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Fact Sheet

State Biosimilar Substitution Laws Could Reduce Consumer Access and Savings

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Biosimilar drugs are less expensive but equally safe and effective substitutes for expensive biologic drugs. Yet biosimilars that qualify for automatic substitution often have to meet more stringent state substitution requirements than traditional generic drugs. This differential treatment in state laws could contribute to lingering concerns about biosimilars and unnecessarily reduce consumer access to and savings from these increasingly important products.

Biologic drugs are made from living organisms and are used to treat conditions that commonly affect older populations, such as cancer, multiple sclerosis, and rheumatoid arthritis. Biologics differ from traditional, chemical-based prescription drugs in many ways, but one of the most obvious differences is price. Many of the most widely used biologics have annual prices that exceed $30,000 per year.[1]

Patients facing high prescription drug costs often see substantial savings when they switch from a brand-name drug to a generic equivalent; however, this option is not yet widely available for biologic drugs. It wasn't until 2010 that the US Food and Drug Administration (FDA) received authority to approve biosimilars, which are highly similar to and have no clinically meaningful differences from their originator biologic equivalents.[2] Twenty-two biosimilars are currently on the market,[3] and FDA has designated only one of the marketed products as interchangeable—meaning it has met additional requirements and can be substituted by a pharmacist without consulting the prescriber.[4]

Despite a relatively slow start, the biosimilar market is expected to grow rapidly over the next decade.[5] In the United States, spending on biologics is now growing more than 10 times faster than spending on traditional drugs; this trend will likely continue as biologics capture more of the prescription drug market.[6] Meanwhile, products representing over half of current biologic spending are either facing or could soon face biosimilar competition.[7]

These trends indicate that consumers and payers could soon see substantial savings from increased utilization of less expensive biosimilars. However, even with a strong body of research that shows these drugs to be safe and effective, state biosimilar substitution laws may be standing in the way.

Given the potential implications for consumers and overall health care spending, AARP's Public Policy Institute recently analyzed drug substitution laws in all 50 states and the District

of Columbia to identify specific differences in state requirements for generic and interchangeable biosimilar substitution.

Considerable variation in state drug substitution laws

Over the past decade, every US state and the District of Columbia passed legislation regulating pharmacist substitution of biologics with interchangeable biosimilars. Often these laws were controversial, as they typically included additional requirements that did not apply to traditional generic substitution.[8]

Supporters of additional requirements for interchangeable biosimilar substitution—which included brand-name biologic manufacturers—contended that increased regulation would protect both patient safety and the prescriber-patient relationship as well as reduce the possibility of adverse drug events.[9] Many of these arguments mirror concerns previously raised about traditional generic drug substitution that ultimately proved groundless.[10]

In contrast, generic drug manufacturers, health insurers, and some consumer groups argued that some drug substitution requirements can create barriers that reduce generic substitution and that additional restrictions could limit biosimilar utilization and savings.[11] The FDA and the US Federal Trade Commission echoed these concerns.[12]

Despite extensive clinical evidence that biosimilars are safe and effective—and that they can be safely switched with their brand-name biologic counterparts[13]—most state drug substitution laws continue to include more stringent requirements for interchangeable biosimilars.[14]

Differential treatment of biosimilar substitution

Our analysis found that state drug substitution laws differentiate between generic and interchangeable biosimilar drugs in a variety of ways (see appendix). For example, 47 states and the District of Columbia require pharmacists to notify the prescriber when they substitute an interchangeable biosimilar. Pharmacists typically must complete this communication within a specific timeframe (e.g., five business days) and via specific channels (e.g., electronic prescribing system, telephone, or facsimile). Only 2 states have comparable requirements for traditional generic substitution.

Similarly, many state drug substitution laws also require pharmacists to notify or obtain consent from patients prior to substitution, which can lower generic drug utilization.[15] However, while 29 states and the District of Columbia require patient notification for traditional generic drugs, 40 states and the District of Columbia require such notification for interchangeable biosimilars. Thus, patients in 11 states will only receive a notification, potentially for the first time, when their pharmacist substitutes an interchangeable biosimilar for its brand-name counterpart.

Some pharmacists also face unique record-keeping requirements when they substitute an interchangeable biosimilar. Thirteen states require pharmacists to keep written or electronic records of each interchangeable biosimilar substitution or each biological product dispensed for a defined period (e.g., at least two years). There are no comparable state requirements for traditional generic substitution.

Yet another difference stems from mandatory substitution laws that require pharmacists to dispense a generic drug when one is available. Although 18 state laws include mandatory generic substitution, only 12 states require substitution for interchangeable biosimilars, giving pharmacists more discretion in the interchangeable biosimilar substitution process.[16]

Benefits of updating state biosimilar substitution laws

Less expensive generic drugs are associated with improved adherence and health outcomes,[17] and pharmacy-level generic substitution is a known driver of generic uptake and price competition.[18] However, the more stringent requirements for interchangeable biosimilar substitution could prevent biosimilars from having a similar impact. Different patient and provider notification requirements could contribute to lingering patient and health care provider concerns about biosimilars and interchangeable biosimilar substitution[19] as well as reduce uptake,[20] particularly since patient[21] and pharmacist awareness of biosimilars remains low.[22] In addition, potentially onerous communication and documentation requirements could reduce pharmacist willingness to substitute interchangeable biosimilars for their brand-name counterparts.[23]

State interchangeable biosimilar substitution requirements can also help improve patient access. Consumers often face high cost-sharing for brand-name biologics, particularly if their insurer requires them to pay a percentage of the drug's price instead of a flat copayment.[24] Like generic drugs, lower-priced interchangeable biosimilars could help reduce these out-of-pocket costs and, in so doing, improve patient adherence and health outcomes[25] as well as reduce overall health care spending.[26] The biosimilar market will be unable to provide such benefits if interchangeable biosimilar substitution is unnecessarily constrained.

Between the rapid rise in the number of biologic drugs and the growing use of products already on the market, biologics are becoming an increasingly common treatment option. Given their substantial costs for patients and government programs, it is critical to ensure that the biosimilar market is competitive and sustainable. As more interchangeable biosimilars begin to enter the market, one critical aspect of this work will be updating state drug substitution laws to ensure that patients have appropriate access to these important products.

Appendix. Comparison of State Substitution Requirements for Traditional Generics and Interchangeable Biosimilars

		Generic							Interchangeable Biologic						
	State Regulation	Automatic Substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention	Automatic substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention
Alabama	Alabama Code § 34-23-8; 34-23-8.1	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
Alaska	Alaska Statutes § 08.80.295	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Arizona	Arizona Rev. Statutes § 32-1963.01	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
Arkansas	Arkansas Code § 17-92-503	N	Y	N	N	N	N	N	N	Y	N	Y	Y	Y	Y
California	California Business and Professions Code § 4073; 4073.5	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Colorado	Colorado Rev. Statutes § 12-280-125	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Connecticut	Connecticut Gen. Statutes § 20-619	N	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	N
Delaware	Delaware Code Ann. 24 § 2549; 2549A	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Florida	Florida Statutes § 465.025; 465.0252	Y	Y	Y	N	N	N	N	N	Y	Y	N	N	N	Y
Georgia	Georgia Code § 26-4-81	N	Y	N	N	N	N	N	N	Y	N	Y	Y	Y	N
Hawaii	Hawaii Rev. Statutes § 328-92	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
Idaho	Idaho Admin. Code § 24.36.01; Code § 54-1769	N	Y	N	N	N	N	N	N	Y	N	Y	Y	Y	N
Illinois	225 Illinois Comp. Statutes 85/25; 85/19.5	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Indiana	Indiana Code § 16-42-22; 16-42-25	Y	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Iowa	Iowa Code § 155A.32	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Kansas	Kansas Statutes Ann. § 65-1637	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Kentucky	Kentucky Rev. Statutes § 217.822	Y	Y	N	N	N	N	N	Y	Y	N	Y	Y	Y	Y
Louisiana	Louisiana Admin. Code 46-25 § 2517	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	N	N
Maine	Maine Rev. Statutes Title 32 §13781	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
Maryland	Maryland Health Occupation Statutes § 12-504; 12-504.1	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N

= *Difference from Generic Regulation*

	State Regulation	Generic							Interchangeable Biologic						
		Automatic Substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention	Automatic substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention
Massachusetts	Massachusetts Gen. Laws Chapter 112, § 12D; 12EE	Y	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Michigan	Michigan Comp. Laws § 333.17755	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Minnesota	Minnesota Statutes § 151.21	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
Mississippi	Mississippi Code Ann. § 73-21-117	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
Missouri	Missouri Rev. Statutes § 338.056; 338.085	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
Montana	Montana Code Ann. § 37-7-505; 37-7-506	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Nebraska	Nebraska Rev. Statutes § 38-28,111	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
Nevada	Nevada Rev. Statutes 639.2583	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
New Hampshire	New Hampshire Rev. Code 318:47-d; Ph 704.6; 318:47-dd	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
New Jersey	New Jersey Rev. Statutes § 24:6E-7; 24:6k-3	Y	Y	N	Y	Y	Y	N	N	Y	N	Y	Y	Y	N
New Mexico	New Mexico Statutes Ann. § 26-3-3	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
New York	New York Education Law §6816-a	Y	Y	N	N	N	N	N	Y	Y	N	Y	Y	Y	N
North Carolina	North Carolina Gen. Statutes § 90-85.28	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N
North Dakota	North Dakota Century Code § 19-02.1-14.1; 19-02.1-14.3	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y
Ohio	Ohio Rev. Code § 4729.38	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Oklahoma	Oklahoma Admin. Code § 317:30-5-76; Oklahoma Statute § 59-355.4	N	Y	N	N	N	N	N	N	Y	Y	Y	N	Y	N
Oregon	Oregon Rev. Statutes § 689.515; 689.522	N	Y	N	N	N	N	N	N	Y	Y	Y	Y	N	Y
Pennsylvania	Pennsylvania Statutes Title 35 § 960.3; Pennsylvania Law 830, No. 95	Y	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Rhode Island	Rhode Island Gen. Laws § 5-19.1-19; 5-19.1-19.1	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N
South Carolina	South Carolina Code Ann. § 40-43-86	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N

= *Difference from Generic Regulation*

	State Regulation	Generic							Interchangeable Biologic						
		Automatic Substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention	Automatic substitution	Dispense as Written	Notification *(pharmacist to patient)*	Notification *(pharmacist to provider)*	Timeframe *(pharmacist to provider)*	Communication Method *(pharmacist to provider)*	Record Retention
South Dakota	South Dakota Codified Laws § 36-11-46.1; 36-11-46.2; 36-11-46.9; 36-11-46.10	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Tennessee	Tennessee Code Ann. § 53-10-204; 53-10-211	Y	Y	N	N	N	N	N	N	Y	N	Y	Y	Y	N
Texas	Texas Occupations Code § 562.008; 562.009; 562.0051	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Utah	Utah Code Ann. § 58-17b-605; 58-17b-605.5	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N
Vermont	18 Vermont Statute Ann. § 4605; 4606	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
Virginia	Virginia Code Ann. § 54.1-3408.03; 54.1-3408.04	N	Y	Y	N	N	N	N	N	Y	Y	N	N	N	Y
Washington	Washington Rev. Code § 69.41.120; 69.41.130; 69.41.125; 69.41.193	Y	Y	N	N	N	N	N	Y	Y	N	Y	Y	Y	N
West Virginia	West Virginia Code §30-5-12b; 30-5-12c	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
Wisconsin	Wisconsin Statutes § 450.13; 450.135	Y	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	N
Wyoming	Wyoming Statutes Ann. § 33-24-149	N	Y	N	N	N	N	N	N	Y	N	Y	Y	Y	N
District of Columbia	DC Code § 48-803.02; 48-803.03; 48-803.03a; 48-803.04; 48-803.06	N	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	N

= *Difference from Generic Regulation*

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