WSR 23-01-081
EMERGENCY RULES
STATE BOARD OF HEALTH

[Filed December 16, 2022, 7:43 a.m., effective December 16, 2022, 7:43 a.m.]

Effective Date of Rule: Immediately upon filing.

Purpose: WAC 246-101-017 Novel coronavirus (SARS-CoV-2), coronavirus disease 2019 (COVID-19) reporting. The Washington state board of health has adopted a ninth 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 P.L. 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.

Statutory Authority for Adoption: RCW 43.20.050 (2)(f).

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; and 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 United States 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 a ninth emergency rule ensures continued compliance with the CARES Act, including updating HHS guidance and CMS requirements and maintaining the necessary public health response to COVID-19.

Number of Sections Adopted in Order to Comply with Federal Statute: New 1, Amended 0, Repealed 0; Federal Rules or Standards: New 1, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 1, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 1, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 1, Amended 0, Repealed 0.

Date Adopted: November 9, 2022.

Michelle A. Davis
Executive Director

OTS-2485.7

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 or-

dering a laboratory test to enable the entities performing the test to report these data to state, territorial, local, and tribal public health departments. During 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) "Antigen test" means an immunoassay test that detects the presence or absence of SARS-CoV-2 protein to indicate current SARS-CoV-2 infection.

(c) "Business day" means any day that the department is open for business.

(d) "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.

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

(f) "Nucleic acid amplification test" or "NAAT" means a viral diagnostic test including reverse transcription polymerase chain reaction (RT-PCR), transcription mediated amplification (TMA), loop-mediated isothermal amplification (LAMP), strand displacement amplifications (SDA), and other NAATs authorized for emergency use by the U.S. Food and Drug Administration for the detection for SARS-CoV-2.

(g) "Reference laboratory" means a laboratory licensed inside or outside of Washington state that receives a specimen from another licensed laboratory and performs one or more tests on that specimen.

(h) "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.

(i) "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.

(j) "Waived test" has the same meaning as WAC 246-338-010 (45)(b).

(k) 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.

(l) 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.

(3) Unless a health care facility has assumed the notification duties of the principal health care provider under subsection (7) 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 (9) 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 24 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 24 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) A health care facility may assume the notification requirements established in this section for a health care provider practicing within the health care facility.

(8) 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.

(9) 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 (12), (13), and (14) of this section.

(10) 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).

(11) 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.

(12) For laboratories licensed to conduct moderate or high complexity testing, the laboratory director shall submit individual laboratory reports of positive, negative, and inconclusive test results from all NAAT and antigen tests performed for novel coronavirus (SARS-CoV-2) to the local health department:

(a) Via secure electronic data transmission using a file format or template specified by the department;

(b) Within 24 hours of results being known or determined; and

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

(13) For laboratories licensed to conduct waived tests under a certificate of waiver, a laboratory director shall submit individual laboratory reports of positive test results from all waived tests, excluding antibody testing, for novel coronavirus (SARS-CoV-2) to the local health department:

(a) Via secure electronic data transmission using a file format or template specified by the department;

(b) Within 24 hours of results being known or determined; and

(c) 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 (15) 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) 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.

(19) 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).

(20) When the department of agriculture submits information under subsection (18) 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.

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

(a) Notify the department within one business day upon receiving a case, laboratory, or animal case report of positive test results, excluding antibody testing, for novel coronavirus (SARS-CoV-2); and

(b) Notify the department within five business days upon receiving a laboratory report of negative or inconclusive test results for novel coronavirus (SARS-CoV-2); and

(c) Submit individual investigation reports of novel coronavirus (SARS-CoV-2) to the department within one business day upon completing the case investigation.

(22) Notifications required under subsection (21)(a) and (b) of this section must include the information identified in Column E of Table 1 in this section.

(23) Investigation reports required under subsection (21)(c) of this section must include the information identified in Column F of Table 1 in this section.

(24) A local health department shall, within one business day, 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.

(25) 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.

(26) 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.

(27) 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 (last name, first name, middle initial)	X	X	X	X	X	X
Patient's street address, including residence zip code and county	X	X	X	X	X	X
Patient's telephone number with area code	X	X	X	X	X	X
Patient's age and date of birth	X	X	X	X	X	X
Patient's ethnicity, using the categories described in subsection (2)(k) of this section	X	X	X	X	X	X
Patient's race, using the categories described in subsection (2)(l) of this section	X	X	X	X	X	X
Patient's sex	X	X	X	X	X	X
Test ordered, performed, and resulted, using appropriate LOINC 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*	X*
Test result (values) using appropriate SNOMED-CT codes as defined by the LIVD Test Code Mapping for SARS-CoV-2 tests provided by the CDC		X	X	X	X*	X*

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Test result date (date format)		X	X		X*	X*
Device identifier		X	X		X*	X*
Accession number or specimen ID		X	X		X*	X*
Date of specimen collection (date format)	X	X	X	X	X	X
Specimen source, using appropriate SNOMED-CT, SPM4 codes, or equivalently detailed alternative codes		X	X	X	X*	X*
Ordering organization or health care provider's name	X	X	X	X	X	X
Ordering organization or health care provider's National Provider Identifier (as applicable) and affiliated organization (specific facility)	X	X	X	X	X	X
Ordering organization or health care provider's telephone number	X	X	X	X	X	X
Ordering organization or health care provider's address including zip code	X	X	X	X	X	X
Performing laboratory or facility name and CLIA number		X	X		X*	X*
Performing laboratory or facility address including zip code		X	X		X*	X*
Performing laboratory or facility phone number		X	X		X*	X*

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Reporting entity name and CLIA number (or appropriate ID)		X	X	X	X*	X*
Reporting entity address including zip code		X	X	X	X*	X*
Reporting entity phone number		X	X	X	X*	X*
Name and telephone number of the person providing the report	X					
Patient's notifiable condition	X				X	X
Patient's diagnosis of disease or condition	X					
Date specimen received by reporting laboratory		X	X		X*	X*
Type of specimen tested	X	X	X	X	X*	X*
Pertinent laboratory data	X					
Initial notification source					X	X
Date local health department was notified						X
Condition symptom onset date (preferred), or alternatively, diagnosis date						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.

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