Washington State Department of Health

COVID-19 REPORTING LISTENING SESSION

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Facilitator

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Agenda

- 3:00-3:15 Recap of the last session and changes
  - Status of the new data elements from HHS and SBOH
  - Electronic reporting options in WA State

- 3:15-3:30 New items
  - CMS compliance update from LQA
  - Point of care devices and congregate care facilities

- 3:30-4:00 Q&A
  - Share questions, comments, and concerns regarding COVID-19 reporting in WA

Recap of the last session and changes

What must be reported?

Washington State (WAC 246-101) requires laboratories to report **all** COVID-19 results

- This includes positive, negative, inconclusive, and other results based on State Health Officer Letters to the local health jurisdiction (LJH) of the patient's residence.
- Antibody tests included

Who must report COVID-19 results?

All entities performing testing related to COVID-19, including all CLIA-waived tests that may be performed at the point of care.

- This reporting requirement applies to all entities defined under Chapter 70.42 RCW as **Medical Test Sites**, including clinical settings not traditionally seen as “labs” (RCW 70.42.010)

What must be reported?

U.S. Department of Health and Human Services' (HHS) June 4, 2020 guidance. These include but are not limited to:

- Test ordered
- Device Identifier
- Test result and test result date
- Accession # / Specimen ID
- Patient age, race, ethnicity, and sex
- Patient residence zip code and county
- Ordering provider name, NPI (as applicable), and zip code
- Performing facility name, CLIA number, and zip code
- Specimen Source
- Date test ordered and date specimen collected

Additional requirements in the Washington State Board of Health's (Board) emergency rule, adopted July 31, 2020. These also include patient's complete contact info & emergency contact, more granular race & ethnicity, primary language, and "Ask on order entry" questions.

Why is the additional info important?

- To curb the pandemic, protect public health, and **promote equity**.
- To understand which communities are impacted by COVID-19.
- To **build partnerships** with community-based organizations to develop community-led prevention strategies.
- Language is needed to improve **outreach**, prevention strategies, and **contact tracing, and case investigations**.
- Emergency contact phone number can help contact tracing efforts in the event the patient's phone number is incorrect or disconnected.

What are the electronic reporting options?

- Laboratories
  1. Electronic Lab Reporting (ELR) - All notifiable conditions
  2. Electronic Lab Flat File (ELFF) – shifting away from
  3. National Flat File Option via APHL – preferred method for COVID-19 only

- Health Care Providers
  - Electronic Case Reporting (ECR) – under development
    - Will meet reporting requirements for providers under WAC Chapter 246-101-101 and can be used for COVID-19 case reporting as well as many other notifiable conditions.

- Once onboarding process is complete, labs or providers will not need to send COVID-19 results to LHJs.

NFF Onboarding Process

The Association of Public Health Laboratories' (APHL) National Flat File (NFF) for COVID-19 results has the ability to generate HL7 messages.

- If labs submit their data through APHL's AIMS hub, results will be routed to the appropriate states.
- DOH will continue to offer SFT or OneHealthPort submissions.
- The NFF and HL7 generator tool package can be found here: https://preparedness.cste.org/?page_id=136

If you are interested in continuing with the electronic reporting process, please complete the registration form and the ELR team will provide more information.

How do I meet the new HHS lab requirements?

- NFF includes the HHS required data fields.
- Submitting to DOH meets CDC daily requirements.
- Submitting to DOH meets federal reporting requirements.
- DOH is developing plans to update our data feeds to accommodate the new data fields.

New Items

CMS compliance

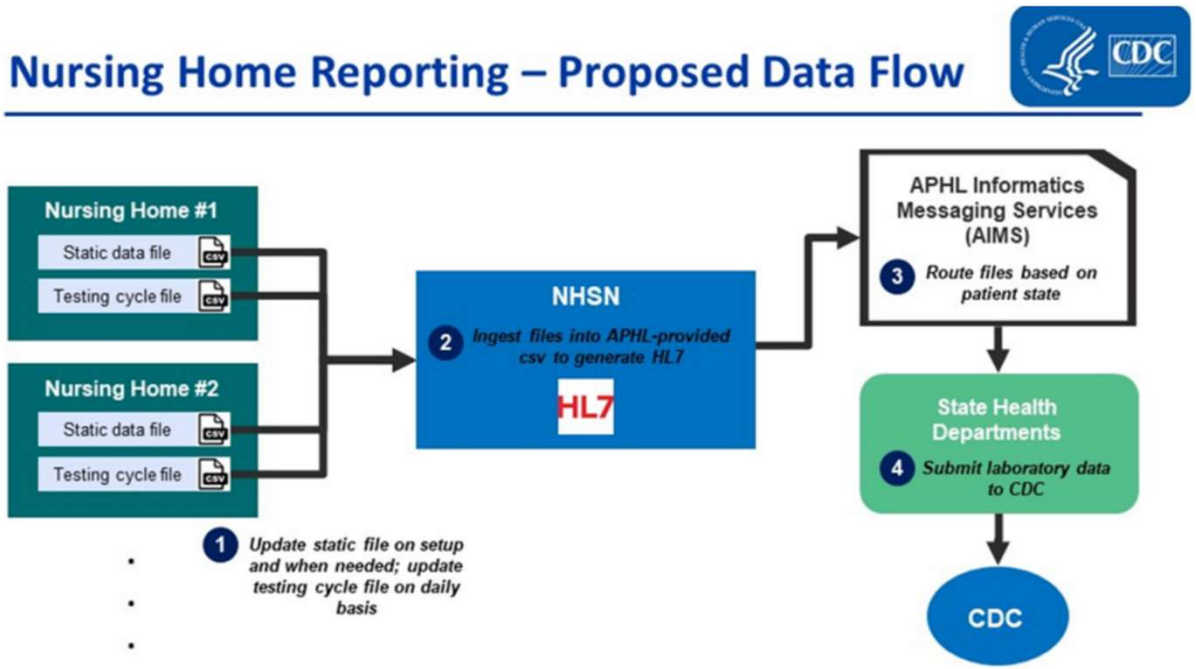
On August 26, 2020, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum regarding new reporting requirements for laboratories perform SARS-CoV-2 (COVID-19) testing. These new reporting requirements were posted to the federal register on September 2, 2020. Changes to federal CLIA rules are to include new requirements for on-site reviews of certificate of wavier and provider performed microscopy licenses to verify compliance with the new rules. Additionally, CMS is requiring new civil money penalties, which will be $1000 for the first day of noncompliance, and $500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results. These changes are expected to be completed by mid-October.

If you have any additional questions regarding compliance or penalties, please reach out to lqa@doh.wa.gov.

Point of care devices and congregate care facilities

Options to send data

- Immediate: Faxing to county of patient's residence (pdf)
- In the works
  - CDC's National Healthcare Safety Network's workflow plan
  - APHL is working with Abbott (could be limited)
  - DOH - EPIC Rover app



Questions, Comments, & Concerns

Questions to Consider

Please "Raise your hand" to be unmuted or type your questions into the chat box.

- Are there any questions about the electronic reporting options DOH currently offers?

- Are there new or unique challenges you are facing with COVID reporting?

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