

General Law Committee JOINT FAVORABLE REPORT

Bill No.: SB-197

Title: AN ACT CONCERNING BIOLOGICAL PRODUCTS.

Vote Date: 3/15/2018

Vote Action: Joint Favorable

PH Date: 2/27/2018

File No.:

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SPONSORS OF BILL:

Representative Peter A. Tercyak, 26th District
Senator Kevin Witkos, 8th District

REASONS FOR BILL:

The reason for this bill is to allow pharmacists to use an interchangeable biologic product that meet the standard of interchangeability by the Federal Drug Administration. The pharmacy will post a sign that notifies its patrons that the pharmacy may be able to interchange the drug product or biologic with a less expensive drug unless you do not approve. If you are given an interchangeable drug you must be notified no later than 48 hours. The pharmacist will also notify the prescriber within 48 hours. The patients chart will be documented by the pharmacist.

Also prior to subscribing a biological product a prescribing practitioner shall discuss with patient or a representative the treatment methods, alternatives and risks associated with the product. This discussion must be documented in the patient's medical record no later than 24 hours after the discussion has taken place.

The commissioner shall adopt regulations in accordance with Chapter 54, to carry out provisions in this section. From the effective date of the section until December 31, 2019, no person shall deliver an interchangeable biologic product to a patient through mail, shipment or parcel delivery services. The commissioner shall study the impact the impact of delivery through mail and report the results of the study.

RESPONSE FROM ADMINISTRATION/AGENCY:

Michelle Seagull, Commissioner of Consumer Protection, State of Connecticut

Commissioner Seagull stated that this proposal is similar to the final version from the 2017 Legislative Session. Department of Consumer Protection reiterated that for patient health and safety patients and prescribers must be notified upon dispensing a substitution.

NATURE AND SOURCES OF SUPPORT:

Tim Boyd, MPH, Director of State Policy, National Organization for Rare Disorders

Mr. Boyd said this bill would ensure that patients with rare disorders receive optimum care. The NORD applauds the development of these innovative and valuable therapeutic treatments. Healthcare providers need to know what was dispensed to the patient and if a substitution was made and if so what was the alternative product.

Kate Kulesher Jarecke, Director, State Government Affairs, Sandoz

Sandoz is a division of Novartis, the world leader in developing, manufacturing and commercializing biosimilars. SB197 could allow Connecticut pharmacists the ability to dispense safe and less expensive biologic medications to patients by allowing substitution of an interchangeable biologic. We do respectfully ask that SB197 be amended and strike the mail order provisions. Since 2013, 37 states have updated their practice act to allow for interchangeable biologic substitution and no other state has added mail order provisions.

NATURE AND SOURCES OF OPPOSITION:

Paul R. Pescatello, JD, PhD, Senior Counsel and Executive Director of the Connecticut Bioscience Growth Council

Connecticut Bioscience Growth Council is a committee of the Connecticut Business Industry Association's biotech and biopharma members. Though we support SB197, we feel it requires additional scrutiny and a crucial revision. The mail order section of this bill is counterproductive to patient interests. Mail order is important to patient's ability to access the product and we hope that SB197 will be revised to allow it.

Brynna Clark, Northeast Government Relations liaison for Walgreens, Connecticut Association of Community Pharmacies

Chain pharmacy is proud to support policies that enable pharmacists to provide cost-effective healthcare. New laws allowing for substitution of interchangeable biosimilar products should align with how today's healthcare systems work so as to promote use of the most cost-effective medications. Decades ago laws were passed to permit generic substitutions, it was called "generic savings pass-through laws). SB 197 contains this language in Sec. 1(h). The nation's healthcare systems have evolved to a point where prescriptions medications are now covered by insurance. If the pharmacy does not follow the formula set forth by the insurer the cost of the drug may not be covered and we therefore are out of compliance with the law. Also, we would like the 48 hour notification of dispensing be changed to 5 days as it is written around the country.

Patrick Plues, Vice President, State Government Affairs, Biotechnology Innovation Organization

BIO supports most of SB 197, however we do not support the bill as it relates to mail order pharmacy. We support efforts across the country to allow pharmacy substitutions, however the mail order section of this bill will ultimately restrict access to the patients who would benefit from these medicines.

Molly Burich, Associate Director of Biosimilars, Reimbursement and Pipeline, Boehringer Ingelheim Pharmaceutical, Inc.

Boehringer Ingelheim Pharmaceutical supports the need to update the Pharmacy Practice Act in Connecticut, as we have seen in 37 other states and Puerto Rico, however BI cannot support SB 197 as written. Updates to the Pharmacy Practice Act are critical for patients in CT to fully benefit from biosimilars. The prohibitive language for the mail order portion of the bill will end up hurting patients.

Connecticut State Medical Society, Connecticut Chapter of the American College of Surgeons Professional Associations.

CSMS believes that if a pharmacy switches or substitutes a medication the prescriber be notified prior to the substitution. We do not oppose the intent of SB197 and do know that pharmacies and pharmacists have the capability to notify prescribers immediately, we caution implementing the 48 hour notification.

Connecticut Association of Health Plans

Connecticut Association of Health Plans opposes bill SB197. Mail order provides patients with ease of having their prescription drugs delivered directly to their homes and very often for a lesser price.

Margherita Giuliano, Connecticut Pharmacists Association

Ms. Giuliano supports legislation that offers alternative, affordable drugs we oppose SB197. This bill will make workflow burdensome and unnecessary for pharmacists related to the documentation that will be required under this bill.

Deb Hutton, Senior Director , Cigna State Government Affairs

While CIGNA understands the good intentions of SB 197 we do not believe that the proposed restrictions placed on notification, reporting, transport and delivery are appropriate.

April C. Alexander, Assistant Vice President, State Affairs, Pharmaceutical Care Management Association

Ms. Alexander opposes SB 197 as its policies would establish a barrier to effective cost management and higher quality in healthcare and deprive patients from accessing lower cost medications.

Heather R. Cascone, Senior Director, Government Affairs, Express Scripts

Express Scripts does not support SB 197 due to Section 1(n). If this bill should advance please consider removing this section.

Connecticut Hospital Association

CHA does not oppose Section 1 of this bill, however opposes Section 2 as it goes well beyond setting rules for substitutions of biologicals. CHA urges that the Committee delete Section 2 of this bill.

Reported by: Bonnie Gray, Asst. Clerk

Date: 03/23/2018

