Temple University Beasley School of Law | Center for Public Health Law Research

Summary Report

Biosimilar Substitution Laws

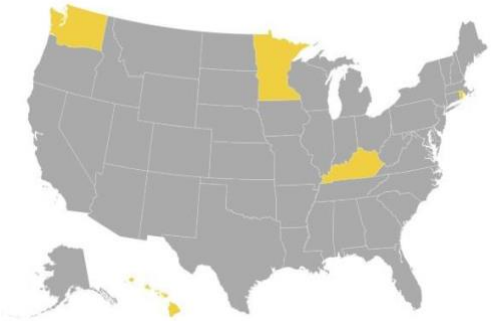
Biologics are vaccines and other therapeutic products isolated from human, animal, or microorganism tissues and cells. States have started implementing policies that regulate pharmacists' ability to substitute prescribed biologics with biosimilars — products that are highly similar to the prescribed biologic. These regulations impact pharmacist autonomy, patients' rights, and the role of the prescribing physician.

This report summarizes key findings from the Biosimilar Substitution Laws dataset. Additional maps and tables are available at www.lawatlas.org.

States Regulating Biosimilar Substitution

Thirty-three states have laws that regulate a pharmacist's authority to substitute a biosimilar for a prescribed biologic.

Jurisdictions: 33 (AZ, CA, CO, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MA, MN, MO, MT, NJ, NM, NC, ND, OH, OR, PA, RI, SC, TN, TX, UT, VA, WA)



States Requiring Pharmacists to Substitute a Biosimilar for a Biologic

In five states, pharmacists must substitute the prescribed biologic with a biosimilar if a biosimilar meets the required criteria. A sixth state, Iowa, requires pharmacists to substitute the prescribed biologic with a biosimilar meeting the required criteria only when the cost of the prescription will be paid with public funds.

Jurisdictions: 5 (HI, KY, MN, RI, WA)

States Where a Biosimilar Must Cost Less in order to Substitute

In 17 states, a biosimilar must cost less than the prescribed biologic in order for substitution to be permitted.

Jurisdictions: 17 (CA, CO, GA, HI, IA, KS, KY, LA, MD, MN, MO, MT, NM, NC, OH, RI, WA)