

WASHINGTON STATE BOARD OF HEALTH

Date: November 9, 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 97 million confirmed cases and over one million 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 October 31, 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 eight 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 starting in July 2020 and most recently in August 2022. 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.

In March 2021, the Board adopted revisions to chapter 246-101 WAC, Notifiable Conditions. In addition to the many changes to the chapter, the updated rules designate COVID-19 as a notifiable condition on a permanent basis. These changes go into effect on January 1, 2023. To comply with the Administrative Procedures Act, the Board also initiated rulemaking that would include additional reporting requirements for COVID-19 in alignment with the CARES Act and associated HHS guidance. The CR-101 for this rulemaking was filed in July 2021 (WSR 21-15-105).

Until permanent rules are in effect, I recommend the Board adopt a ninth emergency rule 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 continue to implement appropriate public health interventions. Further, in order to avoid confusion for regulated entities, I recommend the Board rescind the emergency rule upon enactment of the permanent rules, withdraw the CR-101 for permanent COVID-19 rulemaking, and recommend that the state health officer issue a request for additional information to regulated entities under WAC 246-101-015 to help ensure continued compliance with HHS guidance through the end of the declared public health emergency.

Recommended Board Actions:

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

The Board adopts a ninth 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 do the following:

- File a CR-103E to extend WAC 246-101-017 without lapse, effective December 16, 2022;
- Rescind the emergency rule effective January 1, 2023 when the permanent rules take effect;
- Withdraw the CR-101 for permanent COVID-19 rulemaking (filed as WSR 21-15-105); and

- Work with the Department of Health on communication to regulated entities to ensure continued compliance with HHS guidance through the end of the declared public health emergency.

Staff

Kaitlyn Donahoe

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