

1135 Waiver- At A Glance

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 her regular authorities. For example, under section 1135 of the Social Security Act, she 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 redirection of an individual to receive a medical screening examination in an alternative location pursuant to a 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 to permit Medicare enrollees to use out of network providers in an emergency situation

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.

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

Under this authority, CMS can issue a temporary waiver of the SNF benefit's qualifying hospital stay requirement for those beneficiaries who are evacuated or transferred as a result of the emergency situation. In this way, beneficiaries who may have been discharged from a hospital early to make room for more seriously ill patients will be eligible for Medicare Part A SNF benefits. In addition, beneficiaries who had not been in a hospital or SNF prior to being evacuated, but who need skilled nursing care as a result of the emergency, will be eligible for Medicare Part A SNF coverage without having to meet the 3-day qualifying hospital stay requirement.

Trigger Points

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) convenes a meeting of relevant OPDIVS to determine the need and scope for such modifications. Information considered includes requests from Governor's offices, feedback from individual healthcare providers and associations, requests to regional or field offices for assistance, and information obtained from the Secretary's Operation Center. The intent is to determine whether the waivers or modifications allowed under the 1135 Waiver Authority will assist healthcare providers in dealing with the response to a disaster.

While hurricanes and other disasters represent a date-certain impact and generally known duration, public health emergencies around diseases or viruses may be considered a more diffuse and dispersed event. In evaluating trigger points for implementation of an 1135 waiver, it is important to recognize that a state or geographic region may have limited activity as a whole, while a particular city or community may be experiencing a severe outbreak. This geographic variation makes quantifiable trigger points difficult to define.

One of the best indicators for the need and geographic scope of an 1135 Waiver is healthcare provider and provider association contacts with CMS Regional Offices. As the waivers and modifications allowed under the 1135 waiver authority deal most often with Medicare Conditions of Participation (and EMTALA), most providers and associations will turn first to the CMS Regional Office for relief. Since one of the purposes of the 1135 Waiver is to provide waivers and modifications to assist providers furnishing services to Medicare, Medicaid and CHIP beneficiaries, it seems apparent that any trigger should be set up primarily to track providers' needs.

A tracking mechanism could be utilized and reported weekly to CMS Central Office indicating the number and nature of inquiries for flexibilities.

For example, CMS Regional Offices can collect information on:

- Requests by hospitals to provide screening/triage of patients at a location offsite from the hospital's campus;
- Hospitals housing patients in units not otherwise appropriate under the Medicare Conditions of Participation or for a duration that exceeds regulatory requirements;
- Hospitals or nursing homes requesting increases in their certified bed capacity.

These requests could be grouped by state and city, to allow for more accurate reporting of the impact of a public health emergency. The benefit of a reporting system to the CMS Regional Offices is that information and assistance may be provided on flexibilities available to providers, even without an 1135 waiver, that could assist in their emergency response. This information, in addition to the usual channels of input identified above, should allow ASPR, CMS and the relevant OPDIVs to have the information necessary to recommend whether the Secretary should invoke the 1135 Waiver Authority.

Implementation of 1135 Waiver Authority

Once an 1135 Waiver is authorized, in past emergencies, health care providers have submitted requests to operate under that authority to the State Survey Agency or CMS Regional Office. The requests generally have included a justification for the waiver and expected duration of the modification requested. Providers and suppliers have been asked to keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. The State Survey Agency and CMS Regional Office has reviewed the provider's request and make appropriate decisions, usually on a case-by-case basis. CMS has approved specific waivers and modifications only to the extent that the provider in question has been affected by the disaster or emergency. . Providers are expected to come into compliance with any waived requirements prior to the end 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.

Blanket Waiver Modifications

CMS has, in past disasters, implemented specific waivers or modifications under the 1135 authority on a "blanket" basis, when a determination has been made that all similarly situated providers in the emergency area needed such a waiver or modification. Examples include hospitals that have initiated their disaster plans and are operating under the Emergency Medical Treatment and Labor Act (EMTALA) waiver, the 25-bed limit and 96-hour annual average per patient length of stay requirement for Critical Access Hospitals, and requests for increases in the number of certified beds for providers. While blanket authority for these modifications may be allowed, the provider should still notify the State Survey Agency and CMS Regional Office if operating under these modifications to ensure proper payment. Similarly, most reporting requirements (such as nursing homes providing Minimum Data Set updates on residents) are suspended for all providers in the impacted areas in accordance with the Waiver authority.

The decision to implement a “blanket” waiver or modification of a particular Medicare, Medicaid or CHIP requirement is based on the need and frequency of requests for specific waivers or modifications in response to the disaster or emergency. Using the Waiver Tracking form (example attached), CMS Regional Offices can quickly determine when blanket authority provides greater efficacy and efficiency in responding to the disaster. Factors considered include the scope and severity of the emergency, the expected duration, feedback from the state survey agency and state and federal emergency response officials (who often have personnel able to provide first-hand information), as well as supporting data gathered by state provider associations.