

Supporting Statement Part A
Submissions of 1135 Waiver Request Automated Process (CMS-10752)

A. Background

Waivers under Section 1135 of the Social Security Act (the Act) and certain flexibilities allow the CMS to relax certain requirements, known as the Conditions of Participation (CoPs) or Conditions of Coverage to promote the health and safety of beneficiaries. Under Section 1135 of the 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 services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. These waivers ensure that providers who provide such services in good faith can be reimbursed and exempted from sanctions.

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. In a disaster or emergency, waivers and flexibilities assist health care providers/suppliers in providing timely healthcare and services to people who have been affected and enables 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 Medicare-participating facilities and relocate patients/residents to other provider settings or across state lines, especially, during hurricane and tornado events. CMS must collect relevant information for which a provider is requesting a waiver or flexibility to make proper decisions about approving or denying such requests. Collection of this data aids in the prevention of gaps in access to care and services before, during, and after an emergency. CMS must also respond to inquiries related to a PHE from providers and beneficiaries. CMS is not collecting information from these inquiries; we are merely responding to them.

Prior to this request, CMS did not have a standard process or OMB approval for providers/suppliers impacted to submit 1135 waiver/flexibility requests or inquiries, as these were generally seen on a smaller scale (natural disasters) prior to the COVID-19 public health emergency. 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 and inquiries would be sent directly, via e-mail, to the Survey Operations Group in each CMS Location (previously known as CMS Regional Offices) and the entity would provide a brief summary to CMS for a waiver/flexibility request or an answer to an inquiry.

The collection of the information surrounding 1135 Waiver requests/inquiries is based on a case-by-case basis and not regularly scheduled (e.g. quarterly, annually, by all providers/suppliers). The collection of information only occurs when the healthcare entity, impacted by an emergency, is requesting or inquiring about waivers/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.

We are now developing a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during COVID-19 PHE, primarily based on the

volume of requests to ensure timely response to facility needs.

We are requesting emergency approval for the 1135 web tool for four months. We will also publish a 60-day notice to begin the transition of this collection to be a standard collection.

B. Justification

1. Need and Legal Basis

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, CHIP and Health Insurance Portability and Accountability Act (HIPAA) requirements. Waiving such requirements ensures 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.

The statutory authorities that allow 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. Prior to the COVID-19 PHE, CMS Central and Regional offices executed manual processes using Excel spreadsheets, Access databases, Word documents and Outlook email to monitor, track, respond and report on the volume and specifics of requests and inquiries. However, the COVID-19 PHE presented a new challenge as Medicare and Medicaid providers/suppliers have continued to be impacted on a 24-hour basis throughout the duration of the PHE. While the COVID-19 PHE highlighted challenges due to the volume, CMS acknowledges that a streamlined process will assist in all public health emergencies, such as during hurricanes, wildfires, tornados, active shooters, and other emergencies seen even throughout the existing COVID-19 PHE.

The magnitude and continued volume of 1135 requests and inquiries by CMS-participating providers and suppliers is ongoing to date. The influx of COVID-19 related 1135 submissions, now compiled with wildfire and hurricane requests, has expedited the need for a long-term information technology (IT) solution to support the incoming requests/inquiries, maintain a repository for tracking purposes, improve data quality and automate the process, where possible, to improve program efficiencies and CMS/HHS responsiveness.

2. Information Users

This information will be used by CMS to receive, triage, respond to and report on requests and/or inquiries for Medicare, Medicaid, and CHIP beneficiaries. This information will be used to make decisions about approving or denying waiver and flexibility requests and may be used to identify trends that inform CMS Conditions for Coverage or Conditions for Participation policies during public health emergencies, when declared by the President and the HHS Secretary.

3. Use of Information Technology

This information will be collected electronically using a public-facing web form. This process would include the requesting Medicare-participating provider/supplier or association or State/local government submitting on behalf of a provider/supplier.

CMS is proposing the creation of a public facing web form to support nationwide submission of 1135 waiver requests and inquiries by collecting required information from impacted Medicare/Medicaid providers, Healthcare Associations, Governors and States. Thus, creation of a standard and automated 1135 process by utilizing a publicly accessible web form will enable standardized, user-friendly submission by requesters and more efficient processing for all impacted components within CMS.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

These requirements do affect small businesses, however, the information collection is only collected if requested during an emergency event, which has been declared a public health emergency by the President and HHS Secretary and if an 1135 Waiver request or inquiry is submitted by the Medicare-participating provider, or on behalf of a provider. These paperwork requirements are minimal and are necessary to meet the documentation and disclosure requirements of the law.

Offering an automated process minimizes the burden on small businesses by:

- Standardizing the process so providers don't have to come up with their own form
- Decreasing the amount of time required by providers to submit their requests and/or inquiries to CMS
- Eliminating fragmented responses by CMS
- Improving the timeliness of responses to requesters
- Ensuring nationwide consistency among impacted components
- Reducing the need for CMS to request additional information, so providers do not have to resubmit requests
- 100% of this information will be used electronically

6. Less Frequent Collection

There is no schedule of collection; these waiver requests and inquiries are submitted as needed when there is a natural or man-made disaster or emergency that impacts access to care for Medicare/Medicaid/CHIP beneficiaries.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

CMS consulted with representatives from the Florida and California State Survey Agencies to solicit feedback on the data elements to be collected on the draft web form and related instructions. These users are heavily impacted by public health emergencies such as hurricanes and wildfires and submit substantially more waiver requests than other states.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

Personally identifiable information, including social security numbers (SSN), is not being collected on this web form. Information is being collected electronically in the Service Now system and is covered by that system's Privacy Impact Assessment (PIA), updates for which are expected to be completed by October 23, 2020. Information will be stored electronically in the Service Now system. PII/PHI, should it be submitted, will be identified by a CMS triage agent and will follow the current CMS processes and procedures for reporting PII incidents. This includes opening a security incident, investigation, and remediation. Data collected via the automated process will be retained for seven years, as approved by the National Archives and Records Administration Records Schedule DM-0440-2015-0008. The data will reside in the ServiceNow system. The confidentiality, integrity, and availability of information being processed is protected by a wide variety of organizational, process, and technical controls to ensure professionalism and trustworthiness. Such safeguards include communication protocols, software to facilitate incident analysis and mitigation practices as well as other incident analysis resources.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
------------------	-----------------	--------------------------	--------------------------------------	------------------------------

Blended Occupations – Waiver Requests	See table below	54.81	54.81	109.62
Blended Occupations - Inquiries	See table below	51.56	51.56	103.12

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

In calendar year 2020 to date, CMS has received over 3,000 individual 1135 Waiver Requests. We anticipate that it would generally take 45 minutes per entity to submit the waiver request to CMS. It would also take 15 minutes to consult with the the provider/supplier’s administrator, CEO or other top executive. This would be a total of 60 minutes. The total burden hours would be 3,000(1 hour X 3,000 waivers).

The total cost would be \$328,860 (3,000 hours X 109.62)

Blended Occupations	BLS Occupation Code	Mean hourly wage	Fringe Benefits
Nursing Home Administrator	43-1011	\$28.91	\$28.91
General Physician	29-1216	\$96.85	\$96.85
Hospital Administrator	11*9111	\$55.37	\$55.37
CEO	11-1011	\$93.20	\$93.20
Rehabilitation Therapist	21-1015	\$19.31	\$19.31
Administrator	43-1011	\$28.91	\$28.91
State Agency Director	11-1000	\$61.09	\$61.09
Total Mean Hourly Wage		\$383.64	\$383.64
Average Hourly Wage		\$54.81	\$54.81

\$54.81 average hourly wage
 \$54.81 increased by a factor of 100 percent
\$109.62 Average Hourly wage used in PRA package
 Number of unique respondents: 3,000

In calendar year 2020 to date, CMS has received about 139 individual Inquiries. We anticipate that it would generally take 60 minutes per entity to submit an inquiry to CMS. This would be a total

of 60 minutes. The total burden hours would be 139 (1 hour X 139 inquiries).

The total cost would be \$14,334 (139 hours X 103.12).

Blended Occupations	BLS Occupation Code	Mean hourly wage	Fringe Benefits
Nursing Home Administrator	43-1011	\$28.91	\$28.91
General Physician	29-1216	\$96.85	\$96.85
Hospital Administrator	11*9111	\$55.37	\$55.37
Administrator	43-1011	\$28.91	\$28.91
State Agency Director	11-1000	\$61.09	\$61.09
Medicare/Medicaid Beneficiary*	Civilian Workers	\$38.20	\$38.20
Total Mean Hourly Wage		\$309.33	\$309.33
Average Hourly Wage		\$51.56	\$51.56

* We used data from the U.S. Bureau of Labor Statistics' 2019 National Occupational Employment and Wage Estimates for all salary estimates except Medicare/Medicaid Beneficiaries, for whom we used at <https://www.bls.gov/news.release/ecec.t02.htm>.

We estimate the total cost for healthcare entities to submit waiver requests or inquiries to be \$343,194.

13. Capital Costs

Although there are no capital costs associated with this collection, this public-facing web form provides an automated mechanism for submitting waiver requests.

14. Cost to Federal Government

Development of the public facing web form requires a contract with an application development organization and the purchase of user licenses for CMS users. The total estimated annualized cost is \$1,616,528.08.

	Development Contract	User Licenses
Annual Cost	\$1,588,111.00	\$28,417.08
Total Annual Cost	\$1,616,528.08	

The CMS Locations (formerly known as Regional Offices) are responsible for responding to 1135 waiver requests and inquiries. We estimate that it would take 30 minutes of time by a Regional Office (RO) reviewer to review and determine if the 1135 waiver request and/or inquiry has sufficient information to make a determination.

We estimate that the cost associated with reviewing each web form by the CMS Location would

be \$25.67. We note, these are not reoccurring submissions and are only submitted during emergency events.

These costs were calculated using the annual salary of a GS-13, step 5 reviewer in the Pennsylvania CMS Location, which is \$108,899, and which equates to an average hourly salary of \$52.18. It takes the CMS Location 30 min to review at a rate of \$26.09 (.5 x \$52.18 per hour). The total cost is \$81,897 (\$26.09 X 3,139 forms).

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

There will be no publication.

17. Expiration Date

CMS will display the expiration date on the collection instrument.

18. Certification Statement

There are no exceptions.