
SENATE COMMITTEE ON PUBLIC SAFETY

Senator Loni Hancock, Chair

2015 - 2016 Regular

Bill No: SB 1238 **Hearing Date:** April 19, 2016
Author: Pan
Version: March 29, 2016
Urgency: No **Fiscal:** Yes
Consultant: JRD

Subject: *Inmates: Biomedical Data*

HISTORY

Source: California Correctional Healthcare Services

Prior Legislation: None known

Support: Unknown

Opposition: None known

PURPOSE

The purpose of this bill is to permit records-based biomedical research, using existing information, to be conducted on prisoners, notwithstanding a prohibition on biomedical research on prisoners.

Existing law defines:

- “Behavioral research” as studies involving, but not limited to, the investigation of human behavior, emotion, adaptation, conditioning, and response in a program designed to test certain hypotheses through the collection of objective data. Behavioral research does not include the accumulation of statistical data in the assessment of the effectiveness of programs to which inmates are routinely assigned, such as, but not limited to, education, vocational training, productive work, counseling, recognized therapies, and programs which are not experimental in nature.
- “Biomedical research” as research relating to or involving biological, medical, or physical science.
- “Psychotropic drug” as any drug that has the capability of changing or controlling mental functioning or behavior through direct pharmacological action. Such drugs include, but are not limited to, antipsychotic, antianxiety, sedative, antidepressant, and stimulant drugs. Psychotropic drugs also include mind-altering and behavior-altering drugs which, in specified dosages, are used to alleviate certain physical disorders, and drugs which are ordinarily used to alleviate certain physical disorders but may, in specified dosages, have mind-altering or behavior-altering effects.

- “Research” as a class of activities designed to develop or contribute to generalizable knowledge such as theories, principles, or relationships, or the accumulation of data on which they may be based, that can be corroborated by accepted scientific observation and inferences.
- “Research protocol” as a formal document setting forth the explicit objectives of a research project and the procedures of investigation designed to reach those objectives.
- “Phase I drug” as any drug which is designated as a phase I drug for testing purposes under the federal Food and Drug Administration criteria in Section 312.1 of Title 21 of the Code of Federal Regulations.

(Penal Code § 3500.)

Existing law provides that the Legislature affirms the fundamental right of competent adults to make decisions about their participation in behavioral research. (Penal Code § 3501.)

Existing law provides that biomedical research shall not be conducted on any prisoner in this state. (Penal Code § 3502.)

Existing law provides that notwithstanding Section 3502, any physician who provides medical care to prisoners may provide a patient who is prisoner with a drug or treatment available only through a treatment protocol or treatment IND (investigational new drug) if the physician determines that access to that drug is in the best medical interest of the patient, and the patient has given informed consent. And, notwithstanding any other provision of law, neither a public entity nor a public employee shall be liable for any injury caused by the administration of a drug pursuant, where the administration is made as specified. (Penal Code § 3502.5.)

Existing law states that any physical or mental injury of a prisoner resulting from the participation in behavioral research, irrespective of causation of such injury, shall be treated promptly and on a continuing basis until the injury is cured. (Penal Code § 3504.)

Existing law requires that behavioral research be limited to studies of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons which present minimal or no risk and no more than mere inconvenience to the subjects of the research. Informed consent shall not be required for participation in behavioral research when the department determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent shall be required for participation in behavioral research. (Penal Code § 3505.)

Existing law requires that behavioral modification techniques shall be used only if such techniques are medically and socially acceptable means by which to modify behavior and if such techniques do not inflict permanent physical or psychological injury. (Penal Code § 3508.)

This bill permits records-based biomedical research using existing information, without prospective interaction with human subjects, to be conducted on prisoners, notwithstanding a prohibition on biomedical research on prisoners.

This bill restricts the use or disclosure of individually identifiable records pursuant to the above provision permitting records-based biomedical research to only occurring after both of the following requirements have been met:

- The research advisory committee, established pursuant to specified provisions of existing California regulations pertaining to research involving prisoners (currently limited to behavioral research), approves of the use or disclosure; and,
- The prisoner provides written authorization for the use or disclosure, or the use or disclosure is permitted by specified provisions of federal HIPAA regulations.

This bill excludes from the definition of “biomedical research,” for purposes of provisions of law governing biomedical and behavioral research of prisoners, the accumulation of statistical data in the assessment of the effectiveness of nonexperimental public health programs or treatment programs in which inmates routinely participate

RECEIVERSHIP/OVERCROWDING CRISIS AGGRAVATION

For the past several years this Committee has scrutinized legislation referred to its jurisdiction for any potential impact on prison overcrowding. Mindful of the United States Supreme Court ruling and federal court orders relating to the state’s ability to provide a constitutional level of health care to its inmate population and the related issue of prison overcrowding, this Committee has applied its “ROCA” policy as a content-neutral, provisional measure necessary to ensure that the Legislature does not erode progress in reducing prison overcrowding.

On February 10, 2014, the federal court ordered California to reduce its in-state adult institution population to 137.5% of design capacity by February 28, 2016, as follows:

- 143% of design bed capacity by June 30, 2014;
- 141.5% of design bed capacity by February 28, 2015; and,
- 137.5% of design bed capacity by February 28, 2016.

In December of 2015 the administration reported that as “of December 9, 2015, 112,510 inmates were housed in the State’s 34 adult institutions, which amounts to 136.0% of design bed capacity, and 5,264 inmates were housed in out-of-state facilities. The current population is 1,212 inmates below the final court-ordered population benchmark of 137.5% of design bed capacity, and has been under that benchmark since February 2015.” (Defendants’ December 2015 Status Report in Response to February 10, 2014 Order, 2:90-cv-00520 KJM DAD PC, 3-Judge Court, *Coleman v. Brown, Plata v. Brown* (fn. omitted).) One year ago, 115,826 inmates were housed in the State’s 34 adult institutions, which amounted to 140.0% of design bed capacity, and 8,864 inmates were housed in out-of-state facilities. (Defendants’ December 2014 Status Report in Response to February 10, 2014 Order, 2:90-cv-00520 KJM DAD PC, 3-Judge Court, *Coleman v. Brown, Plata v. Brown* (fn. omitted).)

While significant gains have been made in reducing the prison population, the state must stabilize these advances and demonstrate to the federal court that California has in place the “durable solution” to prison overcrowding “consistently demanded” by the court. (Opinion Re: Order Granting in Part and Denying in Part Defendants’ Request For Extension of December 31, 2013 Deadline, NO. 2:90-cv-0520 LKK DAD (PC), 3-Judge Court, *Coleman v. Brown, Plata v. Brown* (2-10-14). The Committee’s consideration of bills that may impact the prison population therefore will be informed by the following questions:

- Whether a proposal erodes a measure which has contributed to reducing the prison population;
- Whether a proposal addresses a major area of public safety or criminal activity for which there is no other reasonable, appropriate remedy;
- Whether a proposal addresses a crime which is directly dangerous to the physical safety of others for which there is no other reasonably appropriate sanction;
- Whether a proposal corrects a constitutional problem or legislative drafting error; and
- Whether a proposal proposes penalties which are proportionate, and cannot be achieved through any other reasonably appropriate remedy.

COMMENTS

1. Need for This Bill

According to the author:

Ten years ago, federal court placed the state's prison health care system under a receivership after determining that an average of one inmate per week died as a result of medical malpractice or neglect. The receivership has improved healthcare in prisons over the last ten years, but the inability to share data-backed best practices contributes to the challenge of providing quality health care to 127,000 inmates—who are disproportionately Black and Latino. SB 1238 would authorize the publication of statistical data in the assessment of the effectiveness of nonexperimental public health programs or treatment programs in which inmates routinely participate. This would enable health care providers in prisons and jails to learn from the best practices used at state correctional facilities, and utilize these life-saving techniques.

In August of 2015, microscopic bacteria contaminated the water supply of San Quentin State Prison (SQ). A physician working in the prison noticed an unusual number of inmate-patients with pneumonia. Two hours into a collaborative email chain, the healthcare providers of SQ identified the cause of the pneumonia increase: Legionnaires' disease. Data sharing among the health care staff enabled the California Correctional Health Care Services (CCHCS) and the California Department of Corrections and Rehabilitation to respond to the potential health crisis immediately. The quick identification and effective treatment of the disease prevented the crisis from turning fatal. Data sharing enabled this life-saving response. The ability to publish some of this data would allow other health care agencies to learn to better manage similar health crises. Nonexperimental medical data can be used to save lives while completely avoiding the ethical dilemmas of allowing experimental biomedical research in prisons.

California's prison system has been on the cutting edge of providing health care to prison inmates, but current law prevents the publishing of non-experimental medical data that could be used to improve health care in correctional facilities and potentially save lives. Prisons face unique health care challenges, and SB 1238 would allow health care providers to share and learn from non-experimental data in order to provide higher quality health care.

2. California Department of Corrections Healthcare: Federal Receivership

CCHCS (federal receivership) was established as a result of a class action lawsuit (*Plata v. Brown*) brought against the State of California over the quality of medical care in the state's 34 adult prisons. In its ruling, the federal court found that the care was in violation of the Eighth Amendment of the U.S. Constitution which prohibits cruel and unusual punishment. The state settled the lawsuit and entered into a stipulated settlement in 2002, agreeing to a range of remedies that would bring prison medical care in line with constitutional standards. The state failed to comply with the stipulated settlement and on February 14, 2006, the federal court appointed a receiver to manage medical care operations in the prison system. The current receiver was appointed in January of 2008. The receivership continues to be unprecedented in size and scope nationwide.

CCHCS is the sponsor of this legislation and states in support:

Over the last several years, the prison system has been the site of extremely newsworthy medical developments, and has been on the cutting edge of providing treatment to prison inmates that would be beneficial to share with the medical community at large. Between 2012 and 2014, the prison system experienced hunger strikes that lasted for a significant period of time. As a result, prison doctors developed an effective monitoring system that provided appropriate treatment as needed during the strikes. Additionally, for the past several years, the prison system has undertaken a massive program for identifying and treating Valley Fever in our central valley prisons: California was the first health care system in the nation to use a newly developed skin test that identifies exposure/non-exposure to Valley Fever which is now used in making wise housing choices for inmates statewide. Finally, just recently the prison system had an outbreak of Legionnaires Disease at San Quentin (SQ) State Prison where, due to quick identification and effective treatment, doctors were able to successfully treat inmates at SQ without the loss of life.

California Correctional Health Care Services, which oversees prison medical care, would like to publish our findings in medical journals that would be of benefit to other correctional and community entities. However, under current law (added in the 1970s) there currently is a prohibition in the California Penal Code for performing or undertaking biomedical research on prisoners. Unfortunately, the broad nature of the current statute would even prohibit CCHCS from publishing an accumulation of statistical data that provided an assessment of the effectiveness of any non-experimental public health or treatment program such as described above.

This bill would narrowly amend the Penal Code to allow CCHCS to publish findings from non-experimental public health or treatment programs.

3. Effect of This Legislation

This bill provides for the use of statistical data from health treatment programs within prisons in order to publish studies or reports on the efficacy of these health treatment programs. Specifically, this bill excludes from the definition of “biomedical research,” and therefore exempts from the ban on this research, the “accumulation of statistical data” in the assessment of treatment programs in which inmates routinely participated. This bill, additionally, authorizes biomedical research, but only when it is records-based, using existing information, and does not include prospective interaction with prisoners. In this provision, the use or disclosure of individually identifiable records is permitted, either with the written authorization of the prisoner, or when the use or disclosure is otherwise permitted under specified federal privacy regulations that permit disclosure without written authorization under certain circumstances.

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