Prescription Drug Resource Center

Generic Drug Substitution Laws

May 3, 2019

Compiled by the NCSL Health Program

Background

Buying generic versions of prescription drugs instead of their brand-name equivalents can significantly reduce overall prescription drug costs across the health care system. According to the IQVIA Institute, generics make up approximately 90% of all prescriptions but they are only a fraction of overall costs. Brand-name drugs make up the remaining 10% but account for 79% of all drug spending. Furthermore, IQVIA estimates that generic drugs saved the U.S. health care system $1.67 trillion from 2007 to 2016.

Pharmacists can substitute a name-brand drug with a less expensive generic version when dispensing a prescription, depending on state law. Several factors determine whether a pharmacist can make a generic drug substitution: any difference in price between the two drugs, if the physician has blocked the substitution, patient consent and drugs that are approved as bioequivalent. The Food and Drug Administration (FDA) defines a generic drug as bioequivalent if it contains the same active ingredient(s), it is of the same dosage and route of administration, and it is identical in strength or concentration.

Once a generic drug's bioequivalence is proven, the FDA considers it interchangeable with the brand-name medicine. According to the FDA, an interchangeable product is a product that meets additional requirements. As part of fulfilling these additional requirements, evidence is needed to show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Additionally, state laws usually require each generic drug also be designated as interchangeable to be substituted for its brand-name counterparts.

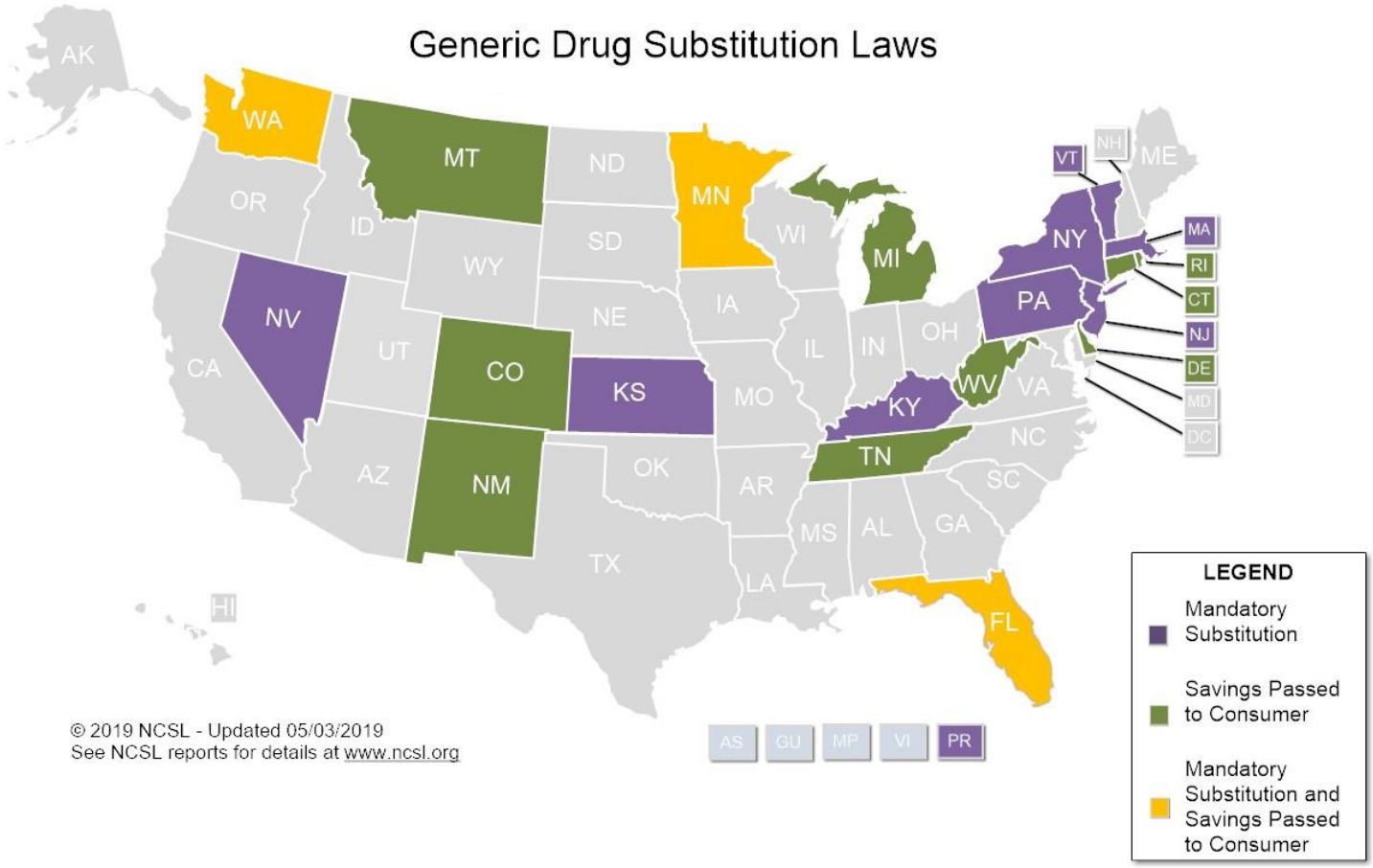
Some states use the FDA publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations*," more commonly known as the Orange Book, to help determine which medicines can be safely substituted by pharmacists for one of equal standing. This is called a "positive formulary" where the drugs on the list are approved as equal to the name-brand drug. Other states use a "negative formulary" approach by creating a list of drugs that are not equivalent to a brand-name drug.

Some drugs are classified as "narrow therapeutic index drugs" (NTIs) that have such narrow dosing requirements it makes substitution potentially unsafe. Certain drugs also have substitution restrictions. For example, in Connecticut, Hawaii, Illinois, Tennessee and Utah, generic substitution for anti-epileptic drugs is prohibited because of concerns about potential adverse reactions.

State Action

To increase access to generic drugs, some state lawmakers have pursued allowing a pharmacist to make a generic drug substitution. Twelve states and one territory require a pharmacist to replace a brand-name drug with a generic if all other prescribing requirements are met: Florida, Kansas, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Puerto Rico, Vermont and Washington. Conversely, in Oklahoma, a pharmacist is not allowed to

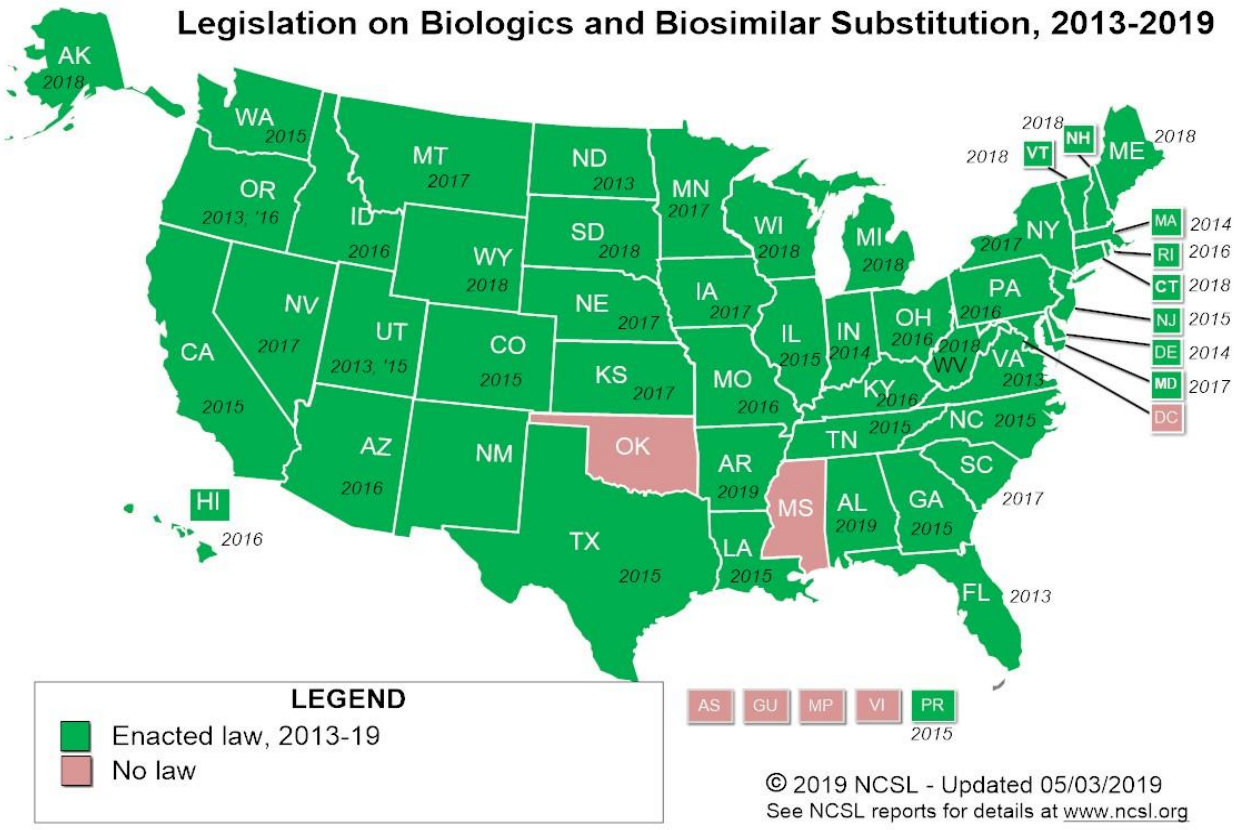
substitute any pharmaceutical products without the consent of both the physician and the patient. In Rhode Island and Washington, a patient may request a generic instead of a name-brand drug, but their prescriber must authorize the generic.



All states allow prescribers options to block pharmacist substitutions. Most involve the prescriber specifically prohibiting a substitution by stating that the name brand drug is (medically) necessary for the patient. The prescriber must also use language such as “no substitution should be made”, “do not interchange” or “dispense as written/D.A.W.” Most states also call for the patient’s consent for a generic drug substitution, or at least that the patient be notified of the change. The states that do not mandate this are Alabama, Idaho, Illinois, Michigan, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Tennessee, Washington and Wyoming.

Most states require that the substitution be less expensive or equal in price to the name-brand drug. Ten states do not have this type of law: Alaska, Arkansas, Idaho, Iowa, Nebraska, Oklahoma, South Carolina, South Dakota, Utah and Wyoming. Some states also explicitly require that the full cost savings, which is the difference between the brand-name

and the generic, be passed directly on to the consumer. States with this requirement include Colorado, Connecticut, Delaware, Florida, Michigan, Minnesota, Montana, New Mexico, Rhode Island, Tennessee and West Virginia. Washington also has this requirement but differs in that 60% of the cost savings is passed directly to the consumer.



A special type of drug product—biologics—are subject to additional requirements for drug substitution. Biologic drugs are complex molecules produced by programmed cells instead of with synthetic chemicals. The FDA maintains a list of approved biologic drugs called the Purple Book but only a handful of their generic equivalents called "biosimilars" have been approved. Manufacturers of biosimilars must demonstrate that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and efficacy. Due to the way biologic and biosimilar products are manufactured, slight variations are normal and expected from lot to lot. As a result, truly identical "generic" versions are currently impossible to produce.

Differences exist between generics and biosimilars. For example, the manufacturer of a generic drug must demonstrate that the generic is bioequivalent, or identical, to the brand name drug and thus interchangeable—a status no biosimilar has achieved. Biosimilar manufacturers can only demonstrate that their product is highly similar to the reference product rather than bioequivalent. Since biosimilars are not considered interchangeable, patients may need a prescription from their provider written specifically for that biosimilar.

So far, 47 states have passed biosimilar substitution laws with most requiring that the drug be designated as interchangeable. These laws usually include allowing doctors to block the substitution by writing that the brand is

medically necessary, the pharmacist notifying the prescriber about the change and only making the substitution for a cheaper drug alternative.

Conclusion

Many policymakers recognize the potential for large cost savings by encouraging patients to use generic drugs. Although there is debate over how to approach this, state lawmakers agree that patients, alongside their health care providers, should be active in deciding what kind of drugs they are being prescribed and dispensed. As we continue to see newer, brand-name prescription drugs increasing in price, generic drug substitution might provide some needed relief both to state budgets and consumers.