

Centers for Disease Control and Prevention (CDC) Atlanta GA 30341-3724

January 18, 2020

Dominic Mancini Deputy Director Office of Information and Regulatory Affairs Office of Management and Budget Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, "Addition of 2019 – Novel Coronavirus (2019-nCoV) to the National Notifiable Diseases Surveillance System (0920-0728)" be processed as an Emergency Revision Request in accordance with section 1320.13, <u>Emergency Processing</u>.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to CDC's emergency response to the outbreak of a novel coronavirus. The outbreak caused by a novel coronavirus has resulted in more than 40 confirmed human infections in China and one exported case in Thailand. Infection is associated with severe pneumonia, and one patient in China is reported to have died. The outbreak is centered in Wuhan City, Hubei Province, China. Chinese health authorities report that most patients have reportedly had exposure to a large seafood and animal market. Much remains unknown about the transmissibility, severity, and other features associated with 2019-nCoV, and investigations are ongoing. While current information indicates the risk from 2019-nCoV to the American public is deemed to be low, CDC is taking proactive preparedness precautions and requires emergency review and clearance to allow for immediate information collection for patients under investigation and potential cases.

CDC cannot reasonably comply with the normal clearance given the urgent necessity to protect the American public from potential importation and spread of this novel health threat. Much remains unknown about the etiology, transmissibility, and characteristics of 2019-nCoV, and as demonstrated by previous outbreaks of SARS-associated coronavirus and Middle East Respiratory Syndrome (MERS), novel coronaviruses provide a significant threat of spreading among humans and causing severe illness. Early detection and intervention remains the best way to control the spread of novel infectious diseases, and complying with normal clearance timelines for 2019-nCoV would delay effective detection and control efforts, potentially threatening public health if this novel, poorly understood virus proves to be



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transmissible among humans.

Therefore, CDC requests a 180-day emergency clearance to launch collection of data for patients under investigation (PUI) and potential cases for 2019-nCoV under OMB Control Number 0920-0728. Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business on January 23, 2020.

Respectfully,

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Nancy Messonnier, MD Director, National Center for Immunization and Respiratory Disease (NCIRD), Centers for Disease Control and Prevention (CDC)