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SB 838 – CalRx Insulin

Purpose
SB 838 furthers efforts of the California Health and Human Services Agency (CHHSA) towards creating a California branded label for generic drugs, and in particular insulin, with the goal of ensuring adequate supplies and access and lowering health care costs through savings to public health care programs and private health insurance coverage.

Prescription drug prices
According to the National Health Expenditure Data from the Centers for Medicare & Medicaid Services, prescription drug spending increased to $333.4 billion in 2017. The price of prescription medications rose 62% between 2011 and 2015, even after accounting for rebates. According to an August 2016 article in the *Journal of the American Medical Association (JAMA)*, the most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon federal Food and Drug Administration (FDA) approval and by patents. Another key contributor to drug spending is physician prescribing choices when comparable alternatives are available at lower costs. Although manufacturers justify prices by pointing to the high cost of drug development, there is no evidence of an association between research and development costs and prices; rather, prescription drugs are priced in the U.S. primarily on the basis of what the market will bear. According to a February 2019 Kaiser Family Foundation Health Tracking Poll, among those currently taking prescription drugs, 24% of adults and 23% of seniors say it is difficult to afford their prescription drugs, including about one in ten saying it is "very difficult." Twenty-nine percent of adults report not taking their medicines as prescribed at some point in the past year because of cost and 8% of these people say their condition got worse as a result of not taking their prescription as recommended.

Insulin
According to the California Health Benefits Review Program (CHBRP), the average list price of brand-name insulin nearly tripled between 2007 and 2018, increasing by 262%. While the average net price also increased, the increase was smaller (51%) and was offset by discounts such as those paid by manufacturers. The price increases were higher between 2012 and 2015, but began to level out in 2016. The reasons insulin prices are increasing are not entirely clear but are due in part to the complexity of drug pricing in general and of insulin pricing in particular. As the price of insulin has increased, so too have patient out-of-pocket costs. Between 2006 and 2013, average out-of-pocket costs per insulin user among Medicare Part D

enrollees increased by 10% per year for all insulin types. The increases in list price, net price, and out-of-pocket costs are substantially higher than increases due to inflation. Overall inflation between 2006 and 2013 was 2.2%, medical care service costs increased by 3.8%, and spending for all prescription drugs increased by an average of 2.8%.

The American Diabetes Association states that as the price of insulin continues to rise, individuals with diabetes are often forced to choose between purchasing the medications or paying for other necessities, exposing them to serious short- and long-term health consequences. To find solutions to the issue of insulin affordability, there must be a better understanding of the transactions throughout the insulin supply chain, the impact each stakeholder has on what people with diabetes pay for insulin, and the relative efficacy of therapeutic options.

State and nonprofit manufacturing of generic drugs

State manufacturing of drugs is not a new concept. California, through the Department of Public Health (DPH) Infant Botulism Treatment and Prevention Program (IBTPP), has been manufacturing the only treatment for infant botulism since 2003. In 1989, CDPH was designated by the FDA to develop and test a Botulism Immune Globulin Intravenous (BIG-IV) for the treatment of infant botulism. CDPH conducted a randomized, double-blinded, placebo-controlled, clinical trial between 1992 and 1997, and in October 2003, the FDA licensed BIG-IV as Baby BIG®. Federal law permits and California law requires CDPH to charge a fee for BabyBIG® in order to meet but not exceed the IBTPP operational expenses, including the developmental and on-going production costs of BabyBIG®. As of December 2018, the cost for a course of BabyBIG® was $57,300.

Massachusetts and Michigan Departments of Health operated manufacturing facilities for production of certain vaccines and biologic treatments. The Massachusetts laboratory is still in operation, but the Michigan laboratory was sold to a private company in 1998. CivicaRx is a member-owned, non-profit private label drug distributor. Several years ago, a number of hospitals came together to put together enough capital to build a manufacturing plant for generic drugs important for inpatient hospital care that are routinely in shortage status. Kaiser Permanente is a governing member of CivicaRx, and has partnered with Civica to assure access to affordable generic medication for inpatient use. Additionally, 18 of the Blues health plans announced their intent to become a subsidiary of CivicaRx for the purpose of manufacturing off-patent drugs that can be dispensed in outpatient settings.

This bill

- Permits CHHSA and its departments to enter into exclusive or nonexclusive contracts on a bid or negotiated basis for the production and distribution of generic prescription drugs.
- Requires generic drug manufacturing partnerships to make a generic insulin product available at production and dispensing costs, to guarantee priority access to insulin supply for the state, guarantee manufacturing of at least four high priority drugs for California, and create a California state brand.
- Requires partnerships to include representation and involvement with the governance of the contractor.
- Requires CHHSA to develop of a California-based manufacturing facility for generic drugs, with the intent of creating high-skill, high-paying jobs in the State.

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