

Waiver Notice

Pursuant to section 319 of the Public Health Service (PHS) Act, 42 U.S.C. 247d, Secretary Alex M. Azar, II determined that, as the result of the confirmed cases of Coronavirus Disease 2019 (COVID-19), a public health emergency (PHE) has existed nationwide since January 27, 2020 and was renewed effective April 26, 2020. The Secretary's determination to declare the PHE was made after consultation with public health officials, as necessary. As a 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 of Health and Human Services' investigation of and response to the COVID-19 pandemic. This waiver applies to information to be collected by the Food and Drug Administration to evaluate various ways to maximize the number of healthy individuals who can donate blood in order to facilitate its response to the PHE.

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 April 29, 2020 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 voluntary information collection related to the COVID-19 pandemic undertaken by the Food and Drug Administration.

This notice will be updated as needed.