ESSENTIAL INFORMATION
October 2017

Biosimilar Substitution Laws
Prepared by the Policy Surveillance Program Staff

SUMMARY

This LawAtlas map shows how state laws vary in how they regulate pharmacists’ ability to substitute prescribed biologics with products called “biosimilars.”

ABOUT BIOSIMILARS LAWS & THE DATA

Biologics are vaccines and other therapeutic products isolated from human, animal or microorganism tissues and cells that are used to treat medical conditions. A biosimilar is a product that is highly similar to a biologic, as the name implies.

State laws that regulate the substitution of biosimilars identify the information that pharmacists need to share with prescribers and patients, define recordkeeping and labeling requirements, and address pharmacists’ liability for substituting a biosimilar for a prescribed biologic.

Until recently, because of the difficulty of producing biologics, the inability to produce exact copies, and a lengthy FDA-approval process required to bring them to market, few alternatives to biologics existed for patients, physicians, and pharmacists. Biosimilars are one alternative, and the new abbreviated approval process means they will be more likely to enter the market. While not identical copies of a biologic, biosimilars have no clinically meaningful differences in terms of safety and effectiveness from the original biologic or “reference” product.¹

In 2009, President Obama signed the Biologics Price Competition and Innovation (BPCI) Act. Based on the Act, the FDA has reviewed and established a new, streamlined process for approving biosimilars. This abbreviated process is meant to open the market and increase competition to drive down prices for expensive biologics, which are used to treat cancer and other complex diseases.

As part of the abbreviated process, the FDA has established two tiers of approval. The first tier is approval of a biologic as a biosimilar, meaning it is highly similar to an already licensed reference biologic. The FDA essentially treats the biosimilar as a separate biologic requiring approval, and it must show no clinically meaningful differences from the reference product. Once approved as a biosimilar, it can then be prescribed by a physician as an alternative to the reference biologic — both products function in the same way, but one may be preferable to the other for clinical or cost reasons. If a biologic has been approved as a biosimilar, the physician may write a prescription for the biosimilar as an alternative to the reference biologic, but pharmacists cannot autonomously substitute a biosimilar for the prescribed biologic.

The second tier is approval as an “interchangeable” biosimilar, which addresses substitution by pharmacists filling a prescription. With traditional, chemically synthesized drugs, pharmacists may autonomously choose to substitute a generic drug for a brand name drug. Pharmacists may choose to make this switch because of cost to the patient or insurance company, or because of what they have in stock, among other reasons. For biologics, the FDA has indicated that pharmacists may only choose to substitute a biosimilar for a reference biologic if the biosimilar has been approved as interchangeable. In addition to meeting the biosimilarity standard, an interchangeable designation means it is expected to produce the same clinical result as the reference product in any given patient.

The FDA approved the first biosimilar in the United States in March 2015. The FDA reported in September 2015 that there were 57 products proposed as biosimilars for 16 reference biologics, with numerous other biosimilars developers in early discussions with the FDA. Three biosimilars were approved in 2016, and three additional biosimilars have been approved this year, for a total of seven FDA-approved biosimilars.

While the FDA has yet to approve any interchangeable biosimilars, and the draft guidance it issued early this year on the approval process for interchangeable biosimilars has not yet been finalized, many states have started passing laws that regulate the issue of pharmacist substitution of biosimilars.

This LawAtlas map details state pharmacy requirements for the substitution of biosimilars for biologics. It includes notification requirements for pharmacists to prescribers and patients, recordkeeping and labeling requirements, and pharmacist liability for substituting a biosimilar for a prescribed biologic.

While individual state criteria may vary, the laws tend to address the same set of core requirements associated with pharmacist substitution of biosimilars.

---

2 Id.
3 Id.
As of October 2017, 33 states regulate whether interchangeable biosimilars may be substituted for prescribed biologics. Seventeen states mandate that biosimilars may only be substituted for a prescribed biologic when the biosimilar is less expensive than the biologic. Five states mandate that pharmacists are required, rather than permitted, to substitute biosimilars for biologics upon meeting certain criteria.

**NAVIGATING THE DATA**

There are two ways to navigate the data by clicking the **Filter** tab or the **Explore** tab — for each option, the data can be visualized in a map and table format or in jurisdiction profiles.

**Filter**
The dataset homepage will default to the Filter tab. Here, users may answer a series of questions to learn more about the characteristics of the laws. Answering more than one question will show all the jurisdictions that meet the combined criteria. Criteria selected will be listed above the questions, and can be removed by clicking the white X or by clicking “Reset” above the questions.

**Explore**
Users can access Explore by clicking the Explore tab in the bar above the questions. Using Explore, users will see the answers to one question across all jurisdictions.

The primary questions in this dataset are:

1. Does the state regulate pharmacist substitution of biologics?
2. Can pharmacists substitute a biosimilar for a biologic?
3. Can the prescriber prevent substitution of an interchangeable biosimilar for the biologic?
4. Does the prescriber need to be notified of the substitution?
5. Must the patient be notified of the substitution?
6. For how many years must pharmacists keep records of the substitution, if specified?
7. What are the labeling requirements specific to the substitution of biologics?
8. Does the law explicitly provide a liability shield for pharmacist substitution of a biologic?
9. Must the state pharmacy board maintain a list of interchangeable biologics on their website?

**DISPLAYING THE RESULTS**

There are two display modes once criteria have been selected by using either the Filter or Explore tab — **Map display mode** and **Profiles display mode**.

**Map Display**
LawAtlas.org dataset homepages default to the map display mode. When querying the data using the Filter tab, all jurisdictions that meet the criteria selected will display in one tone of yellow. Those jurisdictions that do not meet the criteria selected will be colored gray. When querying the data using the Explore tab, the map will illuminate with colors from yellow to red that are associated with the various answer choices (the color-coding is defined by the key to the left of the map).
Below the map, a table will appear. Using the Filter or Explore tab to navigate the questions will change the display:

- Using the Filter tab, you can select an unlimited number of criteria and the applicable jurisdictions that meet the combined criteria will be displayed in the table below.
- Using the Explore tab, you can isolate a single criterion and the applicable jurisdictions will appear in the table below.

**Profiles Display**
The Profiles display presents the results of the criteria selected in a text-based format for each applicable jurisdiction. Using the Filter tab, jurisdictions that meet the criteria selected will display. Using the Explore tab, jurisdictions that meet the criterion selected will display. If no criteria are selected, the full profiles for each state will appear under both Filter and Explore.

**Profile Legend**
Within each Profile box, above the questions and answers, there are additional options and information useful in exploring the law:

<table>
<thead>
<tr>
<th>§§</th>
<th><strong>Toggle Legal Text</strong> – Selecting this option will show all the legal text used to answer questions for this jurisdiction.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Toggle Full Place Profile</strong> – Selecting this option will show all questions and answers for this jurisdiction, regardless of what was selected using the Filter or Explore tabs.</td>
</tr>
<tr>
<td></td>
<td><strong>Toggle Size</strong> – Selecting this option will make the profile larger, but will not change the information displayed.</td>
</tr>
</tbody>
</table>

**Legal Text History** – This interactive timeline displays when changes in the law have occurred within a jurisdiction. Using the arrows to the left or right, users may explore how the law has changed over time as new amendments to the law have been enacted. The timeline will change from gray to a shade of yellow when the jurisdiction passed its first relevant law. Each change in the law after that is marked by a break in the timeline.

![Timeline Image]

**Map and Profile Legend**
There are a few symbols to be aware of in both Map and Profiles display modes:

| §  | **Section Symbol** – Clicking this symbol will open a window that displays excerpts from the law that correspond to the question and answer. |

---

Essential Information for Biosimilar Substitution Laws – October 2017
Caution Note – Clicking on this symbol will open a small window that displays text that describes important caveats about the question and answer.

DATASET RESOURCES
Each dataset homepage includes the following resources available for download:

- **Data**: The Data file exports in CSV format and may contain two tabs. The “Statistical Data” tab contains the legal variables coded in the dataset, displayed as values defined in the accompanying Codebook. The “Summary Data” tab contains the legal variables coded in the dataset in text form, as well as the accompanying citations and any caution notes that may be included. Note: if there is only one tab available for download it will be the “Statistical Data” as described above.

- **Codebook**: The Codebook defines all of the coded variables in the dataset. The Codebook lists the question, question type, variable name, variable value and variable label. The Codebook should be used in conjunction with the Statistical Data extract.

- **Research Protocol**: The Research Protocol is a comprehensive document that outlines the entire methodology of the project, including the scope, inclusion and exclusion criteria, data collection methods, definitions, coding scheme decisions, as well as the quality control process.

- **Summary Report**: The Summary Report provides a snapshot of important findings from the dataset.

ADDITIONAL INFORMATION
The FDA released draft guidance regarding biosimilar interchangeability in January 2017, and is expected to issue either revised draft guidance or final guidance within the next two years. Several resources are listed below to more fully explain the issues surrounding biosimilars.


---


Essential Information for Biosimilar Substitution Laws – October 2017

This collection of biosimilar substitution laws does not provide legal advice, nor does it address law enforcement, administrative policies, case law or any other sources of law. Should you have a specific question about biosimilars laws in your state, please contact an attorney in your jurisdiction.