Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed
collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web Site address at Web Site address at:


FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Submissions of 1135 Waiver Request Automated Process; Use: 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. 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. The waiver request form was approved under an Emergency
information collection request on October 15, 2020.

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.

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.

Subsequent to the Emergency information collection request, we revised 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. Subsequent to the 60-day Federal Register notice which published on
October 21, 2020 (85 FR 66990), we 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. We are also remediating a violation of the Paperwork
Reduction Act by adding the Acute Hospital Care at Home waiver to this package. The initiative
was established 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). There is an increase in burden due to adding this waiver initiative to this package. *Form Number:* CMS–10752 (OMB control number: 0938-1384); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 5,729; *Total Annual Responses:* 5,729; *Total Annual Hours:* 5,729. (For policy questions regarding this collection, contact Adriane Saunders at 404-562-7484.)


William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

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