June 3, 2020

Legal Brief

SOUTH DAKOTA STATE MEDICAL ASSOCIATION
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# Prescriptions – Brand and Generic Prescriptions

This Legal Brief was drafted for general informational purposes only. It is not meant to be a comprehensive guide, nor should it be construed as legal advice. The information in this brief is current as of July 1, 2018; readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

## Summary

*A pharmacist, under certain circumstances, may substitute a generic equivalent of a drug or an interchangeable biological product prescribed by its brand name. The pharmacist must notify the person receiving the drug of the substitution, and must also notify them of their right to refuse the selected drug.*

*The physician may prohibit the substitution of a generic equivalent by handwriting on the prescription order the words "brand necessary" or words of similar meaning. If the prescription order is oral, the physician or his authorized agent must specifically instruct the pharmacist that substitution is prohibited.*

*The selection of an equivalent drug product does not give rise to a cause of action against the practitioner.*

## Discussion

### Substitutes for Name Brands

A pharmacist dispensing a drug prescribed by its brand name may select any equivalent drug if the manufacturer or distributor of the equivalent drug product holds, if applicable, either an approved new drug application or an approved abbreviated new drug application and any other approval required by law.

A pharmacist may not select a substitute drug unless it has been manufactured, labeled, or distributed by a manufacturer, labeler, or distributor who:

1. Marks capsules and tablets with an identification code or monogram;
2. Labels products with their expiration date;
3. Provides reasonable services to accept return goods that have reached their expiration date;
4. Maintains reasonable resources for product information;
5. Maintains recall capabilities for unsafe or defective drugs; and
6. Makes available therapeutic equivalency ratings.

A pharmacy benefits manager may request the dispensation of a substitute prescription drug to a covered individual when a lower-priced generic and therapeutically equivalent drug is available. If the cost to the covered individual of the substitute generic drug is higher than the prescribed drug, the substitution may only be made for medical reasons and requires the prior approval of the prescribing health professional.

**Labeling**

When making a substitution, the pharmacist must label the prescription container with the name of the dispensed drug, unless otherwise instructed by the prescriber. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name or the United States Pharmacopoeia pharmacy equivalent name of the drug dispensed. If a pharmacist selects a generically equivalent drug product in place of the brand name drug product prescribed, the prescription container label must include the generic name, it may identify the brand name for which the selection is made, and must be in the following format: "(generic name) Generic for (brand name)".

**Notification and Right to Refuse**

The pharmacist, or the pharmacist's authorized agent, must inform the person receiving the drug that a substitute product has been selected. The pharmacist or the pharmacist's agent must also inform the person receiving the drug of that person's right to refuse the product selected.

**Brand Necessary Limitation**

A practitioner may prohibit a pharmacist from selecting an equivalent drug product by handwriting on the prescription drug order the words "brand necessary" or words of similar meaning; the prohibition may not be preprinted or stamped on the prescription drug order. If an oral prescription is given to a pharmacist, the practitioner or practitioner's authorized agent, must instruct the pharmacist if selection of an equivalent drug product is prohibited. The pharmacist must note the instructions on the file copy of the prescription drug order.

**Hospital Patients**

The requirements and restrictions relating to the substitution of so-called “generic” drugs or biologicals do not apply to drugs or biologicals prescribed to patients in the hospital.

**No Additional Liability**

A pharmacist who selects an equivalent drug or biological product has no greater liability for selecting the dispensed drug or biological than would be incurred in filling a prescription for a drug or biological product prescribed by its established, generic or proper name.

The selection of an equivalent drug or biological product does not, in itself, in the absence of willful misconduct or negligence, give rise to a cause of action against the prescribing practitioner.

## Conclusion

*The patient must be informed of, and has the right to refuse, a drug or an interchangeable biological product substitution. The physician may prohibit the substitution of a generic or biological product equivalent by handwriting on the prescription order the words “brand necessary” or by specifically informing the pharmacist that a substitution is prohibited.*

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Sources:
SDCL 36-11-46.1; SDCL 36-11-46.2; SDCL 36-11-46.3; SDCL 36-11-46.4; SDCL 36-11-46.5; SDCL 36-11-46.6; SDCL 36-11-46.7; SDCL 36-11-46.8; SDCL 58-29E-8.

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*SDSMA gratefully acknowledges the SDSMA Foundation for its support of this publication through funds awarded by The Physicians Foundation.*