TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 14 DEVICES

16.19.14.1 ISSUING AGENCY: Regulation and Licensing Department, Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[02-15-1889...02-15-96; 16.19.14.1 NMAC - Rn, 16 NMAC 19.14.1, 03-30-02]

16.19.14.2 SCOPE: All individuals and entities subject to the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978.
[02-15-96; 16.19.14.2 NMAC - Rn, 16 NMAC 19.14.2, 03-30-02]

16.19.14.3 STATUTORY AUTHORITY: Section 61-11-6.A.(7) NMSA 1978 authorizes the Board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act. Section 26-1-18 of the Drug, Device and Cosmetic Act authorizes the Board to promulgate regulations for the efficient enforcement of the Act.
[02-15-96; A, 04-30-98; 16.19.14.3 NMAC - Rn, 16 NMAC 19.14.3, 03-30-02]

16.19.14.4 DURATION: Permanent.
[02-15-96; 16.19.14.4 NMAC - Rn, 16 NMAC 19.14.4, 03-30-02]

16.19.14.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[02-15-96; A, 04-30-98; 16.19.14.5 NMAC - Rn, 16 NMAC 19.14.5, 03-30-02]

16.19.14.6 OBJECTIVE: The objective of Part 14 of Chapter 19 is to establish mandatory controls and performance standards for health care devices so as to minimize the risk of injury from the distribution and use of adulterated or misbranded devices.
[02-15-96; 16.19.14.6 NMAC - Rn, 16 NMAC 19.14.6, 03-30-02]

16.19.14.7 DEFINITIONS:

A. "Device", as used in the New Mexico Drug and Cosmetic Act, is any health care product that does not achieve any of its principal intended purpose through chemical action within or on the body of man or other animal and which is not dependent upon being metabolized for achievement of any of its principal intended purposes.

B. [Reserved]

[03-07-80...08-27-90; 16.19.14.7 NMAC - Rn, 16 NMAC 19.14.7, 03-30-02]

16.19.14.8 CLASSIFICATION OF DEVICES: Three regulatory classes are established based on the extent of control necessary to ensure safety and effectiveness of each device:

A. Class I -- General Controls
(1) prohibiting adulteration or misbranding
(2) requiring federal registration and listing by the manufacturer
(3) requiring notification of risks, repairs, replacement or refund
(4) requirement restricting sale, distribution or use
(5) requirement with respect to good manufacturing practices, record keeping, reports and inspections
(6) authority to ban the device

B. Class II -- Performance Standards
(1) general controls not sufficient to assure safety and effectiveness
(2) performance standards required by federal FDA
(3) FDA regulations establishing the performance standard.

C. Class III -- Pre-Market Approval

(1) represents life sustaining, life-supporting or implanted in the body or which presents a potential unreasonable risk of illness or injury.

(2) requires investigational device exemption for research (IDE under federal act Sec. 520 (g)).

[03-07-80...08-27-90; 16.19.14.8 NMAC - Rn, 16 NMAC 19.14.8, 03-30-02]

16.19.14.9 ADULTERATION: A device may be considered to be adulterated:

A. It is subject to a performance standard and does not comply with all requirements of such standard.

B. Class II device FDA pre-market approval is not completed.

C. It is a banned device.

D. It is in violation of good manufacturing practice requirements.

E. It fails to comply with the IDE (Investigational Device Exemption) protocol.

[03-07-80...08-27-90; 16.19.14.9 NMAC - Rn, 16 NMAC 19.14.9, 03-30-02]

16.19.14.10 MISBRANDING: A device may be deemed to be misbranded if:

A. Manufactured in a nonregistered establishment pursuant to federal requirements.

B. If advertising and description literature fails to meet minimum requirements for disclosure of product information.

C. Devices subject to performance standards set by FDA, whose labeling fails to meet those prescribed in the standard.

D. Devices that fail or whose manufacturer refuses to comply with requirements relating to notification and other remedies and requirements or fails to maintain adequate records and necessary reports as required under the federal act Section 518-519.

E. If its label does not bear adequate directions for use and adequate warning against unsafe use.

F. If the labeling is false or misleading.

G. If it is a restricted device and fails to bear required labeling.

[03-07-80...08-27-90; 16.19.14.10 NMAC - Rn, 16 NMAC 19.14.10, 03-30-02]

16.19.14.11 RESTRICTED DEVICE (PRESCRIPTION STATUS):

A. FDA requirements may restrict the sale, distribution, or use of a device if there cannot be reasonable assurance of its safety and effectiveness.

B. Prescription status devices are determined on the basis of its intended use and whether or not the device can be adequately labeled as usable by the layman (i.e., pacemaker, hearing aids, hear valves, etc.).

C. Labeling must contain certain information such as name of device, statement of intended use, relevant warnings, precaution, side effects and contraindications.

D. Labeling of a restricted device, other than surgical instruments, shall bear:

(1) "CAUTION: Federal law restricts this device to sale by or on the order of a _____:, physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the laws of this State to prescribe or use the device in his practice.

(2) The method of its application or use.

(3) The label meets all other requirements under CFR Title 21, Section 801.109 (c) and (d) and (e).

[03-07-80...08-27-90; 16.19.14.11 NMAC - Rn, 16 NMAC 19.14.11, 03-30-02]

16.19.14.12 CUSTOM DEVICES:

A. A custom device is one which is sometimes ordered from manufacturers by practitioners to conform to their own special needs or to those of their patients (i.e. prosthetic devices, dental devices and specially designed orthopedic footwear).

B. Custom devices are exempt from performance standards or pre-market approval requirements; however, they are subject to FDA requirements for investigational use, banning, restriction of distribution, adulteration and misbranding.

C. The exemption applied only to devices which are not generally available in finished form for dispensing, or on prescription, or for commercial distribution or generally available to other practitioners.

[03-07-80...08-27-90; 16.19.14.12 NMAC - Rn, 16 NMAC 19.14.12, 03-30-02]

HISTORY OF 16.19.14 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives:
Regulation No. 14, Devices, 11-25-80.
Regulation No. 14, Devices, 10-24-85.
Regulation No. 14, Devices, 2-2-87.
Regulation No. 14, Devices, 7-27-90.

History of Repealed Material: [RESERVED]

Other History: 16 NMAC 19.14, Pharmacists - Devices, filed 02-02-96, reformatted and renumbered to 16.19.14 NMAC, Devices, effective 03-30-2002.