

Waiver Notice

On August 4, 2022, pursuant to section 319 of the Public Health Service (PHS) Act, Health and Human Services (HHS) Secretary Becerra determined that, as a result of the consequences of the outbreak of monkeypox cases across multiple states, a public health emergency (PHE) exists.

The Secretary's determination to declare the PHE was made after consulting 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 the 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 monkeypox. This waiver applies to information to be collected by the Food and Drug Administration (FDA) pertaining to its guidance documents that relate to the monkeypox outbreak PHE 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 August 19, 2022 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 60 days of expiration of the waiver. The waiver applies to the Food and Drug Administration.

This notice will be updated as needed.