



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

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DATE: July 20, 2021

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WSR 21-15-105

Agency: State Board of Health

Subject of possible rule making: Chapter 246-101 WAC, Notifiable Conditions. The State Board of Health (Board) is considering amending this chapter to establish and clarify requirements for novel coronavirus (SARS-CoV-2), coronavirus disease 2019 (COVID-19), reporting by health care providers, health care facilities, laboratories, and local health jurisdictions consistent with the Board's emergency rule, WAC 246-101-017, and Public Law 116-136, Â§ 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The Board may also consider revisions to clarify the instances in which health care providers and health care facilities must report a notifiable condition to a local health jurisdiction or the Department of Health and other editorial revisions as necessary.

Statutes authorizing the agency to adopt rules on this subject: RCW 43.20.050(2)(f)

Reasons why rules on this subject may be needed and what they might accomplish: The Board will consider amending chapter 246-101 WAC, Notifiable Conditions, to ensure all federally required data components continue to be reported for COVID-19 tests, support statewide COVID-19 disease surveillance, and allow the governmental public health system to identify appropriate public health interventions through the end of the COVID-19 pandemic and beyond.

The CARES Act requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the U.S. Department of Health and Human Services (HHS). In addition, the Act authorizes the Secretary to prescribe the form, manner, timing, and frequency of such reporting. HHS released laboratory data reporting guidance for COVID-19 that specifies standards for reporting laboratory testing data including test results, relevant patient demographic details, and additional information to improve the public health response to COVID-19. Per the guidance, 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, starting August 1, 2020 through the end of the public health emergency as declared by the Secretary.

In September 2020, the Centers for Medicare and Medicaid Services (CMS) published an interim final rule in Federal Register 54826, Volume 85, Number 171, to update requirements for reporting SARS-CoV-2 test results by laboratories. The interim final rule states 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. The interim final rules became effective September 2, 2020.

The Board adopted emergency rules as WAC 246-101-017 (under WSR 20-16-121, WSR 20-24-081, and most recently WSR 21-08-009) 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. To ensure consistency in reporting between regulated entities under chapter 246-101 WAC, COVID-19 reporting was required from health care providers, health care facilities, laboratories, and local health jurisdictions.

In March 2021, the Board adopted permanent revisions to chapter 246-101 WAC. Among these revisions, COVID-19 is designated as a notifiable condition, and many, but not all, of the HHS data components are required reporting for health care providers, health care facilities, laboratories, and local health jurisdictions. These revisions go into effect January 31, 2022.

The Board may consider integrating COVID-19 reporting requirements and provisions consistent with the Board's emergency rule, the CARES Act, and HHS guidance. These include, but are not limited to, adding remaining reportable data components; clarifying requirements for entities conducting point of care testing or rapid screening testing; authorizing local health jurisdictions to forward cases to the Department of Health for data entry; authorizing certain waivers by a local health officer; and clarifying reporting timeframes.

The Board may also consider revisions to clarify the instances in which health care providers and health care facilities must report a notifiable condition to a local health jurisdiction or the Department of Health, and other editorial revisions as

necessary.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: None

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe)

The Board will use a collaborative rulemaking approach. The Board will consult partner health agencies, the regulated community, and other interested parties in drafting the rule. The Board will keep interested parties informed of the rulemaking through email, the Board's listserv and rulemaking website, and notices in the Washington State Register. Interested parties will have opportunities to provide comments throughout the rule-making process, including informal review of the draft rules, formal review and comment on the proposed rules, and providing testimony at the Board's public hearing.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

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Additional comments: If you would like to be added to the listserv for this rulemaking, please email NotifiableConditions@sboh.wa.gov with the subject line "Notifiable Conditions - Subscribe."

Date: 07/20/2021

Name: Michelle A. Davis

Title: Executive Director, Washington State Board of Health

Signature:

