



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-06-ALL

DATE: November 6, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: 2009-H1N1 Influenza Pandemic – Presidential Emergency Declaration and U.S. Department of Health and Human Services Section 1135 Waiver Authorization

Memorandum Summary

- **Situation:** On October 16, 2009, the Centers for Disease Control and Prevention (CDC) reported that 2009-H1N1 influenza cases exist in all 50 States and widespread influenza activities exist in 41 States. Cases of severe respiratory disease, including fatal outcomes, have also been reported.
- **Presidential and Public Health Emergency Declaration:** On October 23, 2009, President Obama signed a declaration pursuant to the National Emergencies Act, as a result of the 2009-H1N1 influenza pandemic. Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services (HHS), had reinstated a nationwide public health emergency, under her authority pursuant to section 319 of the Public Health Service Act, on October 1, 2009.
- **Section 1135 Waiver Authorization:** Secretary Sebelius exercised her waiver authority under section 1135 of the Social Security Act, effective October 23, 2009. The Secretary has delegated to the Centers for Medicare & Medicaid Services (CMS) the determination for a waiver for each case justified by necessity and extent (other than for the Health Insurance Portability and Accountability Act [HIPAA] waivers permitted under section 1135).
- **H1N1 Tracking Tool for State Agency (SA) Staffing:** Attachment 1 contains a tracking tool to assist States in reporting any H1N1 influenza impact to their survey and certification activities.
- **H1N1 Pandemic FAQs:** CMS has developed a Provider Survey & Certification Frequently Asked Question document in response to questions resulting from the 2009-H1N1 influenza pandemic and authorization for 1135 waivers.

2009-H1N1 Pandemic National Emergency Declaration & Section 1135 Waiver

Section 1135 of the Social Security Act [42 USC §1320b–5] permits the Secretary of the U.S. Department of Health and Human Services (HHS) to waive certain statutory and regulatory requirements for healthcare facilities in response to emergencies. However, two conditions must first be met for the Secretary to issue a section 1135 waiver: 1) the President must have declared an emergency or disaster under the Stafford Act or the National Emergencies Act, 2) the HHS Secretary must have declared a Public Health Emergency (PHE) under section 319 of the Public Health Service Act.

On October 23, 2009, President Obama signed a nationwide emergency declaration as a result of the 2009-H1N1 influenza pandemic, pursuant to the National Emergencies Act. 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.

On October 27, 2009, Secretary Sebelius notified Congress of her intention to invoke the 1135 waiver authority effective 5:00 P.M. Eastern Standard Time on October 29, 2009, however, the effect will be retroactive to October 23, 2009. For this event, the “emergency area” is nationwide. The emergency period begins on October 23, 2009, and will last through the duration of the declared public health emergency for the 2009-H1N1 influenza pandemic.

The waiver invokes time-limited statutory authority under section 1135(b) of the Social Security Act (the Act) to permit CMS and its agents to waive or modify certain requirements, or modify certain deadlines and timetables for the performance of required activities. The normal requirements provide important protections for patients during normal day-to-day operations, but they may impede the ability of healthcare facilities to fully implement disaster operations plans that enable appropriate care during emergencies.

The time-limited statutory authority under section 1135(b) of the Act may be tailored to match the specific situational needs during each public health emergency event. This waiver provides flexibility to the extent necessary to ensure that sufficient health care items and services are available to meet the needs of the individuals enrolled in the Medicare, Medicaid, and Children’s Health Insurance Program (CHIP), and to ensure that health care providers furnishing such items and services in good faith, but that are unable to comply with one or more of the usual requirements, may be reimbursed and exempted from sanctions that might otherwise apply, absent any determination of fraud or abuse.

As the 2009-H1N1 influenza emergency declaration is nationwide, the “emergency area” applies to all 50 States and U.S. territories. However, the waivers and modifications apply only to the extent that the provider in question has been affected by the H1N1 influenza (e.g., surge issues, staffing shortages, etc.). The Secretary has delegated to the CMS Administrator the determination in each case of the necessity for a waiver 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 (other than for the Health Insurance Portability and Accountability Act [HIPAA] waivers permitted under section 1135).

CMS is working closely with the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, the Department of Homeland Security (DHS), and the State Survey Agencies (SAs) to track the status of health care providers affected by the H1N1 influenza pandemic. Because of the need to use reasonable waiver discretion only to the extent necessary, the specific answers to provider requests will depend upon each unique circumstance.

1135 Waiver Request Process

Health care providers and suppliers should submit their requests to operate under the section 1135 waiver authority, or for other relief that may be possible, to the CMS Regional Office in their service area by email, and provide a copy of the request to their State Survey Agency (SA). Providers and suppliers will be required to submit justification for the necessity of the waiver. Federally certified/approved providers and suppliers must operate under normal rules and regulations unless they have sought and have been granted modifications under the 1135 waiver authority from specific requirements. The CMS Consortium email addresses are provided on the following page.

CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The cross-regional Waiver Validation Team will review the waiver requests, in consultation with the SAs, to ensure they are justified and supportable. Information to support the request should be clear and concise to ensure the Waiver Validation Team can quickly and efficiently validate the request. The waivers and modifications permitted under the section 1135 authority do not include waivers or modifications that are not actually needed at this time of a provider's request, but rather are anticipated for a later date.

Affected State Survey Agency 2009-H1N1 Influenza Update Report

CMS has also updated the 2009-H1N1 influenza tracking and reporting tool that was issued with S&C Memo 09-36. The purpose of the *Affected State Survey Agency 2009-H1N1 Influenza Update Report* (Attachment I) is to track the operational status of survey and certification activities at both the State and Federal level. SAs should continue to use this tool to track and report on the status of any State survey and certification activities that may be impacted by the 2009-H1N1 influenza pandemic. The SA should submit their completed reports to their CMS Regional Office.

S&C Memo 09-36 also included the *Affected Provider 2009-H1N1 Status Update Report*, which was developed to help SAs track and report on the status of providers. As this report was intended to help determine the need for an 1135 waiver, SAs no longer need to track or submit the report to their CMS Regional Office. SAs may continue on a voluntary basis to use the *Affected Provider 2009-H1N1 Status Update Report* for their own purposes, to assist in tracking the status of providers affected by the H1N1 virus. Providers should continue to stay in touch with the State Survey Agency to be sure any necessary State license waivers are requested.

CMS Consortium Email Addresses

ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas

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

ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska

ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories.

2009-H1N1 Survey and Certification Frequently Asked Questions

CMS has developed a *Provider Survey & Certification Frequently Asked Question* document in response to questions resulting from the 2009-H1N1 influenza pandemic and authorization for 1135 waivers. As the H1N1 influenza is a rapidly evolving situation, this document will be reviewed regularly and updated as new policies and procedures are developed. The FAQ document will be posted on the CMS H1N1 Web site at: <http://www.cms.hhs.gov/H1N1/#TopOfPage>.

CMS has also established the CMS Pandemic mailbox to receive inquiries regarding the 1135 waivers, which can be accessed at: Pandemic@cms.hhs.gov. Questions submitted there will be answered directly and may be compiled into future editions of the FAQs.

2009-H1N1 Influenza Web Sites

Please see the following Web sites for more information on the 2009-H1N1 influenza pandemic:

- CMS Emergency Website, Pandemic Flu: <http://www.cms.hhs.gov/H1N1/>
- Pandemic Flu Website: <http://www.pandemicflu.gov/>
- CDC's 2009 H1N1 Flu (Swine Flu): <http://www.cdc.gov/h1n1flu/>
- U.S. Department of Labor, Occupational Safety & Health Administration (OSHA): Pandemic Flu Respiratory Protection for health care workers:
<http://www.osha.gov/dsg/topics/pandemicflu/index.html>

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments

Affected State Survey Agency 2009-H1N1 Influenza Pandemic Update Report

State:
 Region:
 Date:

City/County where Survey Activities Impacted	Number of Survey Staff Absentees due to H1N1 flu ¹ (self or family member).	Any other Survey Agency Issues/Concerns
	#	

¹ Absentee Survey staff numbers may be based on either possible or confirmed cases of 2009-H1N1 influenza or influenza-like illness (ILI).

Updated November 5, 2009

**CMS Response to the 2009-H1N1 Influenza Pandemic
Public Health Emergency Declaration
With Section 1135 Waiver Authorization**

**Provider Survey and Certification
Frequently Asked Questions (FAQs)**

Introduction

Section 1135 of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (HHS) to waive or modify certain Medicare, Medicaid, Children Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements. The waivers are permitted 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.

However, two prerequisites must be met before the Secretary may invoke her section 1135 waiver authority. First, the President must have declared an emergency or disaster under either the Robert T. 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).

These pre-conditions have been met with respect to the 2009-H1N1 influenza pandemic. On October 23, 2009, President Obama declared a national emergency as a result of 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. On October 27, 2009, Secretary Sebelius notified Congress of her intention to invoke the 1135 waiver authority effective 5:00 P.M Eastern Standard Time on October 29, 2009, with a retroactive effect to October 23, 2009. For this event, the "emergency area" is nationwide.

Other than waivers for the Health Insurance Portability and Availability Act (HIPAA) permitted under section 1135, the Secretary has delegated to the CMS Administrator the determination of the necessity for a waiver in each case 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.

CMS is working closely with the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Department of Homeland Security (DHS) and the State Survey Agencies to track and monitor the impact of the 2009-H1N1 influenza on health care facilities.

The following Q&As describe modifications to survey and certification (S&C) policies and procedures that may be available to health care providers during the current 2009-H1N1 influenza pandemic under the section 1135 waiver authorization (or modifications available under other authorities). CMS will review providers' waiver requests, in consultation with the State Survey Agency, and make case-by-case decisions (with the exception of HIPAA waivers) to ensure that sufficient grounds exist for waiving requirements in a particular circumstance.

The 2009-H1N1 influenza is a rapidly evolving situation and the declared nationwide emergency area presents several new challenges. These *2009-H1N1 Pandemic Provider Survey and Certification FAQs* will be regularly reviewed and updated to reflect any new policy or program information. In addition, the 1135 waiver S&C policies and procedures frequently overlap with the Medicare Fee-for-Service 1135 waiver policies and procedures. To access more information regarding Medicare Fee-for-Service emergency and disaster-related policies and procedures that may be implemented during with a section 1135 waiver authorization, please see the following Q&A document posted on the CMS H1N1 Web site:

http://www.cms.hhs.gov/H1N1/Downloads/H1N1-Medicare_FFS-Emergency_QsAs_IF_1135_WAIVER.pdf

#	Question and Answer
	<p style="text-align: center;">TOPICS</p> <p>A. Section 1135 Waiver Authority</p> <p>B. All Providers & Suppliers</p> <p>C. Clinical Labs</p> <p>D. End Stage Renal Disease Facilities</p> <p>E. Home Health Agencies</p> <p>F. Hospice Services</p> <p>G. Hospital – Emergency Medical Treatment and Labor Act (EMTALA)</p> <p>H. Hospital - Critical Access Hospital (CAH)</p> <p>I. Hospitals – Acute Care Services</p> <p>J. Hospital Services – Long-Term Care Hospitals (LTCHs)</p> <p>K. Hospitals - Inpatient Rehabilitation Facilities (IRFs)</p> <p>L. Skilled Nursing Facilities/Nursing Facilities</p> <p>M. State Survey Agencies</p> <p>N. H1N1 Virus Web Sites and Resources</p>
A	Public Health Emergency Declaration, Section 1135 Waiver Authority
A-1	<p><i>Question: What requirements are covered under the section 1135 waivers?</i></p> <p>Answer: The section 1135 waivers authorized by the statute apply to Medicare, Medicaid and CHIP in the context of the following requirements:</p> <ul style="list-style-type: none"> • Conditions of participation or other certification requirements applicable to providers and suppliers; • Program participation and similar requirements • Preapproval requirements • Physicians and other health care professional requirements to be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure) • Sanctions for violations of certain emergency medical standards under the Emergency Medical Treatment and Labor Act (EMTALA) (Note: See # G-1 of this document for additional prerequisites that are necessary to grant an EMTALA waiver) • Sanctions relating to physician self-referral limitations (Stark) • Performance deadlines and timetables (modified only; not waived) • Certain payment limitations under the Medicare Advantage program
A-2	<p><i>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?</i></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>

#	Question and Answer
	<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 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>
<p>A-3</p>	<p><i>Question: How does a health care provider affected by the H1N1 emergency request and receive approval for an 1135 waiver?</i></p> <p>Answer: Health care providers and suppliers can submit their requests to operate under the section 1135 waiver authority, or for other relief, to the CMS Regional Office in their service area by email, with a copy of the request to their State Survey Agency. Providers and suppliers will be required to submit justification to support their request for granting the waiver.</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 all waiver requests (other than a HIPPA waiver, as noted previously) to ensure they are justified and supportable.</p> <p>Federally-certified/approved providers and suppliers must operate under normal rules and regulations unless they have sought and have been granted modifications under the 1135 waiver authority from specific requirements.</p>

#	Question and Answer
A-4	<p><i>Question: What is the difference between a “flexibility” and a “waiver?”</i></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>
A-5	<p><i>Question: What regulatory requirements can be waived under the 1135 waiver authority?</i></p> <p>Answer: CMS takes steps during each declared public health emergency to identify the specific requirements that will be waived or modified under the section 1135 authority and to whom and under what circumstances such waivers or modifications will apply.</p> <p>During some public health emergencies, waivers may be granted on a categorical basis and may apply to all providers and suppliers in the emergency area during the emergency period that would otherwise be required to comply with the particular cited requirement. For example, to facilitate a smooth transition, CMS may determine that time-limited waivers under the § 1135 authority are necessary to allow critical access hospitals to exceed the 25-bed limits in order to accept evacuees. CMS may determine certain waivers under the § 1135 authority apply only to particular provider(s), requirements, or conditions of participation specified by CMS, and may apply only for a specified period of time -- that is, not for the full emergency period. Examples include: temporary suspension of a pending termination action or denial of payment sanction so as to enable a nursing home to accept evacuees.</p> <p>For this 2009-H1N1 nationwide pandemic, CMS has implemented a cross-regional Waiver Validation Team that will review the waiver requests (other than HIPAA waiver requests) and make case-by-case decisions to ensure they are justified and supportable.</p> <p>Updated information regarding the 1135 waivers authorizations due to the 2009-H1N1 influenza pandemic and other announcements will be communicated on the CMS Emergency Website, which can be accessed at: http://www.cms.hhs.gov/H1N1/#TopOfPage</p>
A-6	<p><i>Question: What is the duration of the section 1135 waivers/modifications granted by the HHS Secretary?</i></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). 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 specific hospital. In general, however, recent practice has been that waivers, when granted, apply to all similarly situated providers and suppliers within the declared area for the duration of the emergency.</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.</p>
A-7	<p><i>Question: Approximately how long will the process take for approving/denying a waiver?</i></p> <p>Answer: CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The Waiver Validation Team will review the waiver requests, in consultation with the State Survey Agency, to ensure they are justified and supportable. The Waiver Validation Team anticipates that requests to operate under 1135 waiver flexibilities should be responded to within three business days of receipt.</p>

#	Question and Answer
A-8	<p><i>Question: Can a healthcare system apply for a waiver or modification of waivable requirements for all or some of its facilities, or can only a facility apply?</i></p> <p>Answer: Healthcare systems or corporations may apply on behalf of their facilities; on an individual basis or for all facilities within the system; however, they should include all the information necessary to allow the Waiver Validation Team, in consultation with the State Survey Agency, to appropriately justify the flexibility requested for each facility.</p>
A-9	<p><i>Question: Are there mechanics for requesting such a waiver proactively?</i></p> <p>Answer: Health care providers and suppliers are asked to submit supported and justifiable requests reflecting actual need (as opposed to an anticipated need). Information to support the request should be clear and concise to ensure that the Waiver Validation Team can quickly validate the request. Further waivers and modifications under the 1135 authority may be granted retroactively to the date the actual need arose up to the beginning of the waiver period, or in the case of this emergency, back to as early as October 23, 2009, if need be.</p>
A-10	<p><i>Question: How will we receive the declaration information and from whom will we receive it (Federal, State or local agency)?</i></p> <p>Answer: HHS will release all declaration information on the following website: www.flu.gov and additionally at the CMS H1N1 Web site at: http://www.cms.hhs.gov/H1N1/.</p> <p>Facilities requesting specific waivers of Medicare, Medicaid, CHIP requirements or EMTALA sanctions will receive a written response from CMS, which may be transmitted via email or otherwise.</p>
A-11	<p><i>Question: To whom and in what form should a facility request an 1135 waiver?</i></p> <p>Answer: Health care providers and suppliers should submit their requests via email to operate under the 1135 waiver authority (or for other relief that may be possible under other authority) to the CMS Regional Office in their service area, with a copy to the State Survey Agency. Your facility information and a justification for requesting the waiver will be required. The CMS Consortium email addresses are listed below:</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>
A-12	<p><i>Question: Must a State or locality declare its own public health emergency (PHE) before it may request that an 1135 waiver be put into place for one or more of its healthcare facilities? If so, is it possible for a</i></p>

#	Question and Answer
	<p><i>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?</i></p> <p>Answer: If a hospital or critical access hospital (CAH) is requesting a waiver from EMTALA requirements, the statutory language governing EMTALA waivers at section 1135(b)(3)(B) of the Social Security Act specifies that the State must have activated an emergency preparedness plan or pandemic preparedness plan in the emergency area and any redirection of individuals for a medical screening examination must be consistent with such a plan. It is not necessary for the State to activate its plan statewide, so long as it is activated in the area where the hospital is located. (See section G of this document for more details on EMTALA waivers, or S&C Memo 10-05: <i>Emergency Medical Treatment and Labor Act (EMTALA) Regulation Changes and H1N1Pandemic Flu and EMTALA Waivers</i>.)</p> <p>For all other 1135 waiver requests, the provider's request may be granted regardless of whether a State or locality has declared its own public health emergency or state of emergency. Health care providers and suppliers can submit requests to operate under the 1135 waiver authority (or for other relief that may be possible under other authority) to the CMS Regional Office in their service area via email and provide a copy to their State Survey Agency. Information on the facility and justification for requesting the waiver will be required.</p>
A-13	<p><i>Question: Is there a mechanism for submitting 1135 waiver questions that have not been addressed on the CMS Emergency Web site?</i></p> <p>Answer: Additional questions regarding section 1135 waivers that are not addressed at the CMS Emergency Web site, Pandemic Flu page at: http://www.cms.hhs.gov/H1N1/ can be sent to the following CMS mailbox: Pandemic@cms.hhs.gov.</p> <p>Healthcare providers and suppliers can also email the CMS Regional Office in their service area. See Q&A A-10 for a list of CMS Consortium email addresses.</p>
A-14	<p><i>Question: Do 1135 waivers affect State laws or regulations?</i></p> <p>Answer: Only certain Federal requirements relating to Medicare, Medicaid, CHIP and HIPAA may be waived or modified as detailed under section 1135. An 1135 waiver does not affect State laws or regulations.</p>
A-15	<p><i>Question: Is the HIPAA Privacy Rule suspended during a national or public health emergency?</i></p> <p>Answer: No. The Health Insurance Portability and Accountability Act (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:</p> <ol style="list-style-type: none"> 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)).

#	Question and Answer
A-16	<p><i>Question: When and to what entities does the HIPAA 1135 waiver granted in response to the 2009-H1N1 influenza pandemic apply?</i></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. Unlike the other types of 1135 waiver requests, hospitals do not need to submit a request for the HIPAA 1135 waiver. 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 the 2009-H1N1 influenza pandemic.</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>
B	All Providers & Suppliers
B-1	<p><i>Question: We are being inundated with information on H1N1. As a small rural health facility, our resources are limited and many leadership staff already have multiple areas of responsibility. Is there a streamlined, short document of the planning activities that are recommended and how to accomplish this within our constraints?</i></p> <p>Answer: The Centers for Disease Control and Prevention's (CDC) has issued a 1-page web page, entitled, <i>10 Steps You Can Take: Actions for Novel H1N1 Influenza Planning and Response for Medical Offices and Outpatient Facilities</i>, which can be accessed at: http://www.cdc.gov/h1n1flu/10steps.htm</p> <p>In addition, CMS has issued several Fact Sheets, including:</p> <ul style="list-style-type: none"> • <i>Emergency Medical Treatment and Labor Act (EMTALA) & Surges in Demand for Emergency Department (ED) Services During a Pandemic</i> • <i>Hospital Alternate Care Site Fact Sheet</i> • <i>H1N1 Fact Sheet - Requesting an 1135 Waiver</i> • <i>Fact Sheet for Medicare Fee-For-Service Providers, Suppliers and Practitioners Billing for H1N1 Flu Vaccine and Administration</i> • <i>Medicare's Coverage of the H1N1 Flu Vaccine</i> • <i>Medicaid and the Children's Health Insurance Program (CHIP) Coverage of the 2009 H1N1 Flu Vaccine and Treatment</i> <p>You can access these Fact Sheets at the CMS H1N1 web Site at: http://www.cms.hhs.gov/H1N1/#TopOfPage</p>
B-2	<p><i>Question: S&C Memo 09-36 indicates that communication regarding H1N1 cases should be reported to their State Survey Agency. Should H1N1 cases also be reported to the local health department for dissemination from an official agency?</i></p> <p>Answer: Health care providers and suppliers were instructed to contact their State Survey Agency (SA) to report when they are having difficulty providing services due to H1N1 virus issues (surge, staffing shortages, etc.). The purpose behind the H1N1 reporting guidance detailed in this memo was to gather information to help make survey and certification operational decisions at both the State and Federal level.</p>

#	Question and Answer
	<p>The reporting instructions are not meant to substitute or supplant any H1N1 flu virus reporting requirements for facilities to their local, State or Federal public health authorities.</p>
B-3	<p><i>Question: Is the communication of information referenced in the guidance to surveyors relating only to when residents are transported between facilities, such as a hospital, another nursing home, etc.?</i></p> <p>Answer: CDC issued updated interim guidance on infection control measures for 2009 H1N1 influenza in healthcare settings on October 14, 2009. The <i>Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel</i> clarifies that health care providers should establish policies and procedures for patient placement and transport, and communicate information about patients with suspected, probable or confirmed influenza to appropriate personnel before transferring them to other departments in the facility (e.g., radiology, laboratory) and to other facilities.</p>
B-4	<p><i>Question: Should providers supply special respiratory protection equipment to healthcare personnel who are exposed to patients with H1N1 influenza?</i></p> <p>Answer: CMS supports CDC's recommendations included in their <i>Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel, including:</i></p> <p><u>Respiratory Protection Recommendations:</u> CDC continues to recommend the use of respiratory protection that is at least as protective as a fit-tested disposable N95 respirator for healthcare personnel who are in close contact with patients with suspected or confirmed 2009 H1N1 influenza. This recommendation applies uniquely to the special circumstances of the current 2009 H1N1 pandemic during the fall and winter of 2009-2010, and CDC will continue to revisit its guidance as new information becomes available.</p> <p><u>Supply considerations:</u> CDC recognizes that some facilities are currently experiencing shortages of respiratory protection equipment and that further shortages are anticipated. Although the exact total supply in the public and private sectors is not known, a large gap between supply and demand is predicted. In the face of shortages, appropriate selection and use of respiratory protection is critical. A key strategy is to use source control, engineering, and administrative measures to reduce the numbers of workers who come in contact with patients who have influenza-like illness in order to reduce the consumption of respiratory protection equipment. Special care should be taken to ensure that respirators are available for situations where respiratory protection is most important, such as performance of aerosol-generating procedures on patients with suspected or confirmed 2009 H1N1 influenza or provision of care to patients with other infections for which respiratory protection is strongly indicated (e.g., tuberculosis). See CDC's Web site for additional information on recommended strategies for reducing exposures and extending the existing supply of respirators through re-use or extended use in the fact of potential shortages, including frequently asked questions at: http://www.cdc.gov/h1n1flu</p> <p><u>Facemasks for healthcare personnel who are not provided a respirator due to the implementation of prioritized respirator use:</u> If a facility is in prioritized respirator use mode and unable to provide respirators to healthcare personnel who provide care to suspected and confirmed 2009 H1N1 influenza cases, the facility should provide those personnel with facemasks. Facemasks that have been cleared for marketing by the U.S. Food and Drug Administration have been tested for their ability to resist blood and body fluids, and generally provide a physical barrier to droplets that are expelled directly at the user. Although they do not filter small particles from the air and they allow leakage around the mask, they are a barrier to splashes, droplet sprays, and autoinoculation of influenza virus from the hands to the nose and mouth. Thus, they should be chosen over no protection. Routine chemoprophylaxis is not recommended for personnel wearing facemasks during the care of patients with suspected or confirmed</p>

#	Question and Answer
	<p>2009 H1N1 influenza.</p> <p>For more information on CDC's interim guidance on infection control measures in health care settings for the 2009-H1N1 influenza, access the following web site: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm</p>
C	Clinical Labs
C-1	<p><i>Question: Will clinical labs be permitted to be suspended during the H1N1 virus infection outbreak?</i></p> <p>Answer: CMS allowed certain Clinical Laboratory Improvement Amendments (CLIA) regulatory activities to be suspended in early May 2009 due to the H1N1 virus outbreak. These suspensions applied to PT testing for viral antigen modules that was conducted through May 15, 2009, and required use of influenza A test kits unless there is immediate jeopardy to patient and health safety. The CLIA program's enforcement plans regarding proficiency testing requirements for modules that were scheduled to ship after May 15, 2009 were addressed through subsequent communications.</p> <p>When notifying your participants, please advise them to continually visit the Centers for Disease Control and Prevention's (CDC) Web site: http://www.CDC.gov/swineflu/specimencollection</p> <p>This site provides access to CDC's <i>Interim Guidance on Specimen Collection, Processing, and Testing for Patients with Suspected Swine-origin Influenza A (H1N1) Virus Infection</i>. Laboratories and clinicians should monitor this site for CDC's updates and any additional guidance.</p> <p>Proficiency testing participants may be notified by whatever means you deem most appropriate. Such means might include fax, U.S. Postal Service, express carrier, etc. Regardless of the method used, we would request that you also post this information on your Web site.</p> <p>If a participant decides to not test a PT sample in accordance with this communication (and in so doing leaves the results for that portion of the PT testing results blank, please use reason code #8, "Excused Participation" and assign a score of 100% when submitting PT test result data to the CMS PT monitoring system.</p>
C-2	<p><i>Question: Will clinical laboratory survey activities be allowed to be suspended due to severe flu-related personnel shortages?</i></p> <p>Answer: CMS did allow such postponements during the May 2009 H1N1 outbreak and will monitor situations during the fall and winter influenza season. If conditions warrant, similar actions may be allowed again. Laboratories should check with either their State Survey Agencies (SAs) or Accrediting Organizations (AOs) as applicable. SAs and AOs should contact the CMS Central Office for guidance.</p>
D	End Stage Renal Disease (ESRD) Facilities
D-1	<p><i>Question: Are ESRD patients on dialysis considered to be "high risk?"</i></p> <p>Answer: The Centers for Disease Control and Prevention (CDC) provided updated guidance specific to end stage renal disease (ESRD) patients on May 8, 2009. These recommendations supplement CDC's Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting, and is provided to clarify novel H1N1 virus infection control recommendations that are specific to outpatient hemodialysis centers. This information complements, but does not replace the general infection control recommendations for novel influenza A (H1N1). CDC's guidance can be found at the following link: http://www.cdc.gov/h1n1flu/guidance/hemodialysis_centers.htm</p>

#	Question and Answer
E	Home Health Services
E-1	<p><i>Question: The Admission criterion and documentation requirements for home care are extensive. Can these requirements be interpreted broadly to accommodate a surge of patients?</i></p> <p>Answer. Medicare requires that beneficiaries be confined to the home in order to be eligible to receive home health services. A beneficiary's home is any place in which a beneficiary resides that is not a hospital, skilled nursing facility (SNF), or nursing facility as defined in §1861(e)(1), §1819(a)(1), or §1919(a)(1) of the Social Security Act, respectively. In an extraordinary circumstance of a declared emergency or disaster, place of residence can include services provided at temporary locations like a family member's home, a shelter, a community facility, a church, or a hotel. However, a hospital, SNF, or nursing facility, as defined in the above-cited references, cannot be considered a temporary residence.</p> <p>Modifications for the timeframe and completion requirements for the Outcome and Assessment Information Set (OASIS) are set in statute, and may be permitted during the 2009- H1N1 section 1135 waiver emergency period, to the extent that it is necessary.</p> <p>Home health agencies should submit their requests for a waiver under the section 1135 waiver authority to the CMS Regional Office in their service area, with a copy to their State Survey Agency. A justification for granting the waiver will be necessary.</p>
E-2	<p><i>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?</i></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 Outcome and Assessment Information Set (OASIS). During this 2009-H1N1 pandemic emergency, an abbreviated assessment may be completed to assure the patient is receiving proper treatment and to facilitate appropriate payment. For those Medicare approved HHAs serving qualified home health patients that have been granted a waiver under section 1135, 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 submit their request to operate under the section 1135 waiver authority to the CMS Regional Office in their area via email, with a copy to their State Survey Agency. Justification will need to be provided for the necessity of the waiver. HHS should continue to maintain adequate documentation to support provision of care and payment.</p>
E-3	<p><i>Question: Does CMS have written guidelines for home health and hospice providers on the minimum documentation requirements related to OASIS and certification requirements in the event of activation of an emergency plan in a geographic area, either from H1N1 or other unforeseen disaster?</i></p> <p>Answer: Certification requirements for hospices are already fairly flexible. If written certification isn't obtained within 2 calendar days, the hospice can get oral certification, and get the written certification</p>

#	Question and Answer
	<p>prior to filing the claim. The oral certification, if needed, must be obtained within 2 calendar days.</p> <p>In addition, please check out the resources posted on the CMS Survey & Certification Emergency Preparedness Website, which can be accessed at: http://www.cms.hhs.gov/SurveyCertEmergPrep/01_Overview.asp#TopOfPage</p> <p>CMS has posted written guidance on the requirements for home health agencies, including OASIS data entry flexibilities that may be permitted during a public health emergency and section 1135 waiver authorization. This guidance is included in the <i>Provider Survey & Certification All-Hazards Public Health Emergency FAQs</i>, which can be accessed at: http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf</p>
E-4	<p><i>Question: How are other home health agencies preparing for the H1N1 flu pandemic?</i></p> <p>Answer: Several emergency preparedness resources for home health agencies can be found on the Health Care Provider web page of the Survey & Certification Emergency Preparedness Web site, including:</p> <ul style="list-style-type: none"> • National Association for Home Care & Hospice's Emergency Preparedness Packet, which can be accessed at: http://www.nahc.org/regulatory/EP_Binder.pdf • HHS Agency for Healthcare Research and Quality's (AHRQ) <i>Home Health During an Influenza Pandemic: Issues and Resources</i>, which can be accessed at: http://www.pandemicflu.gov/plan/healthcare/homehealth.html
F	Hospice Services
F-1	<p><i>Question: What is a hospice agency's responsibility in the event of a disaster?</i></p> <p>Answer: A hospice agency, as indicated in 42 CFR § 418.110(c)(1), "Safety Management," must have an acceptable written plan to be followed in the event of an internal or external disaster, including care of casualties arising from such a disaster.</p>
F-2	<p><i>Question: If a hospice provider cannot provide care for its patients, can these patients transfer to another hospice provider?</i></p> <p>Answer: Under the Social Security Act at § 1812(d)(2)(C) and CMS regulations at 42 CFR § 418.30(a), a Medicare beneficiary may transfer from one hospice agency to another hospice for any reason once per election period. If a Medicare beneficiary has already utilized this one-time right to transfer but needs to move again because of a public health emergency, § 1861(dd)(5)(D) of the Act provides for a hospice agency to arrange with another hospice for the delivery of services in extraordinary circumstances. We would not deem a change in hospice under these circumstances to be a voluntary transfer under 42 CFR § 418.30 (i.e., the beneficiary would still be entitled to a voluntary transfer after a transfer for "extraordinary circumstances"). In order to ensure the continuity of care from one hospice to another, the operating hospice is expected to comply with the clinical record transfer of care requirements at 42 CFR § 410.104(e).</p>
F-3	<p><i>Question: In the event that the originating hospice is able to resume provision of services to their patients, should patients be transferred back to the originating hospice?</i></p> <p>Answer: CMS believes that patients should be provided with the choice of resuming care from the originating hospice or continuing with the existing hospice provider. If the beneficiary remains with the "host"/replacement hospice at the end of the emergency period, we would consider this a transfer under our regulations at 42 CFR § 418.30. If a beneficiary uses the services of an alternate hospice agency</p>

#	Question and Answer
	for a short period of time under arrangement with the patient's "home" hospice due to extraordinary circumstances, neither the departure from nor return to the original hospice agency would be considered a "transfer" within the meaning of 42 CFR § 418.30.
F-4	<p><i>Question: How should a hospice that temporarily receives a patient from another hospice handle administration of that patient's care plan if the patient arrives with no alternate caregiver information, and/or the admissions officer believes that the patient may be legally incompetent to make health care decisions for him/herself?</i></p> <p>Answer: Under CMS rules, the health and safety of the patient always comes first. The receiving hospice should complete an assessment of the patient to identify immediate needs and establish a plan of care with the interdisciplinary group (IDG). The receiving hospice should make every effort to contact the original hospice and/or attending physician to discuss the previously implemented plan of care and, if necessary, to determine if the patient is legally competent. If the receiving hospice has access to the plan of care established by the original hospice every attempt should be made to follow the plan if the needs of the patient are such that the original plan will provide the appropriate interventions.</p>
F-5	<p><i>Question: Who can speak/sign paperwork on behalf of the hospice patient (including discharge and transfer decisions)?</i></p> <p>Answer: A person's legal authority to make healthcare decisions on behalf of another is a matter of State law. Hospices should confer with their counsel to determine whether their State law has provisions which address health care decision-making in emergency/extraordinary circumstances. If the hospice patient cannot speak or sign paperwork, the receiving hospice should make arrangements to get permission for treatment and care pursuant to state requirements.</p>
G	Hospital Services – Emergency Medical Treatment and Labor Act (EMTALA)
G-1	<p><i>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 the prerequisites of the President declaring a national disaster and the HHS Secretary declaring a public health emergency)?</i></p> <p>Answer: The prerequisites to a waiver of EMTALA sanctions under § 1135 of the Social Security Act include the following:</p> <ul style="list-style-type: none"> • The President declares an emergency or disaster under the Stafford Act or the National Emergencies Act, • The Secretary of HHS declares a Public Health Emergency (PHE) under § 319 of the Public Health Service Act, • The Secretary of HHS has exercised her authority pursuant to § 1135 of the Social Security Act and notified Congress at least 48 hours in advance of exercising her authority. Typically the Secretary delegates to CMS the decision as to which requirements will be waived, including the specific authority to waive sanctions for certain EMTALA violations that arise as a result of the circumstances of the emergency, • The hospital or critical access hospital (CAH) in the affected area has activated its disaster protocol, • The State must have activated an emergency preparedness plan or pandemic preparedness plan in the emergency area, and any redirection of individuals for a medical screening examination (MSE) must be consistent with such plan. It is not necessary for the State to activate its plan statewide, so long as it is activated in the area where the hospital is located. • There has been a determination that sufficient grounds exist for waiving EMTALA sanctions with respect to a particular hospital or geographic area. <p>The CMS Waiver Validation Team will review the EMTALA waiver requests, in consultation with the State Survey Agency, and make case-by-case determinations. For more information on EMTALA</p>

#	Question and Answer
	waivers, see S&C memo 10-05: <i>Emergency Medical Treatment and Labor Act (EMTALA) Regulation Changes and H1N1 Pandemic Flu and EMTALA Waivers.</i>
G-2	<p><i>Question: What is CMS's procedure for addressing requests to waive EMTALA?</i></p> <p>Answer: Because each emergency or disaster presents a unique set of circumstances, especially as they relate to the demand for emergency treatment, CMS calibrates its response to EMTALA-related issues to coincide with the nature of each emergency. In the case of localized disasters, such as those related to floods or hurricanes, CMS may exercise its discretion to advise hospitals in the affected areas that they are covered by the EMTALA waiver, without requiring individual requests for waivers. In the case of the 2009-H1N1 influenza pandemic, which includes a nationwide emergency area, a hospital-by-hospital approach is required.</p> <p>Hospitals should submit their EMTALA waiver requests via email to the CMS Regional Office in their service area, and provide a copy to their State Survey Agency. The hospital should provide justification of their need for a waiver, the activation of the State's emergency preparedness or pandemic plan covering the hospital's location, and the time/date that the hospital activated its disaster plan. CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team, in consultation with the State Survey Agency. The cross-regional Waiver Validation Team will review waiver requests to ensure they are justified and supportable.</p>
G-3	<p><i>Question: What is the time frame for the EMTALA waiver of sanctions?</i></p> <p>Answer: The time frame for waivers of sanctions under the Emergency Medical Treatment and Labor Act (EMTALA) during a public health emergency that involves pandemic infectious disease, such as the 2009-H1N1 pandemic, may be extended until the termination of the declaration of a public health emergency. However, application of this general authority to specific hospital/CAH or groups of hospitals and CAHS may limit the waiver's application to a date prior to the termination of the public health emergency declaration, since case-specific applications of waiver authority are issued only to the extent they are necessary, as determined by CMS.</p> <p>For more information on EMTALA waivers, see S&C memo 10-05: <i>Emergency Medical Treatment and Labor Act (EMTALA) Regulation Changes and H1N1 Pandemic Flu and EMTALA Waivers.</i></p>
G-4	<p><i>Question: Has HHS issued any § 1135 waivers in the past that specifically address EMTALA?</i></p> <p>Answer: Since § 143 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 amended § 1135 of the Social Security Act to add the waiver authority, § 1135 waivers have been issued for Hurricanes Katrina, Rita, Gustav and Ike, for the flooding in Iowa and Indiana during CY 2008, the flooding in North Dakota and Minnesota in CY 2009, and this 2009-H1N1 influenza pandemic. In each emergency event, sanctions for certain types of EMTALA violations were waived for 72 hours after implementation of an affected hospital's disaster protocol. However, if a public health emergency involves a pandemic infectious disease, such as the current 2009-H1N1 influenza pandemic, the Secretary could invoke her waiver authority under § 1135 to waive certain EMTALA sanctions and such an EMTALA waiver may continue in effect until the termination of the applicable public health emergency declaration (in accordance with § 1135(e)(1)(B) of the Act), to the extent they are necessary as determined by CMS.</p>
G-5	<p><i>Question: Would it be possible for the HHS Secretary to waive all of EMTALA's provisions, or only some of them?</i></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> <p>(1) For an inappropriate transfer (if the transfer is necessitated by the circumstances of the declared</p>

#	Question and Answer
	<p>emergency in the emergency area during the emergency period), and (2) medical screening for the relocation or direction of an individual to receive m in an alternate location pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan.</p> <p>However, the Secretary must first expressly delegate to CMS authority to waive 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 only applicable if the hospital's actions do not discriminate among individuals based on their source of payment or ability to pay.</p>
G-6	<p><i>Question: Is it permissible for a hospital to triage individuals with suspected cases of an infectious disease (including particularly an H1N1 flu virus infection) to an alternate site for evaluation under the EMTALA regulations?</i></p> <p>Answer: Under current EMTALA law and regulations, hospitals are permitted to move individuals out of their dedicated emergency departments to another part of the hospital (on the hospital's same campus) in order to provide the required medical screening examination (MSE) and then, if an emergency medical condition is found to exist, to provide stabilizing treatment or arrange for an appropriate transfer. Sometimes hospitals refer to these as "fast-track clinics" and use them either all year round or during surge in demand for emergency department services during the seasonal cold and flu season. The medical screening examination provided in the "clinic" must be performed, consistent with the requirements of the EMTALA provision, by qualified medical personnel who can perform an MSE that is appropriate to the individual's presenting signs and symptoms.</p> <p>If, prior to directing the individual elsewhere in the hospital, qualified medical personnel in the emergency department completed an appropriate MSE and determined that the individual does not have an emergency medical condition, then the hospital has no further EMTALA obligation to that individual and the issue of moving the individual to an alternate site, either on or off the hospital's campus, would be moot from an EMTALA perspective.</p>
G-7	<p><i>Question: How limited is the definition of 'care' to meet EMTALA guidelines allowing patients to be moved to other sites less crowded or to limit flu exposure? Can rapid assessment and referral meet this requirement?</i></p> <p>Answer: We do not understand what the requestor means by the term "rapid assessment and referral" and therefore cannot address whether rapid assessment and referral" would be sufficient for any purpose. However, to assist providers, CMS has prepared a Fact Sheet that explains what hospitals can do while continuing to comply with EMTALA requirements. The Fact Sheet can be found at: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf</p> <p>The issue of whether a medical screening examination (MSE) is appropriate is always case-specific. If an individual is protected under EMTALA, absent an applicable 1135 waiver, the hospital must provide an appropriate MSE to determine whether the individual has an emergency medical condition (EMC). Clinical judgment of qualified practitioners is required to determine how extensive the MSE must be, based on the individual's presenting signs and symptoms, in order to reach a determination as to whether there is an EMC.</p> <p>If there is no EMC, then there is no further EMTALA obligation. If there is an EMC, then the hospital must stabilize the EMC itself or arrange an appropriate transfer.</p>
G-8	<p><i>Question: Can the section 1135 waiver authority be revised regarding the timeframes that are permitted for the HIPAA and EMTALA waivers to reflect the Joint Commission time frames? The Joint Commission requires hospitals plan to be self-sufficient for 96 hours after a disaster, but currently EMTALA and HIPAA regulation enforcement can only be waived for 72 hours.</i></p> <p>Answer: The special limits on the duration of EMTALA and Health Insurance Portability and</p>

#	Question and Answer
	<p>Accountability Act (HIPAA) waivers under § 1135 of the Social Security Act are expressly included in the statute; therefore, neither CMS nor the Department of Health and Human Services has the authority to change them. Congressional action would be required to address this concern.</p>
G-9	<p><i>Question: Individuals from other States affected by an emergency may arrive at hospital emergency departments merely to obtain refills of prescriptions due to the public health emergency. Must these individuals be given an EMTALA medical screening examination when they come to the emergency department?</i></p> <p>Answer: Even under non-emergency circumstances, the Emergency Medical Treatment and Labor Act (EMTALA) regulations and CMS' interpretive guidelines make it clear that medical screening examination provided to individuals who come to the emergency department seeking examination or treatment for a medical condition (e.g. prescription refills) must be appropriate, i.e., sufficient, based on the individual's presenting signs and symptoms, to determine whether or not an emergency medical condition (EMC) exists. An appropriate MSE can be very brief and simple, or long and complex, depending on the individual's presentation.</p>
G-10	<p><i>Question: What are the definitions of emergency department to meet the threshold for payment and how broadly is it interpreted to accommodate alternate settings (primary care clinics, triage tents, etc.)?</i></p> <p>Answer: The EMTALA regulations at 42 CFR 489.24 (b) contain a definition of a "dedicated emergency department," which is as follows:</p> <p><i>"Dedicated emergency department</i> means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:</p> <ol style="list-style-type: none"> (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (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; or (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment." <p>Any alternate care site that meets the requirements to be considered part of the hospital and which also meets the EMTALA definition above would be considered a hospital emergency department.</p>
G-11	<p><i>Question: Can patients be diverted for emergency triage or minor care and discharge at an alternate care site (tent, flu screening kiosk, etc.)?</i></p> <p>Answer: CMS has prepared a Fact Sheet that explains what hospitals can do while continuing to comply with EMTALA requirements. The Fact sheet can be found at the following website: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf</p>
G-12	<p><i>Question: Would a hospital be cited for an EMTALA violation if there was an increase in the number of patients (above baseline for this time of year) who left the emergency department (ED) without being seen during the last 24 hours?</i></p>

#	Question and Answer
	<p>Answer: With regards to concerns about potential EMTALA violation investigations and citations for data that indicates an increase in the number of LWBS (leave without being seen) patients, EMTALA is a complaint-driven process. In other words, when an individual or organization has filed a complaint related to EMTALA requirements, CMS will review it to determine whether it appears to raise compliance issues, and if it does, CMS will authorize an EMTALA survey of the hospital. CMS does not typically use statistical data to initiate an EMTALA investigation.</p>
G-13	<p><i>Question: Can the 72-hour waiver time frame be extended if the disaster plan is still in effect?</i></p> <p>Answer: 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 infectious disease, such as the current 2009-H1N1 pandemic, may last until the termination of the pandemic-related public health emergency. However, since case-specific applications of the EMTALA waiver authority will be issued only to the extent they are necessary, as determined by CMS, the waiver may be terminated prior to the termination of the public health emergency declaration.</p>
H	Hospitals - Critical Access Hospitals (CAHs)
H-1	<p><i>Question: Will CMS allow CAHs to stock more than 25 beds on campus, to be ready for surge capacity needs, without being out of compliance as a CAH, since the beds would not be used except in an emergency?</i></p> <p>Answer: Critical Access Hospitals (CAHs) already have the capability of having extra furniture as long as it is clearly in storage and is not staffed and ready for use. The CAH 25-bed limit is statutory and may be authorized under a section 1135 waiver for any exceptions. However, under normal circumstances, CMS counts as part of the 25-bed limit any rooms/spaces that are equipped and clearly ready to be used by simply rolling a “stored” bed into that space. There is a difference between having warehoused beds that provide the ability to add surge capacity during a declared emergency and having beds that can be readily used whenever the CAH wishes to exceed the 25 bed limit.</p> <p>Under the 1135 waiver authorization due to the H1N1 pandemic, CMS will notify providers of the extent to which beds can be moved from storage and readied for use (and not counted).</p>
H-2	<p><i>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?</i></p> <p>Answer: During the 2009-H1N1 public health emergency period, and section 1135 waiver authorization, 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 patients 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.</p>
H-3	<p><i>Question: Critical Access Hospitals (CAHs) 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?</i></p> <p>Answer: CMS is unable to grant approval for 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</p>

#	Question and Answer
	<p>earlier than October 23, 2009).</p> <p>CAHs may submit their request to operate under a section 1135 waiver to the CMS Regional Office in their service area, with a copy to their State Survey Agency. It will also be necessary to submit justification to support the necessity of granting the waiver.</p>
H-4	<p><i>Question: Can a State petition the Federal government for a waiver covering all critical access hospitals and if so, to whom?</i></p> <p>Answer: The State may submit a waiver request on behalf of all critical access hospitals (CAHs). The request maybe submitted to operate under section 1135 waiver authority (or for other relief that may be possible under other authorities) to their CMS Regional Office via email. If the request is from a different State agency, a copy of the request should be provided to the State Survey Agency. Information and a justification for requesting the waiver will be needed for each CAH.</p>
I	<p style="text-align: center;">Hospital – Acute Care Services</p>
I-1	<p><i>Question: Is CMS able to relax the hospital CoPs for alternate care sites, so they can be reimbursed for care, without an 1135 waiver?</i></p> <p>Answer: The question is very broad, and could encompass a number of different scenarios. For example, alternate care sites may include both sites that qualify as a part of a hospital or Critical Access Hospital (CAH) under existing rules, and sites for which an 1135 waiver would be required in order to be treated as part of the hospital or CAH for reimbursement purposes. Further, the question does not specify the types of Medicare Conditions of Participation (CoP) requirements from which relief would be sought.</p> <p>CMS has developed two fact sheets that provide detailed information regarding various scenarios and the flexibilities that may be permitted regarding hospital alternate care sites with or without an 1135 waiver approval. These fact sheets are posted on the CMS H1N1 Web site and can be accessed at:</p> <p><i>Hospital Alternate Care Site Fact Sheet:</i> http://www.cms.hhs.gov/H1N1/Downloads/AlternativeCareSiteFactSheet.pdf</p> <p><i>EMTALA Fact Sheet:</i> http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf</p>
I-2	<p><i>Question: Can a county health department apply on behalf of several hospitals in its county or must each hospital apply individually?</i></p> <p>Answer: A county may apply on behalf of the hospitals in their county, but they should include all the information necessary to allow the CMS Regional Office to appropriately justify the flexibility requested for each facility. The waiver request and appropriate justification should be submitted to the CMS Regional Office in the county's service area, with a copy to the State Survey Agency.</p>
I-3	<p><i>Question: Some States are considering utilizing mobile hospitals, based on military field hospital model as a means of meeting their emergency preparedness needs. Under what scenario could these mobile units be eligible for Medicare funding?</i></p> <p>Answer: It may be possible for a Medicare participating hospital to operate a mobile facility as a part of the hospital, as long as the mobile unit complies with all the hospital Conditions of Participation (including the Life Safety Code) and the provider-based rules (including remaining within 35 miles of the main provider). If the mobile unit meets the provider-based regulations at 42 CFR § 413.65, then they use the main hospital's CMS Certification Number (CCN). If not, then the mobile unit will be treated as a</p>

#	Question and Answer
	freestanding clinic. CMS will gladly work with any State wishing to develop mobile capacity. Situations involving use of mobile units will be evaluated on a case-by case basis.
I-4	<p><i>Question: Has CMS discussed issues related to an altered standard of care environment where usual requirements of care and providers will have to be accommodated in a resource constrained environment? This has implications for varied models of patient care with lesser prepared providers, care with limited laboratory support, recycled and substitutions for care, etc.</i></p> <p>Answer: CMS does not dictate “standards of care” with respect to the practice of medicine, and thus has no comment to the extent the question concerns the way in which physicians practice medicine. However, to the extent that CMS can provide information with respect to our approach for assessing provider compliance with Medicare requirements in an emergency that may put additional strain on provider resources, we have developed two fact sheets that provide detailed information regarding various scenarios and the flexibilities that may be permitted regarding hospital alternate care sites with or without an 1135 waiver approval. These fact sheets are posted on the CMS H1N1 Web site and can be accessed at:</p> <p><i>Hospital Alternate Care Site Fact Sheet:</i> http://www.cms.hhs.gov/H1N1/Downloads/AlternativeCareSiteFactSheet.pdf</p> <p><i>EMTALA Fact Sheet:</i> http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf</p>
I-5	<p><i>Question: Will the hospital medical records documentation requirements be modified after declaration of a disaster or emergency?</i></p> <p>Answer: Medical record documentation requirements are critical components of patient safety, the Medicare claims payment processing system and Medicare payment policy. Medicare providers are required to maintain adequate documentation to support the provision of care and payment for reasonable and medically necessary Medicare covered services. Medicare contractors are required to pay claims that meet the published criteria for payment, including medical record documentation. However, we acknowledge that during situations such as natural disasters, providers may not have documentation immediately at hand. CMS has outlined policies on administrative relief from medical review in the Program Integrity Manual, Section 3.2.2. As part of its disaster preparedness planning efforts, CMS could conduct further review of its documentation requirements.</p> <p>During the current 2009- H1N1 pandemic emergency and section 1135 waiver authorization, it may be possible for medical record standards to be relaxed, but facilities would still be expected to make reasonable efforts to maintain a medical record to support safe patient care. For example, in situations where the patient is evacuated to other care locations, facilities would still be expected to make reasonable efforts to ensure that a patient’s medical records remain with the patient.</p> <p>To request a waiver to operate under the section 1135 waiver, providers should submit their requests to the CMS Regional Office in their service area via email, and provide a copy to their State Survey Agency. Justification for the necessity to grant the waiver is required.</p>
I-6	<p><i>Question: Will a hospital that administers H1N1 vaccine without charge to physicians on its medical staff be subject to sanction under the physician self-referral (“Stark”) law in section 1877 of the Social Security Act (42 U.S.C. 1395nn)?</i></p> <p>Answer: The Stark law would be implicated if the vaccine administration creates a financial relationship between the hospital and a referring physician. Here, the federal government will make the vaccine available to providers at no cost as part of its response to the H1N1 public health emergency. Hospitals will play a critical role in the federal government’s response to the H1N1 flu pandemic. HHS has</p>

#	Question and Answer
	<p>targeted health care workers, including physicians, as a priority group for receiving H1N1 flu vaccination, and hospitals are well positioned to ensure the efficient and convenient vaccination of many in this target population. Under these circumstances, where the hospital administers H1N1 vaccine that it obtained without charge through the federal government’s centralized distribution of the vaccine, no financial relationship would be created between the hospital and the physicians to whom it administers the H1N1 vaccine.</p> <p>In other circumstances, such as if hospitals were to obtain vaccine from an entity other than the government and offer it to physicians without charge, the resulting financial relationship would likely satisfy one of numerous exceptions under the Stark law that would insulate hospitals from sanction. Potentially applicable exceptions to the self-referral prohibition for the provision of a free or discounted vaccine include, but are not limited to, the exceptions for: preventive screening tests, immunizations, and vaccines (§411.355(h)); nonmonetary compensation (§411.357(k) (\$355 aggregate amount per year)); medical staff incidental benefits (§411.357(m) (\$30 per occurrence limit)); or professional courtesy (§411.357(s)).</p> <p>Section 1135 of the Social Security Act (42 U.S.C. § 1320b-5) provides the Secretary of HHS with the authority to waive Stark sanctions. Thus, under the 2009-H1N1 1135 waiver, the Secretary could waive any Stark sanctions in connection with the receipt of H1N1 vaccine or could instruct CMS to determine the appropriateness of such waivers on a case-by-case basis. In addition, waiver of Stark sanctions would be available only to the extent that it is determined to be necessary.</p>
J	Hospital Services – Inpatient Rehabilitation Facilities (IRFs)
J-1	<p><i>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”)?</i></p> <p>Answer: In order to meet the demands of the emergency, CMS may 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>
K	Hospital Services – Long Term Care Hospitals (LTCHs)
K-1	<p><i>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)?</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.(e)(3)(i). LTCHs must clearly indicate in the medical record where an admission is made to</p>

#	Question and Answer
	meet the demands of the emergency.
L	Skilled Nursing Facilities/Nursing Facilities
L-1	<p><i>Question: Under the current regulations, there are certain medical conditions that require the nursing home to admit a resident to a hospital in order for the care to be reimbursed. Can this requirement be relaxed to ensure the care is provided and reimbursed, but does not put the resident at risk of exposure to the H1N1 virus in the ED?</i></p> <p>Answer: There are no requirements that residents of nursing homes must be admitted to the hospital. Rather, nursing homes "must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." As the requirement is already flexible, there is no need to further "relax" the requirement or institute an alternative rule.</p>
L-2	<p><i>Question: Some nursing facilities in areas where the H1N1 Influenza A virus is prevalent may elect to limit visitors to their facility to protect their vulnerable residents. Will this be acceptable to CMS or would a facility be risking a citation relating to protection of individual rights?</i></p> <p>Answer: CMS supports CDC's interim guidance on 2009-H1N1 infection control measures for health care settings to apply a hierarchy of controls to prevent influenza transmission by eliminating the potential source of exposure by taking steps to minimize exposure by denying entry to visitors who have influenza symptoms. Facilities will not be subject to sanction for a deficiency to protect individual rights by taking reasonable and necessary precautions to limit visitors as a means to protect their residents from exposure to the H1N1 virus during the pandemic.</p>
L-3	<p><i>Question: Our nursing home is having difficulty obtaining the seasonal flu vaccine, and we are concerned about meeting CMS requirements to offer and provide seasonal flu vaccinations to our residents. Will we be cited if we are unable to vaccinate our residents?</i></p> <p>Answer: CMS has confirmed with the Centers for Disease Control and Prevention (CDC) that they have received reports that providers and immunization providers are currently unable to obtain seasonal influenza vaccine. CDC relays that the situation is dynamic and they expect it to continue to evolve as the flu season continues. As of the first week in October 2009, 77 million doses have been distributed in the private and public sectors. However, if the anecdotal reports about increased demand turn out to be correct, the extra demand may not be fully met during this flu season. CDC has been working with manufactures, States and immunization providers to identify seasonal flu vaccine and distribute it to the providers who administer to high risk populations. CDC recommends that vaccine providers check the National Influenza Summit Web site where available vaccine is listed by distributor. The link for health care professionals is: http://www.preventinfluenza.org/</p> <p>42 CFR 483.25(n)(1)(iv) requires nursing home resident's medical record to include documentation that indicates, at a minimum, that the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and that the resident either received the influenza immunization during October 1 through March 31 annually, or did not receive the influenza immunization due to medical contraindications or refusal.</p> <p>483.30(n) also requires nursing homes to establish influenza and pneumococcal immunization policies and procedures, which should include processes to address issues outside the facility's control, such as nonavailability of vaccines due to production delays or distribution problems.</p> <p>Nursing homes should document any difficulty they are having in obtaining the seasonal flu vaccine. The survey protocol interpretive guidance notes that for surveys occurring during influenza season, unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program -- especially during the early weeks of the influenza season.</p>

#	Question and Answer
L-4	<p><i>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?</i></p> <p>Answer: Yes. Section 1812(f)A 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 transferred as a result of the 2009-H1N1 pandemic. 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.</p>
L-5	<p><i>Question: Will physician extenders be allowed to initially certify the need for skilled care in the absence or unavailability of physicians?</i></p> <p>Answer: Section 1814(a)(2) of the Social Security Act in fact already allows a nurse practitioner (NP) or a clinical nurse specialist (CNS) to perform not only the subsequent skilled nursing facility (SNF) re-certifications but the initial certification as well, so long as the NP or CNS is working in collaboration with a physician and does not have a direct or indirect employment relationship with the SNF. Beyond that, the already-existing policy that allows for delayed certifications/re-certifications (as set forth in the Internet-Only Manual at Pub. 100-1, Chapter 4, § 40.5) should be sufficient to address any contingencies related to a declared emergency.</p>
M	State Survey Agency Role During H1N1 Pandemic
M-1	<p><i>Question: Will CMS permit States Survey Agencies (SAs) to adjust or forego their Federal survey and certification work if State emergency authorities determine there are no alternatives, and it is necessary to deploy the agency's clinical professionals to provide influenza vaccinations during the H1N1 pandemic, or other issues arise that causes delays to the survey schedule (e.g., survey staff shortages, facility is caring for H1N1 cases during the survey, and does not want to risk exposure, etc.)?</i></p> <p>Answer: When there are no acceptable alternatives and State emergency preparedness and response authorities deem it necessary to deploy SA clinical professionals for emergency assignment, including providing H1N1 vaccinations, or other issues arise due to the H1N1 pandemic that cause delays in the survey schedule, the SA should contact their CMS Regional Office. CMS has an excellent track record in collaborating with States during emergency events, and will work with each State on a case-by-case basis to support effective emergency responses, while accomplishing the Federal Medicare and Medicaid work to the maximum extent practicable.</p> <p>While Federal Medicare Trust funds contracted with the State under section 1864 of the Social Security Act may not be used to perform duties that are not part of the survey and certification (S&C) functions (i.e., other funds must be used during the re-deployment period), CMS will work with the State to adjust their work schedules, mobilize staffing help and take other actions as needed, so that the year-end federal work can still be accomplished to the maximum extent practicable.</p> <p>For more details, see S&C memo 10-02-ALL, which can be accessed at: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter10_02.pdf</p>
N	H1N1 Virus (Swine-Origin Influenza A) Resources

#	Question and Answer
N-1	<p data-bbox="250 254 1052 281"><i>Question: Where can I find more information about the H1N1 virus?</i></p> <p data-bbox="250 321 1430 380">Answer: For more information on the 2009-H1N1 influenza pandemic, please see the following Web sites:</p> <ul data-bbox="261 422 1471 1331" style="list-style-type: none"> <li data-bbox="261 422 1458 480">• U.S. Government – Flu.gov: One-stop access to U.S. Government H1N1, avian and pandemic flu information (managed by HHS): http://pandemicflu.gov/ <li data-bbox="261 499 1438 527">• U.S. Government – Flu.gov: Frequently Asked Questions (FAQ) Search: http://answers.flu.gov/ <li data-bbox="261 546 1398 636">• U.S. Department of Health and Human Services/Centers for Medicare & Medicaid (CMS) Emergency Web Site – Pandemic Flu (EMTALA Fact Sheet, Medicare and Medicaid Vaccine Coverage Fact Sheets, FAQs, etc.): http://www.cms.hhs.gov/H1N1/ <li data-bbox="261 655 1438 714">• U.S. Department of Health and Human Services: Disasters & Emergencies – Pandemics and Diseases: http://www.hhs.gov/disasters/emergency/manmadedisasters/panflu/pandemicflu.html <li data-bbox="261 732 1458 823">• U.S. Department of Health and Human Services/Centers for Disease Control & Prevention (CDC): Interim Guidance on Infection Control Measures for 2009 H1N1 in Health Care Settings, Including Protection of Healthcare Personnel: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm <li data-bbox="261 842 1458 900">• U.S. Department of Health and Human Services/Centers for Disease Control & Prevention (CDC): H1N1 Flu – General Information: http://www.cdc.gov/h1n1flu/general_info.htm <li data-bbox="261 919 1458 978">• U.S. Department of Health and Human Services/Centers for Disease Control & Prevention (CDC): Flu Vaccine Information: http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm <li data-bbox="261 997 1471 1087">• U.S. Department of Health and Human Services/Centers for Disease Control & Prevention (CDC): H1N1 Flu Situation Update – U.S. Map, Weekly Influenza Activity Estimates Reported by State and Territorial Epidemiologists: http://www.cdc.gov/h1n1flu/updates/us/ <li data-bbox="261 1106 1409 1224">• U.S. Department of Labor, Occupational Safety & Health Administration (OSHA): Quick Card: Pandemic Flu Respiratory Protection, Quick Card, Respiratory Infection Control: Respirators Versus Surgical Masks, FAQs for health care workers: http://www.osha.gov/dsg/topics/pandemicflu/index.html <li data-bbox="261 1243 1365 1333">• U.S. Department of Homeland Security/Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities: Disability Preparedness Resource Center: http://www.disabilitypreparedness.gov/