

INFORMATIVE DIGEST

Background

The legislature of the State of California has found and declared that the California Birth Defects Monitoring Program (CBDMP), the Genetic Disease Screening Program (GDSP), and Maternal Child and Adolescent Health Program (MCAH) are mandated to store, analyze, and share biospecimens for research purposes. The California Department of Public Health, Center for Family Health (Department) maintains a large and diverse biobank (and associated data bases) of over 17.5 million prenatal and newborn biospecimens, GDSP data, and CBDMP registry data. It also links these biospecimens and data to the State Registrar of Vital Statistics, databases that include fetal death, live birth and death data. Research requests include biospecimen retrieval, re-inventory, and shipping as well as data requests in association with the biospecimens, which includes data processing, data linkage, data entry, and related data management.

Policy Statement Overview

Problem Statement: The Department must establish guidelines for invoicing, charging and collecting fees from approved researchers that are in an amount that is necessary to cover expenses associated with research requests and to make these resources available to approved researchers. The Governor signed into law, Assembly Bill (AB) 2599 (Stats. 2008, chapter 680) which requires the Department to implement, interpret, or make specific enacted provisions to regulations that specify the protocols and conditions under which requests for biospecimens and/or data will be approved and released to researchers.

Objectives: The broad objectives of this proposed regulatory action are to:

- Provide guidelines for invoicing, charging and collecting fees, in an amount that will cover expenses associated with research requests.
- Specify the protocols and conditions under which requests for research will be approved and released.
- Specify the protocols and conditions for biospecimen retrieval, re-inventory, and shipping.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Approved researchers will be allowed to use biospecimens and /or data for the development of diagnosis and treatment of disorders.

- Establish a uniform system for releasing biospecimens and/or data to approved researchers.
- Provide specific guidance to approved researchers as to the procedures and costs associated with the release of biospecimens and/or data from the Department.

The nonmonetary benefits to the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government of releasing biospecimens and/or data to approved researchers is impossible to determine, but it has the potential to be significant in terms of the possible advances in the diagnosis and treatment of diseases. Early diagnosis and successful treatment of disease may result in a very significant increase in the financial wellbeing, health and welfare of the people of California.

Summary of Proposal

The purpose of these proposed regulations is to implement AB 2599. Health and Safety Code (HSC) Section 125002(e), requires that regulations be adopted that, specify the protocols and conditions under which requests for biospecimens for research will be approved and released. The standards in these proposed regulations are limited to the release of biospecimens and/or data to approved researchers. Existing Department regulations do not address the provisions specified in AB 2599.

The Department proposes to adopt Group 6-Biobank Program, Articles 1 through 5, Sections 6550 through 6557.3, into Title 17 of the California Code of Regulations (CCR), Division 1, Chapter 4, Subchapter 9. Requirements specified in this Group will regulate the dissemination of biospecimens to Department approved researchers for the purpose of biomedical research. They set forth a request process, reasons for denial, and a fee structure for biospecimens, related data, data linkage and processing and additional related services. Requests include biospecimen retrieval, re-inventory and shipping as well as data requests in association with the biospecimens, which includes data processing, data linkage, data entry, and related data management.

Authority and Reference

Authority: The Department is proposing to adopt the regulation sections identified under the authority provided in Sections 124977, 124991, 125002, 131050, 131051, 131052 and 131200 of the Health and Safety Code.

Reference: This proposal implements, interprets and makes specific sections 102175, 102465, 124975-124996, 125000, 125001, 125050, and 125119.5 of the Health and Safety Code.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations

The Department evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to implementation of the California Biobank Program. An internet search of other state agency regulations was also performed and it was determined that no other state regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

Mandated by Federal Law or Regulations: N/A

Other statutory requirements: N/A

Local Mandate

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

FISCAL IMPACT ESTIMATE

A. FISCAL IMPACT ON LOCAL GOVERNMENT: None.

B. FISCAL IMPACT ON STATE GOVERNMENT:

The Departmental costs resulting from the provision of certain biospecimens and/or related data and services, to approved researchers, and resulting from evaluating and approving researchers' requests for such biospecimens and/or data, as authorized under the proposed regulations, are estimated to be \$1,913,190.00.00 per year (See Attachments 1 - 3). These costs will be covered by the fees which the Department will collect from the researchers under the authority of the proposed regulations.

C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS: None.

D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED:

Only those universities, research foundations, biotech companies, and non-profit organizations who choose to request and pay fees for biospecimens/and or data will be impacted. The cost will be determined by the type and quantity of biospecimens and/or data that the approved researcher requests.

E. Other nondiscretionary cost or savings imposed upon local agencies: None.

Statewide Effect on Housing Costs

The Department has determined that the regulations will have no impact on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Business Including the Ability to Compete

The Department has determined that the proposed regulatory action would not have significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. There are no private companies at this time that have access to the number and types of biospecimens and associated data that are contained within the California Biobank Program. Thus, there will be no significant adverse economic impact on California businesses.

Statement of the Results of the Economic Impact Assessment

There are no other businesses in the State of California that can provide biospecimens and/or data to researchers. Hence, the Department has determined that the regulation would not significantly affect the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. The proposed regulation would benefit the health and welfare of California residents, worker safety, and the state's environment by allowing for possible advances in the diagnosis and treatment of diseases.

Cost Impact on Representative Person or Business

The Department has determined that only those universities, research foundations, biotech companies, and non-profit organizations who choose to request and pay fees for biospecimens/and or data will be impacted. The cost will be determined by the type and quantity of biospecimens and/or data that the approved researcher requests.

The Department has determined that there will be no costs for individuals.

Effect on Small Business

The Department has determined that only those small businesses that choose to make a request and pay fees for biospecimens and/or data will be impacted. The cost will be determined by the type and quantity of biospecimens and/or data that the approved researcher requests.

Reporting Requirement

None

Alternatives Considered

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.