SB1934 Biosimilar Interchangeability - Senator Antonio Munoz, D-Chicago

SB1934 amends the Pharmacy Practice Act:

- It creates special requirements for the interchange of biosimilar products that have not been implemented for other types of medications.
- These requirements would make it more burdensome for pharmacists to substitute a less expensive biosimilar agent.
- Impeding interchange of less expensive biosimilar agents would increase health care costs.

While this bill was sent back to the Assignments Committee at the end of last year's session, we anticipate that it will reappear or its language will be re-introduced and it is important to make our case today!

This bill is a **premature** attempt to regulate a drug product category that has not yet been defined the United States Food and Drug Administration. In fact, no biological drug product has yet to be identified as a biosimilar product by the FDA. FDA rules are anticipated this year but until then anything done in Illinois would be done blindly. Last year many States defeated attempts to pass similar legislation and in California, Governor Jerry Brown vetoed a similar bill passed by the California Assembly for this very reason.

The FDA and health care providers understand the complex nature of biologics and the FDA has indicated that there will be rigorous review of whether a biosimilar is interchangeable with an approved referenced product. The FDA is the only U.S. regulatory body with the scientific expertise and legislative authority to determine interchangeability.

As with generic drug substitution, it is anticipated that patients and their health care benefit providers (both insurers and employers) will see significant cost savings with biosimilars that are determined to be safe, effective and interchangeable. This bill could establish Illinois standards that could conflict with the national standards being developed by the FDA which could greatly affect the affordability of these drugs.

Once the FDA has established a definition for biosimilar agents and determined interchangeability on each agent, substitution in Illinois should follow the same process that occurs with generic drug substitution. Prescribers who do not wish to have substitution occur will merely need to write "Do not substitute" on the prescription.

SB1934 is all of the following:

- Premature
- Unnecessary
- Costly

The members of the Illinois Pharmacists Association and the Illinois Council of Health-System Pharmacists urge you to **Please VOTE NO on SB1934!**

Thank you!