

# PUBLICATION

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## What Hospitals Need to Know About the Natural Disaster Exception to Stark Law

September 18, 2017

Hospitals operating in regions affected by the recent hurricanes and other natural disasters may be able to obtain temporary regulatory relief. During times of disasters and emergencies, CMS can provide some flexibility related to the Stark Law in order to ensure that sufficient health services are available to meet the needs of Medicare beneficiaries. Section 1135 of the Social Security Act authorizes the Secretary of the Department of Health and Human Services to waive or modify certain Medicare, Medicaid, CHIP and HIPAA requirements. Specifically, the Secretary is authorized to waive the imposition of the Stark Law self-referral sanctions.

### Section 1135 Waivers

Before a waiver can be issued, the President must declare an emergency or disaster under either the Stafford Act or the National Emergencies Act and the Secretary must have declared a Public Health Emergency under Section 319 of the Public Health Service Act. Once this has occurred, the Secretary can implement waivers that address federal requirements, ensuring that health care providers who provide services can be reimbursed for them, absent any fraud or abuse, without concern of sanctions for noncompliance.

In response to the hurricanes that have caused substantial damage and disruption to large regions of the country, CMS issued a document addressing [Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a § 1135 Waiver](#). (Question and Answer Document). This document continues to be updated by CMS to include the geographic areas subject to the waivers, and it includes deadlines that have been extended as a result of Hurricanes Harvey and Irma, as well as helpful Questions and Answers on the flexibilities and waivers that can be modified under § 1135.

For the specific geographic area(s) and time periods provided for in the emergency declarations, the Secretary may authorize waivers or modifications of one or more of the requirements listed in § 1135(b). Typically it is the Administrator of CMS who determines if a waiver is needed and the extent to which requirements will be waived or modified for a particular provider or supplier, or for a group or class of providers, or to a geographic area. Beyond the Stark Law sanctions, the federal requirements that can be waived under § 1135 include:

- Conditions of participation or other certification requirements for an individual health care provider or types of providers;
- Program participation and similar requirements for an individual health care provider or types of providers; and
- Pre-approval requirements.
- Requirements that physicians and other health professional be licensed in the state in which they provide services, if they provide equivalent services in another state and are not affirmatively excluded from practice in that state or in any state a part of which is included in the emergency area.
- Actions under EMTALA rules (per § 1867 of the Act) regarding:
  - The transfer of an individual who has not been stabilized (if the transfer arises out of the circumstances of the emergency); and
  - The direction or relocation of an individual to receive medical screening at an alternative location in accordance with an appropriate (and applicable) State preparedness plan.

- Deadlines and timetables for performance of required activities (may be modified but not waived).
- Limitations on the ability to make direct payments to providers for services provided to Medicare Advantage enrollees.
- Sanctions and penalties for noncompliance with certain patient privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Note that HIPAA and EMTALA waivers are subject to special time limitations. In addition to these § 1135-based waivers or modifications, in situations where the use of § 1135 authority is appropriate, CMS may consider exercising authority under § 1812(f) to waive the three-day prior hospital stay requirement for coverage of a SNF stay.

### **Stark Law Waiver**

In order to receive a waiver of Stark Law sanctions under § 1135, an individual request must be made to CMS. The Question and Answer document from CMS details the process to follow. Once the § 1135 waiver authority has been invoked by the Secretary, a health care provider can submit requests for such waiver by sending an email to the CMS Regional Office in its service area, or by calling the State or CMS Regional Office. The applicable Regional Office emails are included in the Question and Answer document. The request should include the provider name and type; full address, Medicare provider number; and a contact person and his or her contact information. The substance of the request should focus on describing why the waiver is needed and the type of relief being sought. Additionally, for a Stark Law waiver, the request should include safeguards put in place to ensure CMS that the arrangement addresses a current need and that the request is not simply an attempt to skirt the regulatory restrictions.

Once a waiver is granted, the impact is prospective and does not apply retroactively to any arrangements in place before the waiver was approved unless specifically noted by CMS. The waiver is in place for either 60 days or the length of the emergency period. Providers must resume compliance with normal Medicare rules and regulations as soon as they are able to do so.

In past declarations of emergencies, such as Hurricane Katrina, Stark Law waivers were granted on a case-by-case basis. CMS worked quickly to review the requests and issue the waivers as deemed appropriate so that the proposed arrangements could be put in place to provide the needed health care services. CMS will likely work with the same urgency to grant needed waivers in the current geographic areas subject to these emergency declarations.