

HOUSE BUSINESS AND INDUSTRY COMMITTEE SUBSTITUTE FOR
HOUSE BILL 260

53RD LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2017

AN ACT

RELATING TO HEALTH; AMENDING THE NEW MEXICO DRUG, DEVICE AND
COSMETIC ACT TO PROVIDE FOR REGULATION OF BIOSIMILAR PRODUCTS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. Section 26-1-2 NMSA 1978 (being Laws 1967,
Chapter 23, Section 2, as amended) is amended to read:

"26-1-2. DEFINITIONS.--As used in the New Mexico Drug,
Device and Cosmetic Act:

A. "board" means the board of pharmacy or its duly
authorized agent;

B. "person" includes an individual, partnership,
corporation, association, institution or establishment;

C. "biological product" means a virus, therapeutic
serum, toxin, antitoxin, vaccine, blood, blood component or
derivative, allergenic product, protein, except any chemically

.207414.3

underscored material = new
[bracketed material] = delete

1 synthesized polypeptide or analogous product, or arsphenamine
2 or derivative of arsphenamine or any other trivalent organic
3 arsenic compound applicable to the prevention, treatment or
4 cure of [~~diseases or injuries of humans and domestic animals,~~
5 ~~and, as used within the meaning of this definition:~~

6 (1) ~~a "virus" is interpreted to be a product~~
7 ~~containing the minute living cause of an infectious disease and~~
8 ~~includes filterable viruses, bacteria, rickettsia, fungi and~~
9 ~~protozoa;~~

10 (2) ~~a "therapeutic serum" is a product~~
11 ~~obtained from blood by removing the clot or clot components and~~
12 ~~the blood cells;~~

13 (3) ~~a "toxin" is a product containing a~~
14 ~~soluble substance poisonous to laboratory animals or humans in~~
15 ~~doses of one milliliter or less of the product and, following~~
16 ~~the injection of nonfatal doses into an animal, having the~~
17 ~~property of or causing to be produced therein another soluble~~
18 ~~substance that specifically neutralizes the poisonous substance~~
19 ~~and that is demonstrable in the serum of the animal thus~~
20 ~~immunized; and~~

21 (4) ~~an "antitoxin" is a product containing the~~
22 ~~soluble substance in serum or other body fluid of an immunized~~
23 ~~animal that specifically neutralizes the toxin against which~~
24 ~~the animal is immune] a disease or condition of human beings;~~

25 D. "biosimilar" or "biosimilarity" means, in

1 reference to a biological product that the federal food and
2 drug administration has licensed, that:

3 (1) the biological product is highly similar
4 to the reference product notwithstanding minor differences in
5 clinically inactive components; and

6 (2) there are no clinically meaningful
7 differences between the biological product and the reference
8 product in terms of the safety, purity and potency of the
9 product;

10 ~~[D-]~~ E. "controlled substance" means a drug,
11 substance or immediate precursor enumerated in Schedules I
12 through V of the Controlled Substances Act;

13 ~~[E-]~~ F. "drug" means articles:

14 (1) recognized in an official compendium;

15 (2) intended for use in the diagnosis, cure,
16 mitigation, treatment or prevention of disease in humans or
17 other animals and includes the domestic animal biological
18 products regulated under the federal Virus-Serum-Toxin Act, 37
19 Stat 832-833, 21 U.S.C. 151-158, and the biological products
20 applicable to humans regulated under Federal 58 Stat 690, as
21 amended, 42 U.S.C. 216, Section 351, 58 Stat 702, as amended,
22 and 42 U.S.C. 262;

23 (3) other than food, that affect the structure
24 or any function of the human body or the bodies of other
25 animals; and

.207414.3

1 (4) intended for use as a component of
2 Paragraph (1), (2) or (3) of this subsection, but "drug" does
3 not include devices or their component parts or accessories;

4 ~~[F-]~~ G. "dangerous drug" means a drug, other than a
5 controlled substance enumerated in Schedule I of the Controlled
6 Substances Act, that because of a potentiality for harmful
7 effect or the method of its use or the collateral measures
8 necessary to its use is not safe except under the supervision
9 of a practitioner licensed by law to direct the use of such
10 drug and hence for which adequate directions for use cannot be
11 prepared. "Adequate directions for use" means directions under
12 which the layperson can use a drug or device safely and for the
13 purposes for which it is intended. A drug shall be dispensed
14 only upon the prescription or drug order of a practitioner
15 licensed by law to administer or prescribe the drug if it:

16 (1) is a habit-forming drug and contains any
17 quantity of a narcotic or hypnotic substance or a chemical
18 derivative of such substance that has been found under the
19 federal act and the board to be habit forming;

20 (2) because of its toxicity or other potential
21 for harmful effect or the method of its use or the collateral
22 measures necessary to its use is not safe for use except under
23 the supervision of a practitioner licensed by law to administer
24 or prescribe the drug;

25 (3) is limited by an approved application by

1 Section 505 of the federal act to the use under the
 2 professional supervision of a practitioner licensed by law to
 3 administer or prescribe the drug;

4 (4) bears the legend: "Caution: federal law
 5 prohibits dispensing without prescription.";

6 (5) bears the legend: "Caution: federal law
 7 restricts this drug to use by or on the order of a licensed
 8 veterinarian."; or

9 (6) bears the legend "RX only";

10 ~~[G-]~~ H. "counterfeit drug" means a drug that is
 11 deliberately and fraudulently mislabeled with respect to its
 12 identity, ingredients or sources. Types of such pharmaceutical
 13 counterfeits may include:

14 (1) "identical copies", which are counterfeits
 15 made with the same ingredients, formulas and packaging as the
 16 originals but not made by the original manufacturer;

17 (2) "look-alikes", which are products that
 18 feature high-quality packaging and convincing appearances but
 19 contain little or no active ingredients and may contain harmful
 20 substances;

21 (3) "rejects", which are drugs that have been
 22 rejected by the manufacturer for not meeting quality standards;
 23 and

24 (4) "relabels", which are drugs that have
 25 passed their expiration dates or have been distributed by

.207414.3

underscored material = new
 [bracketed material] = delete

1 unauthorized foreign sources and may include placebos created
2 for late-phase clinical trials;

3 ~~[H.]~~ I. "device", except when used in Subsection
4 ~~[P]~~ R of this section and in Subsection G of Section 26-1-3,
5 Subsection L and Paragraph (4) of Subsection A of Section
6 26-1-11 and Subsection C of Section 26-1-24 NMSA 1978, means an
7 instrument, apparatus, implement, machine, contrivance,
8 implant, in vitro reagent or other similar or related article,
9 including any component, part or accessory, that is:

10 (1) recognized in an official compendium;

11 (2) intended for use in the diagnosis of
12 disease or other conditions or in the cure, mitigation,
13 treatment or prevention of disease in humans or other animals;
14 or

15 (3) intended to affect the structure or a
16 function of the human body or the bodies of other animals and
17 that does not achieve any of its principal intended purposes
18 through chemical action within or on the human body or the
19 bodies of other animals and that is not dependent on being
20 metabolized for achievement of any of its principal intended
21 purposes;

22 ~~[I.]~~ J. "prescription" means an order given
23 individually for the person for whom prescribed, either
24 directly from a licensed practitioner or the practitioner's
25 agent to the pharmacist, including by means of electronic

.207414.3

1 transmission, or indirectly by means of a written order signed
 2 by the prescriber, and bearing the name and address of the
 3 prescriber, the prescriber's license classification, the name
 4 and address of the patient, the name and quantity of the drug
 5 prescribed, directions for use and the date of issue;

6 ~~[J.]~~ K. "practitioner" means a certified advanced
 7 practice chiropractic physician, physician, doctor of oriental
 8 medicine, dentist, veterinarian, euthanasia technician,
 9 certified nurse practitioner, clinical nurse specialist,
 10 pharmacist, pharmacist clinician, certified nurse-midwife,
 11 physician assistant, prescribing psychologist, dental
 12 hygienist, optometrist or other person licensed or certified to
 13 prescribe and administer drugs that are subject to the New
 14 Mexico Drug, Device and Cosmetic Act;

15 ~~[K.]~~ L. "cosmetic" means:

16 (1) articles intended to be rubbed, poured,
 17 sprinkled or sprayed on, introduced into or otherwise applied
 18 to the human body or any part thereof for cleansing,
 19 beautifying, promoting attractiveness or altering the
 20 appearance; and

21 (2) articles intended for use as a component
 22 of any articles enumerated in Paragraph (1) of this subsection,
 23 except that the term shall not include soap;

24 M. "interchangeable biological product" means a
 25 biological product that the federal food and drug

.207414.3

1 administration has licensed and:

2 (1) has determined that the biological product
3 is biosimilar to the reference product and can be expected to
4 produce the same clinical result as the reference product in
5 any given patient;

6 (2) for a biological product that is
7 administered more than once to an individual:

8 (a) has determined to have been
9 administered more than once to the individual; or

10 (b) for which the risk in terms of
11 safety or diminished efficacy of alternating or switching
12 between use of the biological product and the reference product
13 is not greater than the risk of using the reference product
14 without alternation or switching; or

15 (3) has determined to be therapeutically
16 equivalent as set forth in the latest edition or supplement to
17 the federal food and drug administration's approved drug
18 products with therapeutic equivalence evaluation;

19 ~~[L.]~~ N. "official compendium" means the official
20 United States pharmacopoeia national formulary or the official
21 homeopathic pharmacopoeia of the United States or any
22 supplement to either of them;

23 ~~[M.]~~ O. "label" means a display of written, printed
24 or graphic matter upon the immediate container of an article.

25 A requirement made by or under the authority of the New Mexico

1 Drug, Device and Cosmetic Act that any word, statement or other
2 information appear on the label shall not be considered to be
3 complied with unless the word, statement or other information
4 also appears on the outside container or wrapper, if any, of
5 the retail package of the article or is easily legible through
6 the outside container or wrapper;

7 ~~[N.]~~ P. "immediate container" does not include
8 package liners;

9 ~~[O.]~~ Q. "labeling" means all labels and other
10 written, printed or graphic matter:

11 (1) on an article or its containers or
12 wrappers; or

13 (2) accompanying an article;

14 ~~[P.]~~ R. "misbranded" means a label to an article
15 that is misleading. In determining whether the label is
16 misleading, there shall be taken into account, among other
17 things, not only representations made or suggested by
18 statement, word, design, device or any combination of the
19 foregoing, but also the extent to which the label fails to
20 reveal facts material in the light of such representations or
21 material with respect to consequences that may result from the
22 use of the article to which the label relates under the
23 conditions of use prescribed in the label or under such
24 conditions of use as are customary or usual;

25 ~~[Q.]~~ S. "advertisement" means all representations

.207414.3

1 disseminated in any manner or by any means, other than by
2 labeling, for the purpose of inducing, or that are likely to
3 induce, directly or indirectly, the purchase of drugs, devices
4 or cosmetics;

5 ~~[R.]~~ T. "antiseptic", when used in the labeling or
6 advertisement of an antiseptic, shall be considered to be a
7 representation that it is a germicide, except in the case of a
8 drug purporting to be or represented as an antiseptic for
9 inhibitory use as a wet dressing, ointment, dusting powder or
10 such other use as involves prolonged contact with the body;

11 ~~[S.]~~ U. "new drug" means a drug:

12 (1) the composition of which is such that the
13 drug is not generally recognized, among experts qualified by
14 scientific training and experience to evaluate the safety and
15 efficacy of drugs, as safe and effective for use under the
16 conditions prescribed, recommended or suggested in the labeling
17 thereof; or

18 (2) the composition of which is such that the
19 drug, as a result of investigation to determine its safety and
20 efficacy for use under such conditions, has become so
21 recognized, but that has not, otherwise than in such
22 investigations, been used to a material extent or for a
23 material time under such conditions;

24 ~~[T.]~~ V. "contaminated with filth" applies to a
25 drug, device or cosmetic not securely protected from dirt, dust

1 and, as far as may be necessary by all reasonable means, from
2 all foreign or injurious contaminations, or a drug, device or
3 cosmetic found to contain dirt, dust, foreign or injurious
4 contamination or infestation;

5 ~~[U.]~~ W. "selling of drugs, devices or cosmetics"
6 shall be considered to include the manufacture, production,
7 processing, packing, exposure, offer, possession and holding of
8 any such article for sale and the sale and the supplying or
9 applying of any such article in the conduct of a drug or
10 cosmetic establishment;

11 ~~[V.]~~ X. "color additive" means a material that:
12 (1) is a dye, pigment or other substance made
13 by a process of synthesis or similar artifice or extracted,
14 isolated or otherwise derived, with or without intermediate or
15 final change of identity, from a vegetable, mineral, animal or
16 other source; or

17 (2) when added or applied to a drug or
18 cosmetic or to the human body or a part thereof, is capable,
19 alone or through reaction with other substances, of imparting
20 color thereto; except that such term does not include any
21 material that has been or hereafter is exempted under the
22 federal act;

23 ~~[W.]~~ Y. "federal act" means the Federal Food, Drug,
24 and Cosmetic Act;

25 ~~[X.]~~ Z. "restricted device" means a device for

.207414.3

1 which the sale, distribution or use is lawful only upon the
2 written or oral authorization of a practitioner licensed by law
3 to administer, prescribe or use the device and for which the
4 federal food and drug administration requires special training
5 or skills of the practitioner to use or prescribe. This
6 definition does not include custom devices defined in the
7 federal act and exempt from performance standards or premarket
8 approval requirements under Section 520(b) of the federal act;

9 ~~[Y.]~~ AA. "prescription device" means a device that,
10 because of its potential for harm, the method of its use or the
11 collateral measures necessary to its use, is not safe except
12 under the supervision of a practitioner licensed in this state
13 to direct the use of such device and for which "adequate
14 directions for use" cannot be prepared, but that bears the
15 label: "Caution: federal law restricts this device to sale by
16 or on the order of a _____", the blank to be filled with
17 the word "physician", "physician assistant", "certified
18 advanced practice chiropractic physician", "doctor of oriental
19 medicine", "dentist", "veterinarian", "euthanasia technician",
20 "certified nurse practitioner", "clinical nurse specialist",
21 "pharmacist", "pharmacist clinician", "certified nurse-
22 midwife", ~~[ø]~~ "dental hygienist" or "optometrist" or with the
23 descriptive designation of any other practitioner licensed in
24 this state to use or order the use of the device;

25 ~~[Z.]~~ BB. "valid practitioner-patient relationship"

1 means a professional relationship, as defined by the
 2 practitioner's licensing board, between the practitioner and
 3 the patient;

4 ~~[AA.]~~ CC. "pedigree" means the recorded history of
 5 a drug; ~~and~~

6 ~~BB.]~~ DD. "drug order" means an order either
 7 directly from a licensed practitioner or the practitioner's
 8 agent to the pharmacist, including by means of electronic
 9 transmission or indirectly by means of a written order signed
 10 by the licensed practitioner or the practitioner's agent, and
 11 bearing the name and address of the practitioner and the
 12 practitioner's license classification and the name and quantity
 13 of the drug or device ordered for use at an inpatient or
 14 outpatient facility; and

15 EE. "reference product" means the single biological
 16 product against which a biosimilar was evaluated in its
 17 marketing application to the federal food and drug
 18 administration."

19 **SECTION 2.** Section 26-3-3 NMSA 1978 (being Laws 1976,
 20 Chapter 60, Section 4, as amended) is amended to read:

21 "26-3-3. DRUG AND BIOLOGICAL PRODUCT SELECTION
 22 PERMITTED--CONDITIONS--EXCEPTION FOR PROHIBITION--LABELING.--

23 A. Upon receipt of a prescription written by a
 24 licensed practitioner who may prescribe drugs or biological
 25 products for a drug or biological product for which one or more

.207414.3

underscored material = new
 [bracketed material] = delete

1 multiple-source drugs or interchangeable biological products
2 are recognized, listed as final determinations and published in
3 the federal register by the federal department of health and
4 human services, a pharmacist may dispense any one of the drugs
5 or interchangeable biological products that satisfies the final
6 determinations so recognized and listed by the federal
7 department of health and human services and is sold at a lower
8 cost than the drug or biological product listed in the
9 prescription.

10 B. Upon receipt of a prescription written by a
11 licensed practitioner for a drug or biological product that
12 appears on the federal food and drug administration's approved
13 prescription drug products with therapeutic equivalence
14 evaluation list as supplemented, or for a biological product
15 that is listed as interchangeable on the list of the federal
16 food and drug administration's list of licensed biological
17 products with reference product exclusivity and biosimilar or
18 interchangeable evaluations, as supplemented, a pharmacist may
19 dispense any of the listed therapeutically equivalent drugs or
20 interchangeable biological products that [~~appears on that list~~
21 ~~and which~~] is lower in cost than the prescribed drug [~~listed in~~
22 ~~the prescription~~] or biological product.

23 C. Drug and biological product selection shall be
24 permitted only under circumstances and conditions set forth in
25 Subsections A and B of this section unless the licensed

1 practitioner prescribing prohibits drug or biological product
2 selection. A licensed practitioner shall prohibit drug or
3 biological product selection by ~~[writing with his hand]~~ making
4 an entry that is electronically accessible that includes the
5 words "no substitution" or the diminution "no sub" on ~~[the face~~
6 ~~of]~~ a prescription.

7 D. If drug or biological product selection occurs
8 as permitted in Subsections A and B of this section, the
9 pharmacist shall indicate on the label of the dispensed
10 container the brand of drug or the specific biological product
11 prescribed and the name of the drug or interchangeable
12 biological product dispensed.

13 ~~[E. A pharmacist may not select a therapeutically~~
14 ~~equivalent drug unless he passes on to the patient all savings~~
15 ~~between the net cost of the product prescribed and the product~~
16 ~~dispensed.]~~

17 E. A pharmacist who selects an interchangeable
18 biological product shall inform the patient or the patient's
19 representative.

20 F. A pharmacist shall not select a therapeutically
21 equivalent drug or interchangeable biological product unless
22 the substitution is in accordance with the provisions of
23 Subsection A of this section.

24 G. Within five business days following the
25 dispensing of a biological product, the dispensing pharmacist

.207414.3

1 or the pharmacist's designee shall make an entry of the
2 specific product provided to the patient, including the name of
3 the product and the manufacturer. The communication shall be
4 conveyed by making an entry that is electronically accessible
5 to the prescriber through:

6 (1) an interoperable electronic medical
7 records system;

8 (2) an electronic prescribing technology;

9 (3) a pharmacy benefit management system; or

10 (4) a pharmacy record.

11 H. Entry into an electronic medical records system
12 pursuant to Subsection G of this section is presumed to provide
13 notice to the prescriber. Otherwise, the pharmacist shall
14 communicate to the prescriber what biological product was
15 dispensed, using facsimile, telephone, electronic transmission
16 or other prevailing means; provided that communication shall
17 not be required when:

18 (1) there is no interchangeable biological
19 product that has been approved by the federal food and drug
20 administration for the product prescribed; or

21 (2) a refill prescription is not changed from
22 the product dispensed on the prior filling of the prescription.

23 I. The board shall maintain a link on its website
24 to the current list of all biological products that the federal
25 food and drug administration has determined to be

1 interchangeable biological products.

2 [F.] J. For purposes of this section:

3 (1) "multiple-source drug" means a drug
4 marketed or sold by two or more manufacturers, formulators or
5 labelers; and

6 (2) "therapeutically equivalent" means drug
7 products that have the same amount of the active drug in the
8 same dosage form that when administered can be expected to
9 provide the same therapeutic effect.

10 [~~G. For purposes of this section, "therapeutically~~
11 ~~equivalent" means drug products which have the same amount of~~
12 ~~the active drug in the same dosage form which when administered~~
13 ~~can be expected to provide the same therapeutic effect.]"~~

14 - 17 -

15
16
17
18
19
20
21
22
23
24
25
underscoring material = new
[bracketed material] = delete