



DÉPARTMENT OF HEALTH & HUMAN SERVICES

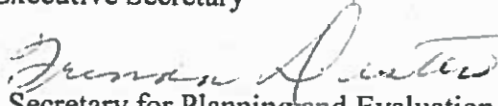
Office of the Secretary

The Assistant Secretary for
Planning and Evaluation
Washington, D.C. 20201

DATE: March 20, 2019

TO: Alex M. Azar II, Secretary

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Brenda Destro 
Deputy Assistant Secretary for Planning and Evaluation (HSP)

SUBJECT: Paperwork Reduction Act Waiver During a Public Health Emergency:
Distribution of Traceable Opioid Material Kits across U.S. Laboratories -
DECISION

ISSUE

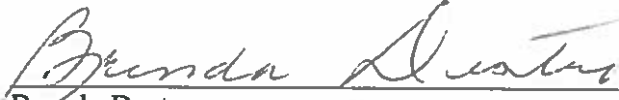
This memorandum seeks your decision regarding a request from the Centers for Disease Control and Prevention (CDC) to waive certain Paperwork Reduction Act (PRA) requirements related to the Public Health Emergency (PHE) declaration for the opioid epidemic.

BACKGROUND

Section 319(f) of the Public Health Service (PHS) Act authorizes you to waive PRA (44 USC § 3501 *et seq.*) requirements with respect to voluntary collection of information during a public health emergency (PHE) or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). This authority provides HHS with the ability quickly to address actual or likely public health emergencies by conducting voluntary collections of information. Without this authority, many of the voluntary collections of information conducted by or for HHS during these critical times would likely require approval by the Office of Management and Budget (OMB) consistent with the PRA. OMB approval usually takes a minimum of six months and sometimes up to a year for a typical request.

According to section 319(f) of the PHS Act, use of the PRA waiver authority requires your determination that the circumstances of a PHE/SLPHE, including the specific preparation for and response to such PHE/SLPHE, necessitate a waiver of the PRA requirements.

approval will be posted on ASPE's website (<https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers>) (Tab C). This waiver will be in effect from the date the notice is posted on ASPE's website. A revised notice will be posted upon the termination of the waiver. This decision only pertains to the request of a waiver for the information collection for this declared public health emergency.



Brenda Destro
Deputy Assistant Secretary for Planning and Evaluation (HSP)

DECISION

I have determined that the circumstances of the PHE for the opioid epidemic justify waiver of the PRA requirements for the proposed information collection.

Approve Disapprove Need More Information



Alex M. Azar II
Secretary

MAR 29 2019
Date

ATTACHMENT

- Tab A – Public Health Emergency Paperwork Reduction Act Waiver Request Form: Distribution of Traceable Opioid Material Kits across U.S. Laboratories
- Tab B – CDC NCEH DLS Contractor Opioid Material Kit Request Web Portal
- Tab C – Waiver Notice for Posting

Waiver Notice

Pursuant to section 319 of the PHS Act, Secretary Azar determined that, as the result of the consequences of opioid epidemic, a PHE has existed in the nation since October 26, 2017. The Secretary's determination to declare the PHE was made after consultation with public health officials as necessary. As result of the PHE, the Secretary also determined pursuant to section 319(f) of the PHS Act that circumstances of the PHE necessitate a waiver from the requirements of the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, effective as of the date of this notice. The waiver is justified to collect information to support the Department's investigation of and response to opioid epidemic. This waiver applies to information being collected from laboratories that request Traceable Opioid Material Kits.

Pursuant to the waiver, the requirements of 44 U.S.C. § 3501 *et seq.* shall not be applicable with respect to voluntary collection of information during the effective time period.

The Paperwork Reduction Act waiver is effective as of March 29, 2019 and is anticipated to remain in effect throughout the time period of the immediate investigation of and response to the emergency declared pursuant to section 319(a) of the PHS Act, and for a reasonable length of time for immediate post response review regarding the public health emergency.

Any initiative subject to this waiver that is ongoing after the termination of the effective period shall be subject to the requirements of the Paperwork Reduction Act within 30 days of expiration of the waiver. The waiver applies to the Centers for Disease Control and Prevention.

This notice will be updated as needed.

Waiver Notice

Pursuant to section 319 of the PHS Act, Secretary Azar determined that, as the result of the consequences of the opioid epidemic, a PHE has existed in the nation since October 26, 2017. The Secretary's determination to declare the PHE was made after consultation with public health officials as necessary. As result of the PHE, the Secretary also determined pursuant to section 319(f) of the PHS Act that circumstances of the PHE necessitate a waiver from the requirements of the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, effective as of the date of this notice. The waiver is justified to collect information to support the Department's investigation of and response to the opioid epidemic. This waiver applies to information being collected from laboratories that request Traceable Opioid Material Kits.

Pursuant to the waiver, the requirements of 44 U.S.C. § 3501 *et seq.* shall not be applicable with respect to voluntary collection of information during the effective time period.

The Paperwork Reduction Act waiver is effective as of March 29, 2019 and is anticipated to remain in effect throughout the time period of the immediate investigation of and response to the emergency declared pursuant to section 319(a) of the PHS Act, and for a reasonable length of time for immediate post response review regarding the public health emergency.

Any initiative subject to this waiver that is ongoing after the termination of the effective period shall be subject to the requirements of the Paperwork Reduction Act within 30 days of expiration of the waiver. The waiver applies to the Centers for Disease Control and Prevention.

This notice will be updated as needed.

Addendum

This Paperwork Reduction Act waiver for the opioid epidemic is terminated effective May 10, 2019.