

DATE: September 30, 2020

TO: Paul Ray
Administrator, OIRA

FROM: Lee Fleisher, MD
Director, CCSQ

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for 1135 Waiver Web Form

Emergency Justification

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 temporarily waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP) and Health Insurance Portability and Accountability Act (HIPAA) requirements. This will ensure that sufficient health care services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods, and to reimburse and exempt from sanctions providers who provide such services in good faith.

During emergencies, such as the current COVID-19 public health emergency (PHE), CMS must be able to apply program waivers and flexibilities under section 1135 of the Social Security Act, in a timely manner, to respond quickly to unfolding events. When there is a disaster or emergency, waivers and flexibilities assist health care providers to give timely healthcare services to people who have been affected by the emergency event or disaster and enable states, Federal districts, and U.S. territories to ensure Medicare and/or Medicaid beneficiaries have continued access to care. During disasters and emergencies, it is not uncommon to evacuate provider facilities and relocate patients to other provider settings or across state lines, especially, during hurricane and tornado events. The waivers and flexibilities allow the Agency to relax certain Conditions of Participation and Conditions of Coverage to promote the health and safety of Medicare and Medicaid covered persons. The statutory authority that allows for the implementation of waivers and flexibilities are Section 1812(f) of the Social Security Act, Section 1135 of the Social Security Act and Section 319 of the Public Health Service Act.

Background

Prior to the COVID-19 PHE, CMS Central and Regional offices executed manual processes using Excel spreadsheets, Word documents, Access databases, and Outlook email to monitor, track, respond and report on the volume and specifics of waiver and flexibilities requests. CMS did not have a standard process or an OMB approved form for impacted providers/suppliers to request 1135 waivers and flexibilities, as these requests were generally seen on a smaller scale (natural disasters) prior to the

COVID-19 PHE. CMS has provided general guidance to Medicare-participating facilities which can be viewed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>. The requests would be sent directly from the facility to the CMS locations within the Survey Operations Group (previously known as CMS Locations) and the facility would explain the situation which is causing them to request CMS for a waiver.

Additionally, we would like to clarify that the collection of the information surrounding 1135 Waiver requests are based on a case-by-case basis and not a regularly scheduled collection (e.g. quarterly, annually, by all providers/suppliers). The collection of information only occurs when facilities, impacted by an emergency, are requesting flexibilities under Section 1135 of the Act. The collection of information is also dependent on provider types: therefore, it is not a collection for all Medicare-participating facilities.

The COVID-19 PHE presented a new challenge as Medicare and Medicaid providers continue to be impacted on a 24-hour basis throughout the duration of the PHE. The magnitude and continued volume of 1135 waiver requests by Medicare-participating providers and suppliers is ongoing to date. The influx of COVID-19 related 1135 waiver submissions has expedited the need for a long-term information technology (IT) solution to support these requests, maintain a repository for tracking purposes, improve data quality and automate the process, where possible, to improve program efficiencies and CMS/HHS responsiveness.

We are now developing a streamlined process and public facing web form to standardize the 1135 waiver requests submitted based on lessons learned during COVID-19 PHE, primarily based on the volume of requests to ensure timely response to facility needs. The burden for this process is primarily cost impact for Federal government (development/implementation) but minimal to no cost for provider/supplier requests. The burden for providers is substantially reduced by the implementation of this automated process. The form requires the facilities to follow a standard process for requesting waivers and does not duplicate existing data collection.

Timeline

September 30, 2020

- Emergency Information Collection Request formally submitted to OMB.

October 2, 2020

- OMB approval of processing as an Emergency package.

October 9, 2020

- Formal submittal to OMB.

October 14, 2020

- OMB approval received (OMB control number issued).