

HOUSE BILL 226

**54TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2019**

INTRODUCED BY

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AN ACT

RELATING TO HEALTH CARE; AMENDING A SECTION OF THE NEW MEXICO  
DRUG, DEVICE AND COSMETIC ACT TO ADD REGISTERED LAY MIDWIVES AS  
PRACTITIONERS.

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 any of the following  
that is applicable to the prevention, treatment or cure of a

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1 disease or condition of human beings:

2 (1) a virus;

3 (2) a therapeutic serum;

4 (3) a toxin;

5 (4) an antitoxin;

6 (5) a vaccine;

7 (6) blood;

8 (7) a blood component or derivative;

9 (8) an allergenic product;

10 (9) a protein, except any chemically  
11 synthesized polypeptide;

12 (10) a product that is analogous to any of the  
13 products listed in Paragraphs (1) through (9) of this  
14 subsection; or

15 (11) arsphenamine, a derivative of  
16 arsphenamine or any other trivalent organic arsenic compound;

17 D. "biosimilar" or "biosimilarity" means, in  
18 reference to a biological product that the federal food and  
19 drug administration has licensed, that:

20 (1) the biological product is highly similar  
21 to the reference product notwithstanding minor differences in  
22 clinically inactive components; and

23 (2) there are no clinically meaningful  
24 differences between the biological product and the reference  
25 product in terms of the safety, purity and potency of the

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1 product;

2 E. "controlled substance" means a drug, substance  
3 or immediate precursor enumerated in Schedules I through V of  
4 the Controlled Substances Act;

5 F. "drug" means articles:

6 (1) recognized in an official compendium;

7 (2) intended for use in the diagnosis, cure,  
8 mitigation, treatment or prevention of disease in humans or  
9 other animals and includes the domestic animal biological  
10 products regulated under the federal [~~Virus-Serum-Toxin~~] Animal  
11 Virus, Serum, Toxin, Antitoxin Act, 37 Stat 832-833, 21 U.S.C.  
12 151-158, and the biological products applicable to humans  
13 regulated under Federal 58 Stat 690, as amended, 42 U.S.C. 216,  
14 Section 351, 58 Stat 702, as amended, and 42 U.S.C. 262;

15 (3) other than food, that affect the structure  
16 or any function of the human body or the bodies of other  
17 animals; and

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

21 G. "dangerous drug" means a drug, other than a  
22 controlled substance enumerated in Schedule I of the Controlled  
23 Substances Act, that because of a potentiality for harmful  
24 effect or the method of its use or the collateral measures  
25 necessary to its use is not safe except under the supervision

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1 of a practitioner licensed by law to direct the use of such  
2 drug and hence for which adequate directions for use cannot be  
3 prepared. "Adequate directions for use" means directions under  
4 which the layperson can use a drug or device safely and for the  
5 purposes for which it is intended. A drug shall be dispensed  
6 only upon the prescription or drug order of a practitioner  
7 licensed by law to administer or prescribe the drug if it:

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

12 (2) because of its toxicity or other potential  
13 for harmful effect or the method of its use or the collateral  
14 measures necessary to its use is not safe for use except under  
15 the supervision of a practitioner licensed by law to administer  
16 or prescribe the drug;

17 (3) is limited by an approved application by  
18 Section 505 of the federal act to the use under the  
19 professional supervision of a practitioner licensed by law to  
20 administer or prescribe the drug;

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

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

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

2 H. "counterfeit drug" means a drug that is  
3 deliberately and fraudulently mislabeled with respect to its  
4 identity, ingredients or sources. Types of such pharmaceutical  
5 counterfeits may include:

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

9 (2) "look-alikes", which are products that  
10 feature high-quality packaging and convincing appearances but  
11 contain little or no active ingredients and may contain harmful  
12 substances;

13 (3) "rejects", which are drugs that have been  
14 rejected by the manufacturer for not meeting quality standards;  
15 and

16 (4) "relabels", which are drugs that have  
17 passed their expiration dates or have been distributed by  
18 unauthorized foreign sources and may include placebos created  
19 for late-phase clinical trials;

20 I. "device", except when used in Subsection R of  
21 this section and in Subsection G of Section 26-1-3, Subsection  
22 L and Paragraph (4) of Subsection A of Section 26-1-11 and  
23 Subsection C of Section 26-1-24 NMSA 1978, means an instrument,  
24 apparatus, implement, machine, contrivance, implant, in vitro  
25 reagent or other similar or related article, including any

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1 component, part or accessory, that is:

2 (1) recognized in an official compendium;

3 (2) intended for use in the diagnosis of  
4 disease or other conditions or in the cure, mitigation,  
5 treatment or prevention of disease in humans or other animals;

6 or

7 (3) intended to affect the structure or a  
8 function of the human body or the bodies of other animals and  
9 that does not achieve any of its principal intended purposes  
10 through chemical action within or on the human body or the  
11 bodies of other animals and that is not dependent on being  
12 metabolized for achievement of any of its principal intended  
13 purposes;

14 J. "prescription" means an order given individually  
15 for the person for whom prescribed, either directly from a  
16 licensed practitioner or the practitioner's agent to the  
17 pharmacist, including by means of electronic transmission, or  
18 indirectly by means of a written order signed by the  
19 prescriber, and bearing the name and address of the prescriber,  
20 the prescriber's license classification, the name and address  
21 of the patient, the name and quantity of the drug prescribed,  
22 directions for use and the date of issue;

23 K. "practitioner" means a certified advanced  
24 practice chiropractic physician, physician, doctor of oriental  
25 medicine, dentist, veterinarian, euthanasia technician,

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1 certified nurse practitioner, clinical nurse specialist,  
2 pharmacist, pharmacist clinician, certified nurse-midwife,  
3 physician assistant, prescribing psychologist, dental  
4 hygienist, optometrist or other person licensed or certified to  
5 prescribe and administer drugs that are subject to the New  
6 Mexico Drug, Device and Cosmetic Act. "Practitioner" also  
7 means a registered lay midwife licensed by the department of  
8 health who is certified or licensed in accordance with  
9 department of health rules to procure, carry and administer  
10 drugs that are subject to the New Mexico Drug, Device and  
11 Cosmetic Act;

12 L. "cosmetic" means:

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

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

21 M. "interchangeable biological product" means a  
22 biological product that the federal food and drug  
23 administration has licensed and:

24 (1) has determined that the biological product  
25 is biosimilar to the reference product and can be expected to

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1 produce the same clinical result as the reference product in  
2 any given patient;

3 (2) for a biological product that is  
4 administered more than once to an individual and:

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

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

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

16 N. "official compendium" means the official United  
17 States [~~pharmacopoeia~~] pharmacopeia and national formulary or  
18 the official homeopathic pharmacopoeia of the United States or  
19 any supplement to either of them;

20 O. "label" means a display of written, printed or  
21 graphic matter upon the immediate container of an article. A  
22 requirement made by or under the authority of the New Mexico  
23 Drug, Device and Cosmetic Act that any word, statement or other  
24 information appear on the label shall not be considered to be  
25 complied with unless the word, statement or other information

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1 also appears on the outside container or wrapper, if any, of  
2 the retail package of the article or is easily legible through  
3 the outside container or wrapper;

4 P. "immediate container" does not include package  
5 liners;

6 Q. "labeling" means all labels and other written,  
7 printed or graphic matter:

8 (1) on an article or its containers or  
9 wrappers; or

10 (2) accompanying an article;

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

22 S. "advertisement" means all representations  
23 disseminated in any manner or by any means, other than by  
24 labeling, for the purpose of inducing, or that are likely to  
25 induce, directly or indirectly, the purchase of drugs, devices

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1 or cosmetics;

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

8 U. "new drug" means a drug:

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

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

21 V. "contaminated with filth" applies to a drug,  
22 device or cosmetic not securely protected from dirt, dust and,  
23 as far as may be necessary by all reasonable means, from all  
24 foreign or injurious contaminations, or a drug, device or  
25 cosmetic found to contain dirt, dust, foreign or injurious

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1 contamination or infestation;

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

8 X. "color additive" means a material that:

9 (1) is a dye, pigment or other substance made  
10 by a process of synthesis or similar artifice or extracted,  
11 isolated or otherwise derived, with or without intermediate or  
12 final change of identity, from a vegetable, mineral, animal or  
13 other source; or

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

20 Y. "federal act" means the Federal Food, Drug, and  
21 Cosmetic Act;

22 Z. "restricted device" means a device for which the  
23 sale, distribution or use is lawful only upon the written or  
24 oral authorization of a practitioner licensed by law to  
25 administer, prescribe or use the device and for which the

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1 federal food and drug administration requires special training  
2 or skills of the practitioner to use or prescribe. This  
3 definition does not include custom devices defined in the  
4 federal act and exempt from performance standards or premarket  
5 approval requirements under Section 520(b) of the federal act;

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

23 BB. "valid practitioner-patient relationship" means  
24 a professional relationship, as defined by the practitioner's  
25 licensing board, between the practitioner and the patient;

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CC. "pedigree" means the recorded history of a drug;

DD. "drug order" means an order either directly from a licensed practitioner or the practitioner's agent to the pharmacist, including by means of electronic transmission or indirectly by means of a written order signed by the licensed practitioner or the practitioner's agent, and bearing the name and address of the practitioner and the practitioner's license classification and the name and quantity of the drug or device ordered for use at an inpatient or outpatient facility; and

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