at the above website can be sent to the following mailbox: Pandemic@cms.hhs.gov</p> <p><u>Email Addresses for CMS Regional Offices</u></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>ROPIDSC@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?</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 apply 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: HHS anticipates that a county may apply on behalf of facilities in their county, but they should include the information necessary to allow the CMS regional office to appropriately justify the flexibility 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 will be required.</p>
1135B-14	<p>Question: Can the 72 hour waiver time frame be extended if the disaster plan is still in effect?</p> <p>Answer: These waivers under section 1135 of the Social Security Act typically end no later than the termination of the emergency period. 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>
1135B-15	<p>Question: Are there mechanics for requesting such a waiver proactively?</p> <p>Answer: Health care providers are asked to submit supported and justifiable requests reflecting actual need. Information to support the request should be clear and concise to ensure that the Waiver Validation Team can validate the request quickly.</p>
1135B-16	<p>Question: How will we receive the declaration or expect to receive it from (Federal, State or local)?</p> <p>Answer: HHS will release all declaration information the information on www.flu.gov and additionally at http://www.cms.hhs.gov/H1N1/. Facilities requesting specific waivers of Medicare, Medicaid, CHIP requirements or EMTALA sanctions will receive a written response from CMS, which may be transmitted via e-mail or otherwise.</p>
1135B-17	<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 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>ROPIDSC@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-18	<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: An 1135 waiver may be issued regardless of whether a State or locality has declared its own public health emergency or state of emergency. 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 will be required.</p>
1135B-19	<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 that are not addressed at the http://www.cms.hhs.gov/H1N1/ website can be sent to the following mailbox: Pandemic@cms.hhs.gov. Healthcare providers can also send 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.</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>ROPIDSC@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-20	<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 in which a determination has been made that the waiver or modification is necessary for a provider or group or type of providers.</p>
1135B-21	<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 only to the extent such waivers are necessary the duration of applicability of a waiver 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 providers within the declared area for the duration of the emergency. Exceptions to that practice in the</p>

	<p>future would be addressed in a general or specific 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-22	<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: 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 outside the scope of the § 1135 waiver authority as discussed in other Q&As. Some of these flexibilities may be extended to areas beyond the declared "emergency area."</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 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. CMS is authorized to waive the Stark law sanctions as of the effective date of the Secretary's waiver.</p>
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-17 is also the process to be followed during the H1N1 pandemic emergency to request waiver of sanctions for violations of the Stark law. 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>
1135C-2	<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>An “alternative care site” (ACS) cannot be considered part of the hospital under existing rules; however, 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 non-critical care to eligible Medicare beneficiaries during the emergency period at an ACS that has been determined under the waiver to be part of the hospital, Medicare will pay for reasonable and necessary services as if the ACS was a part of the hospital.</p>
D	General Billing Procedures (Reserved)
E	Physician Services (Reserved)
F	Ambulance Services
1135F-1	<p>Question: In emergency/disaster situations how does CMS define an “approved destination” for ambulance transports and would it include alternate care centers, 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>We do not expect an emergency/disaster to affect the availability of hospital or other facility services; however, should a facility which would normally be the nearest appropriate facility be unavailable during an 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 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 determined to be part 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). If the alternative care site is granted approval by the State Agency to be part of an institutional provider (hospital, CAH or SNF) that is an approved destination under 42 CFR § 410.40 for an ambulance transport, Medicare will pay for the transport on the same basis as it would to any other approved destination in the absence an 1135 waiver. CMS has developed the <i>Hospital Alternate Care Site Fact Sheet</i>, which provides detailed information regarding permitted actions with or without section 1135 waiver authorization. This Fact Sheet can be accessed at: http://www.cms.hhs.gov/H1N1/Downloads/AlternativeCareSiteFactSheet.pdf</p>
G	Laboratory & Other Diagnostic Services (Reserved)

H	Drugs & Vaccines Under Part B (Reserved)
I	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
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>
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>
L	Hospice Services (Reserved)
M	Hospital Services – General
1135M-1	<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 will be required.</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>

	ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.
1135M-2	<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>
N	Hospital Services – Emergency Medical Treatment and Labor Act (EMTALA)
1135N-1	<p>Questions: 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, typically, delegates 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) There has been a determination 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: These waivers under section 1135 of the Social Security Act typically end no later than the termination of the emergency period. 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, the Secretary has the authority not to impose sanctions if the hospital 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 in an emergency area during the emergency period. These waivers shall be 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 expressly delegate to CMS authority to waive these sanctions and then each</p>

	<p>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 only applicable 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, 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 delegated the specifics to the CMS Administrator, and after 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, CMS now requires hospitals in the emergency area (or portion of the emergency area) to notify CMS, through the appropriate State Survey Agency, when they implement a hospital disaster protocol.</p>
O	<p>Hospital Services – Acute Care (Reserved)</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 (back to the beginning of the waiver period, or in the case of this emergency, no earlier than October 23, 2009). The process for submitting a waiver requests is posted at http://www.cms.hhs.gov/H1N1/.</p>
Q	<p>Hospital Services – Inpatient Rehabilitation Facilities (IRFs)</p>
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, CMS will modify enforcement of the requirements specified in 42 CFR § 412.23(b)(2), which is the regulation commonly referred to as the "60 percent rule." If an IRF admits a patient solely to respond to the 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 would use the "CR" (catastrophic/disaster related) modifier to designate any service line item on the claim that is disaster related. If all of the services on the claim are disaster related, the institutional provider should use the "DR" (disaster related) condition code to indicate that the entire claim is disaster related.</p>

	The IRF 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 remains affected by the emergency.
1135Q-2	<p>Question: In addition to suspending the “60 percent rule” during the emergency, 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 the emergency. In these instances, CMS would not apply the IRF-specific criteria (e.g., the 3-hour rule) to any review of claims. IRFs should clearly document in the patient’s medical record that the patient was admitted solely to meet the demands of the emergency 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 remains affected by the emergency.</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, 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: Will skilled nursing facilities (SNFs) in the declared public health emergency area still be requiring residents to have a 3-day hospital stay prior to their admission?</p> <p>Answer: Section 1812(f) of the Social Security Act allows Medicare to pay for SNF services without a 3-day qualifying 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. During the emergency period, CMS will temporarily provide SNF benefits in the absence of the 3-day prior hospital qualifying stay for those SNF residents affected by the declared public health emergency to facilitate a smooth transition for residents that will fit their individual care needs. This policy applies to any Medicare beneficiary who:</p> <ul style="list-style-type: none"> • Was evacuated from a nursing home provider in the emergency area; • Was discharged from a hospital (in the emergency or receiving locations) in order to provide care to more seriously ill patients; or • Needs SNF care as a result of the emergency, regardless of whether that individual was in a hospital or SNF prior to the disaster.
1135T-2	<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 overall 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 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-3	<p>Question: Can CMS temporarily relaxing 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 a §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 waiver remains in effect.</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)