

Biosimilars: Interchangeable products may increase patient access

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Much like substituting a generic drug for a brand-name, substituting an interchangeable biosimilar product may increase patient access to needed therapeutics and reduce treatment cost. State laws about biosimilars vary.

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How it works in Arizona

Arizona's H2310 (Chapter 293, Section 2. Section 32-1963.01) defines an interchangeable biological product as a biosimilar that meets one or both of the following qualifications:

1. The FDA has licensed the biological product and determined it meets the safety standards for determining interchangeability
2. The FDA has determined the biological product to be therapeutically equivalent as specified in the latest supplement to the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book)

Arizona allows a pharmacist to substitute a biosimilar product for a prescribed biological if **all** of the following conditions are met:

- The FDA has determined that the substituted product is an interchangeable biological product.
- The prescribing provider does not designate that substitution is prohibited.

- The pharmacy informs the patient (or person presenting the prescription) of the substitution.
- The dispensing pharmacist (or pharmacist's designee) makes a record of the specific product provided to the patient; the record must be electronically accessible or communicated by other means to the prescribing provider.
- The pharmacy keeps a record of the interchangeable biological product dispensed.

The pharmacy must also inform the patient of the price difference between the biological product prescribed and the interchangeable biological product.

Learn more about interchangeable biological products

The FDA offers great resources for providers and patients. Here are some links to get you started:

- [Interchangeable Biological Products](#) (one-page summary PDF)
- Comprehensive [biosimilars webpage](#)
- Materials for [healthcare providers](#) (videos, fact sheets, infographics, stakeholder toolkit)
- [Biosimilar Basics for Patients](#) (includes resources in Spanish)
- [Overview of Biosimilar Products](#) (two-page overview PDF)
- [Biosimilar Regulatory Review and Approval](#) (two-page PDF)

Other states may have different laws regarding biosimilar interchangeability. Cardinal Health's website includes a [searchable database of state resources](#).

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