

VAERS AND NOTICE OF PROPOSED RULEMAKING

VAERS

The Vaccine Adverse Events Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). VAERS is intended to detect potential safety problems — called “signals” — that may be related to vaccination. Because VAERS has no comparison group, it cannot determine whether any given reported adverse event is caused by the vaccination that preceded it; any detected “signals” are subsequently analyzed using more robust data systems.

Under the terms of the FDA’s Emergency Use Authorizations (EUAs), health care providers are *required* to report to VAERS the following events associated with COVID-19 vaccination, and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
 - Serious AEs, regardless of causality. Serious AEs are defined by FDA as:
 - Death;
 - A life-threatening AE;
 - Inpatient hospitalization or prolongation of existing hospitalization;
 - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 - A congenital anomaly/birth defect;
 - An important medical event that based on appropriate medical judgment, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
 - Cases of Multisystem Inflammatory Syndrome
 - Cases of COVID-19 that result in hospitalization or death
- Healthcare providers are additionally encouraged to report to VAERS

any clinically significant AEs, even if they are not sure whether vaccination caused the event.

Also report any other AEs as required by FDA revision of the vaccine’s EUA.

Each report of an adverse event provides valuable information that is added to the VAERS database. Accurate, complete, and timely reporting of post-vaccination health issues provides information necessary for vaccine safety monitoring and research.

Patient identity is kept confidential. VAERS complies with all U.S. government security standards and protections concerning health information.

FOR MORE INFORMATION

- <https://vaers.hhs.gov/index.html>
- Details regarding how to report to VAERS: www.youtube.com/watch?v=9IVCzQFOhew

Notice of Proposed Rulemaking

“A place for everything, everything in its place.” – Ben Franklin

BACKGROUND

Although it might sound a bit stale by now to say that the COVID-19 pandemic has affected all Oregonians, it’s important to reiterate that the COVID-19 pandemic has disproportionately affected people of color. For this reason, the Oregon Health Authority (OHA) is proposing additional rules around disease reporting in regard to race, ethnicity, language, and disability (REALD) reporting, as well as federally “waived” laboratory testing, and reporting of illness diagnosed by Oregon health care providers or laboratories in non-Oregon residents.

In June 2020, the Oregon Legislative Assembly passed House Bill (HB) 4212, requiring health care providers, which include hospitals and other health care facilities, to collect REALD

COVID REPORTING RULES

Full text of the proposed changes may be found at: www.oregon.gov/oha/PH/DISEASES/CONDITIONS/COMMUNICABLEDISEASE/REPORTING/COMMUNICABLEDISEASE/Documents/rules/2021/COVID-19/333-018-Notice-ProposedRulemaking-Jan29-2021.pdf

A public hearing will be held on **Wednesday, February 17, 2021, at 1:00 P.M. via conference call. To present oral testimony during the hearing, please call 1-877-848-7030, access code 2030826#.**

You may also **file written comments** before 5:00 P.M. on February 28, 2021, to the Public Health Division Rules Coordinator:

Brittany Hall, Administrative Rules Coordinator
 OHA, Public Health Division
 800 NE Oregon Street, Suite 930
 Portland, Oregon 97232
brittany.a.hall@state.or.us

You can send comments by:
 Fax: 971-673-1299 or
 E-mail: publichealth.rules@state.or.us

data for all COVID-19 encounters and to report those data to OHA through methods described in the following Oregon Administrative Rules (OARs) to help identify racial and ethnic groups that experience disproportionate rates of illness, including from COVID-19: Oregon Administrative Rule (OAR) 333-018-0010, OAR 333-018-0011, and OAR 333-018-0016 (Table). On December 17, 2020, OHA filed a “Notice to Interested Parties” of proposed rulemaking around REALD data collection and reporting requirements for health care providers (HCPs) for COVID-19; these rules will become permanent March 30, 2021.*

Additionally — and the reason for this *CD Summary* — OHA is proposing a few more necessary rule changes around disease reporting in out-of-state residents and the reporting of “CLIA*-waived” point-of-care COVID-19 test results. These rules will take effect at the same time as the aforementioned rules pertaining to REALD and COVID-19 reporting, i.e., March 30, 2021.

This *CD Summary* serves as official notice of these newly proposed rule changes. You are invited to review and to comment on the proposed rules regarding disease reporting in out-of-state residents and reporting “CLIA- waived” test results. Final rules will be filed after consideration of all comments.

OUT-OF-STATE RESIDENTS

Reporting cases on non-Oregon residents: report their test results directly to the state of their residence: do not report them to OHA.

Most disease reports, including patient identifiers and addresses, are reported to OHA electronically. Each reported case is uploaded into a database for visualization and investigation by the local public health authority for the patient’s county of residence, which is inferred from the patient’s address. Occasionally, cases in out-of-state residents are identified by Oregon health care professionals. Our current rule specifies that such cases may be reported to OHA; and OHA, in turn, has to relay them to the relevant public health jurisdiction outside of Oregon. *COVID-19 reporting has made this no longer feasible.* COVID-19 case

* Visit: www.oregon.gov/oha/PH/DISEASES/CONDITIONS/COMMUNICABLEDISEASE/REPORTINGCOMMUNICABLEDISEASE/Pages/COVID-19-Disease_Reporting.aspx

Table. Abbreviated Descriptive Summary of Oregon’s COVID-19-related rules going into effect on March 30, 2021. Newly proposed rules highlighted in red.

OAR Number	Abbreviated Description
333-018-0005	Requires reporting of test results on non-Oregon residents to the public health jurisdiction of the patient’s place of residence, rather than to OHA or the Oregon Local Public Health Authority.
333-018-0010	Requires REALD reporting in addition to other reportable disease information; includes how and when.
333-018-0011	* Specifies which health care providers are required to collect <u>and</u> report REALD data for COVID-19 encounters. * Defines reporting entities, encounter types, and phased-in timeline for various provider types. * Defines how providers can report the data to the agency.
333-018-0015	Housekeeping changes: *Clarifies that “intoxications” are among the illnesses to be reported; *Removes the following outdated reporting language, which is no longer applicable: *(2) When local public health administrators cannot be reached within the specified time limits, reports shall be made directly to the Authority, which shall maintain an around-the-clock public health consultation service.
333-018-0016	Defines which health care providers are required to collect and report REALD information. *Includes negative COVID-19 tests as a reportable encounter. *Requires reporting of positive and negative results of COVID-19 “CLIA-waived” point of care tests

counts have dwarfed those of any other reportable disease: more than 140,000 Oregon cases of COVID-19 have been reported during March 2020–January 2021, compared with 40,239 cases of all reportable diseases during 2018. Moreover, OHA has required reporting of negative tests for COVID-19 as well, and more than 2.7 million such reports have been received. Thus, results of tests on out-of-state residents reported to OHA have risen dramatically — from 13,939 in all of 2019 to 297,944 as of December 2020. **Bottom line: Please report the test results of those patients who reside outside of Oregon directly to the state of their residence — not to OHA.**

The following web site serves as a reference to State and Local Health Officials, which includes a link to State Epidemiologists outside of Oregon: <http://dslo.afdo.org/>

“CLIA-WAIVED TESTS

In April 2020, the FDA clarified the emergency use authorizations for COVID-19 point-of-care tests, deeming such tests be waived by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. It was therefore essential that OHA amend its rule to explicitly require reporting of the results of such “CLIA waived” point-of-care

COVID-19 tests COVID-19 test results — both positive and negative. **Bottom line: All sites using “CLIA waived” point-of-care COVID-19 tests shall report all COVID-19 test results of all Oregonians — positive and negative — to OHA.**

HOUSEKEEPING

While we’re at it, OHA is also proposing to make some housekeeping changes (language proposed for deletion indicated by ~~strikethrough~~ font):

- removing the following language, rendered obsolete as the reporting mechanism has changed to electronic laboratory reporting:
 - (4) ~~In lieu of reporting to the local public health administrator, with the consent of the local public health administrator, licensed laboratories shall report directly to the Authority’s HIV Program (a) All tests indicative of and specific for HIV infection as required by OAR 333-018-0015; (b) All CD4+ T lymphocyte counts; and (c) All HIV viral load tests;~~
- removing the following outdated reporting language, which is no longer applicable:
 - (2) ~~When local public health administrators cannot be reached within the specified time limits, reports shall be made directly to the Authority, which shall maintain~~



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~~an around-the-clock public health consultation service;~~

- clarifying in all relevant places that “intoxications” are among the illnesses to be reported.

HOW TO REPORT

Use our on-line reporting page to report any reportable disease:
healthoregon.org/onlinemorbidityform.

THANK YOU

This pandemic has been especially trying for the health care community; thank you for all that you have done and continue to do on behalf of the health of Oregonians. Though we have skipped some of normal processes involving rules advisory committees, we encourage you to provide comments to the Public Health Division Rules Coordinator as in the box on the first page by 5:00 PM on February 28, 2021.

FOR MORE INFORMATION

- Oregon Administrative Rules: Rules 333-018 regarding disease reporting
<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1233>
- General Disease Reporting:
healthoregon.org/diseasereporting
- REALD Reporting for COVID-19 Encounters (ACDP) www.oregon.gov/oha/PH/DISEASES/CONDITIONS/COMMUNICABLEDISEASE/REPORTINGCOMMUNICABLEDISEASE/Pages/REAL-D-Collection-Toolkit.aspx
- REALD Implementation (Office of Equity and Inclusion) www.oregon.gov/oha/OEI/Pages/REALD.aspx