AN ACT to renumber and amend 450.13 (1); to amend 102.425 (1) (c), 450.11 (4g) (title), 450.11 (4g) (a) 2., 450.13 (2), 450.13 (3) and 450.13 (5) (intro.); and to create 450.01 (1z), 450.11 (4g) (c), 450.11 (4i), 450.12 (4), 450.122, 450.13 (6) and 450.135 of the statutes; relating to: the treatment of biological products for various purposes under the pharmacy practice law.

Analysis by the Legislative Reference Bureau

This bill makes a number of changes to the pharmacy practice laws regarding the prescribing and dispensing of biological products, including changes to address the dispensing of interchangeable biological products.

Current state law contains a number of provisions that address the dispensing of drug product equivalents in lieu of the specific drug product described. Specifically, current law allows a pharmacist to dispense the “drug product equivalent” of a drug prescribed if the drug product equivalent is lower in price to the consumer than the drug product prescribed, unless the prescribing practitioner specifically indicates on the prescription order that no substitution of the drug product prescribed may be made. Current law defines “drug product equivalent” as a drug product that the federal Food and Drug Administration, which regulates drugs pursuant to the Federal Food, Drug, and Cosmetic Act, has determined is therapeutically equivalent to the drug product prescribed. Current law also provides that if a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product
specified in the prescription order, the label required for the drug may include both the
generic name of the drug product equivalent and the brand name specified in the
prescription order, unless the prescribing practitioner requests that the brand name
be omitted from the label.

This bill creates provisions similar to those described above that apply with
respect to biological products, which are regulated somewhat differently from other
drugs by the FDA under the federal Public Health Service Act. Specifically, the bill
allows a pharmacist to dispense an interchangeable biological product in lieu of the
biological product prescribed if the interchangeable biological product is lower in
price to the consumer than the biological product prescribed, unless the prescribing
practitioner specifically indicates on the prescription order that no substitution of
the biological product prescribed may be made. The bill defines “interchangeable
biological product” as a biological product that the FDA has determined is
therapeutically equivalent to the biological product prescribed or that the FDA has
licensed and determined meets standards for interchangeability pursuant to
provisions in federal law. The bill further establishes requirements for pharmacists
who dispense biological products to make an entry into an electronic records system
or to otherwise communicate to the prescribing practitioner regarding the biological
product dispensed, subject to certain exceptions. The bill provides that if a
pharmacist, pursuant to a prescription order that specifies a biological product by its
brand name, dispenses the interchangeable biological product of the biological
product specified in the prescription order, the label required for the drug may
include both the proper name of the interchangeable biological product and the
brand name specified in the prescription order.

Current law also contains provisions regarding the labeling of prescription
drugs, including requirements that certain information be contained on the
commercial container of a prescription drug. The bill creates a similar provision that
applies only to biological products, which includes a requirement that certain
information to be contained on the commercial container of the biological product,
including the brand name, if any, of the biological product, and the proper name of
the biological product.

The provisions newly created in the bill apply only to biological products. The
bill modifies the provisions under current law that apply to drugs generally so that
they apply only to drugs that are not biological products.

The people of the state of Wisconsin, represented in senate and assembly, do
enact as follows:

1. Section 1. 102.425 (1) (c) of the statutes is amended to read:

102.425 (1) (c) “Drug product equivalent” has the meaning given in s. 450.13

2. Section 2. 450.01 (1z) of the statutes is created to read:
450.01 (1z) “Biological product” has the meaning given in 42 USC 262 (i).

Section 3. 450.11 (4g) (title) of the statutes is amended to read:

450.11 (4g) (title) BRAND NAME PERMITTED ON LABEL; DRUGS AND DRUG PRODUCTS.

Section 4. 450.11 (4g) (a) 2. of the statutes is amended to read:

450.11 (4g) (a) 2. “Drug product equivalent” has the meaning given in s. 450.13 (1) (1e).

Section 5. 450.11 (4g) (c) of the statutes is created to read:

450.11 (4g) (c) This subsection does not apply to a prescription order for a biological product.

Section 6. 450.11 (4i) of the statutes is created to read:

450.11 (4i) BRAND NAME PERMITTED ON LABEL; BIOLOGICAL PRODUCTS. (a) In this section:

1. “Brand name” has the meaning given in s. 450.122 (1) (a).
2. “Interchangeable biological product” has the meaning given in s. 450.135 (1).
3. “Proper name” has the meaning given in s. 450.122 (1) (b).

(b) If a pharmacist, pursuant to a prescription order that specifies a biological product by its brand name, dispenses the interchangeable biological product of the biological product specified in the prescription order, the label required under sub. (4) (a) may include both the proper name of the interchangeable biological product and the brand name specified in the prescription order.

Section 7. 450.12 (4) of the statutes is created to read:

450.12 (4) This section does not apply with respect to biological products.

Section 8. 450.122 of the statutes is created to read:

450.122 Labeling of biological products. (1) In this section:
(a) “Brand name” means the name, other than the proper name, that the labeler of a biological product places on its commercial container at the time of packaging.

(b) “Proper name” means the nonproprietary name for a biological product designated by the federal food and drug administration licensure for use upon each package of the product.

(2) The manufacturer’s or distributor’s commercial container of every biological product delivered to any pharmacist, practitioner, hospital, or nursing home shall bear a label containing the proper name of the biological product, the brand name of the biological product, if any, the name and address of the manufacturer of the biological product and, if different from the manufacturer, the name and address of the distributor of the biological product.

(3) Every prescription order or medication profile record for a biological product shall include the brand name, if any, and the name of the manufacturer of the biological product.

SECTION 9. 450.13 (1) of the statutes is renumbered 450.13 (1s) and amended to read:

450.13 (1s) DRUG PRODUCT OR EQUIVALENT TO BE USED. Except as provided in sub. (2), a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription.

(1e) DEFINITION. In this section, “drug product equivalent” means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration as set forth in the latest edition of or
supplement to the federal food and drug administration’s Approved Drug Products
with Therapeutic Equivalence Evaluations.

SECTION 10. 450.13 (2) of the statutes is amended to read:

450.13 (2) EXCEPTION. A prescriber prescribing practitioner may indicate, by
writing on the face of the prescription order or, with respect to a prescription order
transmitted electronically, by designating in electronic format the phrase “No
substitutions” or words of similar meaning or the initials “N.S.”, that no substitution
of the drug product prescribed may be made under sub. (1) (1s). If such indication
is made, the pharmacist shall dispense the prescription with the specific drug
product prescribed. No preprinted statement regarding drug product substitution
may appear on the face of the prescription order.

SECTION 11. 450.13 (3) of the statutes is amended to read:

450.13 (3) RENEWED REFILLED PRESCRIPTIONS. Prescriptions dispensed with a
drug product equivalent may be renewed refilled with a different drug product
equivalent only if the pharmacist informs the consumer of the change.

SECTION 12. 450.13 (5) (intro.) of the statutes is amended to read:

450.13 (5) USE OF DRUG PRODUCT EQUIVALENT IN HOSPITALS. (intro.) Subsections
(1) (1s) to (4) do not apply to a pharmacist who dispenses a drug product equivalent
that is prescribed for a patient in a hospital if the pharmacist dispenses the drug
product equivalent in accordance with written guidelines or procedures previously
established by a pharmacy and therapeutics committee of the hospital and approved
by the hospital’s medical staff and use of the drug product equivalent has been
approved for a patient during the period of the patient’s stay within the hospital by
any of the following:

SECTION 13. 450.13 (6) of the statutes is created to read:
450.13 (6) APPLICABILITY. This section does not apply with respect to a 

prescription for a biological product.

SECTION 14. 450.135 of the statutes is created to read:

450.135 Using interchangeable biological product in dispensing 
prescriptions. (1) DEFINITION. In this section, “interchangeable biological product”

means a biological product that the federal food and drug administration has 

licensed and has determined meets the standards for interchangeability pursuant 

to 42 USC 262 (k) (4) or has determined is therapeutically equivalent as set forth in 

the latest edition of or supplement to the federal food and drug administration’s 

Approved Drug Products with Therapeutic Equivalence Evaluations.

(2) BIOLOGICAL PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT TO BE USED. 

Except as provided in sub. (3), a pharmacist shall dispense every prescription using 

either the biological product prescribed or an interchangeable biological product, if 

the interchangeable biological product is lower in price to the consumer than the 

biological product prescribed, and shall inform the consumer of the options available 

in dispensing the prescription.

(3) EXCEPTION. A prescribing practitioner may indicate, by writing on the face 

of the prescription order or, with respect to a prescription order transmitted 

electronically, by designating in electronic format the phrase “No substitutions” or 

words of similar meaning or the initials “N.S.,” that no substitution of the biological 

product prescribed may be made under sub. (2). If such indication is made, the 

pharmacist shall dispense the prescription with the specific biological product 

prescribed. No preprinted statement regarding biological product substitution may 

appear on the face of the prescription order.
(4) **Refilled Prescriptions.** Prescriptions dispensed with an interchangeable biological product may be refilled with a different interchangeable biological product only if the pharmacist informs the consumer of the change.

(5) **Communication of Biological Product Dispensed.** Within 5 business days after the dispensing of a biological product, the dispensing pharmacist or the pharmacist’s designee shall do one of the following:

(a) Make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescribing practitioner. The communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through one of the following:

1. An interoperable electronic medical records system.
3. A pharmacist benefit management system.
4. A pharmacy record.

(b) If a pharmacist is unable to make an entry as provided in par. (a), communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or another prevailing means, except that communication under this paragraph is not required if any of the following applies:

1. There is no interchangeable biological product for the product prescribed.
2. A refill of the biological product is not changed from the product dispensed on the prior filling of the prescription.

(6) **Limitation of Liability.** A pharmacist who dispenses a prescription with an interchangeable biological product under this section assumes no greater liability
than would be incurred had the pharmacist dispensed the prescription with the 
biological product prescribed.

(7) Use of Interchangeable Biological Product in Hospitals. Subsections (2) 
to (6) do not apply to a pharmacist who dispenses an interchangeable biological 
product that is prescribed for a patient in a hospital if the pharmacist dispenses the 
interchangeable biological product in accordance with written guidelines or 
procedures previously established by a pharmacy and therapeutics committee of the 
hospital and approved by the hospital’s medical staff and use of the interchangeable 
biological product has been approved for a patient during the period of the patient’s 
stay within the hospital by any of the following:

(a) The patient’s individual physician.

(b) The patient’s advanced practice nurse prescriber, if the advanced practice 
nurse prescriber has entered into a written agreement to collaborate with a 
physician.

(c) The patient’s physician assistant.

(8) Applicability. This section applies only with respect to prescriptions for 
biological products.

(9) Links to Be Maintained by Board. The board shall maintain links on the 
department’s Internet site to the federal food and drug administration’s lists of all 
currently approved interchangeable biological products.

(END)