

DEPARTMENT OF HEALTH AND HUMAN SERVICES

200 Independence Avenue, SW
Washington, DC 20201



DATE: July 7, 2021

TO: Sharon Block
Acting Administrator, OIRA

FROM: Chiquita Brooks-LaSure *Chiquita Brooks-LaSure*
Administrator

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for Statement of Deficiency and Plan of Correction (CMS-2567)

Emergency Justification

The Centers for Medicare & Medicaid Services (CMS) is requesting that this information collection request (ICR), for revisions to the form CMS-2567 be processed under the emergency Paperwork Reduction Act of 1995 (PRA) clearance process. As explained in more detail below, we believe this process is warranted for a variety of reasons under 5 CFR 1320.13(a).

The Consolidated Appropriations Act of 2021 (CAA, 2021¹), passed on January 15, 2020, amends Title XVIII of the Social Security Act (Act), by adding nine provisions that establish survey and enforcement requirements for hospice programs. These statutory revisions became public law through Congress on December 27, 2020. The provisions of the CAA begin one year after its enactment, except for the following: (1) the requirement for use of multidisciplinary survey teams; (2) the prohibition of conflicts of interest; (3) expanding CMS-based surveyor training to accrediting organizations (AOs); and (4) the requirement for AOs to begin use of the form CMS-2567. These four (4) requirements are statutorily required to begin on October 1, 2021.²

In order for AOs that accredit hospice programs to use form CMS-2567, the form must first be revised and approved by OMB. The revisions are to include a data field in which to document the name of the AO completing the survey. This is critical information that must be included on the form CMS-2567 in order for the CMS locations and CMS central office to identify which AO performed the survey, or be able to distinguish an AO survey from a survey performed by the State Survey Agency (SA), as they also use the form CMS-2567 to document their survey findings.

¹ [Text - H.R.133 - 116th Congress \(2019-2020\): Consolidated Appropriations Act, 2021 | Congress.gov | Library of Congress](#)

² The provisions for a new hospice hotline, special focus program, and consistency of surveys begin no later than December 27, 2021. The public disclosure of survey information and the requirement to develop and implement a range of remedies begins no later than October 1, 2022.

Additionally, we have added the one-time burden estimate for AOs that accredit hospice programs to update their electronic systems in order to include the form CMS-2567 into their hospice program survey reports. This burden estimate coincides with the proposed conforming regulations through CMS-1747-P.

Emergency approval of the PRA package for form CMS-2567 is a vital first step to implementing the requirement that AOs begin using form CMS-2567 by no later than October 1, 2021 to document their survey findings.

The use of normal PRA clearance procedures would most likely cause CMS to miss the statutorily mandated deadline of October 1, 2021 for AOs, with a hospice program, to begin using the form CMS-2567. Without emergency PRA approval, AOs will not have the revised form to include in their current survey documentation systems and processes and will not meet the deadline of October 1, 2021 for beginning use. If CMS misses the October 1, 2021 deadline, it will jeopardize another CAA, 2021 mandated provision deadline for public posting of these AO hospice program survey reports on our website. The purpose of this requirement is for public transparency of survey and certification information. This statutory provision requires that the hospice program survey reports be posted by no later than October 1, 2022. Emergency PRA approval is critical for AOs and CMS to meet our congressionally mandated responsibilities.

Additionally, public harm is reasonably likely to occur if CMS is not able to meet the deadlines, the public may not have all the information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones. Beneficiaries and the public at large utilize survey findings when evaluating whether or not to receive care from certain facilities.

Background

Form [CMS-2567 Statement of Deficiencies and Plan of Correction³](#) is the legal, documentary basis for how SAs and CMS federal surveyors note findings of compliance or noncompliance (deficiencies) resulting from an inspection of Medicare-participating providers and suppliers. Our regulations require that SAs document all deficiency findings on the form CMS-2567. Additional regulations further delineate how findings must be recorded and that CMS prescribed forms must be used. The form CMS-2567 is used to state concisely and in a standard format, whether or not any deficiencies were identified during a survey, including the evidence to support each finding. Following the survey, the provider/supplier will use the form to document their plan for correcting the identified deficiencies.

Prior to enactment of the CAA 2021, AOs with CMS-approved hospice programs were not required to utilize the same forms as SA surveyors when documenting survey findings of noncompliance. Now with this statutory change, CMS is also proposing regulatory changes to implement the CAA provisions. As part of this process, it was noted that the existing format of form CMS-2567 titled “Statement of Deficiencies And Plan of Correction” (OMB control number 0938-0391), must be modified, as it does not currently have a place for the name of the AO that is performing the survey as this form was historically only used by SAs. Consequently, the form directions do not refer to AOs. Since this is a public document that is frequently used by consumers, advocacy groups, and the public as a source of information about quality of care

³ CMS-2567 available at: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf>

and facility compliance, CMS must make updates to the form to include AO information so it is clear who performed the survey. Additionally, the current information collection request for form CMS-2567, does not account for any information collection related burden associated with AO use and must be included in accordance with the proposed implementing regulation burden calculations noted in CMS-1747-P. The current version of form CMS-2567 was last approved by OMB on May 5, 2020 for a three year approval.

As per the statute, the earliest possible date to require AOs, with CMS-approved hospice programs, to utilize the form CMS-2567 is October 1, 2021. In order to meet this deadline for AOs to be ready to use the form CMS-2567 by October 1, 2021 CMS is requesting emergency approval for the revised form CMS-2567 by August 23, 2021. This will allow several weeks for AOs and CMS to finalize plans and begin use of form CMS-2567 for hospice program survey reporting by October 1, 2021. Prior to the CAA, 2021 statutory change, AOs were not required to use the CMS-2567 and therefore they need time to update their existing documentation systems to capture survey information into the new format. The normal PRA process will not be timely enough to meet the congressionally mandated timeframe and therefore CMS and AOs must move quickly.

We intend to publish the proposed implementing regulation on June 18, 2021 which will provide the rationale for this data collection and the proposed requirements for AO use and submission to CMS. We do not anticipate concerns from stakeholders as the public will welcome increased transparency and consistency between the SAs and AOs. Additionally, while the AOs may react negatively to the overall provisions within the CAA, 2021 that change their survey and reporting process, the edits made resulting in the emergency approval of form CMS-2567 PRA package are minimal.

Requested and Proposed Timeline⁴

June 30, 2021

- Submit Emergency Justification to OMB.

July 8, 2021

- OMB approval received.

July 12, 2021

- 30-day FR notice to the Office of Federal Registers (OFR) for publication.

July 15, 2021

- Target publication date for 30-day FR notice to initiate standard OMB approval process.
- Start of the 30-day public comment period.
- PRA package posted for public review on the CMS PRA web site.

August 16, 2021

- End of 30-day comment period.
- CMS reviews and responds to comments, as needed.
- PRA package revised as needed

⁴ The actual dates may vary slightly from the proposed dates listed in this document.

August 23, 2021

- OMB approval received.

We request OMB's support in approving the form CMS-2567 revisions request under the Emergency PRA procedures to allow us to meet the statutory deadline for AOs to begin using the form not later than October 1, 2021.