

45 States Now Have Biosimilar Substitution Laws

Monday, February 11, 2019

Forty-five states and Puerto Rico have now enacted laws that permit or require pharmacists to dispense an interchangeable biological product in certain situations. The remaining states that have not yet passed legislation on the topic are: Alabama, Arkansas, Maine, Mississippi, Oklahoma, and the District of Columbia. We have been tracking and summarizing these laws over the past three years, and you can find our updated chart [here](#).

There are many similarities across these laws. Typically, in order for the pharmacist to make a substitution, the biosimilar must be "interchangeable" with the prescribed biologic (as determined by FDA), and the pharmacist must provide notice to the patient and the prescriber. However, some states take a more unique approach, like South Carolina, which allows pharmacists to substitute a biosimilar if it is interchangeable or if the pharmacist determines in his or her "professional judgment" that the biosimilar is therapeutically equivalent to the prescribed biologic. In addition, West Virginia requires pharmacists to substitute a less expensive, interchangeable biologic unless the pharmacist believes that the biosimilar is not suitable for the patient. To date, no biosimilar has been approved by FDA as interchangeable with its reference biological product, although more biosimilars have secured U.S. licensure over the past year and FDA has been busy implementing programs and policies for the burgeoning industry, as we most recently discussed [here](#).

Some states have also enacted these biosimilar substitution laws with a focus on lowering the cost of drugs and biologics by requiring substitution if a cheaper interchangeable biosimilar is available, particularly if the state or other governmental agency is paying for the drug. For example:

- Nevada does not allow patients to refuse a substitution of a less expensive, interchangeable biosimilar if the product is being paid for by a governmental agency.
- Michigan requires the pharmacist to pass on the cost savings (i.e., the difference in wholesale price to the pharmacist) to the purchaser or third-party payment source when substituting a less expensive, interchangeable biosimilar.
- New York requires the pharmacist to substitute an interchangeable biosimilar if it is less expensive than the prescribed biologic and the prescriber does not instruct otherwise; if the biosimilar is not available, the pharmacist can dispense the prescribed biologic only if he or she agrees to dispense it for a price that does not exceed the price that would have been charged for the biosimilar if it was available.

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