



Washington State Board of Health

Emergency Rule: WAC 246-101-017, COVID-19 Reporting

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Overview

- Background
 - CARES Act Requirements, HHS Guidance
 - CMS Reporting Requirements
- Prior Emergency Rules
- Proposed Fourth Emergency Rule
- Future Emergency Rules
- Next Steps

Background: CARES Act Requirements, HHS Guidance

- **March 2020:** the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires laboratories to report COVID-19 test results to the Secretary of the U.S. Department of Health and Human Services (HHS) in a manner prescribed by the Secretary
- **June 2020 (updated January 2021):** HHS releases COVID-19 laboratory data reporting guidance specifying standards for reporting testing and demographic data
- **September 2020:** Centers for Medicare and Medicaid Services (CMS) publish an interim final rule stipulating all laboratories conducting COVID-19 testing and reporting patient-specific results who fail to report information required under the CARES Act will be subject to monetary penalties

Background: HHS-required Data Components

Data components that must be collected

- Test ordered; date test ordered; test result
- Device identifier; accession number or specimen ID; specimen source
- Patient age, race, ethnicity, sex, residence zip code and county
- Ordering provider name, national provider identifier (NPI), zip code
- Performing facility name, clinical laboratory improvement amendment (CLIA) number, zip code

Many of these data components are already required reporting under chapter 246-101 WAC, Notifiable Conditions

Data components that should be collected

- Patient name, date of birth, street address, phone number
- Ordering provider address, phone number
- Answers to “ask on order entry” questions
 - First test? Symptomatic?
 - Hospitalized? ICU?
 - Pregnant?
 - Employed in health care?
 - Congregate care setting resident?

Prior Emergency Rules

July 30, 2020

- Required reporters: health care providers & facilities, laboratories, LHJs
- All data components that must and should be collected per HHS
- Additional data reporting (e.g., patient emergency contact, preferred language)
- Disaggregated race and ethnicity

November 9, 2020

- Required reporters: health care providers & facilities, laboratories, LHJs, Dept. of Agriculture
- Closely aligns with HHS guidance; additional data components removed

March 10, 2021

- No changes; rule language identical to November 9, 2020, emergency rule

Proposed Fourth Emergency Rule

- No proposed changes are recommended today
- Fourth emergency rule is identical to the second and third emergency rules adopted by the Board
- Rule language is provided in today's meeting materials



Future Emergency Rules

- Board and Department of Health staff have discussed adding reporting requirements related to genomic sequencing of COVID-19 positive specimens
- Both clinical labs and research labs conduct genomic sequencing
- Research labs are not regulated by the Board at this time
- The Board may wish to discuss the scope of the rule and its authority as it relates to research labs and controlling communicable disease



Next Steps

- The current emergency rule will expire on July 24, 2021.
- If the Board elects to adopt a fourth emergency rule, staff will file a fourth CR-103E to extend current requirements of WAC 246-101-017 without lapse.
- Emergency rule will be in effect for 120 days.

| THANK YOU