



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: July 31, 2020

TIME: 5:10 PM

WSR 20-16-121

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 has adopted an emergency rule to create a new section of rule that designates Novel Coronavirus (SARS-CoV-2), also known as Coronavirus Disease 2019 (COVID-19) as a notifiable condition and requires health care providers, health care facilities, laboratories, and local health jurisdictions to report race, ethnicity, and other demographic data for cases of COVID-19.

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Repealed: None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

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 designating COVID-19 as a notifiable condition, and requiring the reporting of race, ethnicity, and other demographic data by health care providers, health care facilities, laboratories, and local health jurisdictions related to cases of COVID-19 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 this pandemic.

Public Law 116-136, Â§ 18115(a), the Coronavirus Aid, Relief, and Economic Security (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 statute authorizes the Secretary of HHS to prescribe the form and manner, and timing and frequency, of such reporting. On June 4, 2020, the Secretary of HHS finalized and published guidance on COVID-19 CARES Act reporting requirements. The guidance required that all data be reported through existing public health data reporting methods. Of these requirements, demographic information such as the patient's age, race, ethnicity, and sex must be collected and reported to state or local public health departments using existing reporting channels in accordance with state law or policies.

**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: 07/30/2020

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) "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.

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

(c) "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 secure electronic disease surveillance system.

(d) "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.

(e) Patient's race shall be reported using one or more of the following categories:

(i) Afro-Caribbean;

(ii) American Indian or Alaska Native;

(iii) Asian Indian;

(iv) Black or African American;

(v) Chinese;

- (vi) Congolese;
- (vii) Eritrean;
- (viii) Ethiopian;
- (ix) Filipino;
- (x) Guamanian or Chamorro;
- (xi) Japanese;
- (xii) Kenyan;
- (xiii) Korean;
- (xiv) Middle Eastern/North African;
- (xv) Native Hawaiian;
- (xvi) Other African Immigrant;
- (xvii) Other Asian;
- (xviii) Other Pacific Islander;
- (xix) Samoan;
- (xx) Somali;
- (xxi) South African;
- (xxii) Ugandan;
- (xxiii) Vietnamese;
- (xxiv) White; and
- (xxv) Refused to answer.

(f) Patient's ethnicity shall be reported using one or more of the following categories:

- (i) Cuban;
- (ii) Mexican, Mexican American, Chicano/a;
- (iii) Not of Hispanic, Latino/a, or Spanish origin;
- (iv) Other Hispanic, Latino/a, or Spanish origin;
- (v) Puerto Rican; and
- (vi) Refused to answer.

(g) Patient's preferred language shall be reported using one of the following categories:

- (i) Amharic;
- (ii) Arabic;
- (iii) Burmese;
- (iv) Chinese;
- (v) Chuukese;
- (vi) English;
- (vii) Filipino/Pilipino;
- (viii) French;
- (ix) German;
- (x) Hindi;
- (xi) Hmong;
- (xii) Japanese;
- (xiii) Karen languages;
- (xiv) Korean;
- (xv) Lao;
- (xvi) Marshallese;
- (xvii) Nepali;
- (xviii) Oromo;
- (xix) Persian;
- (xx) Portuguese;
- (xxi) Punjabi;
- (xxii) Romanian;
- (xxiii) Russian;
- (xxiv) Samoan;
- (xxv) Somali;
- (xxvi) Spanish;
- (xxvii) Swahili;

- (xxviii) Tagalog;
- (xxix) Tamil;
- (xxx) Telugu;
- (xxxi) Thai;
- (xxxii) Tigrinya;
- (xxxiii) Urdu;
- (xxxiv) Ukrainian;
- (xxxv) Vietnamese;
- (xxxvi) Other language; and
- (xxxvii) Refused to answer.

(h) Ask on order entry questions are:

- (i) Is this the patient's first novel coronavirus (SARS-CoV-2) test? (yes, no, unknown);
- (ii) Is the patient employed in health care? (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/yy);
- (iv) Is the patient hospitalized for novel coronavirus (SARS-CoV-2)? (yes, no, unknown);
- (v) Is the patient in the intensive care unit (ICU)? (yes, no, unknown);
- (vi) Is the patient a resident in a congregate care 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, farmworker 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-19) 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 246-101-120; excluding the requirements in WAC 246-101-105(10).

(4) The local health officer may waive or partially waive subsection (3) of this section if the local health officer determines individual case reports of novel coronavirus (SARS-CoV-19) submitted by health care providers 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 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 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) The local health officer may waive or partially waive subsection (5) of this section if the local health officer determines individual case reports of novel coronavirus (SARS-CoV-19) submitted by 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 facilities upon their determination.

(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-19) 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 (12), (13), (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) 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.

(13) A laboratory director shall submit individual case 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 246-101-230; excluding the requirements in WAC 246-101-205(3).

(14) 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.

(15) 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

(16) If the local health department or the department requests a specimen under subsection (14) 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.

(17) 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.

(18) 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.

(19) Notifications required under subsection (18) (a) of this section must include the information identified in Column E of Table 1 in this section.

(20) Investigation reports required under subsection (18) (b) of this section must include the information identified in Column F of Table 1 of this section.

(21) 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.

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

(23) 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.

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 director shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory director shall provide the department with the following information with each specimen submitted:	Column D: Laboratory director 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	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
Patient's race, using the categories described in subsection (2)(e) of this section	X	X	X	X	X	X
Patient's ethnicity, using the categories described in subsection (2)(f) of this section	X	X	X	X	X	X
Patient's preferred language, 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
Telephone number of patient's emergency contact	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*

	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 director shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory director shall provide the department with the following information with each specimen submitted:	Column D: Laboratory director 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:
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*
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
Answers to the ask on order entry questions under subsection (2)(h) of this section	X	X		X	X	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

	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 director shall provide the local health department with the following information with each laboratory report:	Column C: Laboratory director shall provide the department with the following information with each specimen submitted:	Column D: Laboratory director 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:
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*
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.