Pension & Health Benefits Committee

California Public Employees' Retirement System

Agenda Item 5e

August 20, 2013

ITEM NAME: Senate Bill 598 (Hill) – Prescription Drugs: Biosimilar Products

As Amended August 6, 2013

Sponsor: Author

PROGRAM: Legislation

ITEM TYPE: Action

RECOMMENDATION

Adopt a **Neutral** position on Senate Bill (SB) 598 which has uncertain policy implications given that, to date, the Food and Drug Administration (FDA) has not approved a biological product as biosimilar or interchangeable and the FDA is currently developing regulations and interpretive guidance. In addition, CalPERS is not in a position to adequately determine whether or not it is good public policy for a pharmacist to "notify the prescriber whether the prescription dispensed was a biological product or an interchangeable biosimilar or enter the information in a patient record system shared by the prescriber," as the proposed amendments to SB 598 requires. Therefore, California Public Employees Retirement System (CalPERS) should take a neutral position until we can further understand the policy implications of this bill.

EXECUTIVE SUMMARY

SB 598 would basically allow a pharmacist filling a prescription order for a prescribed biological product to select a biosimilar if the biosimilar is approved and deemed interchangeable with the prescribed biologic product by the FDA, and the prescriber does not affirmatively indicate "Do not substitute" on the prescription order. For prescriptions filled prior to January 1, 2017, the bill generally requires the pharmacist to notify the prescriber whether the prescription dispensed was a biological product or an interchangeable biosimilar, or enter the information in a patient record system shared by the prescriber within five business days of the selection of a biological product or an interchangeable biosimilar.

CalPERS Federal Health Care Policy Initiatives related to prescription drugs include advocating for the development of a clear, efficient and timely regulatory pathway to bring generic biologics to market, including specialty drugs, and remove arbitrary access barriers for patients. While this bill would allow biologics to be substituted under State law, it may be premature and may impose unnecessary physician

notification requirements on pharmacists, potentially reducing the number or prescriptions substituted with biosimilars.

STRATEGIC PLAN

This item is not a specific product of the Annual or Strategic Plans, but is a part of the regular and ongoing workload of the Office of Governmental Affairs.

BACKGROUND

1. Biologic Drugs, Biosimilar Drugs, and Interchangeability

   Biological products are used to prevent, treat, or cure diseases and can include vaccines, blood and blood components, gene therapy, tissues, and proteins. Unlike most traditional, small-molecule prescription drugs that are made through chemical processes, biological products are generally made from human and/or animal materials. Biosimilars are biological products that are highly similar to a United States (U.S.) licensed reference biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency. Interchangeability means that the biologic product is biosimilar to the U.S.-licensed reference biological product and is expected to produce the same clinical result as the reference product in any given patient.

2. CalPERS Drug Costs

   In 2011, CalPERS spent more than $6.67 billion to purchase health benefits for 1.3 million active and retired State and local government public employees and their families. Prescription drugs accounted for about 22 percent–or more than $1.5 billion–of that amount. Specialty drugs, including biologics, make up a significant portion of CalPERS drug spending, as described below:

   - The number of participants using specialty medication has increased by 33 percent between 2004 and 2011, to almost 30,000 participants.
   - Both specialty and traditional drug utilization increased between 2007 and 2011, with specialty drug utilization increasing at a slightly lower rate than traditional drugs (10 percent versus 13 percent); however, the cost for specialty drugs increased at a significantly higher rate than traditional drugs (43 percent versus 28 percent).
   - Total spending for specialty drugs exceeded $250 million in 2011, a 43 percent increase since 2007, and a 120 percent increase since 2004.
   - Specialty drugs comprised 1.2 percent of total drugs dispensed in 2011, but represented 17 percent of CalPERS total drug costs.
   - Of the approximately $250 million spent on specialty drugs, biologics comprised approximately $236 million, or 94 percent, of this cost.

3. Existing Federal Law
   The Patient Protection and Affordable Care Act (ACA), signed into law by President Obama on March 23, 2010, contains a provision establishing an abbreviated pathway for biological products that are demonstrated to be "biosimilar" to, or "interchangeable" with, an FDA-licensed biological product. This pathway is provided in the part of the ACA known as the Biologics Price Competition and Innovation Act (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

   If a biosimilar is considered to be "interchangeable" to an FDA-licensed biological product under the BPCI Act, it may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

   To date, the FDA has yet to approve a biosimilar or determine that one is interchangeable with a U.S.-licensed reference biological product. In addition, the last two sets of guidance issued by the FDA, March 2013 and February 2012 respectively, have been in draft form.

4. Existing State Law Related to the Substitution of Generic Drugs
   Current State law allows the substitution of generic drugs for brand name drugs; however, the substitution of biological products is currently not addressed under California law. Current law allows pharmacists filling prescription orders for brand name drug products to substitute generic drugs for orders if the generic contains the same active chemical ingredients of equivalent strength and duration of therapy, subject to a patient notification and bottle labeling requirement, unless the prescriber specifies that a pharmacist may not substitute another drug product by either indicating on the form submitted for the filling of the prescription drug orders "Do not substitute" or words of similar meaning or selecting a box on the form marked "Do not substitute."

ANALYSIS

1. Proposed Changes
   Specifically, SB 598 would:
   - Establish a substitution process for biosimilars that has similarities to current State law regarding substituting brand name drugs with generic drugs.
   - Allow a pharmacist filling an order for a biological product to select a biosimilar if both the following the conditions are met:
     - Biosimilar is approved and determined interchangeable with the prescribed biologic product by the FDA.
     - Prescriber does not personally indicate "Do not substitute" or words of similar meaning.
   - Require, for prescriptions filled prior to January 1, 2017, that pharmacy notifies the prescriber whether the prescription dispensed was a biological

product or an interchangeable biosimilar approved by the FDA, or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection of a biological product or an interchangeable biosimilar.

- Prohibits a pharmacist from selecting a biosimilar if the cost to the patient of the biosimilar is more than the cost of the biological product intended to be replaced.
- Apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or Medi-Cal, as specified.
- Requires the substitution of a biosimilar to be communicated to the patient when a selection is made.
- Require the Board of Pharmacy to maintain a link on its public website to the current list, if available, of biosimilars determined by the FDA to be interchangeable.
- Define biological product, biosimilar, interchangeable, prescription, and the term “351(k) pathway.”
- Specify that nothing in this bill prohibits the administration of immunization.
- Specify that nothing in this bill prohibits a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

2. Legislative Efforts In Other States
Similar legislation has been proposed in 17 states: Arizona, Arkansas, California, Colorado, Florida, Illinois, Indiana, Maryland, Massachusetts, Mississippi, North Dakota, Oregon, Pennsylvania, Texas, Utah, Virginia, and Washington.

Five states-Virginia, Utah, Oregon, Florida, and North Dakota-have enacted laws specifying the circumstances under which pharmacists could substitute biosimilars for biologics. Oregon, Utah, and Virginia included a physician notification requirement and sunset date on their legislation. However, biosimilar legislation has failed in eight states- Arizona, Colorado, Illinois, Indiana, Maryland, Mississippi, Texas, and Washington. Arkansas referred biosimilar legislation to a study committee for further review. Legislation is currently under consideration in California, Massachusetts, and Pennsylvania.

3. Potential Impacts to the Future Use of Biosimilars
SB 598 would impose additional requirements on pharmacists when dispensing an FDA-approved interchangeable biosimilar beyond what is currently required for generic drugs. The author claims his bill is necessary to update State law so that when the FDA approves interchangeable biosimilars, pharmacists can substitute for these potentially lower cost drugs. He states that biosimilars are not identical to reference drugs, as is the case with generics and that while the use of biologics

is safe, a risk of an immune response from a biologic drug is much more significant than with generic pills.

Many generic drug companies and insurers characterize legislative efforts by the biotechnology industry in other states and SB 598 as an attempt to deter the use of biosimilars by undermining confidence in their safety, even before these products get to market. They believe these efforts attempt to thwart competition as lucrative biologics lose patent protection.

Since passage of the ACA, the FDA has been establishing standards for licensure to ensure the safety and effectiveness of biosimilars when they go to market. However, by imposing additional requirements on pharmacists when they dispense a biosimilar that has been certified by the FDA as interchangeable, this bill could undermine patients' and health care providers' trust in these products. Suggesting biosimilars are inferior to the reference biologics and not safe may deter patients from using these lower-cost treatments.

4. Doctor Notification Requirement Could Have Unintended Consequences
   SB 598 requires the pharmacist notify the prescribing physician upon dispensing either the prescribed biologic or an interchangeable biosimilar within five days of the selection. The physician notification could encourage doctors to check the "Do not substitute" box to avoid being inundated with notifications. Furthermore, doctors may develop a habit of just checking the "Do not substitute" box for all prescriptions which may go beyond biologics and negatively impact CalPERS ability to increase generic drug use. While CalPERS could implement stricter utilization requirements on prescriber, it could impact our members' health by making it harder for them to access the drugs they need.

   Without the ability to access safe, effective, and less expensive biosimilar products, CalPERS may ultimately be forced to raise prescription drug co-payments or raise health care premiums, shifting the costs onto employers, members, and their families.

5. Potential Conflict With Federal Law
   By requiring a pharmacy to notify the prescriber when a prescription order for a prescribed biological product is substituted with an interchangeable biosimilar, this bill may be inconsistent with the BPCI Act which provides that an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

6. Legislation Is Needed for Substitution of Biosimilar
   Because current State law does not address the substitution of biological products, legislation is needed to expand state substitution laws to include biosimilars. This bill would allow a pharmacist to substitute an interchangeable biosimilar for a prescribed biologic product when certain conditions are met.

BUDGET AND FISCAL IMPACTS

1. Benefit Costs
   It is difficult to determine the fiscal impact of this bill with any certainty because as stated earlier, the FDA has neither approved a biosimilar nor determined that a biosimilar is interchangeable with a U.S.-licensed reference biological product. Many in the health care industry estimate that, overall, the cost of biosimilars could be 20 to 30 percent less than their reference products.

   According to the attached chart *Summary of Potential Annual Savings Due to Biosimilars: CalPERS (All Plans),* staff estimates that with a biosimilar penetration rate of 20 percent and a biosimilar discount off of branded price of 20 percent, the potential annual savings due to biosimilars would be $3,550,814.40. However, the notification requirements on dispensing interchangeable biosimilar products could prevent CalPERS from realizing the full cost savings, especially as the use of biologic drugs increases. For example, assuming that as a result of SB 598 the penetration rate is reduced from 20 percent to 15 percent, the lost savings is almost $900,000.

   While the first biologic products are only now beginning to lose their patent protection, the development and manufacture of biosimilars is in its infancy and may not produce an interchangeable substitute for all biologic products manufactured. If even a fraction of CalPERS current annual $236 million spending on biologic products were reduced in the future by the substitution of biosimilars, the tens of millions of dollars in associated savings could potentially lower the rate of increases to member premium costs and drug co-pays.

2. Administrative Costs
   None.

BENEFITS/RISKS

1. Benefits of Bill Becoming Law
   - Allow for the substitution of biosimilar.
   - According to the Alliance for Safe Biologic Medicines, these “measures are necessary to protect patient safety because biosimilars are not identical to the originals.”

2. Risks of Bill Becoming Law
   - May impede the substitution of biosimilars that are 20 to 30 percent less than their reference products would result in missed cost savings.
   - Enacting State law before the FDA finalizes its regulations or guidance on biosimilars could lead to conflict or unnecessary requirements.

ATTACHMENTS

Attachment 1 – Legislative History
Attachment 2 – List of Support and Opposition
Attachment 3 – Summary of Potential Annual Savings Due to Biosimilars: CalPERS (All Plans)

DANNY BROWN, Chief
Office of Governmental Affairs

ANN BOYNTON
Deputy Executive Officer
Benefit Programs Policy and Planning