

/\* California's HIV and AIDS laws follow. They are presented in three parts. \*/

26. AIDS; Human immunodeficiency virus or HIV; HIV test

As used in this code:

- (a) "AIDS" means acquired immune deficiency syndrome.
- (b) "Human immunodeficiency virus" or "HIV" means the etiologic virus of AIDS.
- (c) "HIV test" means any clinical laboratory test approved by the federal Food and Drug Administration for HIV, component of HIV, or antibodies to HIV.

32. Legislative findings; AIDS training in continuing education requirements for specified licensees

(a) The Legislature finds that there is a need to ensure that professionals of the healing arts who have or intend to have significant contact with patients who have, or are at risk to be exposed to, acquired immune deficiency syndrome (AIDS) are provided with training in the form of continuing education regarding the characteristics and methods of assessment and treatment of the condition.

(b) A board vested with the responsibility of regulating the following licensees shall consider including training regarding the characteristics and method of assessment and treatment of acquired immune deficiency syndrome (AIDS) in any continuing education or training requirements for those licensees: chiropractors, medical laboratory technicians, dentists, dental hygienists, dental assistants, physicians and surgeons, podiatrists, registered nurses, licensed vocational nurses, psychologists, physicians' assistants, respiratory therapists, acupuncturists, marriage, family, and child counselors, licensed educational psychologists, and clinical social workers.

54. Right to streets, highways, and other public places; disability

(a) Individuals with disabilities shall have the same right as the general public to the full and free use of the streets, highways, sidewalks, walkways, public buildings, public facilities, and other public places.

(b) "Disability," as used in this part, means any of the following with respect to an individual:

(1) A physical or mental impairment that substantially limits one or more of the major life activities of the individual.

(2) A record of such an impairment.

(3) Being regarded as having such an impairment.

54.1. Access to public conveyances, places of public accommodation, amusement or resort, and housing accommodations

(a) Individuals with disabilities shall be entitled to full and equal access, as other members of the general public, to accommodations, advantages, facilities, and privileges of all common carriers airplanes, motor vehicles, railroad trains, motorbuses, streetcars, boats, or any other public conveyances or modes of transportation (whether private, public, franchised, licensed, contracted or otherwise provided, telephone facilities, adoption agencies, private schools, hotels, lodging places, places of public accommodation, amusement, or resort, and other places to which the general public is invited, subject only to the conditions and limitations established by law, or state or federal regulation, and applicable alike to all persons.

As used in this section, "telephone facilities" means tariff items and other equipment and services which have been approved by the Public Utilities Commission to be used by individuals with disabilities in a manner feasible and compatible with the existing, telephone network provided by the telephone companies.

"Full and equal access," for purposes of this section in its application to transportation, means access that meets the standards of Titles II and III of the Americans with Disabilities Act of 1990 (Public Law 101-362) and federal regulations adopted pursuant thereto, except that, if the laws of this state prescribe higher standards, it shall mean access that meets those

higher standards.

(b) (1) Individuals with disabilities shall be entitled to full and equal access, as other members of the general public, to all housing accommodations offered for rent, lease, or compensation in this state, subject to the conditions and limitations established by law, or state or federal regulation, and applicable alike to all persons.

(2) "Housing accommodations means any real property, or portion thereof, which is used or occupied, or is intended, arranged, or designed to be used or occupied, as the home, residence, or sleeping place of one or more human beings, but shall not include any accommodations included within subdivision (a) or any single-family residence the occupants of which rent, lease, or furnish for compensation not more than one room therein.

(3) Nothing in this subdivision shall require any person renting, leasing, or providing for compensation real property to modify his or her property in any way or provide a higher degree of care for an individual with a disability than for an individual who is not disabled.

(4) Except as provided in paragraph (5) of this subdivision, nothing in this part shall require any person renting, leasing, or providing for compensation real property, if that person refuses to accept tenants who have dogs, to accept as a tenant an individual with a disability who has a dog.

(5) It shall be deemed a denial of equal access to housing accommodations within the meaning of this subdivision for any person, firm, or corporation to refuse to lease or rent housing accommodations to an individual who is blind or visually impaired on the basis that the individual uses the services of a guide dog, an individual who is deaf or hearing impaired on the basis that the individual uses the services of a signal dog, or to an individual with a physical disability on the basis that the individual uses the services of a service dog, or to refuse to permit such an individual who is blind or visually impaired to keep a guide dog, an individual who is deaf or hearing impaired to keep a signal dog, or an individual with a physical disability to keep a service dog on the premises.

Except in the normal performance of duty as a mobility or signal aid, nothing contained in this shall be construed to prevent the owner of a housing accommodation from establishing terms in a lease or rental agreement which reasonably regulate the presence of guide dogs, signal dogs, or service dogs on the premises of a

housing accommodation, nor shall this paragraph be construed to relieve a tenant from any liability otherwise imposed by law for real and personal property damages caused by such a dog when proof of same exists.

As used in this subdivision, "guide dog" means any guide dog which was trained by a person licensed under the provisions of Chapter 9.5 (commencing with Section 7200) of Division 3 of the Business and Professions Code or as defined in the regulations implementing Title III of the Americans with Disabilities Act of 1990 (Public Law 101336).

As used in this subdivision, "signal dog" means any dog trained to alert an individual who is deaf or hearing impaired to intruders or sounds.

As used in this subdivision, "service dog" means any dog individually trained to the individual with a physical disability's requirements including, but not limited to, minimal protection work, rescue work, pulling a wheelchair, or fetching dropped items.

(6) It shall be deemed a denial of equal access to housing accommodations within the meaning of this subdivision for any person, firm, or corporation to refuse to lease or rent housing accommodations to an individual who is blind or visually impaired, an individual who is deaf or hearing impaired, or other individual with a disability on the basis that the individual with a disability is partially or wholly dependent upon the income of his or her spouse, if the spouse is a party to the lease or rental agreement. Nothing in this subdivision shall, however, prohibit a lessor or landlord from considering the aggregate financial status of an individual with a disability and his or her spouse.

(c) Persons licensed to train guide dogs for individuals who are visually impaired or blind pursuant to Chapter 9.5 (commencing with Section 7200) of Division 3 of the Business and Professions Code or guide dogs as defined in the regulations implementing Title III of the Americans with Disabilities Act of 1990 (Public Law 101336), and persons authorized to train signal dogs for individuals who are deaf or hearing impaired, and persons authorized to train service dogs for individuals with physical disabilities, may take dogs, for the purpose of training them as guide dogs, signal dogs, or service dogs in any of the places specified in subdivisions (a) and (b). These persons shall carry and display identification if issued as an authorization, upon request

PART 2.6. CONFIDENTIALITY OF MEDICAL INFORMATION

56.05 Definitions

For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Medical information" means any individually identifiable information in possession of or derived from a provider of health care regarding a patient's medical history, mental or physical condition, or treatment.

(c) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(d) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code; and any group practice prepayment health care service plan regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975, Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

CHAPTER 2. DISCLOSURE OF MEDICAL INFORMATION BY PROVIDERS

56.10. Authorization; necessity; exceptions

(a) No provider of health care shall disclose medical information regarding a patient of the provider without first obtaining an authorization, except as provided in subdivision (b) or (c).

(b) A provider of health care 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) When otherwise specifically required by law.

(c) A provider of health care may disclose medical information as follows:

(1) The information may be disclosed to providers of health care 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 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 1200) 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, 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 as necessary to assist the other provider in obtaining payment for health care services rendered by that provider 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 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 which 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, or to licensed health care service plans, or to professional standards review organizations, or to utilization and quality control peer review organization established by Congress in Public Law 97-248 in 1982, or to persons or organizations responsible for, or defending professional liability which a provider may incur, if the committees, agents, plans, organizations, or persons are engaged in reviewing the competence or qualification 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 may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care. However, no patient identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office.

(7) The information may be disclosed to public agencies, clinical investigators, health care research organizations, and accredited public or private nonprofit educational or health care institutions or bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way which would permit identification of the patient

(8) A provider of health care that has created medical

information as a result of employer 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 which:

(A) Is relevant in a law suit, 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 it 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 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 which the patient seeks coverage by or benefits from, if the information was created by the provider of health care 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 group practice prepayment health care service plan by providers which contract with the plan and may be transferred among providers which contract with the plan, for the purpose of administering the 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 to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 79 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) When the disclosure is otherwise specifically authorized by law.

## Chapter 1.4

### AIDS EARLY INTERVENTION PROJECTS

#### Section

140. Contracts; project purposes; services provided; case management team.

141. Contracts; project models; county health department review; coordination.

142. Data collection; annual reports.

143. Reimbursement; guidelines for identifying public and private payers; fees; federal funds; Medi-Cal.

144. Legislative intent.

140. Contracts; project purposes; services provided; case management team

(a) The State Director of Health Services shall award contracts to early intervention projects to provide long-term services to persons infected with HIV. The purposes of the early intervention projects shall be to provide appropriate medical treatment to prevent or delay the progression of disease that results from HIV infection, to coordinate services available to HIV infected persons, and to provide information and education, including behavior change support, to HIV infected persons to prevent the spread of HIV infection to others. The director shall award contracts to early intervention projects from a variety of geographical areas. In selecting projects, the director shall ensure that each early intervention project will respond to the needs of its projected service area, will be sensitive to

linguistic, ethnic, and cultural differences, and will accommodate the special needs of clients by taking into account the circumstances that placed them at risk for becoming infected with HIV. The director shall award contracts for early intervention services at a pace that reflects the availability of private, state, and federal reimbursement pursuant to Section 144. Prior to awarding contracts to new programs, the director shall consider utilizing existing services and programs with which it currently contracts, or which are currently in operation, and which provide HIV-related services.

(b) Early intervention projects that are awarded contracts pursuant to this section shall provide all of the following services:

(1) Health assessment of HIV infected persons, including, but not limited to, a physical examination and immunologic and clinical monitoring.

(2) Health education and behavior change support related to reducing the risk of spreading HIV infection to others and to maximize the healthy and productive lives of HIV infected persons.

(3) Psychosocial counseling services.

(4) Information and referrals for social services.

(5) Information and referrals on available research for the treatment of HIV infection.

(6) Covered outpatient preventative or therapeutic health care services related to HIV infection, as determined by the director.

(7) Case management.

(c) An early intervention project shall establish a core case management team for each client to assess the needs of the client and to develop, implement, and evaluate the client's written individual service plan. As needed by the client, the individual service plan shall include services specified in subdivision (b), other support services, legal services, public assistance, insurance, and inpatient and outpatient health care services needs of the client. A core case management team shall include, but not be limited to, a physician and surgeon, a physician assistant or nurse practitioner, a health educator, a case manager, and the client. Case management in an early intervention project shall incorporate an interdisciplinary

approach. Other professionals, paraprofessionals, and other interested persons deemed appropriate by the members of the core case management team also may be included. The case manager shall coordinate the objectives specified in the client's individual service plan. The case manager also shall monitor and assist the client through all services provided by the project and shall provide information, guidance, and assistance to the client regarding support services, legal services, public assistance, insurance, and inpatient and outpatient health care services. The project shall designate a sufficient number of case managers to reflect case manager-to-client ratios established by the department.

141. Contracts; project models; county health department review; coordination

(a) The director shall commence awarding contracts to projects on or before July 1, 1990. In awarding contracts to early intervention projects, the director may select projects from each of the following models:

(1) A privately operated profit or nonprofit clinic which is not licensed as part of a health facility and which provides all of the services specified in subdivision (b) of Section 140.

(2) A publicly operated clinic which is not licensed as part of a health facility and which provides all of the services specified in subdivision (b) of Section 140.

(3) A combination of independent privately operated clinics, publicly operated clinics, and other health care providers which in total provide all of the services specified in subdivision (b) of Section 140.

(4) Any other model which the director considers worthy of receiving funds.

(b) An applicant for a contract to operate an early intervention project that is not a part of a county health department shall submit its application to the county health department for review and comment. The county health department shall provide comment on the application to the state department within a time period to be specified by the state department. The failure by a county health department to comment on an application submitted to it within the time period specified by the state department shall

not jeopardize the application, and the state department in a case of this nature may process and award a contract in the absence of comment by the county health department.

(c) An applicant for a contract to operate an early intervention project shall indicate in its application how it intends to coordinate with county health department programs, community-based organizations that provide HIV-related services, and other public and private entities which may provide services to a person who is infected with HIV.

#### 142. Data collection; annual reports

(a) The state department shall collect data from the early intervention projects, assess the effectiveness of the different models of early intervention projects, and report its findings to the Legislature on or before January 1, 1992, and on or before January 1 of each subsequent year.

(b) The state department shall continuously collect data from each early intervention project. The data collected may include, but not be limited to, the following:

- (1) The total number of clients served.
- (2) The number of clients utilizing each service provided by the project.
- (3) Demographics on clients in the aggregate.
- (4) The source of funding for each type of service provided.
- (5) The cost of each type of service provided.
- (6) Medical treatment modalities utilized in the aggregate.
- (7) Changes in the clinical status of clients in the aggregate.
- (8) Changes in behaviors that present risks of transmitting HIV infection of the clients in the aggregate.
- (9) The psychosocial changes of clients in the aggregate.
- (10) Referrals made by the project.
- (11) Perceived unmet needs of the clients served by the project.

(c) The state department shall develop and distribute to each early intervention project forms for data collection that are designed to elicit information necessary for the state department to comply with the requirements of subdivision (b). The data may be used by the state department to comply with the requirements of subdivision (a).

143. Reimbursement; guidelines for identifying public and private payers; fees; federal funds; Medi-Cal

(a) The state department shall establish a reimbursement schedule for all of the services detailed in subdivision (b) of Section 140. The amounts to be reimbursed for these services shall be commensurate with the costs of providing these services.

(b) The state department shall develop and disseminate guidelines to assist early intervention projects in identifying appropriate public and private payers of early intervention services. The guidelines shall take into account each client's access to, and eligibility for, private health insurance and public medical assistance. The guidelines shall include, but not be limited to, the reimbursement schedule established pursuant to subdivision (a) and the elements identified in subdivisions (c) to (h), inclusive.

(c) Reimbursement under this chapter shall not be made for any services which are available to the client under a private health insurance program. Early intervention projects shall inquire of each client as to the client's coverage by a private health insurance policy. Where a client has a private health insurance policy, the early intervention project shall bill the insurer for those services in subdivision (b) of Section 140 that are covered by the client's policy.

(d) The state department shall develop and implement, or cause to be implemented by an early intervention project, a uniform sliding fee schedule for services provided to individuals under this chapter. The schedule shall be based on the client's ability to pay.

(e) The state department may apply for any funds available from the federal government for the reimbursement of those services to be provided by early intervention projects, including, but not limited to, funds available pursuant to Section 2318 of the Public Health Service Act, as added by Public Law 100-607, which

provides for the development of model protocols for the clinical care of individuals who are infected with HIV.

(f) To the extent permitted under existing law, the Medi-Cal program shall provide reimbursement to early intervention projects for services provided under this chapter that are covered under the Medi-Cal program. This subdivision shall not be construed to confer Medi-Cal eligibility on any person who does not meet existing Medi-Cal eligibility requirements.

(g) The state department shall use federal and state general funds which are appropriated for the purpose of purchasing HIV-related drug treatments and related services, to reimburse for covered outpatient preventative or therapeutic health care services, as defined by the director, provided that the client is eligible for a federal or state program that subsidizes the cost of HIV-related drugs and related services. If Assembly Bill 2251 of the 1989-90 Regular Session 2 is enacted, the state department shall use the provisions in Chapter 1.85 (commencing with Section 188) of Part 1 of Division 110 implement this subdivision.

/\*This Assembly Bill became Sections 188 ff. \*/

(h) The state department shall use moneys from the General Fund to cover expenses for early intervention services that are not otherwise reimbursed, to the extent that moneys from the General Fund are expressly appropriated to the state department for early intervention services.

#### 144. Legislative intent

The Legislature hereby finds and declares that people with HIV infection may not avail themselves of early intervention services unless they are aware of the availability of the services and the efficacy of early intervention in prolonging life. This awareness by HIV-infected persons is critical to maximizing the benefits of early intervention. Therefore, it is the intent of the Legislature that the department includes early intervention education as a component of information and education grants in the first grant cycle following enactment of this chapter.

### Chapter 1.8

#### PROVISION OF AZIDOTHYIMIDINE

Section

185. Legislative findings.

186. Legislative intent; continuation of temporary funding of program.

187. Continuation of federal subsidy program; eligibility standards; allocation of funds.

185. Legislative findings

The Legislature hereby finds and declares all of the following:

The drug azidothymidine (AZT) improves and prolongs the quality of life for those suffering from acquired immune deficiency syndrome (AIDS) or AIDS-related conditions, is believed to reduce the infectiousness of a person infected with human immunodeficiency virus (HIV), and is the only drug approved by the federal Food and Drug Administration for treatment of AIDS and AIDS-related conditions;

Hundreds of Californians infected with HIV are receiving AZT due to a subsidy for AZT made available by the federal government for low-income people;

The State Department of Health Services estimates that it will have sufficient federal funds to maintain those enrolling in the program prior to October 1, 1988, through April 1989, if it terminates new enrollees beginning October 1, 1988;

The State Department of Health Services intends to direct counties to cease accepting new enrollees for the subsidy program beginning October 1, 1988, because of the exhaustion of these federal funds;

The federal government has an obligation to continue to support the subsidy program that it has initiated because of the horrendous moral consequences of terminating the access of low-income infected people to the drug;

The funding cycle for federal programs precludes appropriating additional funds to maintain this program until June of 1989.

186. Legislative intent; continuation of temporary funding of program It is the intent of the Legislature that the State of California continue to

provide temporary funding for the program to ensure that those whose health depends on obtaining access to AZT and who are unable to afford it can receive the drug during this interim period.

187. Continuation of federal subsidy program; eligibility standards; allocation of funds

The State Department of Health Services shall continue through June 1989, the AZT subsidy program established in 1987 with federal funds. The department shall maintain the eligibility standards used for the program as of August 1988. The department shall allocate to local health jurisdictions the funds appropriated to support the subsidy program. The department may reallocate funds among these local health jurisdictions as needed to ensure that persons requiring the subsidy receive it through June 1989.

## Chapter 1.85

### HUMAN IMMUNODEFICIENCY VIRUS (HIV) TREATMENT

#### Section

188. Legislative findings and declarations.

188.1. Drug treatments; establishment and administration of program; list of drugs; funding; rates; reimbursement.

188.2. Financial eligibility standards; repayment schedule.

188.3. Persons subject to payment obligation specified in 188.2; added drug.

188. Legislative findings and declarations

The Legislature hereby finds and declares all of the following:



(a) State-of-art knowledge regarding treatment of people infected with the human immunodeficiency virus (HIV) indicates that active HIV infection (AIDS) can be a manageable, though chronic, condition with the use of drugs such as zidovudine (AZT), aerosolized pentamidine, and ganciclovir. AIDS experts across the nation agree that early intervention with these drugs can prolong life, minimize the related occurrences of more serious illnesses, reduce more costly treatments, and maximize the HIV-infected person's vitality and productivity.

(b) For reasons of compassion and cost effectiveness, the State of California has a compelling interest in ensuring that its citizens infected with the HIV virus have access to these drugs.

(c) The department subsidizes the cost of these drugs for persons who do not have private health coverage, are not eligible for Medi-Cal, or cannot afford to purchase the drug privately. The subsidy program is funded through state and federal sources.

(d) Congress is expected to place limitations on the federal subsidy program which will jeopardize access to these life-prolonging drugs for people whose income is higher than federal income eligibility cap but lower than the state's income eligibility cap.

(e) It is critical that suffering persons with limited income have access to life-prolonging drugs. It is also critical that persons currently eligible for the subsidy program remain eligible regardless of changes that may result from the congressional action and the enactment of this chapter. However, it is appropriate that people who can afford to pay a portion of the cost of treatment be obligated to share the cost of these drugs.

188.1. Drug treatments; establishment and administration of program; list of drugs; funding; -rates; reimbursement

(a) To the extent that state and federal funds are appropriated in the Budget Act for these purposes, the director shall establish and may administer a program to provide drug treatments to persons infected with human immunodeficiency virus (HIV), the etiologic agent of acquired immune deficiency syndrome (AIDS). The director shall develop, maintain, and update as necessary a list of drugs to be provided under this program. Drugs on the list shall include, but not be limited to, the drugs zidovudine (AZT) and aerosolized pentamidine.

(b) The director may grant funds to a county public health department through standard agreements to administer this program in that county. To maximize the recipients' access to drugs covered by this program, the director shall urge the county health department in counties granted these funds to decentralize distribution of the drugs to the recipients.

(c) The director shall establish a rate structure for reimbursement for the cost of each drug included in the program. Rates shall not be less than the actual cost of the drug. However, the director may purchase a listed drug directly from the manufacturer and negotiate the most favorable bulk price for that drug.

(d) Reimbursement under this chapter shall not be made for any drugs which are available to the recipient under any other private, state, or federal programs, or under any other contractual or legal entitlements, except that the director may authorize an exemption from this subdivision where exemption would represent a cost savings to the state.

188.2. Financial eligibility standards; payment obligations; exemption; reconsideration request; administration expenses; provision of drugs added to program

(a) The state department shall establish uniform standards of financial eligibility for the drugs under the program established under this chapter.

(b) Nothing in the financial eligibility standards shall prohibit drugs to an otherwise eligible person whose adjusted gross income does not exceed fifty thousand dollars (\$50,000) per year. However, the director may authorize drugs for persons with incomes higher than fifty thousand dollars (\$50,000) per year if the estimated cost of those drugs in one year is expected to exceed 20 percent of the person's adjusted gross income.

(c) The state department shall establish and may administer a payment schedule to determine the payment obligation of a person receiving drugs. No person shall be obligated for payment whose adjusted gross income is less than four times the federal poverty level. The payment obligation shall be the lesser of the following:

(1) Two times the person's annual state income tax liability, less funds expended by the person for health insurance premiums.

(2) The cost of drugs.

(d) Persons who have been determined to have a payment obligation pursuant to subdivision (c) shall be advised by the state department of their right to request a reconsideration of that determination to the state department. Written notice of the right to request a reconsideration shall be provided to the person at the time that notification is given that he or she is subject to a payment obligation. The payment determination shall be reconsidered if one or more of the following apply:

(1) The determination was based on an incorrect calculation made pursuant to subdivision (b).

(2) There has been a substantial change in income since the previous eligibility determination which has resulted in a current income that is inadequate to meet the calculated payment obligation.

(3) Unavoidable family or medical expenses which reduce the disposable income and which result in current income that is inadequate to meet the payment obligation.

(4) Any other situation which imposes undue financial hardship on the person and would restrict his or her ability to meet the payment obligation.

(e) The state department may exempt a person, who has been determined to have a payment obligation pursuant to subdivision (c), from the obligation if both of the following criteria are satisfied:

(1) One or more of the circumstances specified in subdivision (d) exist.

(2) The state department has determined that the payment obligation will impose an undue financial hardship on the person.

(f) If a person requests reconsideration of the payment obligation determination, the person shall not be obligated to make any payment until the state department has completed the reconsideration request pursuant to subdivision (d). If the state department denies the exemption, the person shall be obligated to make payments for drugs received while the reconsideration request is pending.

(g) A county public health department administering this program pursuant to an agreement with the director pursuant to

subdivision (b) of Section 188.1 shall use no more than 5 percent of total payments it collects pursuant to this section to cover any administrative costs related to eligibility determinations, reporting requirements, and the collection of payments.

(h) A county public health department administering this program pursuant to subdivision (b) of Section 188.1 shall provide all drugs added to the program pursuant to subdivision (a) of Section 188.1 within 60 days of the action of the director, subject to the repayment obligations specified in subdivision (d) of Section 188.3.

188.3. Persons subject to payment obligation specified in 188.2; added drug

(a) Effective March 15, 1991, a person determined eligible for benefits under this chapter shall be subject to the payment obligation specified in subdivision (c) of Section 188.2.

(b) Persons who are receiving benefits under a HIV drug treatment subsidy program administered by the state department prior to March 15, 1991, shall not be subject to the payment obligation specified in subdivision (c) of Section 188.2.

(c) Notwithstanding subdivision (b), if a drug is added pursuant to subdivision (a) of Section 188.1, any person determined eligible for benefits under this chapter, regardless of the date of enrollment, shall be subject to the payment obligation specified in subdivision (c) of Section 188.2 for the added drug. The payment obligation for any other drug shall be determined in accordance with subdivision (b).

## Chapter 1.10

### ACQUIRED IMMUNE DEFICIENCY SYNDROME RESEARCH AND WORKSHOP GRANTS

#### Section

195. Legislative findings and declarations.

196. AIDS advisory committee; membership; abolishment.

197. Term of service; compensation; travel expenses; purpose of committee.

198. Grants; rules or criteria; approval of applications.

199. Award of grants; purposes.

199.3. Acceptance of federal funds or gifts from private or public agencies.

199.5. Administration of chapter; limitation on appropriation.

195. Legislative findings and declarations

The Legislature hereby finds and declares that the State Department of Health Services, working with the California AIDS Leadership Committee, has developed a draft state AIDS plan for comprehensive, coordinated government action against AIDS and HIV infection. It is the intention of the Legislature to implement those recommendations pertaining to infectious-disease screening of blood and other body parts and fluids, and to notifying donors of the results of those screening tests.

196. AIDS advisory committee; membership; abolishment

(a) There is hereby created in the state department an AIDS Advisory Committee. The membership of the committee shall be composed of eight members who have knowledge or expertise in the area of public health or AIDS research, or have been educated in the areas for which the grants are to be directed by the committee. These members shall be appointed by the following:

(1) Two by the Speaker of the Assembly.

(2) Two by the Senate Rules Committee.

(3) Four by the Governor.

(b) In addition to the membership prescribed by subdivision (a), the following persons shall be ex officio members:

(1) The Director of Health Services or a designee shall be a voting member.

(2) The Director of Mental Health, or a designee, a designee', requested to be appointed by the President of the University of California, with knowledge, experience, and responsibility for the university-wide allocation of AIDS research grants, shall be

nonvoting members.

(c) The committee shall be abolished effective July 1, 1990, unless extended by subsequent legislative action.

197. Term of service; compensation; travel expenses; purpose of committee

The members of the AIDS Advisory Committee shall serve at the pleasure of the appointing powers. The members shall serve without compensation, but shall be reimbursed for necessary and travel expenses incurred in the performance of the duties of the committee.

The committee shall advise and assist the state in addressing the public health issues associated with Acquired Immune Deficiency Syndrome, and shall work with the State Department of Health Services in statewide efforts to promote primary prevention, public education, and the advancement of knowledge regarding Acquired Immune Deficiency Syndrome.

198. Grants; rules or criteria; approval of applications

The committee may establish such rules or criteria for grants under this chapter as it deems necessary. Pursuant to the rules or criteria, the committee may review and recommend approval by the director of grant applications and monitor programs receiving grants under this chapter.

199. Award of grants; purposes

The director may award grants from any funds which may be made available for the purposes of this chapter to individuals, organizations, or facilities for activities which may include, but need not be limited to, any of the following:

(a) Education regarding primary prevention for high risk groups.

(b) Public education to reduce panic and lessen unnecessary anxiety about AIDS among California residents.

(c) Interdisciplinary or educational workshops to facilitate the interchange of knowledge among investigators regarding AIDS and

related disorders.

(d) Research grants which would assist the state with the educational efforts outlined in subdivisions (a) and (b).

(e) Grants to provide seed money for larger grants funded by the federal government or other sources.

### 199.3. Acceptance of federal funds or gifts from private or public agencies

The State Department of Health Services may do all of the following:

(a) Accept any federal funds provided for any of the purposes of this chapter.

(b) Accept any gift, donation, bequest, or grant of funds from a private or public agency for any of the purposes of this chapter.

### 199.5. Administration of chapter; limitation on appropriation

Not more than 10 percent of any money appropriated for purposes of this chapter shall be utilized for the administration of this chapter.

## Chapter 1.11

### MANDATED BLOOD TESTING AND CONFIDENTIALITY TO PROTECT PUBLIC HEALTH

#### Section

199.19. Inoperative.

199.20. Acquired immune deficiency syndrome (AIDS) blood tests; prohibition against compelling identification of test subjects.

199.21. Unauthorized disclosures; penalties; damages; prohibited uses of results; disclosure pursuant to state reporting requirements; monthly reports; definitions.

- 199.215. Disclosure to subject's health care providers; exceptions.
- 199.22. Written consent of test subjects; exceptions.
- 199.221. Exemptions from certain provisions.
- 199.222. Inapplicability of certain disclosure and consent provisions in medical testing of prisoners.
- 199.23. Liability of state department, blood bank or plasma center.
- 199.24. Disclosure to certain persons without written consent.
- 199.25. Disclosure to patient's spouse, sexual partner, needle sharer, or county health officer; physician liability; prohibition against compelled disclosure.
- 199.26. Inoperative.
- 199.27. Consent; incompetent persons.
- 199.28. Inoperative.
- 199.285. Inoperative.
- 199.29. Inoperative.
- 199.19. Inoperative
- 199.20. Acquired immune deficiency syndrome (AIDS) blood tests; prohibition against compelling identification of test subjects

To protect the privacy of individuals who are the subject of blood testing for antibodies to the probable causative agent of acquired immune deficiency syndrome (AIDS) the following shall apply:

Except as provided in Section 1603.1 or 1603.3, as amended by AB 488 of the 1985-86 Regular Session, no person shall be compelled in any state, county, city, or other local civil, criminal, administrative, legislative, or other proceedings to identify or



provide identifying characteristics which would identify or provide identifying characteristics which would identify any individual who is the subject of a blood test to detect antibodies to the probable causative agent of AIDS.

199.21. Unauthorized disclosures; penalties; damages; prohibited uses of results; disclosure pursuant to state reporting requirements; monthly reports; definitions

(a) Any person who negligently discloses results of an HIV test as defined in Section 26, to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1603.1 or 1603.8 or any other statute that expressly provides an exemption to this section, shall be assessed a civil penalty in an amount not to exceed one thousand dollars (\$1,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test

(b) Any person who willfully discloses the results of an HIV test as defined in Section 26. to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1608.1 or 1608.8 or any other statute that expressly provides an exemption to this section, shall be assessed a civil penalty in an amount not less than one thousand dollars (\$1,000) and not more than five thousand dollars (\$5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(c) Any person who willfully or negligently discloses the results of an HIV test as defined in Section 26, to a third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1603.1 or 1608.3 or any other statute that expressly provides an exemption to this section, which results in economic, bodily, or psychological harm to the subject of the test, is guilty of a misdemeanor, punishable by imprisonment in the county jail for a period not to exceed one year or a fine of not to exceed ten thousand dollars (\$10,000) or both.

(d) Any person who commits any act described in subdivision (a)

or (b) shall be liable to the subject for all actual damages, including damages for economic, bodily, or psychological harm which is a proximate result of the act.

(e) Each disclosure made in violation of this chapter is a separate and actionable offense.

(f) Except as provided in Article 6.9 (commencing with Section 799) of Chapter 1 of Part 2 of the Insurance Code the results of an HIV test as defined in Section 26, which identifies or provides identifying characteristics of the person to whom the test results apply, shall not be used in any instance for the determination of insurability or suitability for employment

(g) "Written authorization," as used in this section, applies only to the disclosure of test results by a person responsible for the care and treatment of the person subject to the test. Written authorization is required for each separate disclosure of the test results, and shall include to whom the disclosure would be made.

(h) Nothing in this section limits or expands the right of an injured subject to recover damages under any other applicable law. Nothing in this section shall impose civil liability or criminal sanction for disclosure of the results of tests performed on cadavers to public health authorities or tissue banks.

(i) Nothing in this section imposes liability or criminal sanction for disclosure of any test as defined in Section 26, in accordance with any reporting requirement for a diagnosed case of AIDS by the state department or the Centers for Disease Control under the United States Public Health Service.

(j) The state department may require blood banks and plasma centers to submit monthly reports summarizing statistical data concerning the results of tests to detect the presence of viral hepatitis and HIV. This statistical summary shall not include the identity of individual donors or identifying characteristics which would identify individual donors.

(k) "Disclosed," as used in this section, means to disclose, release, transfer, disseminate, or otherwise communicate all or any part of any record orally, in writing, or by electronic means to any person or entity.

(l) When the results of an HIV test , as defined in Section 26. are included in the medical record of the patient who is the subject of the test, the inclusion is not a disclosure for purposes of this section.

199.215. Disclosure to subject's health care providers; exceptions

(a) Notwithstanding Section 199.21, the results of an HIV test which identifies or provides identifying characteristics of the person to whom the test results apply may be recorded by the physician who ordered the test in the test subject's medical record or otherwise disclosed without written authorization of the subject of the test, or the subject's representative as set forth in Section 199.27, to the test subject's providers of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, for purposes of diagnosis, care, or treatment of the patient, except that for purposes of this section "providers of health care" does not include a health care service plan regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2.

(b) Recording or disclosure of HIV test results pursuant to subdivision (a) does not authorize further disclosure unless otherwise permitted by law.

199.22. Written consent of test subjects; exceptions

(a) Except in the case of a person treating a patient, no person shall test a person's blood for evidence of antibodies to the probable causative agent of AIDS without the written consent of the subject of the test or the written consent of the subject, as provided in Section 199.27, and the person giving the test shall have a written statement signed by the subject or conservator or other person, as provided in Section 199.27 confirming that he or she obtained the consent from the subject. In the case of a physician and surgeon treating a patient, the consent required under this subdivision shall be informed consent, by the patient,

conservator, or other person provided for in Section 199.27.

This requirement does not apply to a test performed at an alternative site, as established pursuant to Article 8 (commencing with Section 1630) of Chapter 4 of Division 2. This requirement also does not apply to any blood and blood products specified in paragraph (2) of subdivision (a) of Section 1603.1. This requirement does not apply when testing is performed as part of the medical examination performed pursuant to Section 7152.5.

(b) Nothing in this section shall preclude a medical examiner or other physician from ordering or performing a blood test to detect antibodies to the probable causative agent of AIDS on a cadaver when an autopsy is performed or body parts are donated pursuant to the Uniform Anatomical Gift Act, provided for pursuant to Chapter 3.5 (commencing with Section 7150) of Part 1 of Division 7.

(c) The requirements of subdivision (a) do not apply when blood is tested as part of a scientific investigation conducted either by medical researchers operating under institutional review board approval or by the state department in accordance with a protocol for unlinked testing. For purposes of this section, unlinked testing means that blood samples are obtained anonymously or that the individual's name and other identifying information is removed in a manner that precludes the test results from ever being linked to a particular individual in the study.

#### 199.221. Exemptions from certain provisions

Actions taken pursuant to Section 1768.9 of the Welfare and Institutions Code shall not be subject to subdivisions (a) to (c), inclusive, of Section 199.21. In addition, the requirements of subdivision (a) of Section 199.22 shall not apply to testing performed pursuant to Section 1768.9 of the Welfare and Institutions Code.

199.222. Inapplicability of certain disclosure and consent provisions in medical testing of prisoners.

Actions taken pursuant to Title 8 (commencing with Section 7500) of Part 3 of the Penal Code shall not be subject to subdivisions (a) to (c), inclusive, of Section 199.21. In addition, the

requirements of subdivision (a) of Section 199.22 shall not apply to testing performed pursuant to that title.

199.23. Liability of state department, blood bank or plasma center

Neither the state department nor any blood bank or plasma center, including a blood bank or plasma center owned or operated by a public entity, shall be held liable for any damages resulting from the notification of test results, as set forth in paragraph (3) of subdivision (a) of, and in subdivision (c) of, Section 1603.3, as amended by AB 488 of the 1985-86 Regular Session.

199.24. Disclosure to certain persons without written consent

Notwithstanding Section 199.20 or 199.21, the results of a blood test to detect antibodies to the probable causative agent of AIDS may be disclosed to any of the following persons without written authorization of the subject of the test:

(a) To the subject of the test or the subject's legal representative, conservator, or to any person authorized to consent to the test pursuant to subdivision (b) of Section 199.22.

(b) To a test subject's provider of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, except that for purposes of this section, "provider of health care" does not include a health care service plan regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2.

(c) To an agent or employee of the test subject's provider of health care who provides direct patient care and treatment.

(d) To a provider of health care who procures, processes, distributes, or uses a human body part donated pursuant to the Uniform Anatomical Gift Act (Chapter 3.5 (commencing with Section 7150) of Part 1 of Division 7).

199.25. Disclosure to patient's spouse, sexual partner, needle

sharer, or county health officer; physician liability; prohibition against compelled disclosure

(a) Notwithstanding Section 199.21 or any other provision of law, no physician and surgeon who has the results of a confirmed positive test to detect infection by the probable causative agent of acquired immune deficiency syndrome of a patient under his or her care shall be held criminally or civilly liable for disclosing to a person reasonably believed to be the spouse, or to a person reasonably believed to be a sexual partner or a person with whom the patient has shared the use of hypodermic needles, or to the county health officer, that the patient has tested positive on a test to detect infection by the probable causative agent of acquired immune deficiency syndrome, except that no physician and surgeon shall disclose any identifying information about the individual believed to be infected.

(b) No physician and surgeon shall disclose the information described in subdivision (a) unless he or she has first discussed the test results with the patient and has offered the patient appropriate educational and psychological counseling, which shall include information on the risks of transmitting the human immunodeficiency virus to other people and methods of avoiding those risks, and has attempted to obtain the patient's voluntary consent for notification of his or her contacts. The physician and surgeon shall notify the patient of his or her intent to notify the patient's contacts prior to any notification. When the information is disclosed to a person reasonably believed to be a spouse, or to a person reasonably believed to be a sexual partner, or a person with whom the patient has shared the use of hypodermic needles, the physician and surgeon shall refer that person for appropriate care, counseling, and followup. This section shall not apply to disclosures made other than for the purpose of diagnosis, care, and treatment of persons notified pursuant to this section, or for the purpose of interrupting the chain of transmission.

(c) This section is permissive on the part of the attending physician, and all requirements and other authorization for the disclosure of test results to detect infection by the probable causative agent of acquired immune deficiency syndrome are limited to the provisions contained in this chapter, Chapter 1.12 (commencing with Section 199.30) and Sections 1603.1 and 1603.3. No physician has a duty to notify any person of the fact that a patient is reasonably believed to be infected by the probable causative agent of acquired immune deficiency syndrome.

(d) The county health officer may alert any persons reasonably

believed to be a spouse, sexual partner, or partner of shared needles of an individual who has tested positive on a test to detect infection by the probable causative agent of acquired immune deficiency syndrome about their exposure, without disclosing any identifying information about the individual believed to be infected or the physician making the report, and shall refer any person to whom a disclosure is made pursuant to this subdivision for appropriate care and followup. Upon completion of the county health officer's efforts to contact any person pursuant to this subdivision, all records regarding that person maintained by the county health officer pursuant to this subdivision, including but not limited to any individual identifying information, shall be expunged by the county health officer.

(e) The county health officer shall keep confidential the identity and the seropositivity status of the individual tested and the identities of the persons contacted, as long as records of contacts are maintained.

(f) Except as provided in Section 1603.1 or 1603.3, no person shall be compelled in any state, county, city, or local civil, criminal, administrative, legislative, or other proceedings to identify or provide identifying characteristics which would identify any individual reported or person contacted pursuant to this section.

199.26. Inoperative

199.27. Consent; incompetent persons

(a)(1) When the subject of an HIV test is not competent to give consent for the test to be performed, written consent for the test may be obtained from the subject's parents, guardians, conservators, or other person lawfully authorized to make health care decisions for the subject. For purposes of this paragraph, a minor shall be deemed not competent to give consent if he or she is under 12 years of age.

(2) Notwithstanding paragraph (1), when the subject of the test is a minor adjudged to be a dependent child of the court pursuant to Section 360 of the Welfare and Institutions Code, written consent for the test to be performed may be obtained from the court pursuant to its authority under Section 362 or 1369 of the

Welfare and Institutions Code.

(b) Written consent shall only be obtained for the subject pursuant to subdivision (a) when necessary to render appropriate care or to practice preventative measures.

(c) The person authorized to consent to the test pursuant to subdivision (a) shall be permitted to do any of the following:

(1) Notwithstanding Sections 199.20 and 199.21, receive the results of the test on behalf of the subject without written authorization.

Disclose the test results on behalf of the subject in accordance with Sections 199.20 and 199.21.

(3) Provide written authorization for the disclosure of the test results on behalf of the subject in accordance with Sections 199.20 and 199.21.

199.28. Inoperative

199.285. Inoperative

199.29. Inoperative

## Chapter 1.12

### ACQUIRED IMMUNE DEFICIENCY SYNDROME RESEARCH CONFIDENTIALITY ACT

#### Section

199.30. Personally identifying research records not to be disclosed.

199.31. Permitted disclosure; written consent.

199.32. Financial audits or program evaluations; protection of records; use of information disclosed; reporting requirement to state or centers for disease control exempted from liability.



- 199.33. Permitted disclosure without prior written consent.
- 199.34. Disclosure to research subject, legal representative or personal representative.
- 199.35. Production or discovery of records for use in criminal or civil proceedings against subject prohibited; exception.
- 199.36. Consent of research subject participating in study.
- 199.37. Violations; penalties.
- 199.38. Employability or insurability of research subject; disclosed information not to be used.
- 199.39. Disclosure for research efforts not precluded.
- 199.40. Definitions.

199.30. Personally identifying research records not to be disclosed

Research records, in a personally identifying form, developed or acquired by any person in the course of conducting research or a research study relating to Acquired Immune Deficiency Syndrome (AIDS) shall be confidential, and these confidential research records shall not be disclosed by any person in possession of the research record, nor shall these confidential research records be discoverable, nor shall any person be compelled to produce any confidential research record, except as provided by this chapter.

199.31. Permitted disclosure; written consent

Confidential research records may be disclosed in accordance with the prior written consent of the research subject with respect to whom the research record is maintained, but only to the extent, under the circumstances, to the persons, and for the purposes the written consent authorizes. Any disclosure authorized by a research subject shall be accompanied by a written statement containing substantially the same language as follows:

"This information has been disclosed to you from a confidential research record the confidentiality of which is protected by state law and any further disclosure of it without specific prior

written consent of the person to whom it pertains is prohibited. Violation of these confidentiality guarantees may subject you to civil or criminal liabilities."

199.32. Financial audits or program evaluations; protection of records; use of information disclosed; reporting requirement to state or centers for disease control exempted from liability

(a) Confidential research records shall be protected in the course of conducting financial audits or program evaluations, and audit personnel shall not directly or indirectly identify any individual research subject in any report of a financial audit or program evaluation. To the extent it is necessary for audit personnel to know the identity of individual research subjects, authorized disclosure of confidential research records shall be made on a case-by-case basis, and every prudent effort shall be exercised to safeguard the confidentiality of these research records in accordance with this chapter.

Information disclosed for audit or evaluation purposes should be used only for audit and evaluation purposes and may not be redisclosed or used in any other way.

(b) Nothing in this section imposes liability or criminal sanction for disclosure of confidential research records in accordance with any reporting requirement for a diagnosed case of AIDS by the State Department of Health Services or the Centers for Disease Control under the United States Public Health Services.

199.33. Permitted disclosure without prior written consent

Notwithstanding Section 199.31, whether or not the research subject, with respect to whom any confidential research record is maintained, gives prior written consent, the content of the confidential research record may be disclosed in any of the following situations:

(a) To medical personnel to the extent it is necessary to meet a bona fide medical emergency of a research subject.

(b) To the state department to the extent necessary for the conduct of a special investigation pursuant to Section 211, in which case the confidentiality provisions of Chapter 1.13

(commencing with Section 199.42) shall apply.

199.34. Disclosure to research subject, legal representative or personal representative

The content of any confidential research record shall be disclosed to the research subject, the legal representative of the research subject if the research subject is a minor, or the personal representative of a deceased research subject to whom the record pertains, thirty (30) days after written request therefor by the research subject, the legal representative or the personal representative.

199.35. Production or discovery of records for use in criminal or civil proceedings against subject prohibited; exception

(a) No confidential research record may be compelled to be produced in any state, county, city or other proceeding in order to initiate or substantiate any criminal charge or charges against a research subject, or to conduct an investigation of a research subject, unless a court finds there is reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the criminal charge or charges or investigation, and there is no other practicable way of obtaining the information or evidence.

In addition, no confidential research record shall be disclosed, discoverable, or compelled to be produced in order to initiate or substantiate any criminal charge or charges against a research subject until after a showing of good cause. In assessing good cause, the court shall weigh the public interest and need for disclosure against the injury to the research subject and the harm to the research being undertaken. Upon the granting of an order to produce, the court, in determining the extent to which disclosure of all or any part of a confidential research record is necessary, shall impose appropriate safeguards against unauthorized disclosure, which shall include, but not necessarily be limited to, the individuals or bodies which may have access to the data, the purposes for which the data shall be used, prohibitions on further disclosure and protection of the identities of other research subjects.

(b) No confidential research record may be compelled to be produced in any state, county, city or other civil proceeding,

except as expressly provided in this chapter.

199.36. Consent of research subject participating in study

Prior to participation of an individual in a research study relating to AIDS, both of the following requirements shall be met:

(a) The informed consent of each research subject shall be obtained in the method and manner required by Section 46.116, (a) and (b), of Part 46 of Title 45 of the Code of Federal Regulations and be documented in accordance with Section 46.117 of that part.

(b) Each research subject shall be provided with an explanation in writing, in language understandable to the research subject, of the rights and responsibilities of researchers and research subjects under this chapter.

199.37. Violations; penalties

(a) Any person who willfully or maliciously discloses the content of any confidential research record, to any third party, except pursuant to this chapter, shall be assessed a civil penalty in an amount not less than one thousand dollars (~1,000) and not more than five thousand dollars (\$5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(b) Any person who maliciously discloses the content of any confidential research record, to a third party, except pursuant to this chapter, which results in economic, bodily, or psychological harm to the research subject, is guilty of a misdemeanor, punishable by imprisonment in the county jail for a period not to exceed one year or a fine of not to exceed ten thousand dollars (\$10,000) or both.

(c) Any person who commits any act described in subdivision (a) or (b) shall be liable to the subject for all actual damages for economic, bodily, or psychological harm which is a proximate result of the act.

(d) Any person who negligently or willfully violates Section 199.36 is guilty of an infraction punishable by a fine of twenty-

five dollars (\$25).

(e) Each violation of this chapter is a separate and actionable offense.

(f) Nothing in this section limits or expands the right of an injured research subject to recover damages under any other applicable law.

199.38. Employability or insurability of research subject; disclosed information not to be used

In the event that the participation of an individual in a research study is disclosed, the information shall not be used to determine the employability or insurability of the research subject.

199.39. Disclosure for research efforts not precluded

Nothing in this chapter shall preclude disclosure of information in order to further research efforts, including, but not limited to, the publication, dissemination, or sharing of raw data, statistics, or case studies, so long as no confidential research records concerning any research subject are disclosed.

199.40. Definitions

For purposes of this chapter:

(a) "AIDS" means Acquired Immune Deficiency Syndrome.

(b) "Disclosed" means to disclose, release, transfer, disseminate, or otherwise communicate all or any part of any confidential research record orally, in writing, or by electronic means to any person or entity, or to provide the means for obtaining the records.

(c) "Confidential research record or records" means any data in a personally identifying form, including name, social security number, address, employer, or other information that could, directly or indirectly, in part or in sum, lead to the identification of the individual research subject, developed or acquired by any person in the course of conducting research or a

research study relating to AIDS.

### Chapter 1.13

#### ACQUIRED IMMUNE DEFICIENCY SYNDROME PUBLIC HEALTH RECORDS CONFIDENTIALITY ACT

##### Section

199.42. Personally identifying information confidentiality; disclosure; discovery; compelled production; civil penalty; employment or insurance use.

199.43. Subordination to Chapters 1.11 and 1.12 and supersedure of 211.5 by this Chapter.

199.44. Definitions.

199.42. Personally identifying information confidentiality; disclosure; discovery; compelled production; civil penalty; employment or insurance use

(a) Public health records relating to acquired immune deficiency syndrome (AIDS), containing personally identifying information, which were developed or acquired by state or local public health agencies shall be confidential and shall not be disclosed, except as otherwise provided by law for public health purposes or pursuant to a written authorization by the person who is the subject of the record or by his or her guardian or conservator.

(b) State or local public health agencies may disclose personally identifying information in public health records, as described in subdivision (a), to other local, state, or federal public health agencies or to corroborating medical researchers, when the confidential information is necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the state or local public health agency.

(c) Any disclosure authorized by subdivision (a) or (b) shall include only -the information necessary for the purpose of that disclosure and shall be made only upon agreement that the information will be kept confidential and will not be further disclosed without written authorization, as described in subdivision (a).

(d) No confidential public health record, as described in subdivision (a), shall be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

(e) Any person who willfully or maliciously discloses the content of any confidential public health record, as described in subdivision (a), to any third party, except pursuant to a written authorization, as described in subdivision (a), or as otherwise authorized by law, shall be subject to a civil penalty in an amount not less than one thousand dollars (\$1,000) and not more than five thousand dollars (\$5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the person whose record was disclosed.

(f) In the event that a public health record, as described in subdivision (a), is disclosed, the information shall not be used to determine employability, or insurability of any person.

199.43. Subordination to Chapters 1.11 and 1.12 and supersedure of 211.5 by this chapter

(a) To the extent Chapter 1.11 (commencing with Section 199.20) and Chapter 1.12 (commencing with Section 199.30) apply to records or information which would be covered by this chapter, Chapters 1.11 and 1.12 shall supersede this chapter.

(b) This chapter supersedes Section 211.5 to the extent it applies to records or information covered by Section 211 or 211.5.

199.44. Definitions

For purposes of this chapter:

(a) "Disclosed" or "disclosure or 'discloses" has the same meaning as set forth in subdivision (b) of Section 199.40.

(b) "State or local public health agencies" are the State Department of Health Services, and any local entity that a health officer, as defined in Section 3000, serves.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS): IMMUNIZATION

Section

- 199.45. Legislative findings and declarations.
- 199.46. Further findings and declarations.
- 199.47. Additional findings and declarations; legislative intent.
- 199.48. "State" defined.
- 199.49. Repealed.
- 199.50. AIDS vaccine victims compensation fund; payment from fund of damages for personal injuries caused by AIDS vaccine; procedure; rules and regulations; subrogation; AIDS vaccine injury compensation policy review task force; funding.
- 199.51. Guarantee by State of California to purchase 500,000 units of vaccine; AIDS vaccine guaranteed purchase fund; state department of health services administer this section.
- 199.52. AIDS/HIV vaccine; clinical trial procedures; prohibited withholding of insurance coverage or settlement; confidential enrollee certificate; release authorization.

199.45. Legislative findings and declarations

The Legislature finds and declares all of the following:

(a) The rapidly spreading AIDS epidemic poses an unprecedented major public health crisis in California, and threatens, in one way or another, the life and health of every Californian.

(b) The best hope of stemming the spread of the AIDS virus among the general public is the development of an AIDS vaccine to develop an immunity to exposure.

(c) No vaccine has yet been fully developed, tested, or approved for AIDS. An effective vaccine, especially when directed at high-risk groups of unexposed persons, will virtually eliminate the risk of contracting AIDS, just as the risk of contracting polio and smallpox have been virtually eliminated by earlier vaccine development, production, and use among the general public.



(d) Private industry today has the capability of conducting the vaccine research, biological research, immunology, and genetic engineering of appropriate viral components needed to formulate, develop, produce, and test an AIDS vaccine. Whenever these and other appropriate expertise cannot be found within a single company, the formation of multiinstitutional research groups should be encouraged and prioritized, as it is in the public interest to encourage efforts toward vaccine production.

(e) It is of the highest importance and in the public interest to maximize public protection by developing an AIDS vaccine and by establishing high levels of immunization, initially among high-risk populations.

(f) The continuous spread of AIDS and especially the threat of infection spreading among population groups previously considered low-risk demands that the highest of priorities be given to the development of a universal immunoprophylaxis.

(g) The use of vaccines to control the spread of infectious pathogens is recognized as one of the genuinely decisive technologies of modern medicine. Recent advances in pharmaceutical technology combined with better understanding of the immune process offer the hope of an AIDS vaccine that is effective, safe, relatively inexpensive, and relatively easy to administer.

(h) Utilization of this new science may be forestalled, however, by problems that have recently deterred the development of vaccines by traditional means. These problems must be resolved before the full public health benefits of new approaches to vaccine development can be fully and expeditiously realized.

(i) The marketplace conditions facing vaccine manufacturers and developers today have changed considerably over the past 30 years. Private manufacturers and developers of vaccines cannot be forced to produce vaccines, and may choose, under the free enterprise system, not to produce them if marketplace conditions are unfavorable.

(j) Certain market conditions are slowing and threatening to halt the development of an AIDS vaccine. Any delay in the discovery, testing, approval, and production of the vaccine because of these secondary considerations may cost tens of thousands of human lives annually, unnecessary pain and suffering for hundreds of thousands of infected Americans, and billions of dollars in medical costs and in lost productivity.

(k) Resource constraints in the public and private sectors and the time required to bring vaccines to market presently limit investments in vaccines research and development. Although universities constitute a significant resource in AIDS research in particular and vaccines research in general, university funding limitations and conflicting research priorities make reliance on the resources and expertise of the private pharmaceutical industry a necessary supplement to public funding of AIDS research.

(l) There has been a decrease in the willingness of pharmaceutical companies to become involved in vaccine research, development, and manufacturing because of uncertain profitability and perceived and actual marketplace risks and disincentives.

(m) It is clearly in the public interest to provide appropriate and necessary incentives toward the timely development and production of an effective and safe AIDS vaccine.

(n) The development of an AIDS vaccine provides an exceptionally important benefit, making its availability highly desirable. However, certain conditions may preclude that development, including the following:

(1) There is a high cost for capital expenditures for vaccine development (estimated to be from ten million dollars (\$10,000,000) to thirty million dollars (\$30,000,000)). Testing costs of clinical trials (twenty million dollars (\$20,000,000) per vaccine, by some estimates) are particularly burdensome, especially for smaller firms.

(2) There is an uncertain market demand for a vaccine once development costs have been invested and FDA marketing approval has been secured.

(o) Without state intervention to assure minimal profitability of an AIDS vaccine, inadequate incentives may exist for the private sector to commit resources and expertise to the accelerated development of an AIDS vaccine.

(p) In light of the dangers inherent in the AIDS epidemic to the general public of California, it is crucial that to the extent possible any serious obstacles to the development of such a vaccine be removed.

(q) Because an AIDS vaccine provides an exceptionally important public benefit, it is in the public interest to take uncommon action to facilitate the development and production of such a

vaccine.

(r) It is as well in the public interest to assure fair compensation, if necessary at public expense, to any innocent victim who may be injured by an AIDS vaccine, as a part of implementing the socially beneficial policy of establishing high levels of AIDS immunization.

(s) In light of the high incidence of AIDS amongst Californians, the California Legislature must lead our country into the 20th century in this effort.

(t) It is therefore fitting and proper that the State of California enact uncommon and exceptional legislation in order to prevent the further spread of the AIDS epidemic.

#### 199.46. Further findings and declarations

The Legislature further finds and declares all of the following:

(a) Acquired immune deficiency syndrome (AIDS) is caused by the virus human T-cell lymphotropic virus, type III (HTLV-3) which initially cripples the body's immune system and eventually leaves the body open to an array of lethal opportunistic infections.

(b) So far, there is no known cure for AIDS and once a person is AIDS infected, the virus remains throughout the rest of his or her life.

(c) The AIDS virus has a three-to-seven year incubation period, making it one of the most difficult diseases to combat and trace.

(d) An easily administered blood test can determine whether a person has been exposed to the AIDS virus.

(e) In 1979, when AIDS was first diagnosed in the United States, the number of newly diagnosed victims was doubling every six to nine months; today the number of people diagnosed with AIDS doubles each year.

(f) Nationally, between 500,000 and 2,000,000 Americans are estimated to have been exposed to the AIDS virus. Of those exposed, between 25,000 and 500,000 persons (5 percent-25 percent) may be expected to die of AIDS.

(1) Another 25,000 to 500,000 persons may be expected to develop AIDS Related Complex (ARC). The range of illnesses these

individuals will suffer from may range from minor ailments to brain damage.

(2) The remaining majority of those exposed may never suffer its consequences, but may carry and transmit the disease unknowingly.

(3) Some experts estimate as many as 1,000 additional people are exposed daily.

(g) The State Department of Health Services, in its report to the Legislature (March 1986) estimated conservatively that over 30,000 Californians shall have contracted AIDS by 1990, about 50 percent having succumbed. The disease is believed to be fatal within 18 months of diagnosis. To date, more than half the 16,000 people with AIDS in the United States have died.

(h) The AIDS virus is transmitted primarily through sexual contact, and also through the sharing of hypodermic needles, contaminated blood transfusions, and during pregnancy to the fetus.

(i) While the earliest spread of the AIDS virus was primarily among homosexuals, the virus is now found and spreading among heterosexuals as well.

(j) Additionally, drug abusers are highly susceptible to the AIDS virus since the drugs diminish the ability of the body's immune system to function. Intravenous drug abusers traditionally come into contact with the virus from sharing hypodermic needles.

(k) Persons sexually active in the heterosexual community are also at risk. Until a vaccine is developed, the AIDS virus will cross over from the high-risk groups to the lower risk groups. At this time, it is not known how fast the AIDS virus will penetrate other population groups, but it is not expected to be nearly as rapid. To date, partners of high-risk groups (bisexual men and intravenous drug users) are considered the main means of transmitting the AIDS virus to the heterosexual population. Other means include pregnant women who pass the infection on to the child and prostitutes who pass on the infection to their clients.

(1) Of the first 9,000 AIDS cases diagnosed in the United States, almost 1,000 were women. Fourteen percent of these women developed AIDS through sexual contact. Recent studies have demonstrated that the virus can be transmitted by women to their male sexual partners. Sexual contact with an infected partner may transmit the virus and fatally infect the partner.

199.47. Additional findings and declarations: legislative intent

The Legislature further finds and declares all of the following:

(a) The average cost per patient in the treatment of AIDS until death is now one hundred fifty thousand dollars (\$150,000). It is estimated that total costs including health care of the first 10,000 AIDS cases in the United States totaled more than six billion three hundred million dollars (\$6,300,000,000). By 1990, according to the state department, Californians will spend almost five billion dollars (\$5,000,000,000) in medical costs alone in care and treatment of 30,000 AIDS patients, with no realistic hope for their remission or cure. This cost does not include money spent on education, research, and lost income.

(b) To date, the costs of caring for people with AIDS related complex (ARC) has not been officially calculated. However, it is safe to assume the costs are substantial over time. Experts fear that the illnesses of ARC patients, although they may not be fatal, are severe. For example, the virus invades the brain rendering the patients incapable of caring for themselves. It is, therefore, plausible that a percentage of ARC patients will need to be institutionalized.

(c) The Legislature intends by this chapter to take uncommon action to remove the impediments to the expeditious development of an AIDS vaccine.

(d) It is further the intent of the Legislature to provide to any person, whose injury is proximately caused by the use of the vaccine, except to the extent the injuries are attributable to the comparative negligence of the claimant in the use of the vaccine, all of the following:

(1) Compensation for related medical costs associated with the care and treatment of the injury.

(2) Compensation for the loss of any and all earnings caused by the injury.

(3) Compensation for pain and suffering caused by the injury, except that in no action shall the amount of damages for noneconomic losses exceed five hundred fifty thousand dollars (\$550,000).

(e) It is further the intent of the Legislature to establish the

AIDS Clinical Trials Testing Fund which will be available to not more than three California manufacturers of an AIDS vaccine approved by the federal Food and Drug Administration (FDA) or the state department pursuant to Division 21 (commencing with Section 26000) for clinical trials with humans.

(f) The AIDS Vaccine Research and Development Advisory Committee established pursuant to Section 199.57, shall review requests from California manufacturers for funds from the AIDS Clinical Trials Testing Fund and shall make recommendations to the state department regarding the award of funds. including the appropriate amount of funding. The state department, taking into consideration the committee's recommendations, may allocate the funds to the manufacturers specified in the protocol approved by the FDA or the state department pursuant to Division 21 (commencing with Section 26000) for administering the clinical trials.

(g) A California manufacturer seeking the approval of the FDA, rather than the state department, for administering clinical trials of an AIDS vaccine may apply while FDA approval is pending to the AIDS Vaccine Research and Development Advisory Committee for the committee's recommendation that the manufacturer receive funds from the AIDS Clinical Trials Testing Fund upon FDA approval.

199.48. "State" defined

"State," as used in this chapter, has the same meaning as set forth in Section 900.6 of the Government Code.

199.49. Repealed

199.50. AIDS vaccine victims compensation fund; payment from fund of damages for personal Injuries caused by AIDS vaccine; procedure; rules and regulations; subrogation; AIDS vaccine injury' compensation policy review task force; funding

(a) There is hereby created the AIDS Vaccine Victims

Compensation Fund.

(b) For the purposes of this section:

(1) "AIDS vaccine means a vaccine which (A) has been developed by any manufacturer and (B) is approved by the FDA or the state department pursuant to Division 21 (commencing with Section 26000) as a safe and efficacious vaccine for the purpose of immunizing against AID.

(2) "Board" means the State Board of Control.

(3) "Damages for personal injuries," means the direct medical costs for the care and treatment of injuries to any person, including a person entitled to recover damages under Section 877 of the Code of Civil Procedure, proximately caused by an AIDS vaccine, the loss of earnings caused by the injuries, and the amount necessary, but not to exceed five hundred fifty thousand dollars (\$550,000), to compensate for noneconomic losses, including pain and suffering caused by the injuries.

(4) "Fund" means the AIDS Vaccine Victims Compensation Fund.

(c) The board shall pay from the fund, contingent entirely upon the availability of moneys as provided in subdivision (o), damages for personal injuries caused by an AIDS vaccine that is sold in or delivered in California, and administered or dispersed in California to the injured person except that no payment shall be made for any of the following:

(1) Damages for personal injuries caused by the vaccine to the extent that they are attributable to the comparative negligence of the person making the claim.

(2) Damages for personal injuries in any instance in which the manufacturer has been found to be liable for such injuries in a court of law.

(3) Damages for personal injuries due to a vaccination administered during a clinical trial.

(d) An application for payment of damages for personal injuries shall be made on a form prescribed by the board, which application may be required to be verified, within one year of the date that the injury and its cause are discovered. Upon receipt, the board may require the submission of additional information necessary to evaluate the claim.

(e) (1) Within 45 days of the receipt of the application and the submission of any additional information, the board shall do either of the following:

(A) Allow the claim in whole or part.

(B) Disallow the claim.

(2) In those instances of unusual hardship to the victim, the board may grant an emergency award to the injured person to cover immediate needs upon agreement by the injured person to repay in the event of a final determination denying the claim.

(3) If the claim is denied in whole or part, the victim may apply within 60 days of denial for a hearing. The hearing shall be held within 60 days of the request for a hearing unless the injured person requests a later hearing.

(f) At the hearing the injured person may be represented by counsel and may present relevant evidence as defined in subdivision (c) of Section 11513 of the Government Code. The board may consider additional evidence presented by its staff. If the injured person declines to appear at the hearing, the board may act solely upon the application, the staff report, and other evidence that appears on the record.

(g) The board may delegate the hearing of applications to hearing examiners.

(h) The decision of the board shall be in writing and shall be delivered or mailed to the injured person within 30 days of the hearing. Upon the request by the applicant within 30 days of delivery or mailing, the board may reconsider its decision.

(i) Judicial review of a decision shall be under Section 1094.5 of the Code of Civil Procedure, and the court shall exercise its independent judgment. A petition for review shall be filed as follows:

(1) If no request for reconsideration is made, within 30 days of personal delivery or mailing of the board's decision on the application.

(2) If a timely request for reconsideration is filed and rejected by the board, within 30 days of personal delivery or mailing of the notice of rejection.

(3) If a timely request for reconsideration is filed and granted



by the board, or reconsideration is ordered by the board, within 30 days of personal delivery or mailing of the final decision on the reconsidered application.

(j) The board shall adopt rules and regulations to implement this section, including those governing discovery.

(k) The fund is subrogated to any right or claim that any injured person may have who receives compensation pursuant to this section, or any right or claim that such person's personal representative, legal guardian, estate, or survivor may have, against any third party who is liable for the personal injuries caused by the AIDS vaccine, and the fund shall be entitled to indemnity from that third party. The fund shall also be entitled to a lien on the judgment, award, or settlement in the amount of any payments made to the injured person.

(l) In the event that the injured person, or his or her guardian, personal representative, estate, or survivors, or any of them, bring an action for damages against the person or persons liable for the injury or death giving rise to an award by the board under this section, notice of institution of legal proceedings and notice of any settlement shall be given to the board in Sacramento except in cases where the board specifies that notice shall be given to the Attorney General. All notices shall be given by the attorney employed to bring the action for damages or by the injured person, or his or her guardian, personal representative, estate, or survivors, if no attorney is employed.

(m) This section is not intended to affect the right of any individual to pursue claims against the fund and lawsuits against manufacturers concurrently, except that the fund shall be entitled to a lien on the judgment, award, or settlement in the amount of any payments made to the injured party by the fund.

(n) There is hereby created the AIDS Vaccine Injury Compensation Policy Review Task Force consisting of 14 members. The task force shall be composed of 10 members appointed by the Governor, of which two shall be from a list provided by the California Trial Lawyers Association, one from the state department, the Director of Finance, one unspecified member, and one attorney with experience and expertise in products liability and negligence defense work, two representing recognized groups which represent victims of vaccine induced injuries or AIDS victims, or both, and two representing manufacturers actively engaged in

developing an AIDS vaccine. In addition four Members of the Legislature or their designees shall be appointed to the task force, two of which shall be appointed by the Speaker of the Assembly and two of which shall be appointed by the Senate Rules Committee. The chairperson of the task force shall be appointed by the Governor from the membership of the task force. The task force shall study and make recommendations on the legislative implementation of the fund created by subdivision (a). These recommendations shall at least address the following issues:

- (1) The process by which victims are to be compensated through the fund.
- (2) The procedures by which the fund will operate and the governance of the fund.
- (3) The method by which manufacturers are to pay into the fund and the amount of that payment
- (4) The procedural relationship between a potential victim's claim through the fund and a court claim made against the manufacturer.
- (5) Other issues deemed appropriate by the task force.

The task force shall make its recommendations to the legislature on or before June 30, 1987.

(o) The fund shall be funded wholly by a surcharge on the sale of an AIDS vaccine which has been approved by the FDA, or by the state department pursuant to Division 21 (commencing with Section 26000 in an amount to be determined by the state department. The surcharge shall be levied on the sale of each unit of the vaccine sold or delivered, administered, or dispensed in California. The appropriate amount of the surcharge shall be studied by the AIDS Vaccine Injury Compensation Policy Review Task Force which shall recommend the appropriate amount as part of its report, with the amount of the surcharge not to exceed ten dollars (\$10) per unit of vaccine. Expenditures of the task force shall be made at the discretion of the Director of Finance or the director's designee.

(p) For purposes of this section, claims against the fund are contingent upon the existing resources of the fund as provided in subdivision (o), and in no case shall the state be liable for any claims in excess of the resources in the fund.

199.51. Guarantee by State of California to purchase 500,000 units of vaccine; AIDS vaccine guaranteed purchase fund; state department of health services administer this section

(a) Because the development of a vaccine now costs somewhere between twenty million dollars (\$20,000,000) and forty million dollars (\$40,000,000), and because the last vaccine produced and marketed did not sell well, vaccine manufacturers are hesitant to proceed to invest their resources in such a risky venture. It is, therefore, in the public health interest of California to assure that manufacturers proceed to develop this vaccine and protect Californians against this dread disease and protect the State of California against the enormous fiscal costs of treatment for persons getting AIDS. It is a sound and worthwhile investment to provide a guarantee of a market to lessen the risk of loss and assure the development of an AIDS vaccine.

It is anticipated that this AIDS vaccine will consist of a three-unit series. The State of California is willing to guarantee that at least 175,000 persons will be vaccinated, and to guarantee the purchase, within three years after the FDA or the state department pursuant to Division 21 (commencing with Section 26000) approves marketing of an AIDS vaccine, of at least 500,000 units, at a cost of no more than twenty dollars (\$20) per dosage, by all companies, anywhere in the United States.

Therefore, the State of California, by moneys to be appropriated later through the Budget Act, commits itself to purchasing, at the end of three years after the FDA or the state department pursuant to Division 21 (commencing with Section 26000) has approve the marketing on a competitive basis, at not more than twenty dollars (\$20) per dosage, the difference between 500,000 units and the actual amount sold, delivered, administered, or dispensed by all companies throughout the United States, including units sold to or reimbursed by Medi-Cal, Medicare, or other public programs, providing that less than 500,000 units are sold, delivered, administered, or dispensed.

(b) The AIDS Vaccine Guaranteed Purchase Fund is hereby established and shall be administered by the State Department of Health Services, which may develop necessary regulations to carry out the purpose of this section.

(c) The State Department of Health Services may carry out this section, when such funds are appropriated through the State Budget In determining which vaccine shall be purchased by the state from among those manufacturers selling or distributing in California, an AIDS vaccine approved by the FDA or the state

department pursuant to Division 21 (commencing with Section 26000), the state department shall take into consideration at least all of the following factors:

(1) The length of time each AIDS vaccine has been in the marketplace in California.

(2) Each AIDS vaccine's history of efficacy since approval by the FDA or the state department

(3) Each AIDS vaccine's history of side effects experienced by previous recipients of the vaccine.

(4) The relative cost of each competing manufacturer's AIDS vaccine.

199.52. AIDS-HIV vaccine; clinical trial participants; prohibited withholding of insurance coverage or settlement; confidential enrollee certificate; release authorization

(a) In enacting this section the Legislature finds and declares:

(1) It is in the interest of the people of California to develop a vaccine which will prevent the infection of HIV, the agent which causes AIDS.

(2) In order to develop that vaccine, a prototype vaccine must be first given to HIV-negative people to determine the following:

(A) The vaccine's toxicity.

(B) The vaccine's efficacy.

(C) The human immune response to the vaccine.

(3) These studies are currently impossible because vaccine manufacturers fear that by inoculating HIV-negative individuals with an experimental vaccine, they will elicit a positive immune response as measured by an enzyme linked immunosorbent assay (ELISA), western blot or other federal Food and Drug Administration approved in vitro diagnostic test, thereby placing vaccine volunteers at risk for denial of health or life insurance by insurance carriers as a consequence of their participation.

(4) Insurers need a reliable mechanism by which they can verify the insurability of a vaccine trial participant

(b) No health care service plan, disability insurer, nonprofit hospital service plan, self-insured employee welfare benefit plan, or life insurer may withhold any settlement or coverage of an individual solely because of his or her participation in an AIDS/HIV vaccine clinical trial studied under an investigational new drug application effective pursuant to Section 312 of Title 21 of the Code of Federal Regulations, or Section 26679.

(c) The sponsor of any such trial shall make a confidential certificate with all the necessary particulars, which shall be determined by the State Department of Health Services, for each enroll and then submit it to the State Department of Health Services, which shall endorse it and return it the vaccine recipient. A copy of this confidential certificate shall be kept on file indefinitely by both the study sponsor and the State Department of Health Services.

(d) Release of a confidential certificate shall be by written authorization of the enrollee named the certificate. If the enrollee is unable to provide the written authorization, a person designated the certificate by the enrollee may provide the written authorization. The written authorization shall include the name of the person or entity to whom the disclosure would be made.

Disclosure as used in this section means to release, transfer, disseminate or otherwise communicate all or part of any confidential certificate orally, in writing, or by electronic means to any person or entity.