

Waiver Notice

Pursuant to section 319 of the PHS Act, Secretary Azar determined that, as the result of the confirmed cases of 2019 Novel Coronavirus (2019-nCoV), now known as Coronavirus Disease 2019 (COVID-19), a PHE has existed nationwide since January 27, 2020. The Secretary's Declaration was made after consulting with public health officials as necessary. As result of the PHE, the Secretary also waived pursuant to section 319(f) of the PHS Act 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 COVID-19. This waiver applies to information to be collected by the Food and Drug Administration pertaining to its guidance documents that relate to the COVID-19 pandemic public health emergency response.

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 19, 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 Food and Drug Administration.

This notice will be updated as needed.