

PROPOSED REGULATIONS

Title 17. California Code of Regulations
Division 1. State Department of Health Services
Chapter 4. Preventative Medical Service
Subchapter 1. Reportable Diseases and Conditions
Article 1. Reporting

1. Amend Section 2500 to read as follows:

§ 2500. Reporting to the Local Health Authority.

(a) The following definitions shall govern the interpretation of this Subchapter.

- (1) 'CDC' means the Centers for Disease Control and Prevention, United States Department of Health and Human Services.
- (2) 'CSTE' means the Council of State and Territorial Epidemiologists.
- (3) 'MMWR' means the Morbidity and Mortality Weekly Report.
- (4) 'Acute HIV infection' means detectable HIV-1 RNA or p24 antigen in serum or plasma in the setting of a negative or indeterminate HIV-1 antibody test result for patients tested using a currently approved HIV test algorithm, as defined in section 2641.57.
- (5) 'Case' means (A) a person who has been diagnosed by a health care provider, who is lawfully authorized to diagnose, using clinical judgment or laboratory evidence, to have a particular disease or condition listed in subsection (j); or (B) a person who is considered to have a disease or condition that satisfies the most recent communicable disease surveillance case definitions established by the CDC and/or CSTE; or (C) an animal that has been determined, by a person authorized to do so, to have a disease or condition made reportable by these regulations; or (D) a person who has

been diagnosed with HIV infection using a currently approved HIV test algorithm, as defined in section 2641.57.

- (6) 'Clinical signs' means the objective evidence of disease.
- (7) 'Clinical symptoms' means the subjective sensation of disease felt by the patient.
- (8) 'Communicable disease' means an illness due to a specific microbiological or parasitic agent or its toxic products which arises through transmission of that agent or its products from an infected person, animal, or inanimate reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.
- (9) 'Director' means State Director of Public Health.
- (10) 'Drug susceptibility testing' means the process where at least one isolate from a culture of a patient's specimen is subjected to antimicrobial testing to determine if growth is inhibited by drugs commonly used to treat such infections, or another type of test using an isolate or specimen that identifies genetic or other features of a microorganism associated with antimicrobial resistance.
- (11) 'Epidemiological risk factors' means those attributes, behaviors, exposures, or other factors that alter the probability of disease.
- (12) 'Epidemiologically linked case' means a case in which the patient is likely to have had contact with one or more persons who have/had the disease, and transmission of the agent by the usual modes of transmission is plausible.

- (13) 'Foodborne disease' means illness suspected to have resulted from consuming a contaminated food, non-water beverage, or other ingestible item such as a dietary supplement or herbal remedy.
- (14) 'Foodborne disease outbreak' means an incident in which two or more persons experience a similar illness after ingestion of a common contaminated food, non-water beverage, or other ingestible item such as a dietary supplement or herbal remedy.
- (15) 'Health care provider' means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.
- (16) 'Health officer' and 'local health officer' as used in this subchapter includes county, city, and district health officers.
- (17) 'In attendance' means the existence of the relationship whereby a health care provider renders those services which are authorized by the health care provider's licensure or certification.
- (18) 'Infection control practitioner' means any person designated by a hospital, nursing home, clinic, or other health care facility as having responsibilities which include the detection, reporting, control and prevention of infections within the institution.
- (19) 'Laboratory findings' means (A) the results of a laboratory examination of any specimen derived from the human body which yields microscopic, culture, immunologic, serologic, molecular, pathologic, or other evidence

suggestive of a disease or condition made reportable by these regulations; or
(B) the results of a laboratory examination of any specimen derived from an animal which yields evidence of a disease or condition in animals made reportable by these regulations.

- (20) 'Multidrug-resistant *Mycobacterium tuberculosis*' means a laboratory culture or subculture of *Mycobacterium tuberculosis* which is determined by antimicrobial susceptibility testing to be resistant to at least isoniazid and rifampin.
- (21) 'Pandemic potential' means the potential ability of a pathogen to spread easily and efficiently in the human population, crossing international boundaries, and usually affecting many people. Such pathogens may be associated with severe illness and death.
- (22) 'Outbreak' means the occurrence of cases of a disease (illness) above the expected or baseline level, usually over a given period of time, in a geographic area or facility, or in a specific population group. The number of cases indicating the presence of an outbreak will vary according to the disease agent, size and type of population exposed, previous exposure to the agent, and the time and place of occurrence. Thus, the designation of an outbreak is relative to the usual frequency of the disease in the same facility or community, among the specified population, over a comparable period of time. A single case of a communicable disease long absent from a population or the first invasion by a disease not previously recognized may constitute an outbreak and require immediate reporting and epidemiologic investigation.

- (23) 'Personal information' means any information that identifies or describes a person, including, but not limited to, his or her name, social security number, date of birth, physical description, home address, home telephone number, and medical or employment history.
- (24) 'Sexually Transmitted Diseases' means Chancroid, Lymphogranuloma venereum, Syphilis, Gonorrhea, and Chlamydia.
- (25) 'Suspected case' means (A) a person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence, to probably have a particular disease or condition listed in subsection (j); or (B) a person who is considered a probable case, or an epidemiologically-linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC or CSTE; or (C) an animal which has been determined by a veterinarian to exhibit clinical signs or which has laboratory findings suggestive of a disease or condition in animals made reportable by these regulations.
- (26) 'Unusual disease' means a rare disease or a newly apparent or emerging disease or syndrome of uncertain etiology which a health care provider has reason to believe could possibly be caused by a transmissible infectious agent or microbial toxin.
- (27) 'Waterborne disease outbreak' means an incident in which two or more epidemiologically-linked persons experienced a similar illness after exposure to the same water source and epidemiologic investigation by public health authorities implicates the water as the likely source of the illness. This

includes any outbreak of an infectious disease, chemical poisoning, or toxin-mediated illness where water is indicated as the source by an epidemiological investigation.

(b) It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed in subsection (j) of this section, to report to the local health officer for the jurisdiction where the patient resides as required in subsection (h) of this section. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed in subsection (j) of this section may make such a report to the local health officer for the jurisdiction where the patient resides.

(c) The administrator of each health facility, clinic or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local health officer.

(d) Each report made pursuant to subsection (b) shall include all of the following information if known:

(1) name of the disease or condition being reported; the date of onset; the date of diagnosis; the name, address, telephone number, occupation, race, ethnicity, Social Security number, current gender identity, sex assigned at birth, sexual orientation, pregnancy status, age, and date of birth for the case or suspected case; the date of death if death has occurred; and the name, address and telephone number of the person making the report.

(2) If the disease reported pursuant to subsection (b) is hepatitis, syphilis, or tuberculosis, then the report shall include the following applicable information, if known: (A) for hepatitis, the type-specific laboratory findings and sources of exposure, (B) for syphilis, syphilis-specific laboratory findings, and (C) for tuberculosis, information on the diagnostic status of the case or suspected case, bacteriologic, radiologic and tuberculin skin test findings, information regarding the risk of transmission of the disease to other persons, and a list of the anti-tuberculosis medications administered to the patient.

(e) Confidential Morbidity Report forms, are available from the local health department for reporting as required by this section.

(f) Information reported pursuant to this section is acquired in confidence and shall not be disclosed by the local health officer except as authorized by these regulations, as required by state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

(g) Upon the State Department of Public Health's request, a local health department shall provide to the Department the information reported pursuant to this section. Absent the individual's written consent, no information that would directly or indirectly identify the case or suspected case as an individual who has applied for or been given services for alcohol or other drug abuse by a federally assisted drug or alcohol abuse treatment program (as defined in federal law at 42 C.F.R. Section 2.11) shall be included.

- (h) The urgency of reporting is identified by symbols in the list of diseases and conditions in subsection (j) of this section. Those diseases with a diamond (◆) are considered emergencies and shall be reported immediately by telephone. Those diseases and conditions with a cross (+) shall be reported by mailing, telephoning, or electronically transmitting a report within one (1) working day of identification of the case or suspected case, except for acute HIV infection reporting which shall be reported by telephone (see (k) for specific requirements). Those diseases and conditions not otherwise identified by a diamond or a cross shall be reported by mailing a written report, telephoning, or electronically transmitting a report within seven (7) calendar days of the time of identification.
- (i) For foodborne disease, the bullet (•) symbol indicates that, when two (2) or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness, they shall be reported immediately by telephone.
- (j) Health care providers shall submit reports for the following diseases or conditions.

	Anaplasmosis
◆	Anthrax, human or animal
+	Babesiosis
◆	Botulism (Infant, Foodborne, Wound, Other)
◆	Brucellosis, human
	Brucellosis, animal (except infections due to <i>Brucella canis</i>)
+	Campylobacteriosis
<u>+</u>	<u>Candida auris, colonization or infection</u>
	Chancroid
+	Chickenpox (Varicella) (outbreaks, hospitalizations and deaths)
◆	Cholera
◆	Ciguatera Fish Poisoning
+	Chikungunya virus infection
	Coccidioidomycosis
◆ <u>+</u>	Coronavirus disease 2019 (COVID-19)
	Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)
+	Cryptosporidiosis
	Cyclosporiasis
	Cysticercosis or taeniasis
+	Dengue virus infection

◆	Diphtheria
◆	Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
	Ehrlichiosis
+	Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
+	<i>Escherichia coli</i> : shiga toxin producing (STEC) including <i>E. coli</i> O157
◆	Flavivirus infection of undetermined species
+ •	Foodborne Disease
	Giardiasis
	Gonococcal Infections
+	<i>Haemophilus influenzae</i> , invasive disease, all serotypes (report an incident of less than five years of age)
+	Hantavirus Infections
◆	Hemolytic Uremic Syndrome
+	Hepatitis A, acute infection
	Hepatitis B (specify acute, chronic, or perinatal)
	Hepatitis C (specify acute, chronic, or perinatal)
	Hepatitis D (Delta) (specify acute case or chronic)
	Hepatitis E, acute infection
+	Human Immunodeficiency Virus (HIV), acute infection, (see (k) for additional reporting requirements)
	Human Immunodeficiency Virus (HIV) infection, any stage
	Human Immunodeficiency Virus (HIV) infection, progression to stage 3 (AIDS)

	Influenza-associated deaths in laboratory-confirmed cases less than 18 years of age
◆	Influenza due to novel strains (human)
	Legionellosis
	Leprosy (Hansen Disease)
	Leptospirosis
+	Listeriosis
	Lyme Disease
+	Malaria
◆	Measles (Rubeola)
+	Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
◆	Meningococcal Infections
◆	Middle East Respiratory Syndrome (MERS)
◆	<u>Monkeypox or orthopox virus infection</u>
	Mumps
◆	Novel coronavirus infections
◆	Novel virus infection with pandemic potential
◆	Paralytic Shellfish Poisoning
+	Paratyphoid Fever
+	Pertussis (Whooping Cough)
◆	Plague, human or animal
+	Poliovirus Infection

+	Psittacosis
+	Q Fever
◆	Rabies, human or animal
+	Relapsing Fever
	Respiratory syncytial virus-associated deaths in laboratory-confirmed cases less than than five years of age)
	Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus and Typhus-like Illnesses
	Rocky Mountain Spotted Fever
	Rubella (German Measles)
	Rubella Syndrome, Congenital
+	Salmonellosis (Other than Typhoid Fever)
◆	Scombroid Fish Poisoning
◆	Shiga toxin (detected in feces)
+	Shigellosis
◆	Smallpox (Variola)
+	Syphilis (all stages, including congenital)
	Tetanus
+	Trichinosis
+	Tuberculosis
◆	Tularemia, human
	Tularemia, animal

+	Typhoid Fever, Cases and Carriers
+	<i>Vibrio</i> Infections
◆	Viral Hemorrhagic Fevers, human or animal (e.g., Crimean- Congo, Ebola, Lassa and Marburg viruses)
+	West Nile virus infection
+	Yellow Fever
+	Yersiniosis
+	Zika virus infection
◆	OCCURRENCE of ANY UNUSUAL DISEASE
◆	OUTBREAKS of ANY DISEASE (Including diseases not listed in Section 2500). Specify if institutional and/or open community.

(◆) = to be reported immediately by telephone.

(+) = to be reported by mailing a report, telephoning, or electronically transmitting a report within one (1) working day of identification of the case or suspected case.

(No diamond or cross symbol) = to be reported within seven (7) calendar days by mail, telephone, or electronic report from the time of identification.

(•) = when two (2) or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness, they should be reported immediately by telephone.

(k) In addition to routine reporting requirements set forth in section 2643.5, for acute HIV infection reporting, health care providers shall report all cases within one (1) working day to the local health officer of the jurisdiction in which the patient resides by telephone. If evidence of acute HIV infection is based on presence of HIV p24 antigen, providers shall not wait until HIV-1 RNA is detected before reporting to the local health officer.

Note: Authority cited: Sections 120130, 131050, 131051, 131052, 131080 and 131200, Health and Safety Code. Reference: Sections 1603.1, 100325, 103925, 113150, 113155, 120125, 120130, 120140, 120175, 120245, 120250, 131050, 131051 and 131080, Health and Safety Code; Sections 551, 554 and 555, Business and Professions Code; Section 1798.3, Civil Code; 42 C.F.R. Sections 2.11 and 2.12; Cal. Const., art. 1, Section 1; and Section 1040, Evidence Code.

2. Amend Section 2502 to read as follows:

§ 2502. Reports by Local Health Officer to State Department of Public Health.

(a) Summary Reports: Each local health officer shall report at least weekly, on the Weekly Morbidity by Place of Report form to the Director the number of cases of those diseases, conditions, unusual diseases or outbreaks of disease reported pursuant to Section 2500. Copies of the form are available from the Department's Division of Communicable Disease Control.

(b) Individual Case and Outbreak Reports: For the diseases listed below, the local health officer shall prepare and send to the Department along with the summary report described in (a) above an individual case or outbreak report for each

individual case/outbreak of those diseases which the Department has identified as requiring epidemiological analysis reported pursuant to Section 2500. At the discretion of the Director, the required individual case/outbreak report may be either a Confidential Morbidity Report, its electronic equivalent or a hard copy 8.5x11 inch individual case/outbreak report form. The Weekly Morbidity by Place of Report form indicates which format to use. Each individual case report shall include the following: (1) verification of information reported pursuant to Section 2500; (2) information on the probable source of infection, if known; (3) laboratory or radiologic findings, if any; (4) clinical signs and/or symptoms, if applicable; and (5) any known epidemiological risk factors. The Department or CDC has prepared forms that may be used for many of the diseases requiring individual case reports. Copies of these case report forms are available from the Department's Division of Communicable Disease Control. An individual case report is required for the following diseases:

- Anthrax, human
- Botulism (Infant, Foodborne, Wound, Other)
- Brucellosis, human
- Chickenpox (Varicella) deaths (separate reporting form required)
- Chickenpox (Varicella) hospitalizations (separate reporting form required)
- Chikungunya virus infection
- Cholera
- Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)

- Cyclosporiasis
- Cysticercosis
- Dengue virus infection
- Diphtheria
- *Escherichia coli*: shiga toxin producing (STEC) including *E. coli* O157
- Flavivirus infection of undetermined species
- Foodborne Disease Outbreak
- *Haemophilus influenzae*, Invasive Disease
- Hantavirus Infections
- Hemolytic Uremic Syndrome
- Hepatitis A, acute infection
- Hepatitis B, acute only
- Hepatitis C, acute only
- Hepatitis D (Delta), acute infection
- Hepatitis E, acute infection
- Human Immunodeficiency Virus (HIV) infection, stage 3 (AIDS)
- Influenza, deaths in laboratory-confirmed cases for ages 0-64 years
- Influenza, novel strains (human)
- Legionellosis
- Leprosy (Hansen Disease)
- Leptospirosis
- Listeriosis

- Lyme Disease
- Malaria
- Measles (Rubeola)
- Meningococcal Infections
- Monkeypox or orthopox virus infection
- Outbreak of Disease Report
- Pertussis (Whooping Cough)
- Plague, human
- Poliovirus Infection
- Psittacosis
- Q Fever
- Rabies, human or animal (separate reporting forms required for human and animal cases)
- Relapsing Fever
- Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus and Typhus-like Illnesses)
- Rocky Mountain Spotted Fever
- Rubella (German Measles) (a separate form is used for Congenital Rubella)
- Shiga toxin (detected in feces)
- Smallpox
- Streptococcal Outbreaks and Individual Cases in Food Handlers and Dairy Workers Only

- Syphilis
- Tetanus
- Trichinosis
- Tuberculosis
- Tularemia, human
- Typhoid Fever, Cases and Carriers (separate reporting forms required for cases and carriers)
- Unusual Disease Report
- *Vibrio* Infections
- Viral Hemorrhagic Fevers, human (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
- Waterborne Disease Outbreak
- West Nile virus infection
- Yellow Fever
- Zika virus infection

(c) Immediate Reports: Cases and suspect cases of anthrax (human or animal), botulism, brucellosis (human only), cholera, dengue, diphtheria, measles (rubeola), plague (human or animal), rabies (human only), smallpox (variola), tularemia (human only), varicella deaths, viral hemorrhagic fevers (human or animal), yellow fever, occurrence of any unusual diseases, and outbreaks of any disease are to be reported by the local health officer to the Director immediately by telephone.

- (d) Upon request of the Department, the local health officer shall submit an individual case report for any disease not listed in subsection (b) above.
- (e) During any special morbidity and mortality study requested under Section 2501, the local health officer shall be the Director's agent for purposes of carrying out the powers conferred under Government Code Section 11181.
- (f) Confidentiality. Information reported pursuant to this section is acquired in confidence and shall not be disclosed by the local health officer except as authorized by these regulations, as required by state or federal law, or with the written consent of the individual to whom the information pertains or to the legal representative of that individual.
 - (1) A health officer shall disclose any information, including personal information, contained in an individual case report to state, federal or local public health officials in order to determine the existence of a disease, its likely cause or the measures necessary to stop its spread.
 - (2) A health officer may for purposes of his or her investigation disclose any information contained in an individual case report, including personal information, as may be necessary to prevent the spread of disease or occurrence of additional cases.
 - (3) A health officer may disclose any information contained in an individual case report to any person or entity if the disclosure may occur without linking the information disclosed to the individual to whom it pertains, and the purpose of the disclosure is to increase understanding of disease patterns, to develop

prevention and control programs, to communicate new knowledge about a disease to the community, or for research.

(4) Notwithstanding subsections (1), (2), and (3) above, no information that would directly or indirectly identify an individual as one who has applied for or been given services for alcohol or other drug abuse by a federally assisted drug or alcohol abuse treatment program (as defined in 42 C.F.R. § 2.11) shall be included in an individual case report or otherwise disclosed absent the individual's written consent.

(g) Whenever the health officer collects personal information in order to prepare an individual case report required by subsection (b), the health officer shall notify the individual from whom the information is collected that: (1) supplying personal information related to the individual's disease is mandatory; (2) the only disclosure of personal information will be pursuant to subsections 2502(f)(1) and 2502(f)(2); and (3) non-personal information may be disclosed pursuant to subsection 2502(f)(3).

Note: Authority cited: Sections 120130, 131050, 131051, 131052, 131080 and 131200, Health and Safety Code; and Section 555(b), Business and Professions Code.

Reference: Sections 7, 1603.1, 100325, 100330, 103925, 113150, 113155, 120125, 120130, 120140, 120145, 120175, 120190, 120245, 120250, 131050, 131051 and 131080, Health and Safety Code; and Sections 551, 554 and 555, Business and Professions Code; Section 1798.3, Civil Code; Sections 11181 and 11182, Government Code; 42 C.F.R. Sections 2.11 and 2.12; Cal. Const., art. 1, Section 1; and Section 1040, Evidence Code.

3. Amend Section 2505 to read as follows:

§ 2505. Notification by Laboratories.

(a) To assist the local health officer, the laboratory director, or the laboratory director's designee, of a clinical laboratory, an approved public health laboratory or a veterinary laboratory in which a laboratory examination of any specimen derived from the human body (or from an animal, in the case of a disease or condition in animals made reportable by these regulations) yields microscopic, culture, immunologic, serologic, molecular, pathologic, or other evidence suggestive of those diseases listed in subsections (e)(1) and (e)(2) below, shall report such findings to the health officer of the local health jurisdiction where the patient resides. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located. The reporting specified above shall include any initial findings as well as any subsequent findings as a result of additional laboratory examination. In addition, the laboratory director or the laboratory director's designee shall also report negative laboratory test results or other laboratory findings when requested by the Department or a local health officer.

(1) For those diseases listed in subsection (e)(1), the report of such findings shall be made within one hour after the laboratory notifies the health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the health officer of the jurisdiction where the patient resides within one hour from the

time the laboratory notifies the referring laboratory that submitted the specimen. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located.

(2) For those diseases listed in subsection (e)(2), with the exception of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the report of such findings shall be made within one working day from the time that the laboratory notifies the health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the health officer of the jurisdiction where the patient resides within one working day from the time the laboratory notifies the referring laboratory that submitted the specimen. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located.

(3) For severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the report of such findings shall be made within eight hours from the time that the laboratory notifies the health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the health officer of the jurisdiction where the patient resides within eight hours from the time the laboratory notifies the referring laboratory that submitted the specimen. If the patient residence is

unknown. the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located.

- (b) To permit local health officer follow-up of laboratory findings, all specimens submitted for laboratory tests or examinations related to a disease or condition listed in subsections 2505(e)(1) or 2502(e)(2) shall be accompanied by a test requisition which includes the name, gender, race, ethnicity, pregnancy status, address and date-of-birth of the person from whom the specimen was obtained and the name, address and telephone number of the health care provider or other authorized person who submitted the specimen. Whenever the specimen, or an isolate therefrom, is transferred between laboratories, a test requisition with the above patient and submitter information shall accompany the specimen. The laboratory that first receives a specimen shall be responsible for obtaining the patient and submitter information at the time the specimen is received by that laboratory.
- (c) Each notification to the local health officer shall include the date the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the specimen site, the diagnosis code, the laboratory findings for the test performed, the date that the laboratory findings were identified, the name, gender, race, ethnicity, address, telephone number (if known), pregnancy status, and date of birth of the person from whom the specimen was obtained, and the name, address, and telephone number of the health care provider for whom such examination or test was performed.

Laboratories shall report the elements specified above in a format specified by the Department.

(d) The notification shall be submitted as specified in subsections (e)(1) and (e)(2) of this Section to the local health officer in the jurisdiction where the patient resides. When the specimen is from an out-of-state submitter, the state epidemiologist of the submitter shall be provided the same positive findings per subsections (e)(1) and (e)(2) of this Section. If the laboratory that finds evidence for any of those diseases listed in subsections (e)(1) and (e)(2) is an out-of-state laboratory, the California clinical laboratory that receives a report of such findings from the out-of-state laboratory shall notify the local health officer in the same way as if the finding had been made by the California laboratory.

(e) Laboratory reports to the local health officer shall include the information as specified in (c) of this Section and laboratories shall submit the reports within the following timeframes:

(1) The diseases or agents specified shall be reported within one hour after the health care provider or other person authorized to receive the report has been notified. Laboratories shall make the initial reports to the local health officer by telephone and follow the initial report within one working day by a report to the state electronic reporting system or local electronic reporting system that is linked to the state electronic reporting system. If reporting to the state or local electronic system is not possible, reporting by electronic facsimile transmission and electronic mail may temporarily substitute for reporting to the state or local electronic reporting system.

Laboratories shall also report by other means (e.g., electronic facsimile) if requested by a local health officer or the Department. Laboratory findings for these diseases are those that satisfy the most recent communicable disease surveillance case definitions established by the CDC (unless otherwise specified in this Section). The diseases or agents reported pursuant to this requirement are:

- Anthrax, human (*B. anthracis*) (see section 2551 for additional reporting instructions)
- Anthrax, animal (*B. anthracis*)
- Botulism (see section 2552 for additional reporting instructions)
- Brucellosis, human (all *Brucella spp.*) (see section 2553 for special reporting instructions)
- *Burkholderia pseudomallei* and *B. mallei* (detection or isolation from a clinical specimen)
- Coronavirus, novel strains
- Influenza, novel strains (human) (see (i) for additional reporting requirements)
- Plague, human (see section 2596 for additional reporting instructions)
- Plague, animal
- Smallpox (Variola) (see section 2614 for additional reporting instructions)
- Tularemia, human (*F. tularensis*) (see section 2626 for additional reporting instructions)

- Viral Hemorrhagic Fever agents, human (VHF), e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses (see section 2638 for additional reporting instructions)
- Viral Hemorrhagic Fever agents, animal (VHF), e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses

(2) The diseases or agents specified, ~~with the exception of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)~~, shall be reported within one working day after the health care provider or other person authorized to receive the report has been notified. ~~Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) shall be reported within eight hours after the health care provider or other person authorized to receive the report has been notified.~~ Laboratories shall transmit these reports to the state electronic reporting system or local electronic reporting system that is linked to the state electronic reporting system, except for acute HIV infection reporting which shall be reported by telephone (see (j) for specific acute HIV infection reporting requirements). Acute HIV infection shall be reported both by telephone and to the state electronic reporting system within one working day of identification. If reporting to the state or local electronic reporting system is not possible, reporting by electronic facsimile transmission or electronic mail may temporarily substitute for reporting to the state or local electronic reporting system. Laboratories shall also report by other means (e.g., electronic facsimile) if requested by a health officer or the Department. Laboratory findings for

these diseases are those that satisfy the most recent communicable disease surveillance case definitions established by the CDC (unless otherwise specified in this Section). The diseases or agents reported pursuant to this requirement are:

- Acid fast bacillus (AFB) (see (g) for additional reporting requirements)
- Anaplasmosis
- Babesiosis
- *Bordetella pertussis* acute infection, by culture or molecular identification
- *Borrelia burgdorferi* infection
- Brucellosis, animal (*Brucella* spp. except *Brucella canis*)
- Campylobacteriosis (*Campylobacter* spp.) (detection or isolation a clinical specimen)
- *Candida auris*, colonization or infection (see (r) for additional reporting requirements)
- ~~Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing)~~
- Carbapenemase-producing organism, colonization or infection
- Chancroid (*Haemophilus ducreyi*)
- Chikungunya virus infection
- *Chlamydia trachomatis* infections, including lymphogranuloma venereum (LGV)

- Coccidioidomycosis
- Cryptosporidiosis
- Cyclosporiasis (*Cyclospora cayetanensis*)
- Dengue virus infection
- Diphtheria
- Ehrlichiosis
- Encephalitis, arboviral
- *Escherichia coli* shiga toxin producing (STEC) including *E. coli* O157(see (m) for additional reporting requirements)
- Flavivirus infection of undetermined species
- Giardiasis (*Giardia lamblia*, intestinalis , or *duodenalis*)
- Gonorrhea
- *Haemophilus influenzae*, all types (detection of or isolation from a sterile site in a person less than 5 years of age)
- Hantavirus Infections
- Hepatitis A, acute infection
- Hepatitis B, acute or chronic infection (specify gender)
- Hepatitis C, acute or chronic infection
- Hepatitis D (Delta), acute or chronic infection
- Hepatitis E, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)

- Human Immunodeficiency Virus (HIV), acute infection (see (j) for additional reporting requirements)
- Influenza
- Legionellosis (*Legionella spp.*) (antigen or culture)
- Leprosy (Hansen Disease) *Mycobacterium leprae*
- Leptospirosis *Leptospira spp.*)
- Listeriosis *Listeria*) (see (m) for additional reporting requirements)
- Malaria (see (h) for additional reporting requirements)
- Measles (Rubeola), acute infection
- Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
- Monkeypox or orthopox virus infection
- Mumps (mumps virus), acute infection
- *Neisseria meningitidis* (sterile site isolate or eye specimen) (see (m) for additional reporting requirements)
- Poliovirus
- Psittacosis *Chlamydophila psittaci*)
- Q Fever (*Coxiella burnetii*)
- Rabies, animal or human
- Relapsing Fever (*Borrelia spp.*) (identification of *Borrelia spp.* spirochetes on peripheral blood smear)
- *Rickettsia*, any species, acute infection (detection from a clinical specimen or positive serology)

- Rocky Mountain Spotted Fever (*Rickettsia rickettsii*)
- Rubella, acute infection
- Salmonellosis (*Salmonella* spp.) (see Section 2612 (a) for additional reporting requirements)
- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (see (p) and (q) for additional reporting requirements)
- Shiga toxin (detected in feces) (see (m) for additional reporting requirements)
- Shigellosis (*Shigella* spp.) (see (m) for additional reporting requirements)
- Syphilis
- Trichinosis (*Trichinella*)
- Tuberculosis, including *Mycobacterium tuberculosis* complex (see (f) for additional reporting requirements)
- Latent Tuberculosis Infection identified by a positive laboratory test (see (o) for additional reporting requirements)
- Tularemia, animal (*F. tularensis*)
- Typhoid
- *Vibrio* species infections
- West Nile virus infection
- Yellow Fever (yellow fever virus)

- Yersiniosis (*Yersinia spp.*, non-pestis) (isolation from a clinical specimen)
- Zika virus infection (see (m) for additional reporting requirements)

(f) In addition to notifying the local health officer pursuant to subsection (a), any clinical laboratory or approved public health laboratory that isolates *Mycobacterium tuberculosis* complex or identifies *Mycobacterium tuberculosis* complex by molecular testing from a patient specimen shall:

(1) Submit a culture as soon as available from the primary isolate on which a diagnosis of tuberculosis was established. Such a culture shall be submitted to the public health laboratory designated in Title 17 California Code of Regulations, Section 1075 for the local jurisdiction where the patient resides. The following information shall be submitted with the culture: the name, address, and the date of birth of the person from whom the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the date the specimen was obtained from the patient, and the name, address, and telephone number of the health care provider for whom such examination or test was performed. The public health laboratory shall retain the culture received (one culture from each culture-positive patient) in a viable condition for at least six months.

(A) If *Mycobacterium tuberculosis* complex is identified by molecular testing but no culture isolate is available, a specimen available to the laboratory shall be submitted to the public health laboratory designated in Title 17 California Code of Regulations Section 1075

upon request from the local health officer, public health laboratory, or the Department's Microbial Disease Laboratory.

- (2) Unless drug susceptibility testing has been performed by the clinical laboratory on a strain obtained from the same patient within the previous three months or the health care provider who submitted the specimen for laboratory examination informs the laboratory that such drug susceptibility testing has been performed by another laboratory on a culture obtained from that patient within the previous three months, the clinical laboratory shall:
- (A) Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom *Mycobacterium tuberculosis* complex was isolated; and
 - (B) Report the results of drug susceptibility testing including molecular assays for drug resistance, if performed, to the local health officer of the jurisdiction where the patient resides within one working day from the time the health care provider or other authorized person who submitted the specimen is notified; and
 - (C) If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, as soon as available, submit one culture or subculture from each patient from whom multidrug-resistant *Mycobacterium tuberculosis* complex was isolated to the official public health laboratory designated in Title 17 California Code of Regulations Section 1075 for the local health jurisdiction in which the patient resides. The local public health laboratory shall forward

such cultures to the Department's Microbial Diseases Laboratory.

The following information shall be submitted with the culture: the name, address, and the date of birth of the person from whom the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the date the specimen was obtained from the patient, and the name, address, and telephone number of the health care provider for whom such examination or test was performed.

- (g) Whenever a clinical laboratory finds that a specimen from a patient with known or suspected tuberculosis tests positive for acid fast bacillus (AFB) staining and the patient has not had a culture which identifies that acid fast organism within the past 30 days, the clinical laboratory shall culture and identify the acid fast bacteria or refer a subculture to another laboratory for those purposes.
- (h) In addition to notifying the local health officer pursuant to subsection (a), any clinical laboratory that makes a finding of malaria parasites in the blood film of a patient shall immediately submit one or more such blood film slides for confirmation to the public health laboratory designated in Title 17 California Code of Regulations Section 1075 for the local health jurisdiction where the patient resides. When requested, all blood films shall be returned to the submitter.
- (i) Whenever a laboratory receives a specimen for the laboratory diagnosis of influenza, novel strains in a human such laboratory shall communicate immediately by telephone with the Department's Viral and Rickettsial Disease Laboratory for instruction.

- (j) In addition to routine reporting requirements set forth in section 2643.10, for acute HIV infection reporting, laboratories shall report all cases within one working day to the local health officer of the jurisdiction in which the patient resides by telephone. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located. If evidence of acute HIV infection is based on presence of HIV p24 antigen, laboratories shall not wait until HIV-1 RNA is detected before reporting to the local health officer.
- (k) All laboratory notifications herein required are acquired in confidence and shall not be disclosed by the local health officer except (1) as authorized by these regulations; (2) as required by state or federal law; or (3) with the written consent of the individual to whom the information pertains or the legal representative of that individual.
- (l) The local health officer shall disclose any information, including personal information, contained in a laboratory notification to state, federal or local public health officials in order to determine the existence of the disease, its likely cause and the measures necessary to stop its spread.
- (m) An isolate or a specimen as listed in this subsection shall be submitted as soon as available to the public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides. The following information shall be submitted with the isolate or specimen: the name, address, and the date of birth of the person from whom the isolate or specimen was obtained, the patient identification number, the isolate or specimen accession number or other unique

identifier, the date the isolate or specimen was obtained from the patient, the name, address, and telephone number of the health care provider for whom such examination or test was performed, and the name, address, telephone number and the laboratory director's name of the laboratory submitting the isolate or specimen.

(1) The specimens pursuant to the requirements in (m) are:

- Malaria positive blood film slides (see (h) for additional reporting requirements)
- *Neisseria meningitidis* eye specimens
- Shiga toxin-positive fecal broths
- Zika virus immunoglobulin M (IgM)-positive sera

(2) The isolates pursuant to the reporting requirements in (m) are:

- Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only)
- *Listeria monocytogenes* isolates
- *Mycobacterium tuberculosis* isolates (see (f) for additional reporting requirements)
- *Neisseria meningitidis* isolates from sterile sites
- *Salmonella* isolates (see section 2612 for additional reporting requirements)
- Shiga toxin-producing *Escherichia coli* (STEC) isolates, including O157 and non-O157 strains
- *Shigella* isolates

- (3) If there is a laboratory test result indicating infection with any one of the pathogens listed in (m)(2), then the laboratory must attempt to obtain a bacterial culture isolate for submission to the public health laboratory in accordance with (m)(2). This requirement includes identification of Shiga toxin in a clinical specimen, but does not include latent tuberculosis infection identified by a positive laboratory test. The laboratory shall take steps necessary to obtain an isolate, including requesting that additional specimens be collected and sending specimens to a laboratory able to carry out bacterial culture as soon as possible.
- (n) Upon written request and submission instruction by the Department, a laboratory that receives a specimen that is reactive for HIV-1/2 antigen or antibody, as defined within this subsection, shall submit the specimen to either the local public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides, the State Public Health Laboratory, or their designee. The specimen submission shall include the information identified in subdivision (m) and the Clinical Laboratory Improvement Amendments number.
- (1) For purposes of this subsection, the specimen shall be defined as the HIV-1/2 antigen or antibody reactive sera or plasma submitted as part of a diagnostic HIV test algorithm, as defined in section 2641.57
- (o) Results of positive laboratory tests, including positive interferon gamma release assays, should be reported including quantitative components of results, if applicable.

- (p) Upon written request and submission instruction by the Department or a local health officer, a laboratory that tests any specimen for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), shall submit the specimen and any nucleic acid extract to either the local public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides, the State Public Health Laboratory, or their designee. The specimen submission shall include the information identified in subdivision (b), the Cycle Threshold (CT) or Relative Light Units (RLU) value, and the federal Clinical Laboratory Improvement Amendments certificate number.
- (q) A laboratory that performs genetic sequencing of SARS-CoV-2 shall submit sequence data to the Department in an electronic format specified by the Department. In addition, a laboratory that identifies a SARS-CoV-2 strain designated as a variant of public health importance by the Department shall transmit the report in a format specified by the Department to the state electronic reporting system or local electronic reporting system that is linked to the state electronic reporting system. The sequence data submission and the strain report shall include the information identified in subsection (c), and the federal Clinical Laboratory Improvement Amendments certificate number if applicable.
- (r) If a *Candida auris* isolate(s) is identified from a sterile site, and the laboratory has obtained a fungal culture isolate, the isolate(s) must be submitted to a public health laboratory within 10 working days from the date of collection. The specimen submission shall include the information identified in subdivision (m) and the Clinical Laboratory Improvement Amendments number.

- (1) Upon written request and submission instruction by the Department or a local health officer, the laboratory must attempt to obtain a fungal culture isolate from any specimen site for submission as soon as available to the public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides.

Note: Authority cited: Sections 100275, 120125, 120130, 120140, 125095, 131050, 131051, 131052, 131080 and 131200, Health and Safety Code. Reference: Sections 100180, 120125, 120130, 120140, 120175, 120575, 121365, 125100 and 131080, Health and Safety Code; Sections 1209, 1246.5 and 1288, Business and Professions Code; Cal. Const., art. 1, Section 1; and Section 1040, Evidence Code.