A. Background

This is a revision of an Emergency information collection request approved under OMB control number of 0938-1384 on October 15, 2020.

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.

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 provider, their operational status, beneficiary status, and planned resumption of normal operations. This information is provided whether or not a PHE has been declared.

We are now developing a streamlined, automated process to standardize submission of this information directly by the provider during emergencies and eliminating the need for SA to provide it. It will consist of a public facing web form, Healthcare Facility Status Workflow.

Violation Remediation

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 OMB approval for information that was collected prior to OMB approval. The expedited forms were filled out by the initial 8 hospitals (in 6 health systems) and manually entered into the CMS system prior to the online portal going live at the launch of the waiver. Other than those 8 experienced hospitals, all approved hospitals have submitted this

information via an online portal at (https://qualitynet.cms.gov/acute-hospital-care-at-home) the previously mentioned website. To date, 105 hospitals individual hospitals/CCNs have submitted waiver requests and 97 of these hospitals have been approved. In addition to the initial 8 hospitals, 27 hospitals have completed the online expedited waiver request and 61 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.

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.

During disasters and emergencies, it is not uncommon to evacuate provider Medicare-participating facilities and relocate patients/residents to other provider settings or across state lines, especially during hurricane 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, and deliver it to the Office of the Administrator. This is time consuming and delays CMS' ability to meet the needs communicated in the report.

Standardizing reporting of operational status information improves efficiency and accelerates CMS' response to the identified needs of providers and beneficiaries and prevents gaps in access to care.

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.

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

3. Use of Information Technology

This information will be collected electronically using public-facing web forms. 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.

CMS is also proposing the creation of 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. Creation of standard and automated healthcare facility status reporting by utilizing a publicly accessible web form will enable standardized, user-friendly submission by providers and more efficient processing for all impacted components within CMS. Standardized collection of this data helps CMS to prevent gaps in access to care and services during and after an emergency.

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. 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.

Offering 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 disaster or emergency that impacts access to care for Medicare/Medicaid/CHIP beneficiaries. Healthcare provider status is reported only when a facility is not in or anticipates not being in a normal operational status.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on October 21, 2020 (85 FR 66990).
Two comments were received from a hospital association. One comment requested that we further clarify on the automated 1135 waiver request web form that health systems can submit one request form for multiple facilities by allowing for the submission of multiple organization identification numbers – such as multiple CMS Certification numbers (CCNs) – for each impacted facility in their system. While this functionality is present and available on the web form, we agree that further clarification is worthwhile. We added additional help text in support of this comment. The second comment urged CMS to ensure

that hospitals are not responding to multiple data requests during disasters or emergencies. We appreciate the commenter's concern regarding potentially duplicative data reporting requirements. CMS has a responsibility to monitor and ensure adequate access to medical and health resources during a local emergency. Each State obtains this data differently, requiring CMS to collate and normalize. Standardized submission of this information directly by the provider during emergencies allows CMS to respond more quickly and effectively when providers need it most. We urge providers to submit this data using the webform, but we do not require it.

The 30-day Federal Register notice published on February 19, 2021 (86 FR 10282).

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 1135 waiver request 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 annually. CMS also conducted user acceptance testing, resulting in enhancements to the public-facing web form that streamline the submission process and improve the flow and readability of the web form. These enhancements make the automated process easier to use for healthcare providers.

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 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 2 below	54.81	54.81	109.62
Blended Occupations - Inquiries	See Table 3 below	51.56	51.56	103.12
Blended Occupations – Operational Status	See Table 4 below	37.73	37.73	75.46

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 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)

Table 2: 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
	Average Hourly wage used in PRA
= $109.62	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).

Table 3: 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.

$51.56	average hourly wage
$51.56 +	increased by a factor of 100 percent
	Average Hourly wage used in PRA
= $103.12	package
Number of unique respondents:	139

During calendar year 2019, CMS received about 591 healthcare provider operational status

reports. We estimate that it would take about 60 minutes to submit this information to CMS. The total burden hours would be 591 (1 hour x 591 reports).

The total cost would be $44,597 (591 x 75.46).

Table 4: Blended Occupations	**BLS Occupation Code**	**Mean hourly wage**	**Fringe Benefits**
Nursing Home Administrator	43-1011	$28.91	$28.91
Hospital Administrator	11*9111	$55.37	$55.37
Administrator	43-1011	$28.91	$28.91
Total Mean Hourly Wage		$113.19	$113.19
Average Hourly Wage		**$37.73**	**$37.73**

$37.73	average hourly wage
$37.73 +	increased by a factor of 100 percent
= $75.46	Average Hourly wage used in PRA package
Number of unique respondents:	591

We estimate the total annual hours to be 3,730 and cost of all data types to be $387, 791.

Data Type	Count Estimate	Estimated Annual Cost
1135 Waiver Requests	3,000	$328,860
Inquiries	139	$14,334
Operational Status	591	$44,597
Totals	3,730	**$387,791**

Time Burden for Acute Hospital Care at Home Waiver Requests

Description	**Tier 1**	**Tier 2**	**Total**
Number of expected waiver respondents per year	70.0	124.0	N/A
Number of expected one time waiver submission & phone calls per respondent per year	1.0	1.0	N/A
Number of expected total measures (responses) per respondent per year	8.5	36.6	N/A
Time Burden Estimates (hours) EXAMPLE (500 Respondents) x (1 Response/Respondent) x (5 minutes/Response) x (1 hour/60 minutes) = 42 hours	**218.75**	**1381.71**	**1600.46**
Cost Burden Estimates EXAMPLE Total Cost = (500 Respondents) x (1 Response/Respondent) x (5 minutes/Response) x (1 hour/60 minutes) x ($118.22/hour) = $4925	**$10,325.88**	**$65,222.44**	**$75,548.32**

Assumptions: This model necessarily involves several assumptions which may change based on the duration of the public health emergency and the incidence of new COVID-19 infections during 2021. First, an assumption was made that the number of overall approvals for each Tier will double by the end of 2021. This is based on many of

the interested and innovative hospital systems that are the most likely to submit a waiver request already have within the last 2+ months. If the PHE extends until the end of 2021 and this is signaled publicly by CMS, it may spur more systems to submit a waiver request, but it was more reasonable to expect slower uptake for the rest of the year than to assume a linear growth estimate from the beginning of the waiver. Second, it was assumed that of the hospitals that join after the date of this analysis, the growth will be evenly distributed across the remaining ~10 months of the year. Thus, for monitoring metrics, the assumption was made that the 50% of end-of-2021 hospitals that are currently approved will report for 12 months, and the 50% of yet to be approved hospitals will report for an average of 5 (of the remaining 10) months of the year. This led to an average of 8.5 monthly reports per Tier 1 hospital and 36.6 weekly reports per Tier 2 hospital.

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	Total Response Time by Hour for Measures Submission	Median Hourly Wage	Doubled Hourly Wage + Fringe Benefits and Overhead
Medical and Health Services Managers	11-9111	1	2	0.25	$48.55	$97.10
Health Technologist and Technicians	29-2000	1	2	0.25	$21.34	$42.68
Nursing Assistants	31-1131	1	2	0.25	$14.26	$28.52
Miscellaneous Healthcare Support Occupations	31-9090	1	2	0.25	$17.13	$34.26
Medical Assistant	31-9092	1	2	0.25	$16.73	$33.46
Average		**1**	**2**	**0.25**	**$23.60**	**$47.20**

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

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

Subsequent to the Emergency information collection request, we are revising the package to include a second form, Healthcare Facility Status Workflow, which is for operational status information which will be used to assist providers in delivering critical care to beneficiaries during emergencies. The burden hours increased by 591 hours due to this additional form. We are also correcting a grammatical error from the previous submission. The total burden hours should have been 3,139 instead of 3,000.

In addition to the changes mentioned earlier in this section, we are also adding burden to account for a violation of the Paperwork Reduction Act.

Approved hospitals are required to report a small number of measures to CMS to ensure beneficiary safety. Expedited approvals report monthly and detailed waiver approvals report weekly. Prior to January 1 2021, reporting was completed by sending a secure spreadsheet directly to the team email address. There were three weeks of reporting with a total of 13 patients admitted prior to the online submission portal going live. These were reported by 5 different hospitals, three of which submitted one spreadsheet and two of which submitted two over the course of the three weeks.

Starting with submissions in January, all reporting measures have been via the online portal. There have been 23 expedited waiver monthly submissions and 265 detailed waiver weekly submissions.

Violation Estimates For Time Period: 11/23/2020 - 2/1/2021	**Tier 1**	**Tier 2**	**Total**
Number of waivers collected	35.0	61.0	N/A
Number of one time waiver submission & phone calls per respondent	1.0	1.0	N/A
Number of total measures (responses) collected	23.0	265.0	N/A
Time Burden Estimates (hours) EXAMPLE (500 Respondents) x (1 Response/Respondent) x (5	**40.75**	**188.25**	**299.0**

minutes/Response) x (1 hour/60 minutes) = 42 hours			
Cost Burden Estimates EXAMPLE Total Cost = (500 Respondents) x (1 Response/Respondent) x (5 minutes/Response) x (1 hour/60 minutes) x ($118.22/hour) = $4925	**$1,923.56**	**$8,886.15**	**$10,809.72**

We are accounting for a total burden of 299 burden hours and $10,809.72 associated with the violation.

We have provided burden for the violation as well as burden estimates for future efforts related to Acute Hospital Care at Home. In future iterations of this information collection request, all burden will summarized into a single burden estimate.

The total burden hours for this package are 5,629 (3,730 + 299 + 1,600).

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.