Bill Summary

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SENATE BILL 483-485: PRESCRIPTION DRUG AFFORDABILITY BOARD (PDAB)

MAHP POSITION: **SUPPORT**

SUMMARY OF SENATE BILL 483-485

Senate Bill 483-485 creates a Prescription Drug Affordability Board (PDAB) which will regulate in-state charges and payments made for certain drugs among state-licensed health care entities such as drug wholesalers and distributors, pharmacies, hospitals, physicians, and insurers. The PDAB will have the authority to conduct cost and affordability reviews and establish upper payment limits (UPLs) for specified drug products.

WHO SERVES ON THE PDAB?

The PDAB will consist of five members, appointed by the governor with the advice and consent of the Senate. Members of the PDAB must have expertise in health care economics, health policy, and clinical medicine. Individuals who are employed by, a consultant to, or a board member of a drug manufacturer or a trade association of a drug manufacturer, or otherwise have a personal or financial interest that has the potential to bias the individual's decision in matters related to conducting the PDAB's activities are prohibited from serving on the PDAB.

SEVEN MEMBERS appointed by the governor as follows:

- One individual representing manufacturers of brand-name drugs.
- One individual representing manufacturers of generic drugs.
- One individual representing employers.
- One individual representing pharmacy benefit managers.
- One individual representing pharmacists.
- One individual representing a mutual insurance company.
- One member of the public.

SEVEN MEMBERS appointed by the governor from a list of nominees submitted by the Speaker of the House of Representatives who represent the following:

- A statewide organization that advocates for senior citizens.
- A statewide organization that advocates for health care.
- A statewide organization that advocates for diversity within communities.
- A labor union.
- Researchers who specialize in prescription drug products.
- The public.

SEVEN MEMBERS appointed by the governor from a list of nominees submitted by the Senate Majority Leader who represent each of the following:

- Physicians
- Nurses
- Hospitals
- Managed care organizations
- The department of management and budget
- Clinical researchers
- The public

The governor shall ensure that the members appointed to the council have knowledge in one or more of the following areas: the pharmaceutical business model; supply chain business models; the practice of medicine or clinical training; consumer or patient perspectives; health care costs trends; clinical and health services research.

HOW DOES PDAB WORK?

Under Senate Bills 483-485, the PDAB has the authority to select one or more drugs that meet any of the following criteria:

The prescription drug product is a brand-name drug or a biologic that, as adjusted annually for inflation in accordance with the Consumer Price Index, has a wholesale acquisition cost of $60,000.00 or more per year or course of treatment or has a wholesale acquisition cost increase of $3,000.00 or more in any 12-month period.

The prescription drug product is a biosimilar that has a wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic.

The prescription drug product is a generic drug that, as adjusted annually for inflation in accordance with the Consumer Price Index, has a wholesale acquisition cost that meets both of the following requirements:

Is $100.00 or more for any of the following:

- A 30-day supply that lasts a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration.
- A supply that lasts a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration.
- One unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage.

Increased by 200% or more during the immediately preceding 12-month period, as determined by the difference between the resulting wholesale acquisition cost and the average wholesale acquisition cost reported over the immediately preceding 12 months.

The prescription drug product is a prescription drug product that may create affordability challenges for health care systems in this state and patients, including, but not limited to, a prescription drug product needed to address a public health emergency.

In selecting a drug product that meets the criteria above, the PDAB shall determine whether to conduct a cost and affordability review for each selected prescription drug. In its review, the PDAB shall determine whether the prescription drug product has led to or will lead to affordability challenges to health care systems or high out-of-pocket costs for patients. If the board determines that spending on a prescription drug product has led to or will lead to affordability challenges, the board may establish an upper payment limit for the prescription drug product no sooner than six months after the date the upper payment limit is established.

WHO IS AFFECTED BY AN UPPER PAYMENT LIMIT (UPL)?

If the board establishes a UPL for a prescription drug product, a prescription drug product purchaser or third-party payer shall not purchase, bill, or reimburse for the prescription drug product in an amount that exceeds the UPL, regardless of whether the prescription drug product is dispensed or distributed in person, by mail, or by other means.

In other words, a UPL will apply to all payments and purchases for a drug with a UPL. This means that the wholesaler must procure the drug at a cost that is compliant with the UPL in that state, which will allow in-state customers to comply with the UPL. The UPL relies on the exact same procurement and financing chain in place today, and the UPL simply establishes a statewide, uniform, UPL on costs so that everyone has affordable access to drugs. Pharmacies can pay no more than the UPL, and pharmacies can bill no more than the UPL.

PDAB REPORTING REQUIREMENTS

Under the legislation, the PDAB must submit a written report to the legislature that includes all the following information:

- Price trends for prescription drug products.
- The number of prescription drug products that were subject to board review, including the results of the review and the number and disposition of appeals of board decisions.
- Any recommendations that the board may have on further legislation to make prescription drug products more affordable in this state.

The bills also require the PDAB to conduct a one-time study conduct a one-time study on all of the following and report its findings to the legislature:

- The prices of generic drugs on a year-to-year basis.
- The degree to which the prices of generic drugs affect yearly insurance premium charges.
- Annual changes in insurance cost-sharing for generic drugs.
- The potential for and history of drug shortages.
- The degree to which the prices of generic drugs affect yearly Medicaid spending.
- The impact of a UPL on 340B program entities.