

WASHINGTON STATE BOARD OF HEALTH

Date: April 13, 2022

To: Washington State Board of Health Members

From: Umair A. Shah, MD, MPH, Secretary of Health

Subject: WAC 246-101-017, Notification and Reporting Requirements of Novel Coronavirus (SARS-CoV-2)

Background and Summary:

Since the first confirmed case of Novel Coronavirus (SARS-CoV-2), also known as Coronavirus Disease 2019 (COVID-19), was reported in Washington State in January 2020, there have been over 79 million confirmed cases and over 977,000 deaths reported in the United States.¹

The [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#), signed into law on March 27, 2020, includes a requirement for every laboratory that performs or analyzes a test intended to detect or diagnose a possible case of COVID-19 to report the results to the U.S. Department of Health and Human Services (HHS) in a manner prescribed by the HHS Secretary until the end of the public health emergency.

On June 4, 2020, HHS released laboratory data reporting guidance for COVID-19 that specifies standards for reporting laboratory testing data, including test results, relevant demographic details (e.g., patient's age, race, ethnicity, sex), and additional information to improve the public health response to COVID-19. These data must be collected and reported to state or local public health departments using existing reporting channels in accordance with state law or policies.

In September 2020, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule in the [Federal Register Volume 85, Number 171](#) stipulating that all laboratories conducting SARS-CoV-2 testing and reporting patient-specific results, including hospital laboratories, nursing homes, and other facilities conducting testing for COVID-19, who fail to report information required under the CARES Act will be subject to monetary penalties.

HHS has since updated its guidance twice: in January 2021 and March 2022. The most recent update removes requirements to report antibody or self-administered tests and specifies reporting requirements by testing entity and test type. The updated guidance also refines the reportable data components that accompany test results, and no longer suggests reporting answers to ask-on-order entry questions.

¹ Centers for Disease Control and Prevention, [COVID Data Tracker](#), accessed April 1, 2022

The State Board of Health (Board) has the authority under RCW 43.20.050 to adopt rules for the prevention and control of infectious and noninfectious diseases. The purpose of chapter 246-101 WAC, Notifiable Conditions, is to provide critical information to public health authorities to aid them in protecting and improving public health through prevention and control of disease.

The Board previously adopted six emergency rules under WAC 246-101-017 to designate COVID-19 as a notifiable condition and require reporting of essential COVID-19 testing and patient demographic data aligned with the CARES Act:

- CR-103E filed on July 31, 2020 as WSR 20-16-121
- CR-103E filed on November 25, 2020 as WSR 20-24-081
- CR-103E filed on March 26, 2021 as WSR 21-08-009
- CR-103E filed on July 23, 2021 as WSR 21-16-014
- CR-103E filed on August 23, 2021 as WSR 21-18-034
- CR-103E filed on December 21, 2021 as WSR 22-01-200

To ensure consistency in reporting between regulated entities under chapter 246-101 WAC, the Board has required COVID-19 reporting by health care providers, health care facilities, laboratories, local health jurisdictions, and the Department of Agriculture. Additionally, the draft seventh emergency rule goes beyond updated HHS guidance to require reporting of negative and inconclusive results from certain antigen testing in order for the Department of Health to calculate percent positivity for surveillance purposes.

Per the requirements of the Administrative Procedures Act, RCW 34.05.350, the Board has taken steps to integrate requirements of the emergency rules into the permanent Notifiable Conditions chapter. The Board filed a CR-101, Preproposal Statement of Inquiry on July 23, 2021. Rulemaking is currently underway.

Until permanent rules are in effect, I recommend the Board adopt a seventh emergency rule, revised to be aligned with the most up-to-date HHS guidance, to continue to designate COVID-19 as a notifiable condition and require reporting of essential COVID-19 testing and demographic data to allow the governmental public health system to identify appropriate public health interventions. I believe the continuation of these requirements through emergency rule adoption is necessary for the preservation of the public health, safety, and general welfare of the State of Washington.

Recommended Board Actions:

The Board may wish to consider and amend, if necessary, the following motion:

The Board adopts a seventh emergency rule to extend the designation of COVID-19 as a notifiable condition and the required reporting of essential testing and demographic data to maintain the necessary public health response to COVID-19. The Board directs staff to file a CR-103E to extend WAC 246-101-017 without lapse, effective April 20, 2022.

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Staff

Kaitlyn Donahoe

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PO Box 47990 • Olympia, WA 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov