

## **Case Study Codes**

### **California Health & Safety Code**

#### **§ 100182. Refusal to perform duties; offense**

Every person charged with the performance of any duty under the laws of this state relating to the preservation of the public health, who willfully neglects or refuses to perform the same, is guilty of a misdemeanor.

#### **§ 101040. Authority to take preventive measures during emergency**

The county health officer may take any preventive measure that may be necessary to protect and preserve the public health from any public health hazard during any "state of war emergency," "state of emergency," or "local emergency," as defined by [Section 8558 of the Government Code](#), within his or her jurisdiction.

"Preventive measure" means abatement, correction, removal or any other protective step that may be taken against any public health hazard that is caused by a disaster and affects the public health. Funds for these measures may be allowed pursuant to Sections 29127 to 29131, inclusive, and 53021 to 53023, inclusive, of the Government Code and from any other money appropriated by a county board of supervisors or a city governing body to carry out the purposes of this section.

The county health officer, upon consent of the county board of supervisors or a city governing body, may certify any public health hazard resulting from any disaster condition if certification is required for any federal or state disaster relief program.

#### **§ 120175. Prevention of spread of disease**

Each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the department, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases.

#### **§ 120220. Compliance with quarantine**

When quarantine or isolation, either strict or modified, is established by a health officer, all persons shall obey his or her rules, orders, and regulations.

#### **§ 120275. Violation of rule, order, or regulation of state department; offense**

Any person who, after notice, violates, or who, upon the demand of any health officer, refuses or neglects to conform to, any rule, order, or regulation prescribed by the department respecting a quarantine or disinfection of persons, animals, things, or places, is guilty of a misdemeanor.

#### **§ 120290. Willful exposure of self or others to disease; offense**

Except as provided in [Section 120291](#) or in the case of the removal of an afflicted person in a manner the least dangerous to the public health, any person afflicted with any contagious, infectious, or communicable disease who willfully exposes himself or herself to another person, and any person who willfully exposes another person afflicted with the disease to someone else, is guilty of a misdemeanor.

#### **§ 120295. Violations of duties by local health officers; offense; penalty**

Any person who violates [Section 120130](#) or any section in Chapter 3 (commencing with [Section 120175](#), but excluding [Section 120195](#)), is guilty of a misdemeanor, punishable by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000), or by imprisonment for a term of not more than 90 days, or by both. He or she is guilty of a separate offense for each day that the violation continued.

## **California Business & Professions Code**

### **§ 900. Health care practitioners licensed in another state; state of emergency; deploying of practitioners**

- (a) Nothing in this division applies to a health care practitioner licensed in another state or territory of the United States who offers or provides health care for which he or she is licensed, if the health care is provided only during a state of emergency as defined in [subdivision \(b\) of Section 8558 of the Government Code](#), which emergency overwhelms the response capabilities of California health care practitioners and only upon the request of the Director of the Emergency Medical Services Authority.
- (b) The director shall be the medical control and shall designate the licensure and specialty health care practitioners required for the specific emergency and shall designate the areas to which they may be deployed.
- (c) Health care practitioners shall provide, upon request, a valid copy of a professional license and a photograph identification issued by the state in which the practitioner holds licensure before being deployed by the director.
- (d) Health care practitioners deployed pursuant to this chapter shall provide the appropriate California licensing authority with verification of licensure upon request.
- (e) Health care practitioners providing health care pursuant to this chapter shall have immunity from liability for services rendered as specified in [Section 8659 of the Government Code](#).
- (f) For the purposes of this chapter, "health care practitioner" means any person who engages in acts which are the subject of licensure or regulation under this division or under any initiative act referred to in this division.
- (g) For purposes of this chapter, "director" means the Director of the Emergency Medical Services Authority who shall have the powers specified in Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

## **California Civil Code**

### **§ 56.10. Authorization; necessity; exceptions**

- (a) No provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).
- (b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:
- (1) By a court pursuant to an order of that court.
  - (2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.
  - (3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to [Section 1987 of the Code of Civil Procedure](#), or any provision authorizing discovery in a proceeding before a court or administrative agency.
  - (4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.
  - (5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under [Section 1282.6 of the Code of Civil Procedure](#), or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.
  - (6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) By a coroner, when requested in the course of an investigation by the coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant death, suspicious deaths, unknown deaths, or criminal deaths, or when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to [Chapter 2](#) (commencing with [Section 1250](#)) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to any person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required

elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b).

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of any patient or be violative of this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with [Section 791](#)) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with [Section 791](#)) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in [Section 1635 of the Health and Safety Code](#).

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information, including the patient's name, city of residence, age, sex, and general condition, may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in [Section 1399.901 of the Health and Safety Code](#), information may be disclosed as follows: (A) to any entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, provided that the disease management services and care are authorized by a treating physician, or (B) to any disease management organization, as defined in [Section 1399.900 of the Health and Safety Code](#), that complies fully with the physician authorization requirements of [Section 1399.902 of the Health and Safety Code](#), provided that the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

## **California Government Code**

### **§ 8550. Findings and declarations**

The state has long recognized its responsibility to mitigate the effects of natural, manmade, or war-caused emergencies which result in conditions of disaster or in extreme peril to life, property, and the resources of the state, and generally to protect the health and safety and preserve the lives and property of the people of the state. To insure that preparations within the state will be adequate to deal with such emergencies, it is hereby found and declared to be necessary:

(a) To confer upon the Governor and upon the chief executives and governing bodies of political subdivisions of this state the emergency powers provided herein; and to provide for state assistance in the organization and maintenance of the emergency programs of such political subdivisions;

(b) To provide for a state agency to be known and referred to as the Office of Emergency Services, within the Governor's office; and to prescribe the powers and duties of the director

of that office;

(c) To provide for the assignment of functions to state agencies to be performed during an emergency and for the coordination and direction of the emergency actions of such agencies;

(d) To provide for the rendering of mutual aid by the state government and all its departments and agencies and by the political subdivisions of this state in carrying out the purposes of this chapter;

(e) To authorize the establishment of such organizations and the taking of such actions as are necessary and proper to carry out the provisions of this chapter.

It is further declared to be the purpose of this chapter and the policy of this state that all emergency services functions of this state be coordinated as far as possible with the comparable functions of its political subdivisions, of the federal government including its various departments and agencies, of other states, and of private agencies of every type, to the end that the most effective use may be made of all manpower, resources, and facilities for dealing with any emergency that may occur.

### **§ 8558(a) and (b). Conditions or degrees of emergency**

Three conditions or degrees of emergency are established by this chapter:

(a) "State of war emergency" means the condition which exists immediately, with or without a proclamation thereof by the Governor, whenever this state or nation is attacked by an enemy of the United States, or upon receipt by the state of a warning from the federal government indicating that such an enemy attack is probable or imminent.

(b) "State of emergency" means the duly proclaimed existence of conditions of disaster or of extreme peril to the safety of persons and property within the state caused by such conditions as air pollution, fire, flood, storm, epidemic, riot, drought, sudden and severe energy shortage, plant or animal infestation or disease, the Governor's warning of an earthquake or volcanic prediction, or an earthquake, complications resulting from the Year 2000 Problem, or other conditions, other than conditions resulting from a labor controversy or conditions causing a "state of war emergency," which, by reason of their magnitude, are or are likely to be beyond the control of the services, personnel, equipment, and facilities of any single county, city and county, or city and require the combined forces of a mutual aid region or regions to combat, or with respect to regulated energy utilities, a sudden and severe energy shortage requires extraordinary measures beyond the authority vested in the California Public Utilities Commission.

### **§ 8610. Creation; plans; powers; rules and regulations for dealing with local emergencies**

Counties, cities and counties, and cities may create disaster councils by ordinance. A disaster council shall develop plans for meeting any condition constituting a local emergency or state of emergency, including, but not limited to, earthquakes, natural or manmade disasters specific to that jurisdiction, or state of war emergency; such plans shall provide for the effective mobilization of all of the resources within the political subdivision, both public and private. The disaster council shall supply a copy of any plans developed pursuant to this section to the Office of Emergency Services. The governing body of a county, city and county, or city may, in the ordinance or by resolution adopted pursuant to the ordinance, provide for the organization, powers and duties, divisions, services, and staff of the emergency organization. The governing body of a county, city and county, or city may, by ordinance or resolution, authorize public officers, employees, and registered volunteers to command the aid of citizens when necessary in the execution of their duties during a state of war emergency, a state of emergency, or a local emergency.

Counties, cities and counties, and cities may enact ordinances and resolutions and either establish rules and regulations or authorize disaster councils to recommend to the director of the local emergency organization rules and regulations for dealing with local emergencies that can be adequately dealt with locally; and further may act to carry out mutual aid on a voluntary basis and, to this end, may enter into agreements.

### **§ 8630. Proclamation by local governing body; review; termination**

(a) A local emergency may be proclaimed only by the governing body of a city, county, or city and county, or by an official designated by ordinance adopted by that governing body.

(b) Whenever a local emergency is proclaimed by an official designated by ordinance, the local emergency shall not remain in effect for a period in excess of seven days unless it has been ratified by the governing body.

(c)(1) The governing body shall review, at its regularly scheduled meetings until the local emergency is terminated, the need for continuing the local emergency. However, in no event shall a review take place more than 21 days after the previous review.

(2) Notwithstanding paragraph (1), if the governing body meets weekly, it shall review the need for continuing the local emergency at least every 14 days, until the local emergency is terminated.

(d) The governing body shall proclaim the termination of the local emergency at the earliest possible date that conditions warrant.

**§ 8659. Physicians, surgeons, hospitals, pharmacists, nurses and dentists; immunity from liability for services requested; exception**

Any physician or surgeon (whether licensed in this state or any other state), hospital, pharmacist, nurse, or dentist who renders services during any state of war emergency, a state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency shall have no liability for any injury sustained by any person by reason of such services, regardless of how or under what circumstances or by what cause such injuries are sustained; provided, however, that the immunity herein granted shall not apply in the event of a willful act or omission.

## **California Penal Code**

**§ 409.5(c) Authority of peace officers, lifeguard or marine safety officer to close disaster area; exclusion from police command post area; unauthorized entry; exception**

(c) Any unauthorized person who willfully and knowingly enters an area closed pursuant to subdivision (a) or (b) and who willfully remains within the area after receiving notice to evacuate or leave shall be guilty of a misdemeanor.

## **California Code of Regulations**

**8 CCR § 342 Reporting Work-Connected Fatalities & Injuries**

(a) Every employer shall report immediately by telephone or telegraph to the nearest District Office of the Division of Occupational Safety and Health any serious injury or illness, or death, of an employee occurring in a place of employment or in connection with any employment.

Immediately means as soon as practically possible but not longer than 8 hours after the employer knows or with diligent inquiry would have known of the death or serious injury or illness. If the employer can demonstrate that exigent circumstances exist, the time frame for the report may be made no longer than 24 hours after the incident.

Serious injury or illness is defined in [section 330\(h\), Title 8, California Administrative Code](#).

(b) Whenever a state, county, or local fire or police agency is called to an accident involving an employee covered by this part in which a serious injury, or illness, or death occurs, the nearest office of the Division of Occupational Safety and Health shall be notified by telephone immediately by the responding agency.

(c) When making such report, whether by telephone or telegraph, the reporting party shall include the following information, if available:

- (1) Time and date of accident.
- (2) Employer's name, address and telephone number.
- (3) Name and job title, or badge number of person reporting the accident.
- (4) Address of site of accident or event.
- (5) Name of person to contact at site of accident.

- (6) Name and address of injured employee(s).
- (7) Nature of injury.
- (8) Location where injured employee(s) was (were) moved to.
- (9) List and identity of other law enforcement agencies present at the site of accident.
- (10) Description of accident and whether the accident scene or instrumentality has been altered.

(d) The reporting in (a) and (b) above, is in addition to any other reports required by law and may be made by any person authorized by the employers, state, county, or local agencies to make such reports.

### **17 CCR § 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) '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 meets the definition of a case in Section 2564 - Diarrhea of the Newborn, Section 2574 - Food Poisoning, Section 2612 Salmonella Infections (Other than Typhoid Fever), Section 2628 - Typhoid Fever, or Section 2636 - Venereal Disease; or (C) a person who is considered a case of a disease or condition that satisfies the most recent communicable disease surveillance case definitions established by the CDC and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements; or (D) an animal that has been determined, by a person authorized to do so, to have rabies or plague.

(5) 'Clinical signs' means the objective evidence of disease.

(6) 'Clinical symptoms' means the subjective sensation of disease felt by the patient.

(7) '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.

(8) 'Director' means State Director of Health Services.

(9) '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.

(10) 'Epidemiological risk factors' means those attributes, behaviors, exposures, or other factors that alter the probability of disease.

(11) 'Epidemiologically linked case' means a case in which the patient has/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.

(12) 'Foodborne disease' means illness suspected by a health care provider to have resulted from consuming a contaminated food.

(13) 'Foodborne disease outbreak' means an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness. There are two exceptions: even one case of botulism or chemical poisoning constitutes an outbreak if laboratory studies identify the causative agent in

the food.

(14) '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.

(15) 'Health officer' and 'local health officer' as used in this subchapter includes county, city, and district health officers.

(16) '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.

(17) '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.

(18) 'Laboratory findings' means (A) the results of a laboratory examination of any specimen derived from the human body which yields microscopical, cultural, immunological, serological, 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 rabies or plague.

(19) '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.

(20) '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 requires immediate reporting and epidemiologic investigation.

(21) '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.

(22) 'Sexually Transmitted Diseases' means Chancroid, Lymphogranuloma Venereum, Granuloma Inguinale, Syphilis, Gonorrhea, Chlamydia, Pelvic Inflammatory Disease, and Nongonococcal Urethritis.

(23) '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 and published in the Morbidity and Mortality Weekly Report (MMWR) or its supplements; or (C) an animal which has been determined by a veterinarian to exhibit clinical signs or which has laboratory findings suggestive of rabies or plague.

(24) '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.

(25) 'Water-associated disease' means an illness in which there is evidence to suggest that the illness could possibly have resulted from physical contact with or swallowing water from a microbiologically or chemically contaminated source. Examples of such potentially

contaminated water sources are lakes, rivers, streams, irrigation water, wells, public and private drinking water, bottled water, reclaimed water, ocean and bay waters, hot springs, hot tubs, whirlpool spas, and swimming pools. Epidemiologic investigation by public health authorities is required to demonstrate that a suspected water-associated illness was likely to have been waterborne and related to the suspected source.

(26) 'Waterborne disease outbreak' means an incident in which two or more persons experienced a similar illness after consumption or use of the same water intended for drinking or after water contact such as by immersion, and epidemiologic investigation by public health authorities implicates the same water as the source of the waterborne illness. There is one exception: a single case of waterborne chemical poisoning constitutes an outbreak if laboratory studies indicate that the source water is contaminated by the chemical.

(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/ethnic group, Social Security number, sex, 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, a sexually transmitted disease or tuberculosis, then the report shall include the following applicable information, if known: (A) hepatitis information as to the type of hepatitis, type-specific laboratory findings, and sources of exposure, (B) sexually transmitted disease information as to the specific causative agent, syphilis-specific laboratory findings, and any complications of gonorrhea or chlamydia infections, or (C) 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, PM 110 (1/90), 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 Department of Health Services' 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 (r) 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. 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 (w) 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.

Acquired Immune Deficiency Syndrome (AIDS)  
+ Amebiasis  
+ Anisakiasis  
r Anthrax  
+ Babesiosis  
r Botulism (Infant, Foodborne, Wound, Other)  
r Brucellosis  
+ Campylobacteriosis  
Chancroid  
Chlamydial Infections  
r Cholera  
r Ciguatera Fish Poisoning  
Coccidioidomycosis  
+ Colorado Tick Fever  
+ Conjunctivitis, Acute Infectious of the Newborn, Specify Etiology  
+ Cryptosporidiosis  
Cysticercosis  
r Dengue  
r Diarrhea of the Newborn, Outbreaks  
r Diphtheria  
r Domoic Acid Poisoning (Amnesic Shellfish Poisoning)  
Echinococcosis (Hydatid Disease)  
Ehrlichiosis  
+ Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic  
r Escherichia coli O157:H7 Infection  
+w Foodborne Disease  
Giardiasis  
Gonococcal Infections  
+ Haemophilus influenzae, Invasive Disease  
r Hantavirus Infections  
r Hemolytic Uremic Syndrome  
Hepatitis, Viral  
+ Hepatitis A  
Hepatitis B (specify acute case or chronic)  
Hepatitis, C (specify acute case or chronic)  
Hepatitis D (Delta)  
Hepatitis, other, acute  
Kawasaki Syndrome (Mucocutaneous Lymph Node Syndrome)  
Legionellosis  
Leprosy (Hansen Disease)  
Leptospirosis  
+ Listeriosis  
Lyme Disease  
+ Lymphocytic Choriomeningitis  
+ Malaria  
+ Measles (Rubeola)  
+ Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic  
r Meningococcal Infections

Mumps

Non-Gonococcal Urethritis (Excluding Laboratory Confirmed Chlamydial Infections

r Paralytic Shellfish Poisoning

Pelvic Inflammatory Disease (PID)

+ Pertussis (Whooping Cough)

r Plague, Human or Animal

+ Poliomyelitis, Paralytic

+ Psittacosis

+ Q Fever

r Rabies, Human or Animal

+ Relapsing Fever

Reye Syndrome

Rheumatic Fever, Acute

Rocky Mountain Spotted Fever

Rubella (German Measles)

Rubella Syndrome, Congenital

+ Salmonellosis (Other than Typhoid Fever)

r Scombroid Fish Polsoning

r Severe Acute Respiratory Infection (SARS)

+ Shigellosis

r Smallpox (Variola)

+ Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)

+ Swimmer's Itch (Schistosomal Dermatitis)

+ Syphilis

Tetanus

Toxic Shock Syndrome

Toxoplasmosis

+ Trichinosis

+ Tuberculosis

r Tularemia

+ Typhoid Fever, Cases and Carriers

Typhus Fever

r Varicella (deaths only)

+ Vibrio Infections

r Viral Hemorrhagic Fevers (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)

+ Water-associated Disease

+ West Nile virus infection

r Yellow Fever

+ Yersiniosis

r OCCURRENCE of ANY UNUSUAL DISEASE

r OUTBREAKS of ANY DISEASE (Including diseases not listed in Section 2500). Specify if institutional and/or open community.

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(r) = 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. (w) = 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.

**17 CCR § 2501**

s 2501. Investigation of a Reported Case, Unusual Disease, or Outbreak of Disease.

(a) Upon receiving a report made pursuant to Section 2500 or 2505, the local health officer shall take whatever steps deemed necessary for the investigation and control of the disease, condition or outbreak reported. If the health officer finds that the nature of the disease and the circumstances of the case, unusual disease, or outbreak warrant such action, the health

officer shall make or cause to be made an examination of any person who or animal which has been reported pursuant to Sections 2500 or 2505 in order to verify the diagnosis, or the existence of an unusual disease, or outbreak, make an investigation to determine the source of infection, and take appropriate steps to prevent or control the spread of the disease. Whenever requested to do so by the Department, the health officer shall conduct a special morbidity and mortality study under [Health and Safety Code Section 211](#) for any of the diseases made reportable by these regulations.

(b) If a disease is one in which the local health officer determines identification of the source of infection is important, and the source of infection is believed to be outside the local jurisdiction, the health officer shall notify the Director or the health officer under whose jurisdiction the infection was probably contracted if known. Similar notification shall be given if there are believed to be exposed persons, living outside the jurisdiction of the health officer, who should be quarantined or evaluated for evidence of the disease.

## **United States Code**

### **42 U.S.C.A. § 247d Public health emergencies**

#### (a) Emergencies

If the Secretary determines, after consultation with such public health officials as may be necessary, that--

- (1) a disease or disorder presents a public health emergency; or
- (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.

#### (b) Public Health Emergency Fund

##### (1) In general

There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) of this section only if a public health emergency has been declared by the Secretary under such subsection. There is authorized to be appropriated to the Fund such sums as may be necessary.

##### (2) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing--

- (A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and
- (B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

#### (c) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(d) Data submittal and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a) of this section, individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

**42 U.S.C.A. § 247d-6b Strategic National Stockpile**

(a) Strategic National Stockpile

(1) In general

The Secretary, in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) Procedures

The Secretary, in managing the stockpile under paragraph (1), shall--

- (A) consult with the working group under [section 247d-6\(a\)](#) of this title;
- (B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;
- (C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;
- (D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;
- (E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;
- (F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;
- (G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and
- (H) ensure the adequate physical security of the stockpile.

(b) Smallpox vaccine development

(1) In general

The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) of this section includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) Rule of construction

Nothing in this section shall be construed to limit the private distribution,

purchase, or sale of vaccines from sources other than the stockpile described in subsection (a) of this section.

(c) Additional authority regarding procurement of certain biomedical countermeasures; availability of special reserve fund

(1) In general  
(A) Use of fund

A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).

(B) Security countermeasure

For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by [section 321\(g\)\(1\) of Title 21](#)), biological product (as that term is defined by [section 262\(i\)](#) of this title), or

device (as that term is defined by [section 321\(h\) of Title 21](#)) that--

(i)(I) the Secretary determines to be a priority (consistent with [sections 182\(2\)](#) and [184\(a\) of Title 6](#)) to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under subchapter V of chapter 9 of Title 21 or licensed under [section 262](#) of this title; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under [section 360bbb-3 of Title 21](#).

(2) Determination of material threats

(A) Material threat

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis--

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) Public health impact; necessary countermeasures

The Secretary shall on an ongoing basis--

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) Notice to Congress

The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10)) that a determination has been made pursuant to subparagraph (A) or (B).

(D) Assuring access to threat information

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under [section 122 of Title 6](#), including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) Assessment of availability and appropriateness of countermeasures

The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(4) Call for development of countermeasures; commitment for recommendation for procurement

(A) Proposal to the President

If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to--

- (i) issue a call for the development of such countermeasure; and
- (ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) Countermeasure specifications

The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)--

- (i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);
- (ii) necessary measures of minimum safety and effectiveness;
- (iii) estimated price for each dose or effective course of treatment regardless of dosage form; and
- (iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) Presidential approval

If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved--

- (i) the call for the countermeasure;
- (ii) specifications for the countermeasure under subparagraph (B); and
- (iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund

(A) In general

The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) of this section pursuant to procurements made with amounts in the special reserve fund under

paragraph (10) (referred to in this subsection individually as a "procurement under this subsection").

(B) Requirements

In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

- (i) The quantities of the product that will be needed to meet the needs of the stockpile.
- (ii) The feasibility of production and delivery within eight years of sufficient quantities of the product.
- (iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendation for President's approval

(A) Recommendation for procurement

In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) Presidential approval

The special reserve fund under paragraph (10) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) Notice to designated Congressional committees

The Secretary and the Homeland Security Secretary shall notify the designated congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) Rule of construction

Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) Procurement

(A) In general

For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) Interagency agreement; costs

(i) Interagency agreement

The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for payments made by the Secretary to a vendor for such procurement.

(ii) Other costs

The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.

(C) Procurement

(i) In general

The Secretary shall be responsible for--

- (I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this subparagraph; and
- (II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) Contract terms

A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) Payment conditioned on delivery

The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.

(II) Discounted payment

The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) Contract duration

The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) Storage by vendor

The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(iii) Availability of simplified acquisition procedures

(I) In general

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in [section 403\(11\) of Title 41](#), for purposes of application to such procurement, pursuant to [section 252a\(a\) of Title 41](#), of--  
(aa) [section 253\(g\)\(1\)\(A\) of Title 41](#) and its implementing regulations; and  
(bb) [section 252a\(b\) of Title 41](#) and its implementing regulations.

(II) Application of certain provisions

Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

- (aa) Chapter 37 of Title 40 (relating to contract work hours and safety standards).
- (bb) [Subsections \(a\) and \(b\) of section 57 of Title 41](#).
- (cc) [Section 254d of Title 41](#) (relating to the examination of contractor records).
- (dd) [Section 3131 of Title 40](#) (relating to bonds of contractors of public buildings or works).
- (ee) [Subsection \(a\) of section 254 of Title 41](#) (relating to contingent fees to middlemen).
- (ff) [Section 6962](#) of this title.
- (gg) [Section 1354 of Title 31](#) (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) Internal controls to be established

The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) Authority to limit competition

In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) Procedures other than full and open competition

(I) In general

In using the authority provided in [section 253\(c\)\(1\) of Title 41](#) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase "available from only one responsible source" in such [section 253\(c\)\(1\) of Title 41](#) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(II) Relation to other authorities

The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) Applicable Government-wide regulations

The Secretary shall implement this clause in accordance with government-wide regulations implementing such [section 253\(c\)\(1\) of Title 41](#) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) Premium provision in multiple award contracts

(I) In general

If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that--

- (aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and
- (bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) Determination of Government's requirement not reviewable

If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) Extension of closing date for receipt of proposals not reviewable

A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) Limiting competition to sources responding to request for information

In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under [section 253a\(a\)\(1\)\(B\) of Title 41](#) if such request has given notice that the Secretary may so exclude such a source.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(9) Restrictions on use of funds

Amounts in the special reserve fund under paragraph (10) shall not be used to pay--

(A) costs for the purchase of vaccines under procurement contracts entered into before July 21, 2004; or

(B) costs other than payments made by the Secretary to a vendor for a procurement of a security countermeasure under paragraph (7).

(10) Definitions

(A) Special reserve fund

For purposes of this subsection, the term "special reserve fund" has the meaning given such term in [section 320 of Title 6](#).

(B) Designated Congressional committees

For purposes of this section, the term "designated congressional committees" means the following committees of the Congress:

(i) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(ii) In the Senate: the appropriate committees.

(d) Disclosures

No Federal agency shall disclose under [section 552 of Title 5](#), any information identifying the location at which materials in the stockpile under subsection (a) of this section are stored.

(e) Definition

For purposes of subsection (a) of this section, the term "stockpile" includes--

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a) of this section; or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a) of this section.

(f) Authorization of appropriations

(1) Strategic National stockpile

For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated \$640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (c)(10)(A) of this section.

(2) Smallpox vaccine development

For the purpose of carrying out subsection (b) of this section, there are authorized to be appropriated \$509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

**42 U.S.C.A. § 1320b-5 Authority to waive requirements during national emergencies**

(a) Purpose

The purpose of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period (as defined in subsection (g)(1) of this section)--

(1) that sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the programs under subchapters XVIII, XIX, and XXI of this chapter; and

(2) that health care providers (as defined in subsection (g)(2) of this section) that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in subsection (b) of this section, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

(b) Secretarial authority

To the extent necessary to accomplish the purpose specified in subsection (a) of this section, the Secretary is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of subchapters XVIII, XIX, or XXI of this chapter, or any regulation thereunder (and the requirements of this subchapter other than this section, and regulations thereunder, insofar as they relate to subchapters XVIII, XIX, or XXI), pertaining to--

(1)(A) conditions of participation or other certification requirements for an individual health care provider or types of providers,

(B) program participation and similar requirements for an individual health care provider or types of providers, and

(C) pre-approval requirements;

(2) requirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;

(3) actions under [section 1395dd](#) of this title (relating to examination and treatment for emergency medical conditions and women in labor) for--

(A) a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period; or

(B) the direction or relocation of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan;

(4) sanctions under [section 1395nn\(g\)](#) of this title (relating to limitations on physician referral);

(5) deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived;

- (6) limitations on payments under [section 1395w-21\(i\)](#) of this title for health care items and services furnished to individuals enrolled in a Medicarek Choice plan by health care professionals or facilities not included under such plan; and
- (7) sanctions and penalties that arise from noncompliance with the following requirements (as promulgated under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 ([42 U.S.C. 1320d-2](#) note))--
  - (A) [section 164.510 of title 45, Code of Federal Regulations](#), relating to--
    - (i) requirements to obtain a patient's agreement to speak with family members or friends; and
    - (ii) the requirement to honor a request to opt out of the facility directory;
  - (B) [section 164.520 of title 45, Code of Federal Regulations](#), relating to the requirement to distribute a notice; or
  - (C) [section 164.522 of title 45, Code of Federal Regulations](#), relating to--
    - (i) the patient's right to request privacy restrictions; and
    - (ii) the patient's right to request confidential communications.'; and

Insofar as the Secretary exercises authority under paragraph (6) with respect to individuals enrolled in a MedicarekChoice plan, to the extent possible given the circumstances, the Secretary shall reconcile payments made on behalf of such enrollees to ensure that the enrollees do not pay more than would be required had they received services from providers within the network of the plan and may reconcile payments to the organization offering the plan to ensure that such organization pays for services for which payment is included in the capitation payment it receives under part C of subchapter XVIII of this chapter. A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.

(c) Authority for retroactive waiver

A waiver or modification of requirements pursuant to this section may, at the Secretary's discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such period specified by the Secretary.

(d) Certification to Congress

The Secretary shall provide a certification and advance written notice to the Congress at least two days before exercising the authority under this section with respect to an emergency area. Such a certification and notice shall include--

- (1) a description of--
  - (A) the specific provisions that will be waived or modified;
  - (B) the health care providers to whom the waiver or modification will apply;
  - (C) the geographic area in which the waiver or modification will apply; and
  - (D) the period of time for which the waiver or modification will be in effect; and
- (2) a certification that the waiver or modification is necessary to carry out the purpose specified in subsection (a) of this section.

(e) Duration of waiver

(1) In general

A waiver or modification of requirements pursuant to this section terminates upon--

(A) the termination of the applicable declaration of emergency or disaster described in subsection (g)(1)(A) of this section;

(B) the termination of the applicable declaration of public health emergency described in subsection (g)(1)(B) of this section; or

(C) subject to paragraph (2), the termination of a period of 60 days from the date the waiver or modification is first published (or, if applicable, the date of extension of the waiver or modification under paragraph (2)).

(2) Extension of 60-day periods

The Secretary may, by notice, provide for an extension of a 60-day period described in paragraph (1)(C) (or an additional period provided under this paragraph) for additional period or periods (not to exceed, except as subsequently provided under this paragraph, 60 days each), but any such extension shall not affect or prevent the termination of a waiver or modification under subparagraph (A) or (B) of paragraph (1).

(f) Report to Congress

Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a) of this section, including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

(g) Definitions

For purposes of this section:

(1) Emergency area; emergency period

An "emergency area" is a geographical area in which, and an "emergency period" is the period during which, there exists--

(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(B) a public health emergency declared by the Secretary pursuant to [section 247d](#) of this title.

(2) Health care provider

The term "health care provider" means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.

42 U.S.C.A. § 1320d-5 General penalty for failure to comply with requirements and standards

(a) General penalty

(1) In general

Except as provided in subsection (b) of this section, the Secretary shall impose on any person who violates a provision of this part a penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

## (2) Procedures

The provisions of [section 1320a-7a](#) of this title, (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such [section 1320a-7a](#) of this title.

### (b) Limitations

#### (1) Offenses otherwise punishable

A penalty may not be imposed under subsection (a) of this section with respect to an act if the act constitutes an offense punishable under [section 1320d-6](#) of this title.

#### (2) Noncompliance not discovered

A penalty may not be imposed under subsection (a) of this section with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

#### (3) Failures due to reasonable cause

##### (A) In general

Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) of this section if--

- (i) the failure to comply was due to reasonable cause and not to willful neglect; and
- (ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

##### (B) Extension of period

###### (i) No penalty

The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

###### (ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

## (4) Reduction

In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) of this section that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

42 U.S.C.A. § 2000d Prohibition against exclusion from participation in, denial of benefits of, and discrimination under Federally assisted programs on ground of race, color, or national origin

No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

## **42 U.S.C.A. § 5191 Procedure for declaration**

### **(a) Request and declaration**

All requests for a declaration by the President that an emergency exists shall be made by the Governor of the affected State. Such a request shall be based on a finding that the situation is of such severity and magnitude that effective response is beyond the capabilities of the State and the affected local governments and that Federal assistance is necessary. As a part of such request, and as a prerequisite to emergency assistance under this chapter, the Governor shall take appropriate action under State law and direct execution of the State's emergency plan. The Governor shall furnish information describing the State and local efforts and resources which have been or will be used to alleviate the emergency, and will define the type and extent of Federal aid required. Based upon such Governor's request, the President may declare that an emergency exists.

### **(b) Certain emergencies involving Federal primary responsibility**

The President may exercise any authority vested in him by [section 5192](#) of this title or [section 5193](#) of this title with respect to an emergency when he determines that an emergency exists for which the primary responsibility for response rests with the United States because the emergency involves a subject area for which, under the Constitution or laws of the United States, the United States exercises exclusive or preeminent responsibility and authority. In determining whether or not such an emergency exists, the President shall consult the Governor of any affected State, if practicable. The President's determination may be made without regard to subsection (a) of this section.