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

A. Background

This is a revision of an information collection request approved under Office of Management and Budget (OMB) control number of 0938-1384 with an expiration date of May 31, 2024.

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 healthcare entities/caregivers who provide such services in good faith can be reimbursed and exempted from sanctions.

During emergencies, 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 patients in health care facilities to other provider settings or across state lines, especially, during hurricane, wildfire, 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 Public Health Emergency (PHE) from providers. CMS is not collecting information from these inquiries; we are merely responding to them.

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 waivers/flexibilities under Section 1135 of the Act or inquiring about PHEs. The collection of information is also dependent on provider types; therefore, it is not a collection for all Medicare-participating facilities.

In 2021, we implemented a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during the COVID-19 PHE.

Furthermore, the normal operations of a healthcare provider are disrupted by emergencies or disasters occasionally. When this occurs, State Survey Agencies (SA) deliver a provider/beneficiary tracking report regarding the current status of all affected healthcare providers and their beneficiaries. This report includes demographic information about the beneficiary status, provider, their operational status, anticipated needs and planned resumption of normal operations. This information is provided whether or not a PHE has been declared.

We are revising this information collection   streamlined automated process to update for clarity during emergencies. To quickly identify patient risks/needs, CMS added fields to assess sufficient staffing, equipment and supplies as well as added an assessment of a cyber security attack on the care and services provided to patients (if applicable). Furthermore, to decrease the time/effort of stakeholders (State Survey Agencies (SAs)/Providers) submitting this data during emergencies, CMS also added a feature to autofill multiple fields when the stakeholder documents a valid CMS Certification Number (CCN).   This streamlined automated process will consist of a public facing web form as well as a process for SAs/Providers to submit data using extracts (CSV or Excel) on emergent events impacting Health Care Facilities via automated mail handler system. Both processes (public facing web form and extracts via an automated mail handler system) are known as the Health Care Facility (HCF) Operational Status.

Acute Hospital Care at Home

Acute Hospital Care at Home is a waiver initiative established by CMS on November 23, 2020 in response to the unprecedented strain on hospital capacity due to the severe national increase in coronavirus disease 2019 (COVID-19) witnessed. This waiver, which is granted at the individual hospital/CMS Certification Number (CCN) level, waives **§482.23(b)** and **(b)(1)** of the Hospital Conditions of Participation (CoPs) which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient. In exchange for this flexibility, hospitals will utilize models of at-home hospital care that have seen prior success in several leading hospital institutions and networks. This care and its results have been reported in leading academic journals, including a major study funded by a Healthcare Innovation Award from the Center for Medicare and Medicaid Innovation (CMMI). This extensive research has shown that quality and safety are at least as high as that received by similar patients admitted to traditional brick and mortar hospitals.

This program clearly differentiates the delivery of acute hospital care at home from traditional home health services. Home health care provides important skilled nursing and other services, Acute Hospital Care at Home is for beneficiaries who require acute inpatient admission to a hospital and who require at least daily rounding by a physician and medical team monitoring their care needs on an ongoing basis. A minimum of two in-person visits will occur daily by either registered nurses or mobile integrated health paramedics, based on the patient's nursing plan and hospital policies. Hospitals may only treat patients with this waiver if they are admitted from their Emergency Department or if they are transferred from inpatient hospital beds. There is no payment change, and hospitals are not permitted to bill Medicare or its beneficiaries for any costs outside of a typical inpatient admission.

CMS is seeking to obtain continued OMB approval for information. All approved hospitals have submitted this information via an online portal at () the previously mentioned website. To date, 331 hospitals individual hospitals/CCNs have submitted waiver requests and 295 of these hospitals have been approved. At this time, 65 hospitals have completed the online expedited waiver request and 286 hospitals have completed the online detailed waiver request.   When a hospital submits a waiver request, it completes one of two online forms found on the waiver landing page, depending on its level of experience with this type of care. Experienced hospitals, defined as treating at least 25 patients with acute hospital care at home previously, have an expedited submission that is based on a series of attestations, seen in the screenshot attachment. Additionally, all hospitals with an approved waiver are asked to submit data for patient admissions and discharges, escalations of care back to the brick-and-mortar hospital, and unexpected patient mortalities to CMS on a monthly (Tier 1) or weekly (Tier 2)[1]. This data is submitted voluntarily through the same online portal as the waiver submission and is not a requirement of ongoing participation in the Waiver. Of note, without further Congressional action, this waiver submission process will end December 31, 2024. The elements of the additional data submission requirements can be found in the attachments.

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 Health and Human Services (HHS) Secretary declares a PHE 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 healthcare entities/caregivers 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 Locations (formerly known as 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 were impacted on a 24-hour basis throughout the duration of the PHE. CMS acknowledges that the streamlined process implemented since 2021 continues to assist in all PHEs (e.g., hurricanes, wildfires, tornados and other emergencies).

The magnitude of 1135 requests and PHE-related inquiries by CMS-participating providers and suppliers is ongoing to date. This long-term information technology (IT) solution supports incoming requests/inquiries, maintains a repository for tracking purposes, improves data quality and automates the process, where possible, to improve program efficiencies and CMS/HHS responsiveness.

1 Tier 1 hospitals have provided hospital at home care to at least 25 inpatients prior to waiver approval and Tier 2 hospitals have provided inpatient care to less than 25 patients in the home prior to waiver approval. The difference in reporting requirements is based on the hospital’s experience. This was used as method to expedite more experienced hospitals during the PHE.

During disasters and emergencies, it is not uncommon to evacuate patients/residents/clients in health care facilities to other provider settings or across state lines, especially during hurricane, wildfire, and tornado events. When healthcare providers cannot operate normally, CMS must understand how and where they are operating. Providers coordinate with their SAs to provide this information to CMS, and each State determines the format and media in which the information is provided. This results in the need for CMS to gather and organize the information, standardize the format and media for efficient planning and coordination across HHS. Standardizing the reporting of operational status information improves efficiency and prevents gaps in access to care as well as accelerates CMS' response to the identified needs of beneficiaries and providers.

2. Information Users

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

Operational status information will be used to assist providers in delivering critical care to beneficiaries during emergencies.

3. Use of Information Technology

This information is collected electronically using public facing web forms. This process includes requests from Medicare-participating provider/suppliers, associations, corporations, or State/local governments submitting on behalf of a provider/supplier.

CMS created 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 this standard and automated 1135 process by utilizing a publicly accessible web form enabled a standardized, user-friendly submission by requesters and more efficient processing for all impacted components within CMS.

CMS created a second public facing web form to support nationwide reporting about the operational status of healthcare providers and their beneficiaries impacted by emergencies and disasters. CMS is enhancing this process by utilizing the publicly accessible web form as well as an alternate process to obtain this data using extracts (single event or bulk) sent from States/Providers/Suppliers impacted by the emergent event via an automated mail handler system. Standardized collection of this data helps CMS to prevent gaps in access to care and services before, during and after an emergency/disaster. Enhancements to both processes (public facing web form and extracts submitted using an automated mail handler system) includes, buts not limited to, the ability to prepopulate general Health Care Facility (HCF) information (e.g., HCF name, HCF address (street, City, State, zip code), number of beds/stations (if applicable), etc.) if a valid CCN is provided, the ability to assess if assistance is needed with patient care by requiring census and existence of sufficient staffing, the creation of fields to capture common data (e.g., receiving location of evacuated patients {other HCFs, families, etc.}, supply/equipment concerns, cyber security issues, etc.) to decrease the size of the narrative statements, etc. These enhancements to this Health Care Facility (HCF) Operational Status report assist CMS to quickly identify patient risks/needs and decrease the time/effort of stakeholders (States/Providers) submitting data during emergencies.

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 and if an 1135 Waiver request or PHE-related inquiry is submitted. Additionally, operational status information is only necessary if a healthcare provider is or anticipates being unable to function normally. These paperwork requirements are minimal and are necessary to meet the documentation and disclosure requirements of the law.

An automated process minimizes the burden on small businesses by:
- Standardizing the process so providers don’t have to design their own form
- Decreasing the amount of time required by providers to submit their requests, inquiries, or operational status to CMS
- Eliminating fragmented responses by CMS
- Improving the timeliness of responses to healthcare entities
- Ensuring nationwide consistency among impacted components
- Reducing the need for CMS to request additional information, so providers do not have to resubmit information
- 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 emergency/disaster that impacts access to care for Medicare/Medicaid/CHIP beneficiaries. The HCF status is reported only when a facility is not in or anticipates not being in a normal operational status.

For Acute Hospital Care at Home, each hospital will submit a waiver request at the time of requesting approval. This is only a one-time collection. Once a waiver request is approved, Tier 1 hospitals report every month and Tier 2 hospitals on a weekly basis to collect data to monitor the progress of the initiative to be included in a study to Congress, as required under the CAA, 2023.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on March 25, 2024 (89 FR 20658). There were no public comments received.

The 30-day Federal Register notice published on May 31, 2024 (89 FR 47153).

In addition, CMS consulted with several SAs (A SA representative from Alabama, California, Florida, Louisiana, South Carolina and Texas) and Health Care Facilities (A Health Care provider from Georgia, Hawaii, North Carolina and Oklahoma) via a Human Centered Design (HCD) approach on the enhancements reflected to the HCF Workflow Status.

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 these web forms. Information is being collected electronically in the ServiceNow system and is covered by that system's Privacy Impact Assessment (PIA) with an approval date of April 12, 2022. Information is stored electronically in the ServiceNow system. Personal Identifiable Information/Personal Health Information (PII/PHI), if 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 is retained for seven years, as approved by the National Archives and Records Administration Records Schedule DM-0440-2015-0008. The data resides 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' 2022

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 2 below	$63.00	$63.00	$126.00
Blended Occupations - Inquiries	See Table 3 below	$60.08	$60.08	$120.16
Blended Occupations – Operational Status	See Table 4 below	$43.35	$43.35	$86.70

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 2023 to date, CMS has received over 11,214 Waiver Requests (11,183 Waiver Requests from non-State Medicaid Agencies (SMAs) and 31 Waiver Requests from SMAs). It takes 15 minutes per entity to submit the waiver request to CMS. It also takes 15 minutes to consult with the provider/supplier's administrator, Chief Executive Officer (CEO) or another top executive. This would be a total of 30 minutes. The total annual burden hours would be 5,607 (0.5 hour X 11,214 waivers).

The total annual cost would be $706,482.00 (5,607 hours X $126.00)

Table 2: Blended Occupations	**BLS Occupation Code**	**Mean hourly wage**	**Fringe Benefits**
Nursing Home Administrator	43-1011	$31.49	$31.49
General Physician	29-1216	$108.30	$108.30

Hospital Administrator	11*9111	$67.06	$67.06
CEO	11-1011	$118.48	$118.48
Rehabilitation Therapist	21-1015	$22.13	$22.13
Administrator	43-1011	$31.49	$31.49
State Agency Director	11-1000	$62.04	$62.04
Total Mean Hourly Wage		$440.99	$440.99
Average Hourly Wage		**$63.00**	**$63.00**

$63.00	average hourly wage
$63.00 +	increased by a factor of 100 percent
= $126.00	Average Hourly wage used in PRA package
Number of unique respondents:	493

In calendar year 2023 to date, CMS has received about 154 individual Inquiries. We anticipate that it would generally take 30 minutes per entity to submit an inquiry to CMS. This would be a total of 30 minutes. The total annual burden hours would be 77 (0.5 hour X 154 inquiries).

The total annual cost would be $9,252.32 (77 hours X 120.16).

Table 3: Blended Occupations	**BLS Occupation Code**	**Mean hourly wage**	**Fringe Benefits**
Nursing Home Administrator	43-1011	$31.49	$31.49
General Physician	29-1216	$108.30	$108.30
Hospital Administrator	11*9111	$67.06	$67.06
Administrator	43-1011	$31.49	$31.49
State Agency Director	11-1000	$62.04	$62.04
Total Mean Hourly Wage		$300.38	$300.38
Average Hourly Wage		**$60.08**	**$60.08**

* We used data from the U.S. Bureau of Labor Statistics' 2022 National Occupational Employment and Wage Estimates for all salary estimates.

$60.08	average hourly wage
$60.08 +	increased by a factor of 100 percent
= $120.16	Average Hourly wage used in PRA package
Number of unique respondents:	154

During calendar year 2023, CMS received about 1,015 Health Care Facility (HCF) operational status reports. We estimate that it would take about 60 minutes to submit this information to CMS. The total burden annual hours would be 1,015 (1 hour x 1,015 reports).

The total annual cost would be $88,000.50 (1,015 x $86.70).

Table 4: Blended Occupations	**BLS Occupation Code**	**Mean hourly wage**	**Fringe Benefits**
Nursing Home Administrator	43-1011	$31.49	$31.49
Hospital Administrator	11*9111	$67.06	$67.06
Administrator	43-1011	$31.49	$31.49
Total Mean Hourly Wage		$130.04	$130.04
Average Hourly Wage		**$43.35**	**$43.35**

$**43.35**	average hourly wage
$**43.35** +	increased by a factor of 100 percent
= $86.70	Average Hourly wage used in PRA package
Number of unique respondents:	1,015

We estimate the total annual hours to be 6,699 and cost of all data types to be $803,734.82.

Data Type	2023 Responses	Annual Total Burden Hours requested	Estimated Annual Cost
1135 Waiver Requests	11,214	5,607	$706,482.00
Inquiries	154	77	$9,252.32
Health Care Facility (HCF) Operational Status	1,015	1,015	$88,000.50
Totals	12,383	6,699	$803,734.82

Time Burden for Acute Hospital Care at Home Waiver Requests

We estimate the total annual hours to be 103.75 and a cost of all data submissions to be $8585.58.

Description	Tier 1	Tier 2	Annual Total
Number of expected waiver respondents per year	17	66	83
Number of expected one time waiver submission & phone calls per respondent per year	2.0	2.0	2.0
Number of expected total measures (responses) per respondent per year	1	1	1
Time Burden Estimates (hours) (Total Respondents) x (Total Response/Respondent) x (75 minutes/Response) x (1 hour/60 minutes) =	**21.25**	**82.5**	**104**
Cost Burden Estimates Total Cost = (Total Respondents) x (Total Response/Respondent) x (75 minutes/Response) x (1 hour/60 minutes) x ($Average salary/hour)	**$ 1,752.93**	**$ 6,832.65**	**$ 8,585.58**

Assumptions: This model assumes that there is an average rate of waiver submissions is 83 requests per year, with 17 Tier 1 and 66 Tier 2. Both Tier 1 and Tier 2 hospitals are required to conduct a phone call with CMS when requesting a waiver as well as submit the waiver request through the portal. The purpose of the call is to verify the process outlined in the submission as well as resolve any questions that may arise. The time it takes to have a phone call to review the waiver and the time to submit the waiver through the portal is approximately 75 minutes. The hourly rate average is $82.82 per hour.

Cost Burden for Acute Hospital Care at Home Waiver Requests

Respondent	BLS Occupation Labor Code	Total Response Time by Hour for Tier 1 Waiver Submission & Phone Call	Total Response Time by Hour for Tier 2 Waiver Submission & Phone Call	Median Hourly Wage	Doubled Hourly Wage + Fringe Benefits and Overhead

Medical and Health Services Managers	11-9111	1.25	1.25	$61.53	$123.06
Registered Nurses	29-1141	1.25	1.25	$41.80	$83.60
Miscellaneous Healthcare Support Occupations	31-9090	1.25	1.25	$20.91	$41.82
Average		1.25	1.25	41.41	82.82
		1.25			

This is the estimate of burden for the data submission requirements for all hospitals that have an approved waiver. Once a waiver request is approved, Tier 1 hospitals are expected to submit data to CMS on a monthly basis and Tier 2 hospitals are expected to submit data to CMS on a weekly basis through the online portal. This data is a voluntary submission, but to date the data submission rate is 100%. Please see the data submission elements in the attachment

Time Burden for Acute Hospital Care at Home Waiver Requests Data Submissions

We estimate the total annual hours to be 1521 and the cost to be $125,969.22

Description	Tier 1	Tier 2	Total
Number of expected waiver respondents per year	82	332	413
Number of expected total measures (responses) per respondent per year	12	52	64
Time Burden Estimates (hours) (Total Respondents) x (Total Response/Respondent) x (5 minutes/Response) x (1 hour/60 minutes) =	82	1439	1521
Cost Burden Estimates Total Cost = (Total Respondents) x (Total Response/Respondent) x (5 minutes/Response) x (1 hour/60 minutes) x ($Average salary/hour)	$6,791.24	$119,177.98	$125,969.22

Assumptions: This model assumes that each hospital with an approved waiver (331) would provide the data measures either weekly or monthly depending on the Tier and the anticipated average of 83 additional waivers each year (17 Tier 1 and 66 Tier 2). For Tier 1 hospitals, the data measures are collected once monthly. For Tier 2 hospitals, data is submitted once weekly. The salary factor is $82.82/ hr because the same staff submitting the waiver request are submitting the data submissions.

The total annual burden hours are 8,324 (5,607 [1135 waivers] + 77 [inquiries] + 1,015 [HCF] + 104 [AHCAH waivers] + 1521 [AHCAH data submissions].

13. Capital Costs

Although there are no capital costs associated with this collection, these public-facing web forms provide an automated mechanism for submitting waiver requests, inquiries and operational status.

14. Cost to Federal Government

Implementation of the public facing web form required a contract with an application development organization and the purchase of user licenses for CMS users. The total annual cost is $710,703.56.

	Development Contract	**User Licenses**
Annual Cost	$640,913.60	$69,789.96
Total Annual Cost	$710,704	

The CMS Locations are responsible for responding to 1135 waiver requests and inquiries. We estimate that it would take 30 minutes of time by a CMS Location 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 $30.41. 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 $126,949, and which equates to an average hourly salary of $60.83. It takes the CMS Location 30 min to review at a rate of $30.41 (.5 x $60.83 per hour). The total annual cost is $376,567.03 ($30.41 x 12,383 forms).

The total annual cost to the government is $1,087,271.

15. Changes to Burden

The annual burden hours have increased from 5,629 to 8,324 due to the increase number of waiver submissions and the addition of the data submission. The wage rates have been updated to year 2023. The annual cost has changed from $81,897 to $502,536.25.

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.