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# Health and Welfare

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# Health and Welfare

## Health and Welfare; biomedical and behavioral research on prisoners

Business and Professions Code §1241 (amended); Government Code §844.6 (amended); Penal Code Title 2.1 (commencing with §3500 (new)).

AB 1592 (Alatore); STATS 1977, Ch 1250

Support: California Peace Officers' Association

Opposition: California Department of Health

Currently, California is one of only seven states in the country that permit prisoners to participate in biomedical research, although such research has been limited to the California Correctional Facility at Vacaville [*Hearings on the Status of Biomedical Experimentation in California's State Prisons Before the California Assembly Select Comm. on Corrections*, Jan. 28, 1977, at vii (Committee Findings), 3 (testimony of Earl Muff, Assistant Legislative Officer, Department of Corrections)]. Prior to the enactment of Chapter 1250, criticisms of the biomedical research program at Vacaville reportedly included: minimal outside control over the research programs; greater remuneration received by *nonprison* subjects than by participating prisoner subjects for the same type of experimentation; failure to fully inform prisoners of their right to maintain malpractice actions for negligent acts of the researchers; failure to always obtain prisoners' informed consent for participation in research projects; and allegations of use of prisoners in Central Intelligence Agency drug and counter-drug experimentation [*Id.* at vi-ix (Committee Findings)]. Furthermore, there were reported behavioral treatment and research program abuses involving aversion therapy, utilizing such drugs as "succinylcholine," which produces respiratory arrest similar to drowning [*Id.* at 152-55 (Assessment of an Aversive "Contract" Program, appendix to written testimony of Paul Lambert, Public Affairs Director, Marin Broadcasting Co., Inc.)].

Chapter 1250 establishes comprehensive controls on the practice of using prisoners in biomedical and behavioral research. Generally, the new law bans the use of "Phase I," or new drugs, as defined by federal regulations, unless they have been previously tested on other human beings [CAL. PENAL CODE §3506. *See generally* CAL. PENAL CODE §3500(g); 21 C.F.R. §312.1 (1977)] and restricts the use of "psychotropic," or mind altering drugs to carefully controlled medical treatment or, if used in a research test, only to cases in which there is no serious risk to the prisoner's mental or physical well-being [CAL. PENAL CODE §3507. *See generally* CAL. PENAL CODE

§3500(d)]. Furthermore, Chapter 1250 limits behavioral research to specified studies of incarceration that present no more than minimal risk and mere inconvenience to the research subject [CAL. PENAL CODE §3505. *See generally* CAL. PENAL CODE §3500(a)]. Moreover, the use of behavioral modification is restricted to those techniques that are both medically and socially acceptable and which do not inflict permanent physical or psychological injury on the research subject [CAL. PENAL CODE §3508]. The new law also bans the use of *any* operative procedure requiring an incision unless the procedure is clearly necessary for therapeutic purposes [CAL. PENAL CODE §3509].

Chapter 1250 further requires any physical or mental injury resulting from participation in biomedical or behavioral research, regardless of cause, to be promptly and continually treated until the injury is cured [CAL. PENAL CODE §3504]. Moreover, any institution carrying on such research is required to have "good quality medical facilities" approved by an outside accrediting agency [CAL. PENAL CODE §3503], and after July 1, 1979, clinical laboratories used for such research are subject to the licensing requirements of Business and Professions Code Sections 1200 through 1322 [CAL. BUS. & PROF. CODE §1241]. If, however, any clinical laboratory to be used for research does not meet these licensing requirements and is necessary or incident to the proposed research, an alternative laboratory may be used [CAL. PENAL CODE §3503.1].

Chapter 1250 specifically delineates the rights and remedies of prisoners subject to biomedical and behavioral research. Before a prisoner may be a subject of any such research project, his or her informed consent to such participation must be supplied [CAL. PENAL CODE §3502]. The informed consent requirement of Chapter 1250 is not satisfied unless the following conditions are met: (1) the prisoner's consent was given without fraud, duress, coercion, or undue influence [CAL. PENAL CODE §3521(a)]; and (2) the prisoner was informed *in writing* of the potential risks and/or benefits of the proposed research, the amount of remuneration to be received for his or her participation, and the manner in which he or she can obtain medical treatment for research related injuries [CAL. PENAL CODE §§3521(b), 3522]. The prisoner must also be informed, *both orally, in writing, and in a language in which he or she is fluent*: (1) of the nature of the experiment, the procedures to be used, *all* known risks, and the expected time of recovery; (2) that he or she is free to ask any questions about the research; and (3) that he or she is free to withdraw consent at any point during the research without prejudice [CAL. PENAL CODE §3521(c)]. Chapter 1250, however, does not require the informed consent of a prisoner who is the subject of behavioral research if the Institutional Review Board determines that such consent is either unnecessary or would significantly inhibit the

research project [CAL. PENAL CODE §3505]. Although there appear to be no guidelines for determining when informed consent is “unnecessary,” it is apparently limited to those situations in which the researcher is merely collecting objective data [*Compare* CAL. PENAL CODE §3505 with CAL. PENAL CODE §3500(a)]. Chapter 1250 further requires that the remuneration paid to prison research subjects must be *comparable* to that paid to non-prisoner subjects of similar research [CAL. PENAL CODE §3523].

Under the new law, prisoners may maintain an action in tort for wrongful or negligent acts against the responsible party or *public entity* and damages may be awarded as “may be just” under the particular facts of the case, *i.e.* an amount that would compensate the prisoner, or his or her heirs, for all “detriment proximately caused” [CAL. GOV’T CODE §844.6; CAL. PENAL CODE §3524(a); *see* CAL. CIV. CODE §3333]. Chapter 1250 also provides that under such circumstances an action for wrongful death may be brought by a prisoner’s heirs, personal representative, or if dependent upon the decedent, his or her parents, stepchildren, putative spouse, and children of the putative spouse [CAL. PENAL CODE §3524(c), (e). *See generally* CAL. PROB. CODE §§200-258]. A “putative spouse” is the spouse of the decedent by a void or voidable marriage, but who the court finds to have had a good faith belief in the validity of the marriage [CAL. PENAL CODE §3524(e)(2)].

Chapter 1250 establishes the Institutional Review Board to administer the provisions of this new law [CAL. PENAL CODE §3510]. The seven member Board, which is to be a cultural and racial cross section of California, is to be composed in the following manner: (1) three members are to be licensed physicians and surgeons, one of which shall be a psychiatrist; (2) one member must hold a doctorate degree in either pharmacy or pharmacology; (3) one member is to be an inmate representative; and (4) two members must hold doctorate degrees in the social sciences [CAL. PENAL CODE §3511]. The inmate representative is to be appointed by the Inmate Advisory Councils at the institutions conducting the research [CAL. PENAL CODE §3512]. Moreover, the remaining members of the Board are to be appointed by the Governor for specified terms, or, if the Governor fails to act within 60 days, the appointments shall be made by the Speaker of the Assembly [CAL. PENAL CODE §3512].

It is the duty of the Board to ensure compliance with the provisions of Chapter 1250, to promulgate certain regulations for the effective administration of the law, and to establish specified procedures for prisoner grievances [*See* CAL. PENAL CODE §§3515, 3517, 3518]. More importantly, before any research project is commenced, the Board must first determine that the sum of the benefits to the prisoner and the importance of the knowledge to be obtained outweigh the risks to the prisoner consenting to the research [CAL.

PENAL CODE §3515(a)]. Generally, it is also the duty of the Board to protect the rights and welfare of the prisoners involved in research projects sanctioned by the Board, and to ensure that the selection procedures for participation in the project are fair and equitable [CAL. PENAL CODE §3515(b), (c)]. Finally, the Board is required to evaluate the impact of biomedical and behavioral research on human subjects, including any adverse effects [CAL. PENAL CODE §3519] and to make biannual public reports to the legislature, reviewing each research program that has been approved and conducted [CAL. PENAL CODE §3520]. In summary, Chapter 1250 establishes comprehensive statutory controls on biomedical and behavioral research in California prisons that allow the prisoner to participate in such research if his or her informed consent has been given.

### **Health and Welfare; developmental disabilities**

Health and Safety Code §§38009.1, 38009.2 (repealed); Welfare and Institutions Code §§6513, 6514, 6515, 6516, 6517, 6518, 6519 (new).  
AB 175 (Lanterman); STATS 1977, Ch 984  
(*Effective September 23, 1977*)

The legislature in 1976 revised the Lanterman Developmental Disabilities Services Act to establish certain protective procedures for the discharge of any developmentally disabled person residing in a state hospital who has not been judicially committed [CAL. STATS. 1976, c. 1364, §2, at —]. This 1976 revision also redefined “developmental disability” as one that originates before an individual is 18 years of age, continues, or can be expected to continue indefinitely, and constitutes a severe handicap to such person, such as mental retardation, cerebral palsy, epilepsy, or autism [CAL. HEALTH & SAFETY CODE §38010(a)]. Chapter 984 now expands the procedural safeguards provided by this Act in an attempt to ensure that the constitutional rights of specified developmentally disabled persons are protected.

Under prior law, Section 38009.1 of the Health and Safety Code authorized the discharge of voluntary or nonprotesting developmentally disabled residents of a state hospital upon the request of the resident or his or her representative [CAL. STATS. 1976, c. 1364, §2, at —]. Nonetheless, an assessment of the resident’s condition by a regional center in accordance with the state hospital’s discharge procedure could be required if, in the opinion of the chief director of the state hospital, release might result in serious personal harm to the resident [CAL. STATS. 1976, c. 1364, §2, at —]. If such an assessment were required, the patient would be detained for a period not to exceed 14 days while a determination was made as to his or her condition [CAL. STATS. 1976, c. 1364, §2, at —]. If the patient were found to require continued state hospital care, the regional center could file a

petition seeking judicial commitment to the appropriate State Department of Health facility [CAL. STATS. 1976, c. 1364, §2, at —].

Chapter 984 retains these procedures although they are now located in the Welfare and Institutions Code rather than the Health and Safety Code [See CAL. WELF. & INST. CODE §6513]. The regional center, however, is now directed to request the district attorney, unless the board of supervisors delegates the duty to the county counsel pursuant to Welfare and Institutions Code Section 6519, to file a petition for the commitment of an individual when the center believes voluntary placement is inappropriate and the person is in continued need of state hospital care [CAL. WELF. & INST. CODE §6513]. Such a request to the district attorney or county counsel may also be made by the parent, guardian, conservator, or any person designated for that purpose by the judge of the court [CAL. WELF. & INST. CODE §6513]. The patient has a right to judicial review of a petition for commitment filed pursuant to Section 6513 of the Welfare and Institutions Code and must be informed of his or her right to counsel by the state hospital and the court [CAL. WELF. & INST. CODE §6514. See generally CAL. HEALTH & SAFETY CODE §§38450, 38451]. The court must appoint a public defender or other attorney for the proceedings if the patient does not have an attorney [CAL. WELF. & INST. CODE §6514]. Prior to the enactment of Chapter 984, however, the only notice to be received by a patient of these constitutional rights was from the court and the staff of the state hospital [CAL. STATS. 1976, c. 1364, §2, at —]. Chapter 984 expands these notification requirements by establishing a detailed procedure for informing a patient of the regional center's assessment and of the patient's right to judicial review and counsel [See CAL. WELF. & INST. CODE §§6515, 6516, 6517, 6518]. Furthermore, Chapter 984 outlines a form to verify such notification, which must be signed by the directors of the state hospital and the directors of the program unit in which the patient resides [CAL. WELF. & INST. CODE §§6515, 6516]. Copies of this form are to be delivered personally to the resident undergoing assessment and also sent to other affected parties [CAL. WELF. & INST. CODE §6518]. The party delivering such notification to the resident is also required to inform the patient of his or her rights to judicial review and right to counsel [CAL. WELF. & INST. CODE §6517]. Thus, Chapter 984 apparently ensures that developmentally disabled persons who reside in state hospitals and their immediate family or guardian(s) will be informed of the patient's rights to judicial review and counsel in the event that additional assessment should be required or should such an assessment indicate that further confinement is required to protect the patient from serious personal harm [CAL. WELF. & INST. CODE §§6513-6519].

The procedures retained by Chapter 984, which were formerly contained in Sections 38009.1 and 38009.2 of the Health and Safety Code as well as

those that are newly established by Chapter 984 will become inoperative as of January 1, 1979 [CAL. WELF. & INST. CODE §6519]. Thus, these provisions of the Lanterman Developmental Disabilities Services Act would appear to be interim measures designed to protect the rights of the developmentally disabled, while the legislature continues to study the quality and availability of state mental programs for these individuals [See House Resolution 106, JOURNAL OF THE CALIFORNIA ASSEMBLY 19,237-19,238 (1975-1976 Reg. Sess.)].

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**See Generally:**

- 1) 8 PAC. L.J., REVIEW OF SELECTED 1976 CALIFORNIA LEGISLATION 382 (revision of Lanterman Developmental Disabilities Services Act) (1977).
- 2) 7 PAC. L.J., REVIEW OF SELECTED 1975 CALIFORNIA LEGISLATION 422 (right to counsel in all commitment proceedings) (1976).
- 3) 5 PAC. L.J., REVIEW OF SELECTED 1973 CALIFORNIA LEGISLATION 361 (rights of developmentally disabled persons) (1974).
- 4) 4 PAC. L.J., REVIEW OF SELECTED 1972 CALIFORNIA LEGISLATION 438 (rights of developmentally disabled persons) (1973).

### **Health and Welfare; referral of developmentally disabled minors**

Health and Safety Code §38224 (new).

AB 45 (Alatorre); STATS 1977, Ch 856

*(Effective September 17, 1977)*

Support: California Association for the Retarded; California Nurses Association

Pursuant to the Lanterman Developmental Disabilities Services Act, the State Department of Health is authorized to contract with private nonprofit community agencies to maintain a network of regional centers that provide services for persons with developmental disabilities [CAL. HEALTH & SAFETY CODE §§38200, 38201]. Chapter 856 now establishes a procedure for the referral of minor patients with developmental disabilities to the regional centers, by qualified physicians and surgeons [CAL. HEALTH & SAFETY CODE §38224]. This procedure is apparently designed to increase access to regional centers and the services that they provide.

The term "developmental disability" is defined as a disability that originates before an individual attains age 18, continues, or can be expected to continue indefinitely, and constitutes a substantial handicap, such as mental retardation, cerebral palsy, epilepsy, or autism [CAL. HEALTH & SAFETY CODE §38010(a)]. It includes mental retardation, but does not include other handicaps that are solely physical in nature [CAL. HEALTH & SAFETY CODE §38010(a)]. The area boards on developmental disabilities are established on a regional basis to coordinate and encourage the development of services for the developmentally disabled [CAL. HEALTH & SAFETY CODE §38178]. Prior to the enactment of Chapter 856, the dissemination of information to professional groups and the general public to increase awareness of services

available to persons with developmental disabilities was the joint responsibility of the area boards on developmental disabilities and the regional centers [CAL. HEALTH & SAFETY CODE §§38171, 38217].

Chapter 856 requires qualified physicians and surgeons, those with a specialized practice in childhood disabilities, who diagnose a minor patient as developmentally disabled to inquire whether the patient has been previously referred to a regional center for the developmentally disabled [CAL. HEALTH & SAFETY CODE §38224(a)]. If no previous referral can be determined, the physician is required to inform the child's parents or guardian of the services of the regional center and, if requested by the parents or guardian, to provide written referral to the regional center [CAL. HEALTH & SAFETY CODE §38224(a)]. Chapter 856 does not, however, prevent a physician from providing care or treatment to developmentally disabled minors, nor does it deprive such minors of adequate care through sources other than a regional center [CAL. HEALTH & SAFETY CODE §38224(d)]. Chapter 856 additionally requires that referring physicians and surgeons notify the selected regional center of all referrals of developmentally disabled minors and that the regional centers maintain a record of all such referrals [CAL. HEALTH & SAFETY CODE §§38224(a), 38224(b)]. To ensure that this referral procedure is universally adopted, Chapter 856 requires the Department of Health to provide information concerning the regional centers and the referral procedures to all licensed physicians and surgeons as well as all licensed general acute care hospitals in the state [CAL. HEALTH & SAFETY CODE §38224(c)]. Thus, by enacting Chapter 856, the legislature has now provided a procedure for the referral of developmentally disabled minors to regional centers in an apparent effort to facilitate access to the services provided by the Lanterman Developmental Disabilities Services Act.

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**See Generally:**

- 1) 8 PAC. L.J., REVIEW OF SELECTED 1976 CALIFORNIA LEGISLATION 382 (revision of Lanterman Developmental Disabilities Act) (1977).

## **Health and Welfare; detention of mentally disordered persons**

Welfare and Institutions Code §5157 (new); §5325 (amended).

AB 1306 (Brown); STATS 1977, Ch 1021

Support: National Organization for Women

When a person suffering from a mental disorder is a danger to himself or herself or others, or is gravely disabled, Section 5150 of the Welfare and Institutions Code authorizes a peace officer or mental health professional, upon probable cause, to take such an individual into custody and place him or her in a mental health facility for 72 hour treatment and evaluation [CAL. WELF. & INST. CODE §5150]. Prior to the enactment of Chapter 1021,



however, information concerning the rights of involuntarily detained persons for evaluation and treatment was limited to a posted list of rights at the treatment facility [CAL. WELF. & INST. CODE §5325] and the requirement of informed consent for any treatment [*See, e.g.*, CAL. WELF. & INST. CODE §§5326.2, 5326.6].

Newly added Section 5157 of the Welfare and Institutions Code requires the detaining officials to identify themselves and to inform the mentally disabled person being detained of the bases of his or her detention, including the facts upon which the allegations of dangerous or grave disability are founded [CAL. WELF. & INST. CODE §5157(c)]. Newly added Section 5157 of the Welfare and Institutions Code now requires that persons detained pursuant to Section 5150 be provided orally with the following information: (1) the name of the agent and agency taking the individual into custody; (2) that he or she is not under criminal arrest; (3) the name of the facility to which the individual is being taken; and (4) if taken into custody at their residence, the fact that he or she may bring a few approved personal items and may call or leave a note to advise family or friends where they have been taken [CAL. WELF. & INST. CODE §5157(a)]. After a person has been admitted to a psychiatric evaluation facility, pursuant to Section 5150, Chapter 1021 also requires the admission staff to inform the patient, orally in a language accessible to the person and written in the person's native language, of the basis of his or her detention, including any additional facts arising from admission interviews conducted pursuant to Section 5152 of the Welfare and Institutions Code [CAL. WELF. & INST. CODE §5157(c); *see* CAL. WELF. & INST. CODE §5152]. Further, the staff of the evaluation facility is also required to inform these patients of statutory procedures for evaluation, treatment, and care [CAL. WELF. & INST. CODE §5157(c); *see* CAL. WELF. & INST. CODE §§5152, 5275, 5276]. Moreover, the staff must advise the patient, orally and in writing and in a language accessible to the person, that he or she may be detained for longer than 72 hours and that such detainment gives rise to his or her right to a lawyer and a hearing before a judge [CAL. WELF. & INST. CODE §5157(c)]. Each evaluation facility to which dangerous mentally disabled or gravely disabled persons are admitted is required to maintain specified records of the advisements given to these patients pursuant to Section 5157 [CAL. WELF. & INST. CODE §5157(b), (d)]. Additionally, Chapter 1021 requires that patients admitted to mental health facilities be given a patients' rights handbook prepared by the Department of Health [CAL. WELF. & INST. CODE §5325]. Thus, the enactment of Chapter 1021 appears to be an effort by the legislature to ensure that persons being involuntarily detained for temporary evaluation are made aware of the procedures to be followed during their evaluation and treatment and of their constitutional and statutory rights during this period.

See Generally:

- 1) 7 PAC. L.J., REVIEW OF SELECTED 1975 CALIFORNIA LEGISLATION 333 (commitment of mentally disordered persons) (1976).

## Health and Welfare; deaths in mental institutions

Government Code §27491 (amended); Welfare and Institutions Code §5328.8 (new).

SB 190 (Ayala); STATS 1977, Ch 498

Support: California Department of Health

Prior to the enactment of Chapter 498, the State Department of Health apparently had sole responsibility for the investigation of patient deaths involving any person held in custody as mentally disordered, mentally retarded, or otherwise incompetent [*See* CAL. STATS. 1965, c. 1797, §2, at 4138]. The State Department of Health was also required to keep records of each patient in custody, which included, *inter alia*, the cause of death of any such patient and the circumstances thereof [CAL. WELF. & INST. CODE §§4019, 7251]. A coroner's inquiry was instigated only when a death was reported by a physician, the State Department of Health, or other persons having knowledge of the death as occurring under specified circumstances [*See* CAL. STATS. 1974, c. 1259, §4, at 2732; CAL. HEALTH & SAFETY CODE §10250].

In an apparent response to several deaths that occurred in state mental hospitals during 1976 under unusual circumstances, Chapter 498 has been enacted to require a coroner's investigation into the nature and circumstances of *all* patient deaths in state hospitals operated by the State Department of Health or any successor agency [*See* CAL. GOV'T CODE §27491; Sacramento Bee, Mar. 29, 1977, §A, at 8, col. 5]. Pursuant to Section 5328 of the Welfare and Institutions Code, all records and information regarding a patient's mental condition or the services and treatments he or she has received pursuant to state health programs are confidential with specified exceptions. To facilitate the coroner's investigation, Section 5328.8, as added by Chapter 498, now requires the State Department of Health, the physician in charge of the patient, or the professional person in charge of the facility or his or her designee to release all factual and clinical information to the coroner whenever a patient dies from any cause, natural or otherwise, while hospitalized in a state mental hospital. The information released to the coroner must remain confidential, and once this disclosed material has served its purpose to the coroner, the information must be sealed and may not be made part of the public record [*See* CAL. WELF. & INST. CODE §5328.8]. Thus, Chapter 498 now provides for an objective and independent investigation into patient deaths in an apparent effort to detect more accurately cases of abuse or neglect in state mental institutions.

## **Health and Welfare; adverse reactions to immunizations**

Health and Safety Code §§429.35, 429.36 (new).

SB 967 (Smith); STATS 1977, Ch 1097

Support: California Medical Association; Children's Lobby

The intent of the legislature in enacting Chapter 1097 is to provide rehabilitative treatment and support to children under the age of 18 who suffer severe adverse reactions to immunizations required by state law [CAL. HEALTH & SAFETY CODE §429.35]. Current law prohibits children under the age of 17 from being admitted to any public or private school in California unless they have been immunized against poliomyelitis and measles (rubeola) [CAL. HEALTH & SAFETY CODE §§3380, 3400]. Immunizations against diphtheria and tetanus are a prerequisite to admitting children under the age of 18 into any public or private child care center, day nursery, nursery school, or other school; and immunization against pertussis (whooping cough) is required for children six years of age or under [CAL. HEALTH & SAFETY CODE §3481]. With the enactment of Chapter 1097, a child under the age of 18 may now receive medical, institutional, supportive, and rehabilitative treatment if he or she suffers a "severe adverse reaction" to any immunization required by state law [CAL. HEALTH & SAFETY CODE §429.35]. As used in Chapter 1097, a "severe adverse reaction" is one which manifests itself not more than 30 days after an immunization and requires extensive *medical* care, as defined by Department of Health regulations [CAL. HEALTH & SAFETY CODE §429.35]. Section 429.35 further provides that medical expenses incurred by children suffering such a reaction are to be reimbursed by the Department of Health in an amount not to exceed \$25,000. This reimbursement, although limited to persons requiring extensive medical care, is to be granted without regard to the ability to pay and neither the parents nor the estates of such injured persons are to be liable for repayment of any reimbursement provided by the state [CAL. HEALTH & SAFETY CODE §429.35]. Upon payment of any claim for medical expenses provided for by Chapter 967, however, the State of California becomes subrogated to the rights of such reimbursed persons regarding these medical expenses as against any third party for an amount equal to the claim paid [CAL. HEALTH & SAFETY Code §429.35]. Finally, Chapter 967 provides immunity from civil liability to any person administering an immunization required by state law for injuries caused by any act or omission not constituting willful misconduct or gross negligence [CAL. HEALTH & SAFETY CODE §429.36]. Thus, while apparently limiting the alternative remedies available to children who suffer reactions to required immunizations, Chapter 967 would seem to ensure that children suffering such reactions are properly cared for and their families are uniformly compensated.

See Generally:

- 1) Bennett, *Allocation of Child Medical Care Decision-Making Authority: A Suggested Interest Analysis*, 62 VA. L. REV. 285 (1976).

## Health and Welfare; refilling of prescriptions

Business and Professions Code §4229.5 (new); Health and Safety Code §11201 (new); Welfare and Institutions Code §14105.7 (new).

AB 859 (Rosenthal); STATS 1977, Ch 1211

Support: California Employed Pharmacists; California Office of Aging; California Pharmaceutical Association

Opposition: California District Attorneys' Association

Existing law generally prohibits a pharmacist from refilling a prescription for any dangerous drug without the prescriber's authorization, which may be given orally or at the time when the original prescription was given [CAL. BUS. & PROF. CODE §4229]. Dangerous drugs are defined as any drug unsafe for self-medication, except those listed in Section 4211 of the Business and Professions Code that are designed for the purpose of feeding or treating animals other than man [See CAL. BUS. & PROF. CODE §4211(e), (f), (g), (i)]. In addition, existing law also restricts prescription refills by prohibiting more than five refills of controlled substances and forbidding any refills more than six months after the date of the prescription [CAL. HEALTH & SAFETY CODE §11200]. A controlled substance is defined by Section 11007 of the Health and Safety Code as any drug, substance or immediate precursor listed in Schedules I through V [CAL. HEALTH & SAFETY CODE §§11054-11058].

Chapter 1211 modifies the law by authorizing a pharmacist to refill a prescription for either dangerous drugs or controlled substances, except those in Schedule II (such as opiates and its derivatives or amphetamines), when the prescriber is unavailable and it is the pharmacist's professional opinion that failure to refill the prescription might present an immediate hazard to the patient's health or might result in subjecting such person to intense suffering [CAL. BUS. & PROF. CODE §4229.5; CAL. HEALTH & SAFETY CODE §11201. See generally CAL. HEALTH & SAFETY CODE §11055]. In order to refill a prescription for these drugs without the prescriber's authority and without incurring liability, Chapter 1211 requires a pharmacist to: (1) make every reasonable effort to contact the prescriber; (2) give the patient only a reasonable amount sufficient to maintain the patient until the prescriber can be contacted; (3) note the date and quantity of the refill, the fact that the prescriber was unavailable, and the basis for his or her judgment to refill on the reverse side of the prescription; and (4) inform the patient that the refill was given without authorization because of the prescriber's absence and that in the pharmacist's judgment, failure to provide

*Selected 1977 California Legislation*

the drug will be detrimental to the patient's health or lead to intense suffering [CAL. BUS. & PROF. CODE §4229.5; CAL. HEALTH & SAFETY CODE §11201]. In addition, after dispensing the necessary drugs pursuant to Chapter 1211, the pharmacist is further required to inform the prescriber within a reasonable time that a prescription has been refilled without his or her prior authorization [CAL. BUS. & PROF. CODE §4229.5; CAL. HEALTH & SAFETY CODE §11201].

Chapter 1211 further provides that the prescriber is immune from any claims that may arise as the result of a prescription refill pursuant to this new law [CAL. BUS. & PROF. CODE §4229.5; CAL. HEALTH & SAFETY CODE §11201]. Finally, Section 14105.7 has been added to the Welfare and Institutions Code to ensure that the rate of payment for the professional fee portion of any prescription services rendered pursuant to Chapter 1211 does not exceed the professional fee that would have been charged had the refill been made under normal circumstances. Thus, it appears that through the enactment of Chapter 1211 pharmacists have been assured greater latitude in dispensing certain nonrefillable prescription drugs in situations in which the prescriber is unavailable and the health, welfare, and comfort of the patient requires continued medication.

### **Health & Welfare; prescription blanks**

Business and Professions Code §4390.1 (new).

AB 1248 (Stirling); STATS 1977, Ch 1212

Support: California Attorney General; California District Attorney's Association; California Peace Officers' Association

The Department of Justice issues free of charge to any person authorized to write a prescription, nontransferable prescription blanks [CAL. HEALTH & SAFETY CODE §1161] that must be used when prescribing certain narcotic drugs [CAL. HEALTH & SAFETY CODE §11164(a). *See generally* CAL. HEALTH & SAFETY CODE §11027 (definition of prescription)]. Possession of these official prescription blanks, other than as allowed by law, is a misdemeanor [CAL. HEALTH & SAFETY CODE §11161]. It is apparently not illegal, however, to possess locally or commercially prepared prescription blanks that can be used to obtain certain other controlled substances [*See generally* CAL. HEALTH & SAFETY CODE §11164 (prescriptions for controlled substances)]. On the other hand, falsely representing oneself as a physician in a phone conversation to obtain prescription drugs is a misdemeanor [CAL. BUS. & PROF. CODE §4390.5; CAL. PENAL CODE §377], and forging a prescription is punishable as a felony or a misdemeanor [CAL. BUS. & PROF. CODE §4390. *See generally* CAL. BUS. & PROF. CODE §4036 (definition of prescription)]. Chapter 1212, apparently in a continued effort to deter the

traffic of illegally obtained controlled substances, has added Section 4390.1 to the Business and Professions Code to make it a misdemeanor for any person, other than those specified, to knowingly and willfully manufacture, copy, reproduce, or cause to be so produced, any prescription blank purporting to bear certain identifying information of those professionals authorized by law to dispense, administer, or prescribe controlled substances [See CAL. BUS. & PROF. CODE §4390.1]. Those specified professionals who are allowed to manufacture, reproduce, or copy the prescription blanks, or cause them to be locally or commercially produced, are: (1) physicians; (2) dentists; (3) podiatrists; (4) veterinarians; (5) pharmacists; (6) other persons authorized by law to dispense, administer, or prescribe controlled substances; and (7) agents of the above named professionals acting under their authorization to print prescription blanks and in the regular practice of the principal's profession [See CAL. BUS. & PROF. CODE §4390.1]. To be prohibited, the prescription blank must purport to bear the name, address, and federal registry or other identifying information of one of the six above named professionals [CAL. BUS. & PROF. CODE §4390.1].

With respect to the precise language used in Chapter 1212, the California Uniform Controlled Substances Act [CAL. HEALTH & SAFETY CODE §§11000-11651] defines the term "controlled substances" generally to include opiates, opium derivatives, hallucinogenic substances, certain depressants, and narcotics [Compare CAL. BUS. & PROF. CODE §4035 with CAL. HEALTH & SAFETY CODE §§11007, 11054-11058]. Chapter 1212 does not define the terms "knowingly and willfully," but a profitable analogy may be drawn with the definitions provided in Penal Code Section 7. Consequently, if the courts apply the definitions contained in the Penal Code to Section 4390.1 of the Business and Professions Code, then Chapter 1212 would appear to require a showing that a violator knew he or she was producing the prohibited prescription blanks and was not authorized to do so and that he or she simply possessed a purpose or willingness to produce these forms, but not to require proof of knowledge of the illegality of the act or proof of any intent to violate the law [Compare CAL. PENAL CODE §7 with CAL. BUS. & PROF. CODE §4390.1]. Punishment for violating Chapter 1212 is a fine of \$50 to \$500, or imprisonment for 30 days to six months, or both [CAL. BUS. & PROF. CODE §§4382, 4390.1]. In summary, Chapter 1212 makes it illegal for anyone, except specified professionals as authorized by law, to knowingly and willfully manufacture, cause to be manufactured, or otherwise produce prescription blanks and thereby appears to take a further step toward limiting the unlawful access to controlled substances [See CAL. BUS. & PROF. CODE §4390.1].

See Generally:

- 1) 2 B. WITKIN, CALIFORNIA CRIMES, *Crimes Against Public Peace and Welfare* §697 (administering or prescribing), §736 (pharmacy) (1963); §697 (administering or prescribing), §736 (pharmacy) (Supp. 1975).
- 2) 4 PAC. L.J., REVIEW OF SELECTED 1972 CALIFORNIA LEGISLATION 383 (pharmaceutical prescriptions) (1973).

### Health and Welfare; charitable food donations

Food and Agricultural Code §§58501, 58502, 58503, 58504, 58505, 58506, 58507, 58508, 58509 (new); Revenue and Taxation Code §§17202.4, 24343.7 (new).

SB 199 (Nejedly); STATS 1977, Ch 977

Support: California Department of Aging; California Department of Food and Agriculture

Opposition: California Department of Consumer Affairs

Chapter 977 has established administrative procedures to assist nonprofit, charitable organizations in California in obtaining donated food and has provided incentives to food sellers and distributors in the form of tax deductions and exemption from tort liability to encourage donations of surplus food to charity [See CAL. FOOD & AGRIC. CODE §§58501-58508; CAL. REV. & TAX. CODE §§17202.4, 24343.7]. Since the prior law did not prohibit the donation of food to charity unless done in restraint of trade [See CAL. FOOD & AGRIC. CODE §58381], the provisions of Chapter 977 are apparently designed to encourage and facilitate charitable food donations.

Chapter 977 permits any county board of supervisors to develop a food collection and distribution system, including the establishment of food storage facilities and a 24-hour information center to facilitate the collection of surplus food from donors and its distribution to charitable organizations [CAL. FOOD & AGRIC. CODE §58503]. All food donated pursuant to Chapter 977 is required to be "customary food," or that which is fit for human consumption [See CAL. FOOD & AGRIC. CODE §58501(a)]. In accordance with Chapter 977 the county board of supervisors may provide for inspection of all donated food by a county health officer to determine that the food is fit for human consumption, although such inspection is not required [CAL. FOOD & AGRIC. CODE §58504]. Chapter 977 further requires any county that establishes a food collection and distribution system to screen the donee charities to ensure that food is not distributed to organizations that are capable of purchasing it [CAL. FOOD & AGRIC. CODE §58508]. Further, to ensure the proper use of donated food, Chapter 977 provides that the resale or out of state transfer of food donated or distributed under its provisions is prohibited unless the donated food fails to meet the requirements of Division 17 of the Food and Agriculture Code establishing fruit, nut and vegetable standards [CAL. FOOD & AGRIC. CODE §§42501-48371] in which case such

food may be exported in accordance with regulations established by the Director of the Department of Agriculture [CAL. FOOD & AGRIC. CODE §58507(a)].

As an incentive for the donation of surplus food by sellers, distributors, and processors, donors are allowed personal or corporate income tax deductions under Chapter 977 for the amount equal to the cost of the food donated [CAL. REV. & TAX. CODE §§17202.4, 24343.7]. This deduction is allowed in addition to the one provided for trade or business expenses involved in producing the food donated [CAL. REV. & TAX. CODE §§17202, 24343]. In addition to this tax incentive both the donor and the county are relieved from any liability for damages or injury due to “any act, or the omission of any act,” in connection with donating any “agricultural product” that is proper food for human consumption unless the damage or injury results from gross negligence or a willful act [See CAL. FOOD & AGRIC. CODE §§58501(a). 58505]. Chapter 977 does not, however, relieve any nonprofit charitable organization from such liability [CAL. FOOD & AGRIC. CODE §58506].

Finally, Chapter 977 specifies that its provisions will remain in effect only until January 1, 1980 unless extended by subsequent legislation [CAL. FOOD & AGRIC. CODE §58509]. Thus, it appears that Chapter 977 is an attempt to minimize food waste in California by establishing administrative procedures, tax deductions, and tort liability restrictions, to encourage sellers, distributors, and processors of food to donate any surplus to charity, and to establish an effective system for the disbursement of these food donations [See Senator John A. Nejedly, Press Release, no. 28, Sept. 22, 1977].