



RULE-MAKING ORDER

EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

Agency: State Board of Health

Effective date of rule:

Emergency Rules

- Immediately upon filing.
 Later (specify) 08/18/2022

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes No If Yes, explain:

Purpose: WAC 246-101-017, Novel coronavirus (SARS-CoV-2), coronavirus disease 2019 (COVID-19) reporting. The Washington State Board of Health has adopted an eighth emergency rule to continue to designate COVID-19 as a notifiable condition and establish reporting requirements for health care providers, health care facilities, laboratories, local health jurisdictions, and the Department of Agriculture to report certain data with COVID-19 test results, including relevant demographic details (e.g., patient's age, race, ethnicity, sex), and testing information. The rule allows for certain waivers by a local health officer. The rule establishes what testing and demographic data need to be reported as well as the timing and mechanism of reporting in accordance with Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

Citation of rules affected by this order:

New: WAC 246-101-017
 Repealed: None
 Amended: None
 Suspended: None

Statutory authority for adoption: RCW 43.20.050(2)(f)

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate adoption of a rule to designate COVID-19 as a notifiable condition, and require the reporting of demographic, testing, and other relevant data by health care providers, health care facilities, laboratories, local health jurisdictions, and the Department of Agriculture for each COVID-19 test is necessary to comply with federal law and related guidance. Immediate adoption of this rule is necessary for the preservation of the public health, safety and general welfare of the State of Washington during the global COVID-19 pandemic.

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). The Act authorizes the HHS Secretary to prescribe the form, manner, timing, and frequency of such reporting. The HHS Secretary released laboratory data reporting guidance for COVID-19 on June 4, 2020, and later updated the guidance on January 8, 2021, and March 8, 2022. The guidance requires all COVID-19 test results and accompanying data be reported through existing state, territorial, local, and Tribal public health data reporting methods. Of these requirements, any person or entity ordering a test, registering an individual to be tested, collecting a specimen, or performing a test should make every reasonable effort to collect complete demographic data of the patient (e.g., ethnicity, race, age, sex). Updated guidance specifies which test results must be reported by entities based on entity and test type, and refines the list of reportable data components that must accompany test results.

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.

Adoption of an eighth emergency rule ensures continued compliance with the CARES Act, including updated HHS guidance, CMS requirements, and maintain the necessary public health response to COVID-19. The Board intends to incorporate these provisions into permanent rule, and filed a CR-101 on July 20, 2021 as WSR 21-15-105.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted:

Name: Michelle A. Davis

Title: Executive Director, Washington State Board of Health

Signature: