Waiver Notice

Pursuant to section 319 of the Public Health Service (PHS) Act, 42 U.S.C. § 247d, Acting Secretary Hargan determined on October 26, 2017, that a public health emergency (PHE) exists as a result of the consequences of the opioid crisis affecting the Nation and renewed that determination on January 24, 2018. Secretary Azar renewed this determination on the following dates: April 24, 2018; July 23, 2018; October 21, 2018; January 19, 2019; April 19, 2019; July 18, 2019; October 16, 2019; January 14, 2020; April 13, 2020; July 12, 2020; October 10, 2020; and January 8, 2021. Secretary Xavier Becerra renewed this determination effective April 8, 2021; July 7, 2021; October 6, 2021; January 4, 2023; April 4, 2022, and July 4, 2022; October 3, 2022; January 1, 2023; April 1, 2023; July 1, 2023; September 29, 2023; December 28, 2023; March 27, 2024; and June 25, 2024.

The Secretary's determination to declare the PHE was made after consultation with public health officials, as necessary. As a result of the PHE, Secretary Xavier Becerra 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 (PRA), 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 of Health and Human Services' investigation of and response to the opioid crisis. This waiver applies to information to be collected by the Food and Drug Administration (FDA) from individuals who are participants of harm reduction programs, have administered naloxone or nalmefene for overdose reversal within the last 12 months, and currently use drugs with overdose risk or have social contacts who do. The purpose of the information collection is to better understand the barriers and facilitators to consistent and correct community-based administration of opioid reversal agents.

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 PRA waiver is effective as of September 16, 2024 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 PHE.

Any initiative subject to this waiver that is ongoing after the termination of the effective period shall be subject to the requirements of the PRA within 30 days of expiration of the waiver. The waiver applies to the voluntary information collection related to the opioid crisis PHE undertaken by the FDA.

This notice will be updated as needed.