Dear Hospital Leaders,

I have heard from a couple members of your quality departments with questions about how to apply for a 1135 waiver.

Please see the attached memos that outline the information CMS is requiring at this point for waiver requests.

The second attachment addresses what a waiver request needs to include. You will see at the bottom of the second attachment a list of CMS email boxes.

The waiver mailbox for Vermont is: ROPHIDSC@cms.hhs.gov

I am requesting that you copy me when you submit your waiver request via email to CMS.

I serve as the liaison for state hospital licensing under David Herlihy, and want to ensure that any changes in location or provision of services remain in alignment with our state licensing requirements. Additionally, we want keep the Vermont Board of Health apprised of any changes as needed.

I have received a couple questions about whether or not a waiver is needed for screening sites. The answer will vary depending on where you intend to locate the screening site, and whether or not that location is currently under your federal provider number. I am available to help navigate these questions and follow up with your hospital as needed.

The State Survey Agency is available to provide technical assistance during this time. Please feel free to contact me with any questions related to waivers or CMS regulatory compliance questions.

Many thanks for your attention to this process. Information from CMS is evolving and will be provided on an ongoing basis. I will continue to share pertinent notices.

Here is the link to the CMS webpage where updates are being posted:

https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

Sincerely,

Sarah Sherbrook, MS, RN
Acute Care Administrator
State of Vermont
Division of Licensing and Protection
www.dlp.vermont.gov
Cell: 802-318-8218
Office: 802-241-0335

Requesting an 1135 Waiver – 11.16.2016

Definition of an 1135 Waiver

When the President declares a disaster or emergency under the Stafford Act or National Emergencies Act and the HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act, the Secretary is authorized to take certain actions in addition to his/her regular authorities. For example, under section 1135 of the Social Security Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods and that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). Examples of these 1135 waivers or modifications include:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals 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)
- Emergency Medical Treatment and Labor Act (EMTALA) sanctions for direction or relocation or of an individual to receive a medical screening examination in an alternative location pursuant to an appropriate state emergency preparedness plan (or in the case of a public health emergency involving pandemic infectious disease, a state pandemic preparedness plan) or transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency. A waiver of EMTALA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay.
- Stark self-referral sanctions
- Performance deadlines and timetables may be adjusted (but not waived).
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

These waivers under section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period. Waivers

for EMTALA (for public health emergencies that do not involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic-related public health emergency. The 1135 waiver authority applies only to Federal requirements and does not apply to State requirements for licensure or conditions of participation.

Other Flexibilities

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for skilled nursing facility (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).

Determining if Waivers Are Necessary

In determining whether to invoke an 1135 waiver (once the conditions precedent to the authority's exercise have been met), the Assistant Secretary for Preparedness and Response (ASPR) with input from relevant OPDIVS determine the need and scope for such modifications. Information considered includes requests from Governor's offices, feedback from individual healthcare providers and associations, and requests to regional or field offices for assistance.

How States or Individual Healthcare Providers Can Ask for Assistance or a Waiver

Once an 1135 Waiver is authorized, health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority to either the State Survey Agency or CMS Regional Office. Request can be made by sending an email to the CMS Regional Office in their service area, or by calling the State or CMS Regional Office. Email addresses are listed below. Information on your facility and justification for requesting the waiver will be required.

Review of 1135 Waiver requests

CMS will review and validate the 1135 waiver requests utilizing a cross-regional Waiver Validation Team. The cross-regional Waiver Validation Team will review waiver requests to ensure they are justified and supportable.

Implementation of 1135 Waiver Authority

Providers must resume compliance with normal rules and regulations as soon as they are able to do so, and in any event the waivers or modifications a provider was operating under are no longer available after the termination of the emergency period.

Federally certified/approved providers must operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

Frequently Asked Questions

Further information on the 1135 Waiver process can be found under downloads at: CMS Emergency Agency Information

Questions regarding 1135 that are not addressed at the above website can be sent to the following mailbox: EPRO@cms.hhs.gov

Email Addresses for CMS Regional Offices

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

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

1135 Waiver Request
Communication Method- Best Practice

The specific State Dept. of Health should provide responses to the following basic questions for any impacted provider seeking a potential 1135 waiver:

- Provider Name/Type

- Full Address (including county/city/town/state) CCN (Medicare provider number)

- Contact person and his or her contact information for follow-up questions should the Region need additional clarification

- Brief summary of why the waiver is needed**. For example:** CAH is sole community provider without reasonable transfer options at this point during the specified emergent event (e.g. flooding, tornado, fires, or flu outbreak). CAH needs a waiver to exceed its bed limit by X number of beds for Y days/weeks (be specific).

- Consideration – Type of relief you are seeking or regulatory requirements or regulatory reference that the requestor is seeking to be waived.

- There is no specific form or format that is required to submit the information but it is helpful to clearly state the scope of the issue and the impact.

If a waiver is requested, the information should come directly from the impacted provider to the appropriate Regional Office mailbox with a copy to the appropriate State Agency for Health Care Administration to make sure the waiver request does not conflict with any State requirements and all concerns are addressed timely.

Email Addresses for CMS Regional Offices:

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.

COVID-19 Emergency Declaration
Health Care Providers Fact Sheet

The Trump Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers combat and contain the spread of 2019 Novel Coronavirus Disease (COVID-19). In response to COVID-19, CMS is empowered to take proactive steps through 1135 waivers and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are available:

- **Skilled Nursing Facilities**
  CMS is waiving the requirement at Section 1812(f) of the Social Security Act for a 3-day prior hospitalization for coverage of a skilled nursing facility (SNF) stay provides temporary emergency coverage of (SNF services without a qualifying hospital stay, for those people who need to be transferred as a result of the effect of a disaster or emergency. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period.

  Second, CMS is waiving 42 CFR 483.20 to provides relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.

- **Critical Access Hospitals**
  CMS is waiving the requirements that Critical Access Hospitals limit the number of beds to 25, and that the length of stay be limited to 96 hours.

- **Housing Acute Care Patients In Excluded Distinct Part Units**
  CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatient. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

- **Durable Medical Equipment**
  Where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable, contractors have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.

- **Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital**
  CMS is waiving to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the hurricane. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

- **Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital**
  CMS is waiving requirements to allow acute care hospitals with excluded distinct part inpatient Rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

  CMS is waiving requirements to allow IRFs to exclude patients from the hospital's or unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (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. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

- **Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCH)s**
  Allows a long-term care hospital (LTCH) to exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement which allows these facilities to be paid as LTCHs.

- **Home Health Agencies**
  Provides relief to Home Health Agencies on the timeframes related to OASIS Transmission. Allows Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.

- **Provider Locations**
  Temporarily waive requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. This applies to Medicare and Medicaid.

- **Provider Enrollment**
  - Establish a toll-free hotline for non-certified Part B suppliers, physicians and non-physician practitioners to enroll and receive temporary Medicare billing privileges
  - Waive the following screening requirements:
    - Application Fee - 42 C.F.R 424.514
    - Criminal background checks associated with FCBC - 42 C.F.R 424.518
    - Site visits - 42 C.F.R 424.517
  - Postpone all revalidation actions
  - Allow licensed providers to render services outside of their state of enrollment
  - Expedite any pending or new applications from providers

- **Medicare appeals in Fee for Service, MA and Part D**
  - Extension to file an appeal
  - Waive timeliness for requests for additional information to adjudicate the appeal;
  - Processing the appeal even with incomplete Appointment of Representation forms but communicating only to the beneficiary;
  - Process requests for appeal that don't meet the required elements using information that is available.
  - Utilizing all flexibilities available in the appeal process as if good cause requirements are satisfied.

Medicaid and CHIP

When the President declares an emergency through the Stafford Act or National Emergency Act, and the Secretary declares a Public Health Emergency, the Secretary is authorized to waive certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) authorities under Section 1135 of the Social Security Act.

There is no specific form or format that is required to submit the request for a Section 1135 waiver, but the state should clearly state the scope of the issue and the impact. States and territories may submit a Section 1135 waiver request directly to Jackie Glaze, CMS Acting Director, Medicaid & CHIP Operations Group Center for Medicaid & CHIP Services by e-mail (Jackie.Glaze@cms.hhs.gov) or letter.

The following are examples of flexibilities that states and territories may seek through a Section 1135 waiver request:

- Waive prior authorization requirements in fee-for-service programs
- Permits providers located out of state/territory to provide care to another state's Medicaid enrollees impacted by the emergency
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care.
- Temporarily waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state, and
- Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home residents
- States and territories are encouraged to assess their needs and request these available flexibilities, which are more completely outlined in the Medicaid and CHIP Disaster Response Toolkit. For more information and to access the toolkit, visit: https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html.

For questions please email: 1135waiver@cms.hhs.gov