



Washington State Board of Health

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

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Overview

- Background
- Prior Emergency Rules
- Updated HHS Guidance
- Proposed Seventh Emergency Rule
- Next Steps

Background: CARES Act Requirements, HHS Guidance

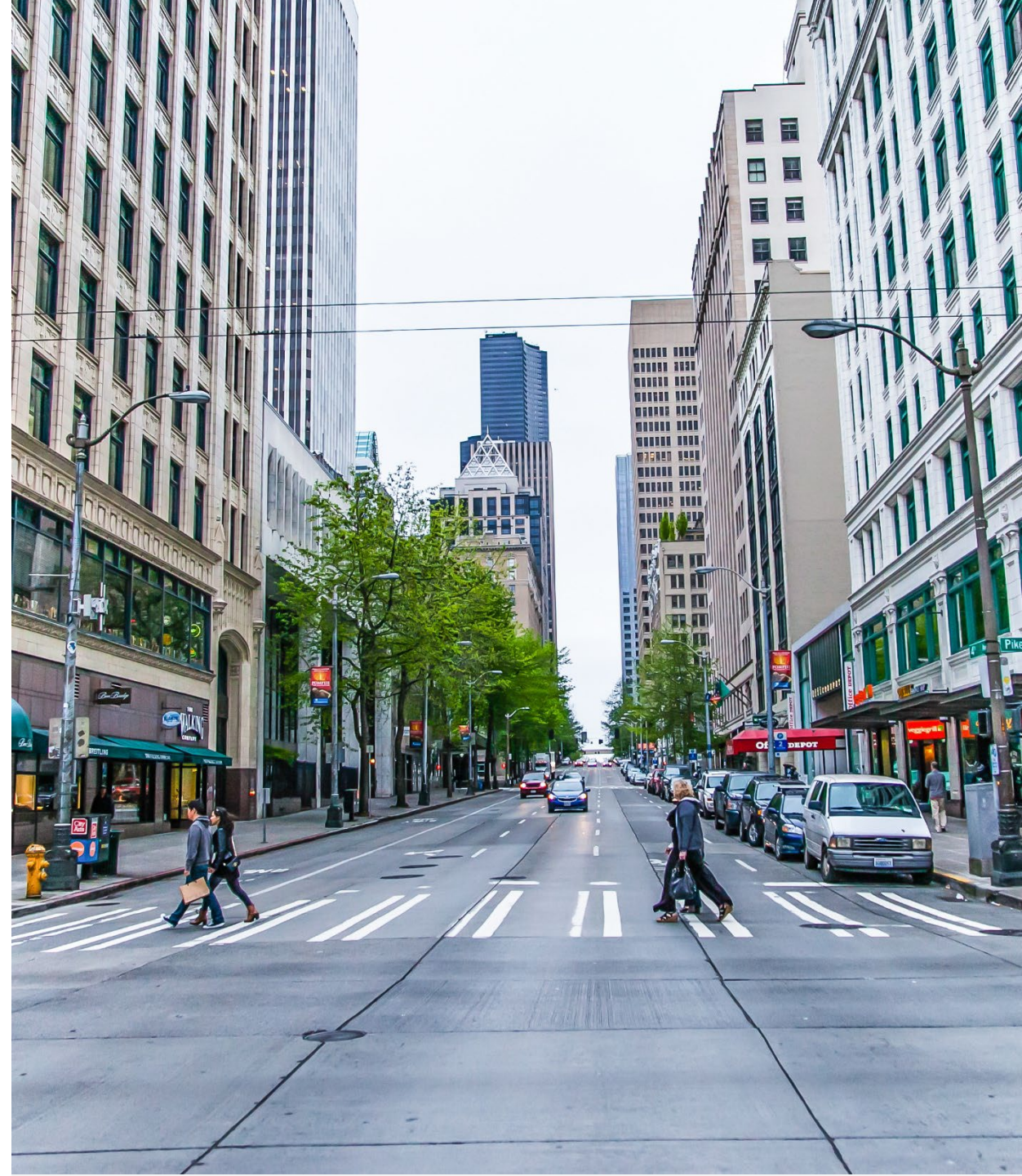
- **March 2020:** the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires laboratories to report COVID-19 test results to the Secretary of the U.S. Department of Health and Human Services (HHS) in a manner prescribed by the Secretary
- **June 2020 (updated January 2021, March 2022):** 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

Prior Emergency Rules

July 30, 2020	November 9, 2020	March 10, 2021	June 9, 2021	August 11, 2021	November 10, 2021
<ul style="list-style-type: none">• Required reporters: health care providers & facilities, laboratories, LHJs• All data components required by HHS• Additional data reporting (e.g., patient emergency contact, preferred language)• Disaggregated race and ethnicity	<ul style="list-style-type: none">• Dept. of Agriculture added to the list of required reporters• More closely aligned with HHS guidance; additional data components not required by HHS removed	<ul style="list-style-type: none">• No changes; rule language identical to November 9, 2020, emergency rule	<ul style="list-style-type: none">• No changes; rule language identical to November and March, emergency rules	<ul style="list-style-type: none">• Adjusted reporting requirements for LHJs to report to the Dept. of Health to better reflect the capacity of the Dept. of Health and LHJs to receive and send these data• All other requirements unchanged	<ul style="list-style-type: none">• No changes; rule language identical to August emergency rule

Updated HHS Guidance

- Specifies reporting requirements by testing entity and test type
- Removes reporting requirements for antibody and self-administered tests
- Removes reporting for ask-on-order entry questions (previously voluntary reporting)
- Refines list of reportable data components that accompany test results



Updated HHS Guidance

- Specifies reporting requirements by testing entity and test type:
 - Nucleic Acid Amplification Test (NAAT) testing conducted in a facility certified to perform high- or moderate-complexity tests: **positive, negative, and inconclusive results**
 - All other testing: **positive results**
 - No antibody or self-administered tests



Proposed Seventh Emergency Rule

- New definitions: antigen test, nucleic acid amplification test, reference laboratory, waived test
- Removed voluntary reporting for ask-on-order entry questions
- Labs licensed to conduct moderate or high complexity testing must report positive, negative, and inconclusive results for all NAAT and antigen tests
- Labs licensed to conduct waived test under a certificate must report positive results for all waived tests, excluding antibody testing

Proposed Seventh Emergency Rule

- Local health officers must notify DOH of all positive results within one business day
- Local health officers must notify DOH of negative and inconclusive results within five business days
- Aligned required reportable data components with updated HHS guidance
- Editorial edits for clarity and useability

Permanent Rulemaking

- Per the Administrative Procedures Act, the Board filed a CR-101 on July 20, 2021 to integrate emergency rule requirements and provisions into permanent rule
- Permanent revisions to the Notifiable Conditions chapter may not go into effect until January 2, 2023 at the earliest



Next Steps

- Current emergency rule expires April 20, 2022.
- If the Board elects to adopt a seventh emergency rule, staff will file a CR-103E with the code reviser to extend WAC 246-101-017 without lapse.
- Emergency rule will be in effect for 120 days.

| THANK YOU