



DATE: February 24, 2017

TO: Dominic Mancini
Acting Administrator, OIRA

FROM: Patrick Conway
Acting Administrator

A handwritten signature in blue ink that reads "Patrick Conway, MD". The signature is written in a cursive style and is positioned to the right of the typed name "Patrick Conway" and above the typed title "Acting Administrator".

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package Related to the Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies and Supporting Regulations (OMB no. 0938-0365; CMS-R-39)

Emergency justification

The Centers for Medicare and Medicaid Services (CMS) is requesting a Paperwork Reduction Act (PRA) package related to the Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies and Supporting Regulations at 42 CFR part 484, to be processed under the emergency clearance process associated with 5 CFR 1320.13(a)(2)(i). Public harm is reasonably likely to ensue if the normal, non-emergency clearance procedures are followed. The approval of this information collection package is necessary because in the absence of such approval CMS will be unable to effectively enforce these essential health and safety requirements. Among other things, CMS will be unable to enforce requirements that HHAs must provide a notice of rights to each patient, assure the proper training of home health aides before those aides provide hands-on care to patients, and disclose the names and addresses of all individuals with an ownership or management position so that we can assure that those with a history of fraud are not involved in HHA operations. Being unable to enforce these rules would harm patient health and safety, as well as create risks to the integrity of the Medicare and Medicaid programs.

Background

Under section 1891(b) of the Act, the Secretary is responsible for assuring that the Conditions of Participation (CoPs), and their enforcement, are adequate to protect the health and safety of individuals under the care of a home health agency (HHA), and to promote the effective and efficient use of Medicare funds. The majority of the current HHA CoPs were established in 1989 and are currently approved under OMB control number 0938-0365. The current PRA package was last renewed in 2014 and is scheduled to expire on February 28, 2017. The CoPs apply to an HHA as an entity as well as the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. To implement the CoPs, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the CoPs. HHAs are required to maintain certain documentation within their

own agency records that demonstrates compliance with specific CoPs. This documentation is examined on-site as part of the HHA survey process, and is necessary for the effective enforcement of the CoPs.

HHAs provide care planning and hands-on patient care. Home health services are provided on a visiting basis in the patient's place of residence, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, or occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

This emergency clearance request is solely for the purpose of extending the OMB approval associated with the current HHA CoPs under OMB control number 0938-0365. As stated earlier, the majority of the current HHS CoPs were established in 1989, and last approved by OMB in 2014. The approval is due to expire February 28, 2017.

Timeline

February 17, 2017

- Submit Emergency Justification to OMB.

February 21, 2017

- Request OMB approval of Emergency Justification.

February 22, 2017

- Submit the ICR to OSORA.

February 28, 2017

- Target date for publishing the emergency Federal Register notice for this collection.
- Target date for submitting the ICR to OMB.
- Start of 30 day public comment period.

March 30, 2017

- End of 30 day public comment period.
- CMS will respond to public comments (if applicable).
- Start of OMB review period.

April 5, 2017

- Requested OMB approval date.