Date of Hearing: August 3, 2022

ASSEMBLY COMMITTEE ON APPROPRIATIONS
Chris Holden, Chair
SB 1500 (Committee on Health) – As Amended June 13, 2022

Policy Committee: Health Vote: 15 - 0

Urgency: No State Mandated Local Program: No Reimbursable: No

SUMMARY:

This bill exempts certain biologic drugs, human whole blood and human whole blood derivatives, and tissues from state licensing requirements when the drugs or tissues are being used for investigational purposes, as specified, and extends, until January 1, 2028, the exemption from annual inspections for accredited home medical device retail facilities.

Specifically, this bill:

1) Aligns state law governing the production of biologic drugs other than human whole blood or human whole blood derivatives with state law governing all other drugs by exempting biologic drugs from state licensing requirements when the biologic drug is part of a new investigational drug trial.

2) Exempts from existing licensure requirements human whole blood and human whole blood derivatives intended for use in investigating the safety and effectiveness of drugs or devices, under specified conditions.

3) Exempts from tissue bank licensure requirements tissue intended solely for investigational use under specified conditions.

4) Extends to January 1, 2028, the exemption for home medical device retail facilities from annual inspections if they are accredited by an accrediting body approved by the Centers for Medicare and Medicaid Services (CMS).

FISCAL EFFECT:

The Department of Public Health (DPH) anticipates no costs.

The University of California (UC) estimates low tens of millions of dollars at risk over several years for biologics projects if this bill fails. The figure represent a loss from clinical trials UC would no longer be able to participate in due to licensing requirements. UC states the funds are from industry, National Institutes of Health, and other sponsors that subsidize the costs of running the trials.

COMMENTS:

1) **Purpose**. According to the author, this bill will align the licensing requirements for non-biologic and biologic drugs used solely for investigational purposes. The Sherman Food,

Drug, and Cosmetic Law (Sherman Law) exempts drugs and devices from state licensing requirements when these drugs are the subject of an approved Investigational New Drug (IND) clinical investigation. However, a separate body of state law governs biologics and exempts biologics produced in a federally licensed facility, without mention of an exemption for uses of biologics in investigational studies. This bill conforms the biologics statute to the exemption that already exists in the Sherman Law for clinical investigations.

2) **Biologics**. Biologics are a type of drug (drugs are defined in state and federal law to be articles used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and which are not devices. (California Health and Safety Code § 109925(a); 21 U.S.C. § 321(g)(1)). The key difference between biologics and non-biologic drugs is that biologics are manufactured in a living system such as a microorganism, or plant or animal cells. Most biologics are very large, complex molecules or mixtures of molecules. Biologic drugs are subject to the same federal approval pathways for their use in clinical trials as non-biologic drugs, and the federal Food and Drug Administration must grant an IND application prior to use of a biologic in humans.

3) **Home Medical Device Retail Facilities**. DPH licenses home medical device retailers and requires an annual inspection. In 2006, the federal CMS began requiring medical device retailers to be accredited by a recognized accrediting organization in order to participate in Medi-Cal and Medicare. The accreditation process requires, among other things, an unannounced inspection at least once every three years. AB 1387 (Arambula), Chapter 213, Statutes of 2017, exempted home medical device retailers from the annual inspections if they were accredited (while retaining the initial inspection for licensure, as well as complaint-driven inspections). AB 1387 had a sunset of January 1, 2023. This bill extends that sunset by five more years.

4) **Sponsor**. This bill is sponsored by UC, which states clinical trials are one of the most important ways that potential new treatments are developed, and are a cornerstone of UC's clinical research enterprise. UC states their researchers are currently running more than 4,600 clinical trials investigating treatments for more than 2,400 conditions. UC believes the misalignment of existing statutes concerning biologics and other drugs is largely a technical oversight, and this bill will streamline unnecessary administrative burdens for clinical trials without jeopardizing patient safety.

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