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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
01/29/2021 12:57 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Disease reporting in out-of-state residents; reporting COVID19 laboratory reports of “CLIA-waived” tests

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 02/28/2021 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 02/17/2021
TIME: 1:00 PM
OFFICER: Staff
ADDRESS: VIA CALL-IN ONLY
Following direction from the Gov/CDC
public meetings are being held
remotely
Portland, OR 97232
SPECIAL INSTRUCTIONS:
Due to COVID-19, public meetings are
being held remotely. To
provide oral testimony during this
hearing, please dial 1-877-848-7030,
Access Code: 2030826#

NEED FOR THE RULE(S):

The Oregon Health Authority (OHA), Public Health Division, is proposing permanent amendment to OAR 333-018-0005 relating to reporting of diseases in out-of-state residents; to OAR 333-018-0015 to remove outdated language regarding reporting to OHA rather in lieu of reporting to the local public health administrator, and making consistent language indicating that some illnesses to be reported are “intoxications”; and to OAR 333-018-0016 relating to reporting of COVID-19 specifically. The amended rules require reporters to report out-of-state cases to the jurisdictional public health authority of the patient’s residence, rather than to OHA. The proposed amendments would not affect case reporting for residents of Oregon-based Tribes. Such reports would continue to be made to the local (county) public health authority and OHA. The amendments remove language rendered obsolete by electronic

laboratory reporting. The amendments also require reporting of positive and negative COVID-19 laboratory reports of tests "waived" in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), whether or not the tests were performed in a laboratory accredited for higher complexity testing. This proposed permanent rulemaking replaces temporary rules filed and effective January 7, 2021.

OAR 333-018-0005. Most reportable diseases, including patient identifiers and address, are reported to the Oregon Health Authority (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. OAR 333-018-0005(4) currently specifies that such cases may be reported to OHA; and OHA, in turn, manually relays them to the relevant public health jurisdiction outside of Oregon. COVID-19 reporting has made this no longer feasible. COVID-19 case counts have dwarfed those of any other reportable disease: more than 100,000 Oregon cases of COVID-19 have been reported during March–December 2020, compared with 40,239 cases of all reportable diseases during 2018. Moreover, OHA required reporting of negative tests for COVID-19 as well, and more than 2.3 million such reports have been received. As a result, 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.

Housekeeping changes include removing the following outdated reporting language, as the reporting mechanism 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.

OAR 333-018-0015. Housekeeping changes are being made to clarify in all relevant places that "intoxications" are among the illnesses to be reported. The following outdated reporting language is also removed, 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.

OAR 333-018-0016. Because the U.S. Food and Drug Administration (FDA) has deemed point-of-care tests to be waived by Clinical Laboratory Improvement Amendments of 1988 (CLIA) for the duration of the national emergency declaration for COVID-19 testing, it is essential to amend this rule to explicitly include the results of such "CLIA-waived" point-of-care tests for COVID-19 – both positive and negative – to effectively investigate and prevent further spread of COVID-19 for the good of the public's health.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

04/09/2020: Lab Update: FDA Clarifies CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations (https://www.cdc.gov/csels/dls/locs/2020/fda_clarifies_clia-waived_status.html)

FISCAL AND ECONOMIC IMPACT:

Laboratories will experience an increased workload in having to report to the jurisdiction associated with the residence of each out-of-state patient with a reportable disease, rather than funneling such test results to the Authority, which has hitherto hamstrung the Authority's operations, as well as delayed ultimate reporting to the out-of-state jurisdiction

responsible for follow-up investigation and prevention of further spread of COVID-19 and other diseases. Entities using "CLIA-waived" point-of-care tests will experience an increased burden in reporting their COVID-19 results to the Authority – 42 such entities are currently in production sending comma-separated value (CSV) files to the Authority; 55 are in testing with regard to sending CSVs. Those "CLIA-waived" point-of-care test results will continue to contribute to the necessary and ongoing public health response to the COVID-19 pandemic, including morbidity and mortality prevention.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Although the burden of out-of-state reports will be eased, the Authority has already experienced a 110% increase in non-traditional electronic messages and reports from "CLIA-waived" point-of-care testing sites, which continue to add to the caseloads of the already overburdened local health departments and Tribes. There is no anticipated cost of compliance impact to the public.

(2)(a) Private physicians' offices and other entities may decide to offer point-of-care testing using "CLIA-waived" tests. The number of small businesses that will eventually do so is unknown.

(b) While the number of small businesses that will eventually conduct "CLIA-waived" point-of-care testing is unknown, the Authority assumes that the cost of compliance, that is, the reporting of positive and negative COVID-19 test results, will be absorbed in their cost of doing business. The Authority has created a point-of-care electronic reporting standard in the comma-separated value format to facilitate this reporting and lessen the cost of compliance.

(c) While the number of small businesses that will eventually conduct "CLIA-waived" point-of-care testing is unknown, the Authority anticipates that no new equipment or supplies will be required. Some labor will be required for entry of demographic data and test results into the comma-separated format and subsequent transmission to the Authority. The Authority assumes that impact of compliance cost will not preclude the cost of conducting these tests.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Due to the urgency of enacting these rules, small businesses were not involved in developing these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Due to the pandemic, the Public Health Division did not host a formal Rules Advisory Committee (RAC) to allow Health Care workers to continue supporting the emergent needs during this time. In lieu of a formal RAC, the following stakeholder populations were notified/consulted about these rulemaking changes Nurse Practitioners of Oregon, Oregon Association of Hospitals and Healthcare Systems; Oregon Medical Association, Oregon Academy of Family Physicians; Oregon Thoracic Society; Oregon Pediatric Society; Society of Critical Care Medicine; Oregon Society of Physician Assistants; Southwest Chapter of Association of Professionals in Infection Control; Oregon's Health Alert Network; subscribers of our CD Summary newsletter, which includes thousands of health-care professionals.

RULES PROPOSED:

333-018-0005, 333-018-0015, 333-018-0016

AMEND: 333-018-0005

RULE SUMMARY: Amend OAR 333-018-0005: Requires reporters to report out-of-state (non-Oregon) cases to the jurisdictional public health authority of the patient's residence, rather than to OHA. Housekeeping changes remove the following outdated reporting language, as the reporting mechanism 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.

CHANGES TO RULE:

333-018-0005
To Whom Reports Shall Be Made ¶

(1) I~~n general,~~f an individual who i~~f~~s the ~~patien~~subject of a report is an Oregon resident or temporarily resides in Oregon, reports shall be made to the local public health administrator for the patient's ~~place~~county of residence.~~¶~~
~~(2) In lieu of reporting to the local public health administrator, with the consent of the local public health administrator and the Authority, reports may be made directly to the Authority (for example, via electronic reporting)~~, except for laboratory reports that must be reported by laboratories in accordance with OAR 333-018-0013.¶
(~~3~~2) In urgent situations when local public health staff are unavailable, case reports shall be made directly to the Authority.¶
(~~4~~3) ~~Where the case is not an Oregon resident, reports shall be made either to the patient's local public health authority (if the patient resides in the United States) or directly to the Authority.¶~~
~~(5) 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 in~~Reports for an individual who is not an Oregon resident or who does not reside in Oregon may not be made to the Oregon local public health administrator or the Authority, but shall be made to the jurisdicati~~ve 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~~onal public health authority of the patient's residence.
Statutory/Other Authority: ORS 431.110, 433.001, 433.004, 433.006
Statutes/Other Implemented: ORS 431.110, 433.001, 433.004, 433.006, 433.106

AMEND: 333-018-0015

RULE SUMMARY: Amend OAR 333-018-0015: Housekeeping changes clarify in all relevant places that “intoxications” are among the illnesses to be reported; and 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.

CHANGES TO RULE:

333-018-0015
What Is to Be Reported and When ¶

(1) Health care providers shall report all human cases or suspected human cases of the diseases, infections, microorganisms, intoxications, and conditions specified below. The timing of health care provider reports is specified to reflect the severity of the illness or condition and the potential value of rapid intervention by public health agencies. ¶
(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.~~ ¶
~~(3)~~ Licensed laboratories shall report all test results indicative of and specific for the diseases, infections, microorganisms, intoxications, and conditions specified below for humans. Such tests include but are not limited to: microbiological culture, isolation, or identification; assays for specific antibodies; and identification of specific antigens, toxins, or nucleic acid sequences. ¶
(43) Human reportable diseases, infections, microorganisms, intoxications, and conditions, and the time frames within which they must be reported are as follows: ¶
(a) Immediately, day or night: ¶
(A) Select biological agents and toxins: Avian influenza virus; Bacillus anthracis (anthrax); Bacillus cereus biovar anthracis; Botulinum neurotoxins; Botulinum neurotoxin-producing species of Clostridium; Brucella (brucellosis); Burkholderia mallei (glanders); Burkholderia pseudomallei (melioidosis); Conotoxins; Clostridium botulinum (botulism); Coxiella burnetii (Q fever); Crimean-Congo hemorrhagic fever virus; Diacetoxyscirpenol; Eastern Equine Encephalitis virus; Ebola virus; Francisella tularensis (tularemia); Hendra virus; Lassa fever virus; Lujo virus; Marburg virus; Monkeypox virus; Newcastle disease virus; Nipah virus; Reconstructed replication-competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus);, Ricin; Rickettsia prowazekii (louse-borne typhus); Rift Valley fever virus; Severe Acute Respiratory Syndrome (SARS) and infection by SARS coronavirus; Saxitoxin (paralytic shellfish poisoning); South American Hemorrhagic Fever viruses (Chapare, Guanarito, Junin, Machupo, Sabia); Staphylococcal enterotoxins A,B,C,D,E subtypes; T-2 toxin; Tetrodotoxin (puffer fish poisoning); Tick-borne encephalitis complex (flavi) viruses (Far Eastern subtype, Siberian subtype); Kyasanur Forest disease virus; Omsk hemorrhagic fever virus, Variola major (Smallpox virus); Variola minor virus (Alastrim); Yersinia pestis (plague).¶
(B) The following other infections, microorganisms, and conditions: Corynebacterium diphtheriae (diphtheria); novel influenza; poliomyelitis; rabies (human); measles (rubeola); rubella; Vibrio cholerae O1, O139, or toxigenic (cholera); yellow fever; intoxication caused by marine microorganisms or their byproducts (for example, domoic acid intoxication, ciguatera, scombroid); ¶
(C) Any known or suspected disease outbreak, including any outbreak associated with health care, regardless of whether the disease, infection, microorganism, or condition is specified in this rule; and ¶
(D) Any uncommon illness of potential public health significance. ¶
(b) Within 24 hours (including weekends and holidays): ~~Candida auris,~~ Haemophilus influenzae (any invasive disease; for laboratories, any isolation or identification from a normally sterile site); Neisseria meningitidis (any invasive disease; for laboratories, any isolation or identification from a normally sterile site); and pesticide poisoning. ¶
(c) Within one local public health authority working day: amebic infection of the central nervous system (for

example, by Naegleria or Balamuthia);; any infection that is typically arthropod vector-borne (for example, mosquito-borne: California encephalitis, chikungunya, dengue, Eastern equine encephalitis, Plasmodium [(malaria]), St. Louis encephalitis, West Nile fever, Western equine encephalitis, Zika; tick-borne: anaplasmosis, babesiosis, Borrelia [relapsing fever, Lyme disease], ehrlichiosis, Colorado tick fever, Heartland virus infection, Rickettsia [prowazekii, report immediately, see paragraph (43)(a)(A) above, Rocky Mountain spotted fever, and others]; or other arthropod vector-borne: trypanosomiasis [Chagas disease], leishmaniasis, and any of the typhus fevers); Bordetella pertussis (pertussis); cadmium demonstrated by laboratory testing of urine; Campylobacter (campylobacteriosis); Chlamydia psittaci (psittacosis); Chlamydia trachomatis (chlamydiosis; lymphogranuloma venereum); Clostridium tetani (tetanus); Coccidioides (coccidioidomycosis), Creutzfeldt-Jakob disease and other transmissible spongiform encephalopathies; Cryptococcus (cryptococcosis), Cryptosporidium (cryptosporidiosis); Cyclospora cayetanensis (cyclosporosis); bacteria of the Enterobacteriaceae family found to be resistant to any carbapenem antibiotic-; Escherichia coli (enterotoxigenic, Shiga-toxigenic, including E. coli O157 and other serogroups); Giardia (giardiasis); Grimontia; Haemophilus ducreyi (chancroid); hantavirus; hepatitis A; hepatitis B; hepatitis C; hepatitis D (delta); hepatitis E; HIV infection (does not apply to anonymous testing) and AIDS; death of a person ~~less than~~ ≤18 years of age with laboratory-confirmed influenza; lead poisoning; Legionella (legionellosis); Leptospira (leptospirosis); Listeria monocytogenes (listeriosis); mumps; Mycobacterium tuberculosis and M. bovis (tuberculosis); nonrespiratory infection with nontuberculous mycobacteria; Neisseria gonorrhoeae (gonococcal infections); Salmonella (salmonellosis, including typhoid); Shigella (shigellosis); Taenia solium (including cysticercosis and undifferentiated Taenia infections); Treponema pallidum (syphilis); Trichinella (trichinosis); Vibrio (other than Vibrio cholerae O1, O139, or toxigenic; vibriosis); Yersinia (other than pestis; yersiniosis); a human bitten by any other mammal; hemolytic uremic syndrome; and rabies post-exposure prophylaxis.¶
(d) Within seven days: Any blood lead level tests including the result. ¶
(54) Licensed laboratories shall report, within seven days, the results of all tests of CD4+ T-lymphocyte absolute counts and the percent of total lymphocytes that are CD4 positive, and HIV nucleic acid (viral load) tests.
Statutory/Other Authority: ORS 413.042, 433.004, 433.006
Statutes/Other Implemented: ORS 433.004, 437.010

AMEND: 333-018-0016

RULE SUMMARY: Amend OAR 333-018-0016: Requires reporting of positive and negative COVID-19 laboratory reports of tests "waived" in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), whether or not the tests were performed in a laboratory accredited for higher complexity testing.

CHANGES TO RULE:

333-018-0016
Reporting of COVID-19 Related Test Results, Cases and Deaths
(1) Health care providers ~~shall report within 24 hours (including weekends and holidays)~~or other individuals described in OAR 333-018-0000(1) shall report, in accordance with section (~~2~~3) of this rule~~, the following:~~ and other applicable rules in OAR chapter 333, division 18, the following within 24 hours (including weekends and holidays):¶
(a) All human cases of COVID-19.¶
(b) All human cases of MIS-C.¶
(c) The hospitalization of any individual with COVID-19, whether or not the case was previously reported.¶
(d) The death of any individual due to COVID-19, whether or not the case was previously reported.¶
(2) Health care providers or any individual who is authorized to conduct a waived laboratory test in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 shall report all negative test results for COVID-19 in accordance with section (3) of this rule and other applicable rules in OAR chapter 333, division 18, within one local public health authority working day.¶
(3) Health care providers shall report the information required in sections (1) and (2) of this rule, in one of two ways, in order of preference, in addition to complying with other applicable rules in OAR chapter 333, division 18:¶
(a) Submission of an Electronic Initial Case Report (eICR) in accordance with the Authority's Electronic Case Reporting (ECR) Manual; or¶
(b) Through the Online Morbidity Report System, which can be found at: www.healthoregon.org/howtoreport.¶
(~~3~~4) ~~A health care facility or health care system, where~~When more than one health care provider may know the information that is required to be reported under sections (1) and (2) of this rule, they may establish policies and procedures to ensure that the information is reported to the local public health administrator or Authority as required, but duplicate reporting is minimized.¶
(~~4~~5) Licensed laboratories shall report, in accordance with OAR 333-018-0013 and other applicable rules in OAR chapter 333, division 18:¶
(a) All test results indicative of and specific for COVID-19 within 24 hours (including weekends and holidays).¶
(b) All negative test results for COVID-19 within one local public health authority working day.
Statutory/Other Authority: ORS 413.042, ORS 433.004, 433.006
Statutes/Other Implemented: ORS 433.004