

CMS Manual System	Department of Health & Human Services
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services
Transmittal 454	Date: March 6, 2009
	Change Request 6378

SUBJECT: Influenza Pandemic Emergency Preparedness – Waiver of Certain Medicare Requirements

I. SUMMARY OF CHANGES: This change request implements guidance related to the waiver of certain Medicare Requirements in the event of a pandemic influenza outbreak.

New / Revised Material

Effective Date: For Preparedness: April 6, 2009;

For Operational Implementation: as specified by the CMS notice of the existence of an emergency

For Operational Termination: as specified by the CMS notice of the termination of the emergency

Implementation Date: For Preparedness: April 6, 2009;

For Operational Implementation: within two business days upon notice of an emergency

For Operational Termination: within two business days upon notice to terminate

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One-Time Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 454	Date: March 6, 2009	Change Request: 6378
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I. GENERAL INFORMATION

A. Background: As part of its preparedness efforts for an influenza pandemic, the Centers for Medicare & Medicaid Services (CMS) has developed certain emergency guidances and procedures that may be implemented for the Medicare fee-for-service program in the event of a pandemic. CMS has also developed certain additional emergency guidances and procedures that may be implemented if: 1. the President declares an emergency or disaster under the National Emergencies Act or the Stafford Act; and 2. the Secretary of the Department of Health and Human Services declares – under §319 of the Public Health Service Act – that a public health emergency exists, and 3. the Secretary elects to waive one or more requirements of Title XVIII of the Social Security Act (Act) pursuant to §1135 of such Act. Until CMS declares these guidances to be in effect, the guidances are considered to be pending and provider outreach is not required.

In the event of a pandemic, the guidances and procedures described in this Transmittal will be implemented in whole or in part via one or more Joint Signature Memoranda (JSM)/Technical Direction Letters (TDL). Such JSMs/TDLs will specify which guidances and procedures are being implemented, the effective date(s) of such guidances, the geographic scope of the JSM/TDL, a summary of the Secretary's declaration (if any), and other pertinent facts and instructions. A template of such a JSM/TDL is attached (Attachment A).

Additional pandemic-specific preparedness guidances and procedures may be issued in future Change Requests. In the event of an apparent conflict between or among guidances/procedures, contractors shall advise the post-implementation contact in Section V of the apparent conflict and, until such time as the contractors are furnished with a response, shall construe such policies in such a manner as to give full effect to both/all such guidances.

This Transmittal implements selected influenza pandemic-specific guidances and procedures, in the form of questions and answers (Qs&As) concerning the following topic:

- Waiver of Certain Medicare Requirements

Until CMS declares these guidances to be in effect, no provider outreach is required (see JSM 09027). In the event CMS implements these guidances, the contractor will be instructed to begin extensive outreach including notice to providers to monitor the contractor's Web site, as well as, the CMS pandemic flu Web page:

B. Policy: Contractors shall be prepared to implement the guidances and procedures specified in this Transmittal and shall, upon notice from CMS, implement such guidances and procedures in accordance with such notice, and shall, upon further notice from CMS, amend or terminate the implementation of such guidances and procedures in accordance with such further notice. The Questions and Answers specified in Attachment B to this Transmittal constitute Medicare fee-for-service guidances applicable during an influenza pandemic, subject to amendment and clarification via subsequently issued Transmittals or JSM/TDLs.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6378.1	Contractors shall construe the term “guidance” or “guidances”, as used in the following Requirements, as meaning an Answer or Answers as specified in the Q&As in Attachment B to this Transmittal.	X	X	X	X	X					
6378.2	Contractors shall be prepared to implement the guidances specified in this Transmittal within two business days of receiving notice from CMS to do so.	X	X	X	X	X					
6378.2.1	Each contractor shall be prepared to implement only those guidances that are consistent with the nature of the contractor’s work (e.g., a policy relating to institutional provider billing would apply to fiscal intermediaries (FI) or to the respective component of Medicare Administrative Contractors (MAC) rather than to carriers or to the respective component of MACs).	X	X	X	X	X					
6378.3	Contractors shall, upon notice from CMS, implement the guidances and procedures specified in this Transmittal within two business days of receiving such notice and in accordance with such notice.	X	X	X	X	X					
6378.3.1	Each contractor shall implement only those guidances that are within the contractor’s scope of work (e.g., a policy relating to institutional provider billing would apply to fiscal intermediaries (FI) or to the respective component of Medicare Administrative Contractors (MAC) rather than to carriers or to the respective component of MACs).	X	X	X	X	X					
6378.3.2	Contractors shall, in the event that one or more guidances cannot be fully or timely implemented, implement those guidances that can be fully and timely implemented and shall advise the Regional Office (RO) or Project Officer (PO), as applicable, of the nature and scope of each problem.	X	X	X	X	X					
6378.4	Contractors shall implement such further instructions relating to these guidances, including but not limited to implementing amendments to such guidances, as may be	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	issued via a subsequent Transmittal, a Joint Signature Memorandum (JSM), a Technical Direction Letter (TDL), or other CMS notification. See Attachment A.										
6378.4.1	Each contractor shall implement only such further instructions as relate to those guidances that are consistent with the nature of the contractor's work (e.g., a policy relating to institutional provider billing would apply to fiscal intermediaries (FI) or to the respective component of Medicare Administrative Contractors (MAC) rather than to carriers or to the respective component of MACs).	X	X	X	X	X					
6378.4.2	Contractors shall, in the event that one or more further instructions cannot be fully and timely implemented, implement those instructions that can be fully and timely implemented and shall advise the RO or PO, as applicable, of the scope and nature of each problem.	X	X	X	X	X					
6378.5	Contractors shall, in the event of an apparent conflict between or among the guidances stated in this Transmittal, or as may be stated in another pandemic flu-related Transmittal, JSM, or TDL (including but not limited to Questions & Answers (Q&A) issued thereby), advise their respective RO or PO, as applicable, of the apparent conflict and, until such time as the contractor is furnished with a response on the matter, construe the affected polices in such a manner as to give full effect to both/all such guidances.	X	X	X	X	X					
6378.6	Contractors shall be prepared to cease applying the guidances specified in this Transmittal within two business days of receiving notice from CMS to do so.	X	X	X	X	X					
6378.6.1	Contractors shall, upon notice from CMS, cease applying the guidances specified in this Transmittal within two business days of receiving such notice and in accordance with such notice.	X	X	X	X	X					
6378.7	ROs and POs shall notify the pre-implementation contact concerning: any problem in the implementation of any guidance specified in this Transmittal as discussed in 6378.3.2; any problem in the implementation of any further instruction as discussed in 6378.4.2; any apparent policy conflict as discussed in 6378.5; or any problem in ceasing to apply any guidance specified in this Transmittal as discussed in 6378.6.1.									ROs POs	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6378.8	Upon notification from CMS to begin communications, contractors shall, when communicating with the provider community concerning such emergency preparedness guidances, advise the provider community to monitor the contractor's Web site in the event of an influenza pandemic in order to determine whether and to what extent such guidances are being implemented and when and where such guidances are applicable. The provider community shall monitor the contractor's and the CMS website in the event of an influenza pandemic at: http://www.cms.hhs.gov/Emergency/10_PandemicFlu.asp .	X	X	X	X	X					
6378.9	Upon notification from CMS to begin communications, contractors shall, when communicating with the provider community concerning such emergency preparedness guidances, advise the provider community that providers should await contractor guidance before considering any such guidance to be operationally effective.	X	X	X	X	X					

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): For questions regarding Waivers of Certain Medicare Requirements, please contact Peggy Sparr at margaret.sparr@cms.hhs.gov or (410) 786-0355.

Post-Implementation Contact(s): Your appropriate Regional Office (RO) or Project Officer (PO).

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Carriers and Regional Home Health Intermediaries (RHHIs):

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs):*

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachments (2)

JSM and Q&As

DEPARTMENT OF HEALTH & HUMAN SERVICE
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



JSM/TDL-[XXXXXX, DATE]

MEMORANDUM

DATE:

FROM: Director, Provider Billing Group
Center for Medicare Management

Director, Medicare Contractor Management Group
Center for Medicare Management

SUBJECT: Implementation of Emergency Pandemic Influenza Policies

TO: All Fiscal Intermediaries (FIs), Carriers, Durable Medical
Equipment Medicare Administrative Contractors (DME MACs),
and All Part A and Part B MACs (A/B MACs)

This joint signature memorandum/technical direction letter (JSM/TDL) implements certain emergency Medicare policies and procedures in response to the influenza pandemic. As you may be aware, on [date][insert information concerning the relevant declaration, including the date it was effective, its geographic coverage and whether § 1135 waivers apply].

In accordance with previously issued Transmittal xxxx, all contractors serving the aforementioned States shall, within 2 business days of receipt of this JSM/TDL, implement Policies #s [insert #s] as specified in that Transmittal with an effective date of [insert date]. [If not all of the policies are being addressed, insert the following statement: "Policies #s [insert #s] are not included within the scope of this JSM/TDL". Delete authoring directors/signatories as appropriate.]

[If any further instructions are required with respect to particular policies, insert the following: "Of the aforementioned policies, certain amendments/clarifications are to be implemented/noted as follows:"

[Insert amendments/clarifications.]

Except as may otherwise be noted, contractors shall, within two business days of receipt of this JSM/TDL, and consistent with the provider education business requirements of Transmittal xxxx, including but not necessarily limited to business requirements xxxx.12, xxxx.12.1, and xxxx.12.2:

1. post the approved information provided in Transmittal xxxx as operationally effective on their respective Web sites;
2. issue listserv messages to the appropriate communities to announce the implementation of the emergency policies in One Time Notification xxxx;
3. advise providers as soon as practicable but no later than 2 business days after receipt of such notice – by all means that are likely to ensure prompt receipt of notice – that such emergency policies have been implemented, as specified in such CMS notice;
4. remove from their respective web sites, the “Pending” designation of those policies being implemented;
5. remove from their respective web sites any policy not being implemented under such notice; and
6. amend on their respective web sites any policies that have been amended by this JSM/TDL and advise providers and beneficiaries of all such changes.

NOTE: MEDICARE ADMINISTRATIVE CONTRACTORS (MACs)

DME MAC Contract Numbers

Jurisdiction A ~ HHSM-500-2006-M0001Z
Jurisdiction B ~ HHSM-500-2006-M0002Z
Jurisdiction C ~ HHSM-500-2006-M0006Z
Jurisdiction D ~ HHSM-500-2006-M0004Z

A/B MAC Contract Numbers

Jurisdiction 3 ~ HHSM-500-2006-M0005Z
Jurisdiction 4 ~ HHSM-500-2007-M0001Z
Jurisdiction 5 ~ HHSM-500-2007-M0002Z

This Joint Signature Memorandum is being issued to you as technical direction under your MAC contract. This technical direction is not construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of the contract entitled Limitation of Cost, FAR 52.232-20. If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Should you require further technical clarification, you may contact your Project Officer. Contractual questions should be directed to your CMS Contracting Officer. Please copy the Project Officer and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

**Questions and Answers
Concerning
Medicare Emergency Preparedness
for an
Influenza Pandemic Emergency**

Control #	Question and Answer
	Waiver of Certain Medicare Requirements
1	<p>Question: Do the modifications and flexibilities described in Q&As in response to an influenza pandemic apply to providers located only in States in which the Secretary of Health and Human Services (HHS) has declared a Public Health Emergency under §319 of the Public Health Service Act, and in which FEMA or the President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act?</p> <p>Answer: Yes, but only to the extent that the Secretary has also invoked his authority under §1135 of the Social Security Act, and then only to the extent that the provider in question has been affected by the flu pandemic. Note, however, that Medicare does allow for certain limited flexibilities outside the scope of the §1135 waiver authority, as discussed in other Q&As.</p>
2	<p>Question: What is the duration of the waivers granted by the HHS Secretary under §1135 of the Social Security Act?</p> <p>Answer: In general, the length of the waiver period is the same as the length of the public health emergency. However, waivers are terminated sooner if the provider regains its ability to comply with the waived requirement. Additionally, requirements may be waived only to the extent necessary to achieve the purposes of the statute. For example, if a critical access hospital (CAH) regains 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 apply to that CAH. Note: if a waiver of EMTALA or HIPAA sanctions is granted, such a waiver is subject to special limits on duration specified in the statute.</p>
3	<p>Question: In addition to those services provided in the emergency area, can the §1135 waiver authority be used to include waivers regarding benefits and services provided for evacuees from emergency areas who are receiving those services in non-emergency areas?</p> <p>Answer: No. The §1135 waiver authority does not extend beyond the "emergency area," which is defined as the geographic area in which there exists an emergency or major disaster as declared by the President under either the Stafford Act or National Emergencies Act, and a public health emergency as determined by the Secretary under §319 of the Public Health Services Act. Medicare does allow for certain limited flexibilities outside the scope of the §1135 waiver authority as discussed in other Q&As.</p>
4	<p>Question: Does the §1135 authority allow CMS to waive Medicare or Medicaid requirements that apply to affected individuals, e.g., flu victims? If so, would there be a set period of time for the emergency to exist, or would such waiver vary by affected individual?</p> <p>Answer: No. The §1135 authority – if such a waiver is made – authorizes the waiver or modification of certain requirements that otherwise would apply to health care providers. Therefore, the 1135 waiver authority does not apply to requirements that apply to individual beneficiaries. Nevertheless, the effect of an 1135 waiver may be situation specific depending not upon the waiver authority itself, but rather upon particular circumstances, e.g., whether an individual was evacuated to a facility for which requirements were waived (as opposed to a facility to which the waiver did not apply).</p>

Control #	Question and Answer
5	<p>Question: Will CMS or FEMA provide disaster relief funding to hospitals following a pandemic flu to make up for the lost reimbursement? If so what documentation will be required in patient clinical and financial records?</p> <p>Answer: There is currently no standing authority for CMS to provide special disaster relief funding following a pandemic flu or any other disaster, in order to compensate providers for lost reimbursement. Congress has used its discretion to appropriate disaster-specific special funding for example, after Hurricane Katrina. For that situation, CMS has been administering 11 disaster-related grants. In the absence of such special provisions, Medicaid and Medicare do not provide funding for lost reimbursement.</p>
6	<p>Question: What is HHS's process for approving and issuing Emergency Medical Treatment and Labor Act (EMTALA) waivers for hospitals that have implemented hospital disaster protocols in response to an emergency ?</p> <p>Answer: There are 4 prerequisites for a hospital waiver of EMTALA sanctions under HHS's authority under Section 1135 of the Social Security Act. They are as follows:</p> <ol style="list-style-type: none"> (1) the President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act, (2) the Secretary of HHS has declared a Public Health Emergency (PHE) under Section 319 of the Public Health Service Act, (3) the Secretary of HHS has invoked his authority under Section 1135 of the Social Security Act and authorized CMS to waive sanctions for certain EMTALA violations that arise as a result of the circumstances of the emergency, and (4) the hospital in the affected area has implemented its hospital disaster protocol
7	<p>Question: It was my understanding that only the HHS Secretary had the authority to issue 1135 waivers (which could be requested by States), but a 12/7/07 CMS memo (Waiver of Emergency Medical Treatment and Labor Act (EMTALA) Sanctions in Hospitals Located in Areas Covered by a Public Health Emergency Declaration) indicates that the Regional Office (RO) "may issue an advisory notice that hospitals with dedicated emergency departments in the emergency area will not, during the emergency period, be subject to" certain EMTALA sanctions, if both the President and Secretary declare emergencies. Does the issuance of an advisory notice by the RO carry the same weight as an 1135 waiver</p> <p>Answer: No. The December 7, 2007 CMS memorandum referenced in the question is part of the standard operating procedure describing how CMS will implement the EMTALA provisions of a Section 1135 waiver issued by the Secretary. The RO's issuance of an "advisory notice" occurs only <u>after</u> the Secretary has invoked his 1135 waiver authority delegating the specifics to the CMS Administrator, and after the Administrator of CMS has waived certain EMTALA sanctions for 72 hours for the hospital(s) in the affected area with dedicated emergency departments that have implemented their hospital disaster protocol. Furthermore, in a refinement to the process described in the December 7 memorandum, CMS now requires hospitals in the affected area to notify CMS, through the appropriate State Survey Agency, when they implement a hospital disaster protocol.</p>
8	<p>Question: What is HHS's procedure for addressing requests from States to waive EMTALA? How frequent are such requests?</p> <p>Answer: We currently handle these matters on a case-by-case basis. In any local, regional or national disaster - tornado, hurricane, wildfires, etc, --States, providers, trade groups and other stakeholders can and do communicate regularly with CMS and the State survey agencies to inform CMS about local conditions that may require unique consideration. State survey agencies are responsible for reporting the status of health care providers affected by the emergency to their CMS Regional Office. CMS makes recommendations to the Secretary, based on the status information. Because our recommendations are informed by the specific circumstances, we do not believe that a formal procedure is necessary at this time.</p>

Control #	Question and Answer
9	<p>Question: Aside from Hurricane Katrina, has HHS issued any 1135 waivers that specifically address EMTALA?</p> <p>Answer: Since Section 143 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 amended section 1135 of the Social Security Act to add the waiver authority, Section 1135 waivers have been issued for Hurricanes Katrina, Rita, Gustav and Ike, and for the flooding in Iowa and Indiana during CY 2008. 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. NOTE: if a public health emergency involves a pandemic infectious disease and the Secretary invokes his waiver authority under section 1135 to waive EMTALA sanctions, such an EMTALA waiver will continue in effect until the termination of the applicable declaration of the PHE (in accordance with section 1135(e)(1)(B) of the Act).</p>
10	<p>Question: Can the 72-hour EMTALA waiver be extended for a non-pandemic related emergency?</p> <p>Answer: Section 1135 does not authorize an extension of the EMTALA waiver beyond 72-hours after the implementation of a hospital disaster protocol, for other than a public health emergency involving a pandemic infectious disease. NOTE: the hospital needs to implement its disaster protocol to "start the clock" on its ability to rely on an EMTALA waiver under Section 1135.</p>
11	<p>Question: Would it be possible for the HHS Secretary to waive all of EMTALA's provisions, or only some of them?</p> <p>Answer: There are only two EMTALA provisions for which the sanctions can be waived under a section 1135 waiver. Under the Section 1135 authority, CMS can waive sanctions, (1) for an inappropriate transfer (if the transfer arises out of the circumstances of the emergency), and (2) for the relocation or redirection of an individual to receive an appropriate medical screening examination pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan. However, each hospital in the affected area must first implement its disaster protocol in order for the waiver 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>