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 nationwide 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; June 25, 2024; September 23, 2024; and December 22, 2024. Secretary Robert F. Kennedy Jr. renewed this determination effective March 22, 2025. 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 Robert F. Kennedy, Jr. determined pursuant to section 319(f) of the PHS Act, and after consultation with public health officials, as necessary, 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) to develop and pilot a rigorous survey program that is tailored to meeting FDA's regulatory science data needs and provide FDA and broader stakeholder groups with real-time, prospective evidence on trajectories of opioid misuse and use disorders, alone and in combination with other substances, correlates of use, and associated outcomes (e.g., development of risky behaviors and use disorders). The information collection will include rigorous study development activities (such as quantifying selection bias, testing of population enrichment and retention strategies, and content validation of new survey content) and a comprehensive pilot of new survey modules.

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 May 6, 2025, 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.