



RULE-MAKING ORDER EMERGENCY RULE ONLY

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

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STATE OF WASHINGTON
FILED

DATE: March 26, 2021

TIME: 7:47 AM

WSR 21-08-009

Agency: State Board of Health

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

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 (Board) has adopted a third emergency rule to continue to designate COVID-19 as a notifiable condition and extends reporting requirements for health care providers, health care facilities, laboratories, local health jurisdictions, and the Department of Agriculture to report certain data with each COVID-19 test, 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. 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, Å§ 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. This emergency rule will take effect upon the expiration of the existing emergency rule.

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- Repealed: None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 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 CARES Act authorizes the 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. The guidance requires all data components be reported through existing state and local public health data reporting methods until the end of the public health emergency. Of these requirements, demographic information such as the patient's age, race, ethnicity, and sex must be collected and reported in accordance with state law or policies.

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 previously adopted emergency rules on July 31, 2020 as WSR 20-16-121 and November 25, 2020 as WSR 20-24-081 to designate COVID-19 as a notifiable condition and require laboratories, health care providers, health care facilities, local health jurisdictions, and the Washington State Department of Agriculture to report demographic, testing, and other

relevant data for each COVID-19 test through Washington's existing public health reporting mechanism for notifiable conditions. The immediate adoption of a third emergency rule to extend these requirements is necessary for the preservation of the public health, safety and general welfare of the State of Washington during this pandemic and to ensure continued compliance with the federal law and related guidance.

**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>1</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: 03/23/2021

Name: Michelle A. Davis

Title: Executive Director, Washington State Board of Health

Signature:



NEW SECTION

WAC 246-101-017 Novel coronavirus (SARS-CoV-2), coronavirus disease 2019 (COVID-19) reporting. (1) Designating coronavirus disease 2019 (COVID-19), and the novel coronavirus (SARS-CoV-2) that causes it, as a notifiable condition, and requiring the reporting of race and ethnicity and other essential data by health care providers, health care facilities, laboratories, and local health departments related to cases of COVID-19 are necessary to ensure that public health agencies receive complete notice of COVID-19 cases and to address racial and ethnic inequities in morbidity and mortality among individuals with the disease. This rule is also necessary to align with the federal Coronavirus Aid, Relief, and Economic Security (CARES) Act and the U.S. Department of Health and Human Services laboratory data reporting requirements for COVID-19 testing, which require reporting of COVID-19 data to the appropriate state or local health department and the U.S. Department of Health and Human Services, and further, that any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test should make every reasonable effort to collect complete demographic information and include such data when ordering a laboratory test to enable the entities performing the test to report these data to state and local public health departments. In the midst of this global pandemic, immediate adoption of a rule requiring notice of novel coronavirus (SARS-CoV-2) as a notifiable condition and reporting of race, ethnicity, and other essential data is necessary for the preservation of public health, safety, and general welfare.

(2) For the purpose of this section:

(a) "Animal case" means an animal, alive or dead, with a diagnosis of novel coronavirus (SARS-CoV-2) made by a veterinarian licensed under chapter 18.92 RCW, veterinary medical facility licensed under chapter 18.92 RCW, or veterinary laboratory as defined under chapter 16.70 RCW based on clinical criteria, or laboratory criteria, or both.

(b) "Health care facility" means:

(i) Any assisted living facility licensed under chapter 18.20 RCW; birthing center licensed under chapter 18.46 RCW; nursing home licensed under chapter 18.51 RCW; hospital licensed under chapter 70.41 RCW; adult family home licensed under chapter 70.128 RCW; ambulatory surgical facility licensed under chapter 70.230 RCW; private establishment licensed under chapter 71.12 RCW; or enhanced service facility licensed under chapter 70.97 RCW; and

(ii) Clinics or other settings where one or more health care providers practice.

(c) "Immediately" means without delay, twenty-four hours a day, seven days a week.

(d) "Secure electronic data transmission" means electronic communication and accounts developed and maintained to prevent unauthorized access, loss, or compromise of sensitive information including, but not limited to, secure file transfer, secure facsimile, a health information exchange authorized under RCW 41.05.039, and the secure electronic disease surveillance system.

(e) "Secure electronic disease surveillance system" means the secure electronic data transmission system maintained by the department and used by local health departments to submit notifications, investigation reports, and outbreak reports under this chapter.

(f) Patient's ethnicity shall be identified by the patient and reported using one of the following categories:

- (i) Hispanic or Latino;
- (ii) Non-Hispanic or Latino;
- (iii) Unknown; or
- (iv) Asked, but unknown.

(g) Patient's race shall be identified by the patient and reported using one or more of the following categories:

- (i) American Indian or Alaska Native;
- (ii) Asian;
- (iii) Black or African American;
- (iv) Native Hawaiian or Other Pacific Islander;
- (v) White;
- (vi) Unknown; or
- (vii) Asked, but unknown.

(h) Ask on order entry questions are:

(i) Is this the patient's first test of any kind for novel coronavirus (SARS-CoV-2)? (yes, no, unknown);

(ii) Is the patient employed in health care with direct patient contact? (yes, no, unknown);

(iii) Is the patient symptomatic as defined by the Centers for Disease Control and Prevention (CDC)? (yes, no, unknown). If yes, then provide date of symptom onset (mm/dd/yyyy);

(iv) Is the patient hospitalized for novel coronavirus (SARS-CoV-2) at the time of testing? (yes, no, unknown);

(v) Is the patient in the intensive care unit (ICU) for novel coronavirus (SARS-CoV-2) at the time of testing? (yes, no, unknown);

(vi) Is the patient a resident in a congregate care or living setting (including, but not limited to, nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care, correctional facilities, and temporary worker housing)? (yes, no, unknown); and

(vii) Is the patient pregnant? (yes, no, unknown).

(3) Unless a health care facility has assumed the notification duties of the principal health care provider under subsection (8) of this section, or a laboratory director in a health care facility where laboratory point of care testing occurs under a certificate of waiver as described in WAC 246-338-020 has fulfilled the laboratory notification requirements as described in subsection (10) of this section, the principal health care provider shall submit individual case reports of novel coronavirus (SARS-CoV-2) to the local health department via secure electronic data transmission using a file format or template specified by the department:

(a) Within twenty-four hours of receiving a laboratory confirmed positive test result; and

(b) Following the requirements of this section, WAC 246-101-105, and WAC 246-101-120; excluding the requirements in WAC 246-101-105(10).

(4) The local health officer may waive or partially waive subsection (3) or (5) of this section, or both if the local health officer determines individual case reports of novel coronavirus (SARS-CoV-2) submitted by health care providers or health care facilities are not needed and are not promoting public health for any reason including, but not limited to, the local health department being unable to process the volume of case reports. The local health officer shall notify health care providers and health care facilities upon their determination.

(5) A health care facility shall submit individual case reports of novel coronavirus (SARS-CoV-2) to the local health department via secure electronic data transmission using a file format or template specified by the department:

(a) Within twenty-four hours of receiving a laboratory confirmed positive test result; and

(b) Following the requirements of this section, WAC 246-101-305, and WAC 246-101-320; excluding the requirement in WAC 246-101-305(4).

(6) Health care providers and health care facilities shall provide the local health department with the information identified in Column A of Table 1 in this section for individual case reports concerning novel coronavirus (SARS-CoV-2).

(7) Health care providers and health care facilities may provide the local health department with responses to ask on order entry questions under subsection (2)(h) of this section for individual case reports concerning novel coronavirus (SARS-CoV-2).

(8) A health care facility may assume the notification requirements established in this section for a health care provider practicing within the health care facility.

(9) A health care facility shall not assume the notification requirements established in this section for a laboratory that is a component of the health care facility.

(10) A principal health care provider is not required to submit individual case reports of novel coronavirus (SARS-CoV-2) to the local health department when the provider practices in a health care facility where laboratory point of care testing occurs under a certificate of waiver as described in WAC 246-338-020 and the laboratory director has fulfilled the laboratory notification requirements under subsections (14), (15), and (16) of this section.

(11) Health care providers and health care facilities shall provide the laboratory with the information identified in Column A of Table 1 in this section for each test ordered for novel coronavirus (SARS-CoV-2).

(12) Health care providers and health care facilities may provide the laboratory with responses to ask on order entry questions under subsection (2)(h) of this section for each test ordered for novel coronavirus (SARS-CoV-2).

(13) For specimens associated with novel coronavirus (SARS-CoV-2) sent to a laboratory outside of Washington state, health care providers, health care facilities, and laboratories shall provide the out-of-state laboratory with a copy of chapter 246-101 WAC if they arrange for the out-of-state laboratory to report the test results consistent with WAC 246-101-105 (5)(a), 246-101-205 (1)(f)(i), or 246-101-305 (1)(e)(i) to the local health department as required under this subsection.

(14) A laboratory director shall submit individual laboratory reports of positive, negative, and indeterminate test results for novel coronavirus (SARS-CoV-2) to the local health department via secure electronic data transmission using a file format or template specified by the department:

(a) Within twenty-four hours; and

(b) Following the requirements of this section, WAC 246-101-205, and WAC 246-101-230; excluding the requirements in WAC 246-101-205(3).

(15) A laboratory director shall provide the information identified in Column B of Table 1 in this section to the local health department with each novel coronavirus (SARS-CoV-2) laboratory report.

(16) A laboratory director may provide the local health department with responses to ask on order entry questions under subsection (2)(h) of this section with each novel coronavirus (SARS-CoV-2) laboratory report.

(17) A laboratory director, upon request by the local health department or the department, shall submit novel coronavirus (SARS-CoV-2) presumptive positive isolates or, if no isolate is available, the specimen associated with the presumptive positive result to the Washington state public health laboratories within two business days of request. Specimens shall be sent to:

Washington State Public Health Laboratories
Washington State Department of Health
1610 N.E. 150th Street
Shoreline, WA 98155

(18) If the local health department or the department requests a specimen under subsection (17) of this section, a laboratory director shall provide the Washington state public health laboratories with the information identified in Column C of Table 1 in this section with each specimen submitted.

(19) When referring a specimen to another laboratory for a test for novel coronavirus (SARS-CoV-2), a laboratory director shall provide the reference laboratory with the information identified in Column D of Table 1 in this section for each test referral.

(20) When referring a specimen to another laboratory for a test for novel coronavirus (SARS-CoV-2), a laboratory director may provide the reference laboratory with responses to ask on order entry questions under subsection (2)(h) of this section with each test referral.

(21) The department of agriculture shall submit individual case reports for each animal case of novel coronavirus (SARS-CoV-2) to the department via secure electronic data transmission using a file format or template specified by the department within twenty-four hours of being notified of the animal case.

(22) The department of agriculture shall call the department and confirm receipt immediately after submitting a case report for each animal case of novel coronavirus (SARS-CoV-2).

(23) When the department of agriculture submits information under subsection (21) of this section, the department shall:

(a) Consult with the department of agriculture on all animal cases; and

(b) Notify the local health department of animal cases submitted to the department.

(24) A local health department shall, using a secure electronic disease surveillance system:

(a) Notify the department immediately upon receiving a case report of positive, negative, or indeterminate test results for novel coronavirus (SARS-CoV-2); and

(b) Submit individual investigation reports of novel coronavirus (SARS-CoV-2) to the department immediately upon completing the case investigation.

(25) Notifications required under subsection (24)(a) of this section must include the information identified in Column E of Table 1 in this section.

(26) Investigation reports required under subsection (24)(b) of this section must include the information identified in Column F of Table 1 in this section.

(27) A local health department may submit responses to ask on order entry questions under subsection (2)(h) of this section with each notification required under subsection (24)(a) of this section and each investigation report required under subsection (24)(b) of this section.

(28) A local health department shall immediately reassign cases to the department upon determining the patient who is the subject of the case:

- (a) Is a resident of another local health department; or
- (b) Resides outside Washington state.

(29) A local health department, upon consultation with the department, may forward novel coronavirus (SARS-CoV-2) individual laboratory or case reports submitted by laboratories, health care providers, and health care facilities to the department for data entry and processing.

(30) The local health officer or the state health officer may request additional information of epidemiological or public health value when conducting a case investigation or otherwise for prevention and control of a specific notifiable condition.

(31) Health care providers, health care facilities, laboratories, and the department of agriculture may provide, via secure electronic data transmission using a file format or template specified by the department, additional health information, demographic information, or infectious or noninfectious condition information than is required under this section to the department, local health department, or both when it determines that the additional information will aid the public health authority in protecting the public's health and preventing the spread of novel coronavirus (SARS-CoV-2).

Table 1

Required Reporting for Health Care Providers, Health Care Facilities, Laboratories, and Local Health Departments

	Column A: Health care providers and health care facilities shall provide the following information to the local health department with each case report, and to the laboratory with each test ordered:	Column B: Laboratory directors shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory directors shall provide the department with the following information with each specimen submitted:	Column D: Laboratory directors shall provide the following information when referring a specimen to another laboratory:	Column E: Local health department notifications to the department must include:	Column F: Local health department investigation reports to the department must include:
Patient's name	X	X	X	X	X	X
Patient's notifiable condition	X				X	X
Patient's date of birth, or if not available, patient's age	X	X	X	X	X	X
Patient's sex	X	X	X	X	X	X

	Column A: Health care providers and health care facilities shall provide the following information to the local health department with each case report, and to the laboratory with each test ordered:	Column B: Laboratory directors shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory directors shall provide the department with the following information with each specimen submitted:	Column D: Laboratory directors shall provide the following information when referring a specimen to another laboratory:	Column E: Local health department notifications to the department must include:	Column F: Local health department investigation reports to the department must include:
Patient's ethnicity, using the categories described in subsection (2)(f) of this section	X	X	X	X	X	X
Patient's race, using the categories described in subsection (2)(g) of this section	X	X	X	X	X	X
Patient's full physical address including zip code	X	X	X	X	X	X
Patient's telephone number	X	X	X	X	X	X
Initial notification source					X	X
Patient's diagnosis of disease or condition	X					
Pertinent laboratory data	X					
Test ordered, using harmonized LOINC codes provided by the CDC		X	X	X	X*	X*
Date test ordered		X	X	X	X*	X*
Device identifier		X	X		X*	X*
Type of specimen tested	X	X	X	X	X*	X*
Specimen source, using appropriate SNOMED-CT, or equivalently detailed laboratory local codes, or a specimen-specific LOINC code for test performed		X	X	X	X*	X*
Date of specimen collection	X	X	X	X	X	X
Date specimen received by reporting laboratory		X	X		X*	X*

	Column A: Health care providers and health care facilities shall provide the following information to the local health department with each case report, and to the laboratory with each test ordered:	Column B: Laboratory directors shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory directors shall provide the department with the following information with each specimen submitted:	Column D: Laboratory directors shall provide the following information when referring a specimen to another laboratory:	Column E: Local health department notifications to the department must include:	Column F: Local health department investigation reports to the department must include:
Accession number or specimen ID		X	X		X*	X*
Test performed and result, using appropriate LOINC and SNOMED codes, as defined by the Laboratory in Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 tests provided by the CDC		X	X		X*	X*
Test result date		X	X		X*	X*
Condition symptom onset date (preferred), or alternatively, diagnosis date						X
Ordering health care provider's name	X	X	X	X	X	X
Ordering health care provider's National Provider Identifier (as applicable)	X	X	X	X	X	X
Ordering health care provider's telephone number	X	X	X	X	X	X
Ordering health care provider's address including zip code	X	X	X	X	X	X
Name and telephone number of the person providing the report	X					
Performing laboratory's name		X	X		X*	X*
Performing laboratory's CLIA number, if known		X	X		X*	X*
Performing laboratory's zip code		X	X		X*	X*
Performing laboratory's phone number		X	X		X*	X*

	Column A: Health care providers and health care facilities shall provide the following information to the local health department with each case report, and to the laboratory with each test ordered:	Column B: Laboratory directors shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory directors shall provide the department with the following information with each specimen submitted:	Column D: Laboratory directors shall provide the following information when referring a specimen to another laboratory:	Column E: Local health department notifications to the department must include:	Column F: Local health department investigation reports to the department must include:
Date local health department was notified					X	X
Hospitalization status of the patient						X
Whether the patient died during this illness						X
Source or suspected source						X

* Local health departments are not required to submit this information if the notification came from a health care provider or health care facility. All other information indicated in Columns E and F is still required in these instances.