Pharmacy Law Update

Presented by
New Mexico Board of Pharmacy

January 20, 2024

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State Drug Inspector

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October 2023

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FEDERAL LAW

Drug Disposal

- **Secure and Responsible Drug Disposal Act**
- The goal of this Act is to allow for the collection and disposal of Controlled Substances in a secure, convenient, and responsible manner
- Also reduces diversion and the introduction of some potentially harmful substances into the environment

https://www.congress.gov/111/plaws/publ273/PLAW-111publ273.pdf

DEA Diversion Control

DEA NATIONAL Rx TAKE BACK

National Prescription Drug Take Back Day

- Occurs in April and October of every year
- Last DEA Drug Take Back- October 28, 2023.
- Next DEA Drug Take Back- April 2024 10am-2pm

https://www.dea.gov/takebackday

DEA Diversion Control

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

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National Prescription Drug Take Back Day

National Prescription Drug Take Back Day is April 22, 2023 – 10AM to 2PM

The National Prescription Drug Take Back Day aims to provide a safe, convenient, and responsible means of disposing of prescription drugs, while also educating the general public about the potential for abuse of medications.

Law Enforcement Agencies Only:

For law enforcement agencies that wish to host a collection site, please call the POC in your area.

Search for Year Round Pharmaceutical Disposal Locations

DEA Authorized Collectors provide year round drop off locations to the public to dispose of unwanted pharmaceuticals.

Download For Pipe Delimited Year Round Pharmaceutical Disposal Locations

About Pipe Delimited File (PDF)

Home Disposal Methods

E-Cigarette & Vaping Devices Disposal Information

DEA Registrant Drug Disposal & Drug Disposal Rulemaking

National Prescription Take Back Day Results 2010-present

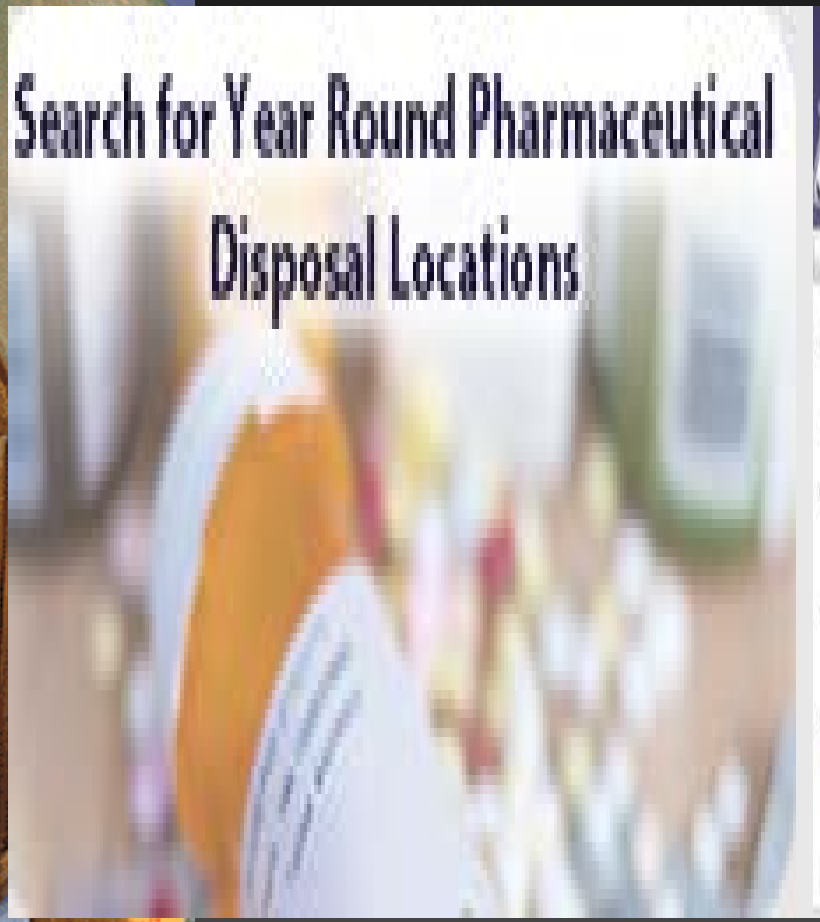
News Releases

Get Email Updates:

- Chemical Control Program
- CMEA (Combat Meth Epidemic Act)
- Controlled Substance Schedules
- COVID-19 Information
- DEA TOX Toxicology Testing Program
- Drug Disposal Information
- Drug and Chemical Information
- E-commerce Initiatives
- Federal Agencies & Related Links
- Federal Register Notices
- Guidance Document Portal
- National Prescription Drug Take Back Day
- NFLIS
- Publications & Manuals
- Questions & Answers
- Synthetic Drugs
- Title 21 Code of Federal Regulations
- Title 21 USC Codified CSA

https://www.deadiversion.usdoj.gov/drug_disposal/takeback/

DEA Diversion Control
Search by zip code



https://www.deadiversion.usdoj.gov/

- DEA Diversion Control
- Year-Round Disposal Sites

U.S. Department of Justice ★ Drug Enforcement Administration

Diversion Control Division

Year-Round Drop-Off Locations - Search Utility

Public Controlled Substance Disposal Locations:

Bus Name	Addr 1	Addr 2	City, State Zip	Dist	Map
UNM TRUMAN HEALTH SERVICES	801 ENCINO PL NE STE B4		ALBUQUERQUE, NM 87102	1 miles	Map
CANCER CENTER PHARMACY	1201 CAMINO DE SALUD NE		ALBUQUERQUE, NM 87102	1 miles	Map
UNIV HOSP OUTPATIENT PHARMACY	1209 UNIVERSITY BLVD NE		ALBUQUERQUE, NM 87102	1 miles	Map
UNM STUDENT HEALTH CTR PHCY	UNIVERSITY OF NEW MEXICO	BLDG. 73, ROOM 21	ALBUQUERQUE, NM 87131	2 miles	Map
NORTH VALLEY CENTER FOR FAMILY AND COMMUNITY HEALT	3401 4TH ST NW	STE 106	ALBUQUERQUE, NM 87107	2 miles	Map
UNM MENTAL HEALTH CENTER OUTPATIENT PHARMACY	2600 MARBLE AVE NE		ALBUQUERQUE, NM 87106	2 miles	Map
UNM HOSPITALS OUTPATIENT AND DISCHARGE PHARMACY	2211 LOMAS BLVD NE # 4ACC		ALBUQUERQUE, NM 87106	2 miles	Map
PHS INDIAN HOSPITAL	801 VASSAR DR NE		ALBUQUERQUE, NM 87106	2 miles	Map
PHARMERICA	2720 A BROADBENT PKWY, NE		ALBUQUERQUE, NM 87107	2 miles	Map
FIRST NATIONS COMMUNITY HEALTHSOURCE PHARMACY	5608 ZUNI RD SE		ALBUQUERQUE, NM 87108	5 miles	Map
WALGREEN CO.	3400 COORS BOULEVARD NW		ALBUQUERQUE, NM 87120	5 miles	Map
SW MESA CENTER FOR FAMILY AND COMMUNITY HEALTH	301 UNSER BLVD NW	STE 106	ALBUQUERQUE, NM 87121	6 miles	Map
WALGREEN CO.	3401 ISLETA BOULEVARD SW		ALBUQUERQUE, NM 87105	6 miles	Map
UNITED SUPERMARKETS, LLC	4950 MONTGOMERY N.E.		ALBUQUERQUE, NM 87109	6 miles	Map
UNITED SUPERMARKETS, LLC	6200 COORS BLVD NW		ALBUQUERQUE, NM 87120	6 miles	Map
UNITED SUPERMARKETS, LLC	1625 RIO BRAVO BLVD SW		ALBUQUERQUE, NM 87105	6 miles	Map
WALGREEN CO.	5001 MONTGOMERY BLVD NE		ALBUQUERQUE, NM 87109	6 miles	Map
377TH MEDICAL GROUP/SGGM	1501 SAN PEDRO DR SE BLDG 47	BLDG 47	ALBUQUERQUE, NM 87108	6 miles	Map
KIRTLAND AFB NM	7901 GIBSON BLVD SE BLDG 20169		KIRTLAND AFB, NM 87117	7 miles	Map
UNITED SUPERMARKETS, LLC	7101 WYOMING BLVD. N.E.		ALBUQUERQUE, NM 87109	9 miles	Map

https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

CONTACT INFO

- DEA Office for Northern NM (North of Socorro)
- 2660 Fritts Crossing SE
  Albuquerque, NM 87106
- Diversion Number: (505) 452-4500
  Diversion Fax: (505) 873-9921

CONTACT INFO

- DEA Office for Southern NM

(South of Socorro)

- 660 Mesa Hills Drive, Suite 2000
  El Paso, TX 79912
- Las Cruces (575) 526-0700
- El Paso (915) 832-6000

STILL MORE FROM DEA

- DEA Updates the electronic 106 Form for Reporting Theft or Loss of Controlled Substances
- Requires registrants to include the NDC which will help to accurately track controlled substances reported as stolen or lost
- Required to report a “Significant Loss”

https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

What is Significant?

According to the DEA . . .

- What constitutes a significant loss for one registrant may be construed as insignificant for another
- ". . . the repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem that must be reported to DEA, even though the individual quantity of each occurrence is not significant."

https://www.uspharmacist.com/article/dea-form-106-and-loss-of-controlled-substances

NMBOP Definition

- Significant Loss: includes suspected diversions, in-transit losses or any other unexplained loss and must be reported to the Board of Pharmacy within five (5) days of becoming aware of that loss

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.36B

STILL MORE FROM DEA

- **Registrant type (first letter of DEA Number):**
  - **A/B/F/G – Hospital/Clinic/Practitioner/Teaching Institution/Pharmacy**
  - **M – Mid-Level Practitioner (NP/PA)**
  - **P/R – Manufacturer/Distributor/Researcher/Analytical Lab/Importer/Exporter/Reverse Distributor/Narcotic Treatment Program**

https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.13

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner/new-practice-guidelines-faqs#:~:text=Yes%20an%20%22X%20number%22%20is,the%20validity%20of%20the%20prescription.

https://www.deadiversion.usdoj.gov/drugreg/

DEA Issues Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register*, reminds health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice.

https://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr1006.htm

CFR 1306.04

DEA Issues Policy Statement on Role of Agents in Communicating CS Prescriptions

- An authorized agent may prepare the prescription. . . for the signature of that DEA-registered practitioner.
- For a Schedule III–V drug, an authorized agent may transmit a *practitioner-signed* prescription to a pharmacy via facsimile; or orally to a pharmacy on behalf of the practitioner.
- An authorized agent may transmit by facsimile a *practitioner-signed* Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

Consolidated Appropriations Act of 2023

- Effective December 29, 2022
- **Eliminated the "DATA-Waiver Program"**
- Elimination of the X-waiver program including elimination of
  - X-waiver DEA Registration
  - Patient limits, discipline restrictions and certification related to provision of counseling
- Opioid use disorder prescriptions now only require a standard DEA registration number

Consolidated Appropriations Act of 2023

- The Act introduced new training requirements for all prescribers to go into effect June 27, 2023
- Section 1263 of the Act requires new or renewing Drug Enforcement Administration (DEA) registrants, starting June 27, 2023, upon submission of their application, to have at least one of the following:
  - A total of 8 hours of training opioid or other substance use disorders for practitioners renewing or newly applying for a registration from the DEA to prescribe any Schedule II-V controlled medications;
  - Board certification in addiction medicine or addiction psychiatry
  - Doesn't apply to veterinarians
  - Graduation within 5 years and status in good standing from medical, advanced practice nursing, or physician assistant school in the United States that included successful completion of an opioid or other substance use disorder curriculum of at least eight hours.

https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act

Electronically Prescribed Controlled Substances by January 1, 2022

- The SUPPORT for Patients and Communities Act, which Congress passed and President Trump signed into law in October 2018, mandates the use of electronic prescribing of controlled substances (EPCS) for all controlled substances under Medicare Part D by January 1, 2022.

https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1

https://www.congress.gov/bill/115th-congress/house-bill/6

https://www.federalregister.gov/documents/2020/08/04/2020-16897/medicare-program-electronic-prescribing-of-controlled-substances-request-for-information-

E-PRESCRIBING

- 21 CFR 1311.100 Electronic Prescriptions

https://www.ecfr.gov/current/title-21/chapter-II/part-1311

- NMAC 16.19.20.42 Electronic prescriptions

https://www.srca.nm.gov/parts/title16/16.019.0020.html

CARA 2016

- The Comprehensive Addiction and Recovery Act (CARA)
- Signed into law by President Obama on July 22, 2016
- First major federal addiction legislation in 40 years and the most comprehensive effort to address the opioid epidemic.

https://www.congress.gov/bill/114th-congress/senate-bill/524/text

CARA 2016

- Title VII: Sec. 702 of the CARA ACT of 2016
  - ***Partial Fills of Schedule II Controlled Substances***: Amends the Controlled Substances Act by allowing schedule II substances to be partially filled if certain conditions and restrictions are met.
- Title VIII: Sec. 303 of the CARA ACT of 2016
  - ***Medication-assisted treatment for recovery from addiction***: NPs and PAs who have completed 24 hours of required training may seek a DATA 2000 waiver for up to 30 patients to prescribe BUPRENORPHINE.
- Complete bill language available at

https://www.congress.gov/bill/114th-congress/senate-bill/524/text

Controlled Substance Prescription Transfer

- CFR 1306.25 Transfer between pharmacies
  - (a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

https://www.ecfr.gov/current/title-21/chapter-II/part-1306/subject-group-ECFRe4ae2bfb4eae102/section-1306.25

EMPLOYMENT SCREENING

- According to DEA regulations:
  - The registrant shall not employ, as an agent or employee who has **access to controlled substances**, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.

https://www.ecfr.gov/current/title-21/chapter-II/part-1301

CFR 1301.76

https://www.nmcourts.gov/Default.aspx

The Drug Quality and Security Act (H.R. 3204)

- Differentiates compounders engaged in traditional pharmacy practice (503A, a licensed pharmacy) from those making large volumes of sterile compounded drugs without individual prescriptions (503B, an FDA-registered outsourcing facility).

https://www.congress.gov/bill/113th-congress/house-bill/3204

Outsourcing Facility licensure in NM

- Any outsourcing facility, that distributes or causes to be distributed, compounded sterile drugs into New Mexico shall be registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act and be licensed by the NMBOP as an outsourcing facility
- Providers may purchase non patient-specific compounded sterile product, for administration, from an outsourcing facility.

https://www.srca.nm.gov/parts/title16/16.019.0037.html

NMAC 16.19.37

FDA Section 503A: Compounding Drugs That Are Commercially Available

- To qualify for the 503A exemptions:
  - Compounder cannot compound regularly or in an inordinate amount any drug products that are essentially copies of a commercially available drug product
  - Not considered a copy if there is a change made for an individual patient, which produces for that patient a significant difference from the commercially available drug, as determined by the prescriber

https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies

FDA Guidance for Compounding
"Essentially a copy" of a commercially available drug

- Same Active Pharmaceutical Ingredients (API) as a commercially available drug product
- API have same, similar (within 10%), or an easily substitutable dosage strength
- Commercially available drug product that can be used by the same route of administration

https://www.fda.gov/media/98964/download

New Mexico Law
&
Board Activity

New Applications/ Remodel or Relocation of Pharmacies or Clinics

- **Remodel or relocation application:**
- **Submit BEFORE**:
  - **changing location, or**
  - **physical dimensions** or
  - ***elements of physical security***,
  - Follow the directions on the application.
  - Once the inspector approves the floorplan, then construction, remodel or relocation may begin.

https://www.rld.nm.gov/wp-content/uploads/2021/06/Request-for-Inspection_Temporary-License-request1.pdf

NMAC 16.19.6.19 (Pharmacy)
NMAC 16.19.10 (Clinic)

Dishonorable Conduct-Update

- **Dishonorable conduct by a facility (business)" shall mean but not to be limited to:**
- **(18)** failure to provide a work environment that allows a pharmacist and pharmacist intern to adequately perform duties requiring professional judgment, and for a pharmacist to fulfill duties as enumerated in 16.19.4.16 NMAC and all other duties and responsibilities of a pharmacist as listed in the rules of the board. In determining whether a work environment is appropriate, the board may consider factors including workload (e.g. sufficiency of staffing to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to complete required duties);
- **(19)** introducing or enforcing external factors, such as productivity or production quotas or other programs against pharmacists, pharmacist interns or pharmacy technicians, to the extent that they interfere with the ability of those individuals to provide appropriate professional services to the public.
- **(20)** retaliation against a pharmacy employee for reporting or filing a complaint regarding violation of board requirements that the business has the authority to correct. Violation of board requirements includes unreasonable workload, such that pharmacy employee(s) are not able to adequately fulfill duties and responsibilities as outlined in board administered rules and statutes

NMAC 16.19.27.7B(18)(19)(20)

Compounding of Non-Sterile Veterinary Drug Preparations

- A licensed pharmacy may compound non-sterile veterinary drug preparations in reasonable quantities for veterinarian office use
- Office use preparations may be dispensed by a veterinarian for a patient under specific conditions which include:
  - a valid veterinarian client patient relationship exists
  - dispensed amount is for use in a single course of treatment, not to exceed a 5-day supply
  - the patient has an emergency condition that the compounded drug is necessary to treat
  - timely access to a compounding pharmacy is not available
  - medication is not a controlled substance

https://www.srca.nm.gov/parts/title16/16.019.0030.html

NMAC 16.19.30.9A(4)

Compounded non-sterile controlled substances veterinary office use preparations may be distributed by a pharmacy under the following conditions:

- Preparation is not readily available from an outsourcing facility
- Ordering and distribution occur in compliance with state and federal law
- The pharmacy shall be registered with the DEA as a manufacturer
- In addition to other required labeling, such preparations shall bear a statement “For administration only. Not for dispensing or resale”

https://www.srca.nm.gov/parts/title16/16.019.0030.html

Prescription Adaptation by a Pharmacist

- A pharmacist, using professional judgement, may perform the following adaptations in filling a new non-controlled substance prescription:
  - change quantity, dosage, dosage form, or directions for use if it meets the intent of the prescriber, OR
  - complete missing information on a prescription
- The pharmacist must notify the prescriber within 24 hours, maintain documentation and provide counseling to include information pertinent to the prescription adaptation

https://www.srca.nm.gov/parts/title16/16.019.0006.html

NMAC 16.19.6.23I

Controlled Substances

- **16.19.20 NMAC- amendment to Section 42** requires electronic prescribing of controlled substance (EPCS) prescriptions effective **April 1, 2021**, and specifies exceptions

- **16.19.20 NMAC- amendment to Section 69** deschedules a drug product approved for marketing by the FDA and which contains cannabidiol derived from cannabis and no more than 0.1 percent tetrahydrocannabinols

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.42B and NMAC 16.19.20.69C

NMAC 16.19.20.42 B (1) (a-j)
All CS prescriptions electronically transmitted except:

(a) for patients residing in an intermediate care, skilled nursing or correctional facility;
(b) for patients enrolled in hospice;
(c) for an animal by a licensed veterinarian;
(d) a prescription dispensed by a federal facility not subject to state regulation (e.g. department of veteran affairs, Indian health services, military bases);
(e) a prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments; or new medications not yet in electronic system;
(f) for compounded prescriptions;
(g) for prescriptions issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location;
(h) for prescriptions issued in an emergency pursuant to federal law and rules of the board;
(i) for prescriptions issued in response to a public health emergency where a non-patient specific prescription would be permitted;
(j) under extenuating circumstance, not inconsistent with federal law and where the practitioner communicates directly with the pharmacist. The pharmacist, using professional judgment, may accept the non-EPCS and is responsible for ensuring documentation of the circumstance in the prescription record; and that the prescription is otherwise in compliance with state and federal law and rules.

Compounded Sterile Preparations

- Must be compounded properly in accordance with all applicable USP chapters numbered less than <1000>
- Currently USP <797>
- USP <800> effective on December 1, 2019
  - Hazardous compounding must be done in a negative pressure room
  - Can no longer have hazardous and non-hazardous compounding in the same room
- USP <795> and <797> available and official November 2023

NMAC 16.19.36.6

https://www.srca.nm.gov/parts/title16/16.019.0036.html

Repackaging and Distribution by a Pharmacy for Administration

- Pharmacy licensed by the board may repackage under the following conditions:
  - By a managing pharmacy for use in an automated drug distribution system of a licensed health care facility (**for administration**)
  - To a clinic under the same ownership as the pharmacy, **for administration** to clinic patients (not dispensing)
  - Must be repackaged into a sealed unit-dosed container with appropriate BUD, and properly labeled

https://www.srca.nm.gov/parts/title16/16.019.0006.html

NMAC 16.19.6.30

Automated Drug Distribution Systems

- A managing pharmacy may use an automated drug distribution system to supply medications for patients of a health care facility licensed under 16.19.11 or inpatient hospice facility
- The system may be located in a health care facility that is not at the same location as the managing pharmacy
- Considered an extension of the managing pharmacy.
- If the system contains controlled substances for **routine dosing**, the managing pharmacy must submit and maintain a separate registration with the DEA

https://www.srca.nm.gov/parts/title16/16.019.0006.html

NMAC 16.19.6.27

Emergency drug supply for a licensed custodial care facility

- "E-Kit"- emergency drug supply may not be used for routine doses.
- Accessed only by licensed personnel on duty
- Controlled substances only if 24-hour/365 days per year on-site nurse
- Can be an automated drug distribution system
- These do not require separate registration with the DEA (because may not used for routine dosing)

https://www.srca.nm.gov/parts/title16/16.019.0011.html

NMAC 16.19.11.8

Drug, Device & Cosmetic Act

- Pharmacists may combine refills up to a 90 day supply.
- No controlled substances.
- Practitioner can specify no combining of refills on prescription.

https://nmonesource.com/nmos/nmsa/en/item/4355/index.do#!fragment/zoupio-_Toc98941227/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zgE4AODgFgEYATIIDsASgA0ybKUIQAiokK4AntADk6iREJhcCRcrWbtu-SADKeUgCE1AJQCiAGUcA1AIIA5AMKOJpGAARtCk7GJiQA

NMSA 26-1-16J

Conscientious Objection

- A pharmacist who declines to fill a prescription for reasons of conscience shall personally:
- (1) **promptly so inform the patient**, if possible, and any person then authorized to make health-care decisions for the patient;
- (2) **provide continuing care to the patient until a transfer can be effected**; and
- (3) unless the patient or person then authorized to make health-care decisions for the patient refuses assistance, **immediately make all reasonable efforts to assist in the transfer of the patient to another health-care practitioner or health-care institution that is willing to comply with the individual instruction or decision**.

https://nmonesource.com/nmos/nmsa/en/item/4384/index.do#!fragment/zoupio-_Toc79147922/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zgHYBOARgBZuAJkEBKADTJspQhACKiQrgCe0AOSqxEQmFwJ5iles3bdIAMp5SAIRUAlAKIAZewDUAggDkAwvbGkwAEbQpOwiIkA

NMSA 24-7A-7

CII Partial Filling

- A prescription for a Schedule II may be partially filled if the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
- Remaining portions shall be filled no later than 30 days after the date on which the prescription is written.

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.46

CII Partial Filling

- A CII initially filled more than 30 days from date written may be partially filled if:
  - **(1)** the pharmacist is unable to dispense the total quantity prescribed;
  - **(2)** the partial fill amount is recorded on the written prescription or in the electronic prescription record;
  - **(3)** the remaining portion is filled within 72 hours of the partial filling; and
  - **(4)** the pharmacist notifies the prescribing physician if the remaining portion cannot be filled within the 72 hour period. No further quantity may be supplied beyond 72 hours without a new prescription.

NMAC 16.19.20.46

CII RX "LTCF"/"terminal" patient

- Partial filling of a CII RX for Hospice or LTCF patients is allowed for a period of 60 days from the date of issuance.

NMAC 16.19.20.46

CIII-V Partial Filling

- Partial filling is allowed provided that:
  - Total quantity of all partial fills does not exceed the total quantity prescribed
  - No dispensing occurs after 6 months from written date

NMAC 16.19.20.46

PAIN RELIEF ACT (2019 amendment)

- Relating to Opioid Overdose
- Requires health care providers who prescribe, distribute, or dispense, under certain circumstances, to advise patients about risks of overdose and to co-prescribe an opioid antagonist
- Note: A health care provider in this context is not a pharmacist who is dispensing

https://nmonesource.com/nmos/nmsa/en/item/4384/index.do#!fragment/zoupio-_Toc79147721/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zgHYBOARgBYOHAEw8AlABpk2UoQgBFRIVwBPaAHI14iITC4ECpao1adekAGU8pAEKqASgFEAMg4BqAQQByAYQfjSYABG0KTsoqJAA

NMSA 24-2D-1

PAIN RELIEF ACT

- Advise on risks and inform of antagonist availability –
  - First time an opioid analgesic is prescribed to a patient
  - First time each calendar year
- Co-prescribe antagonist if opioid is at least a five day supply (first time, and first time each year)

https://www.nmlegis.gov/Sessions/19%20Regular/final/SB0221.pdf

PAIN RELIEF ACT

- Provide written information regarding the temporary effects of the opioid antagonist and techniques for administration
  - Written information shall contain a warning that a person administering the opioid antagonist should call 911 immediately after administering the opioid antagonist

Controlled Substance Prescriptions

- Expiration Dates
  - All CS prescriptions expire 6 months from the date written

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.45A,B

Prescription Requirements

- Shall verify the identity of the patient or representative who is receiving any prescription for a CS before it is released
- Current government issued photo identification required, and the documentation of:
  - Name
  - Number
  - Identification Type (DL, ID card, passport)
  - State (If applicable)

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.42 E

Prescription Transfers

- A pharmacy may not refuse to transfer original prescription information to another pharmacy who is acting on behalf of a patient and who is making a request for this information
- In the case of a hard copy unfilled CS Rx, the patient may pick it up and take to another pharmacy

https://www.srca.nm.gov/parts/title16/16.019.0006.html

NMAC 16.19.6.23D

Controlled Substance Refills

- 16.19.20.45 PRESCRIPTION REFILL REQUIREMENTS:
- (1) Controlled substance prescriptions dispensed directly to a patient shall not be refilled before 75% of the prescription days supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.45A

Controlled Substance Refills

- 16.19.20.45 PRESCRIPTION REFILL REQUIREMENTS:
- (2) Controlled substance prescriptions delivered to a patient indirectly (as in mail order) to a patient shall not be refilled before 66% of a 90 day supply has passed or 50% of a 30 day supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.45A

Controlled Substance Inventory Records

- Inventory record must include:
  - date, time (i.e. open or close of business)
  - name, address, DEA# and signature(s)
  - drug name, strength and form
  - number of units or volume; total quantity
  - expired or unusable CS documented as such and inventoried
- Initial Inventory
- Annual Inventory
  - Actual inventory within 4 days of annual inventory date (May 1st, or alternate set date on record with Board)
- Inventory when there is a CS Schedule change
- Inventory required for change of PIC
  - Must be taken within 72 hours by the new PIC
- Upon transfer of ownership of a pharmacy

https://www.srca.nm.gov/parts/title16/16.019.0020.html

NMAC 16.19.20.20

Solicitation & Unprofessional and Dishonorable Conduct

- Prohibition of solicitation of prescription business via preselected medications on prescription blanks and/or prescription requests that are not initiated by either the prescriber or the patient.
- Licensed individuals and/or facilities not in compliance with the new regulations may be subject to disciplinary actions.

https://www.srca.nm.gov/parts/title16/16.019.0027.html

NMAC 16.19.4.9C(10-12) & 16.19.27.7A (9-11), B(9-11)

Update - Hospital Pharmacy Dispensing

16.19.7.17 NMAC – Hospital Pharmacies

- Language was added to NMAC to allow an inpatient hospital pharmacy, not otherwise licensed as a retail pharmacy, to dispense medication to a patient on hospital discharge, on a limited basis
- Dispensing restrictions include, but not limited to:
  - Medication must be prescribed by a licensed practitioner of the hospital
  - Medication must be dispensed by a pharmacist
  - No controlled substances (CS) may be dispensed
  - Prescription or order may not be refilled or transferred

https://www.srca.nm.gov/parts/title16/16.019.0007.html

NMAC 16.19.7.17

Optometrist Prescribing

An Optometrist:

- May prescribe hydrocodone and hydrocodone combination medications;
- Shall not prescribe any other controlled substance classified in Schedule I or II pursuant to the CS Act

https://www.srca.nm.gov/parts/title16/16.016.0007.html

NMAC 16.16.7.9

Naturopathic Doctors
Licensed by NM Medical Board
Have limited prescriptive scope of practice

- INCLUDES
  - All Legend Drugs
  - Controlled Substances Schedule III, IV and V including testosterone
- EXCLUDES
  - Controlled Substances in Schedule II
  - Opiates, opioids, and benzodiazepines

https://www.srca.nm.gov/parts/title16/16.010.0022.html

NMAC 16.10.22.11

Examination Repeats

- A candidate who fails either the NAPLEX or MPJE may repeat that examination upon submittal of the proper application and fee. A candidate may not take either the NAPLEX or MPJE more than five consecutive times without passing. Failure to finish an examination is counted as an attempt. Candidates who fail or do not complete the NAPLEX shall wait a period of at least 45 days prior to retaking the examination. Candidates who fail or do not complete the MPJE shall wait a period of at least 30 days prior to retaking the examination.

https://www.srca.nm.gov/parts/title16/16.019.0002.html

NMAC 16.19.2.9

Pharmacist

- ACTIVE STATUS

Any pharmacist who maintains competency through the development and maintenance of knowledge, skill and aptitude, to ensure continuing competence as a pharmacy professional, and is able to demonstrate to the board said competence in the practice of pharmacy shall be issued an active license.

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.14

CPE Requirements
Pharmacist Continuing Education Requirements

- Live CPEs
- A minimum of 10 contact hours excluding the law requirement, shall be obtained through live programs
- Must be ACPE, ACCME, or board approved programs

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10 B

CPE Requirements

- Live Programs
  - "Live programs" means CPE activities that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, workshops, etc.

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.7O

CPE Requirements

- Patient Safety
- A minimum of 0.2 CEU (2 contact hours) per renewal period shall be in the area of PATIENT SAFETY as applicable to the practice of pharmacy

https://www.srca.nm.gov/parts/title16/16.019.0004.htm

NMAC 16.19.4.10B

CPE Requirements

- Pharmacy Law
- A minimum of 0.2 CEU (2 contact hours) per renewal period shall be in the subject area pharmacy law offered by the N.M. Board of Pharmacy

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10B

CPE Requirements

- Safe and appropriate use of opioids
- A minimum of 0.2 CEU (two contact hours) per renewal period shall be in the area of safe and appropriate use of opioids.

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10B

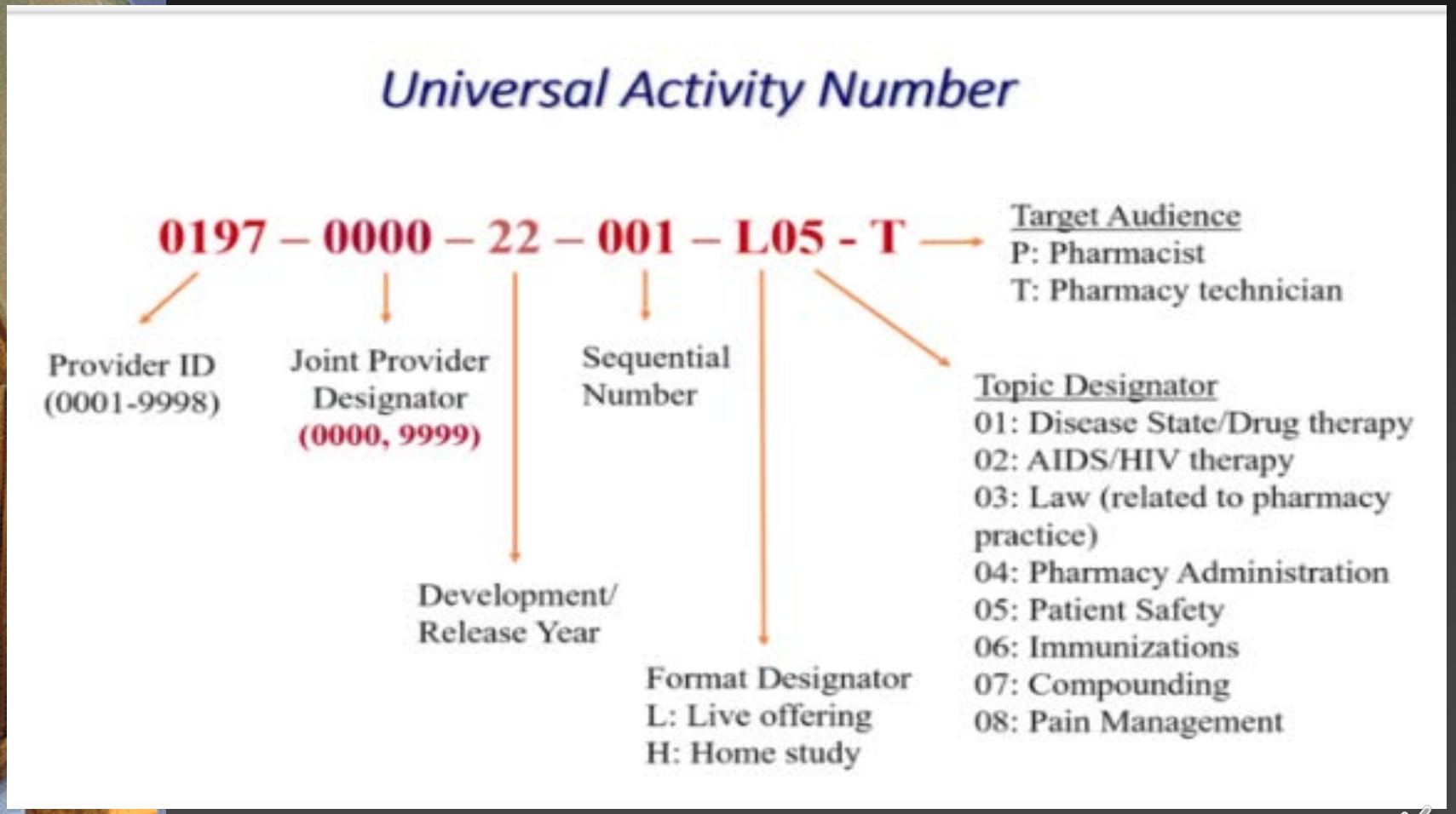
CPE Requirements

- **30 Total Hours Required**
  - 10 Hours of Live Programs
  - 2 Hours Patient Safety (Applicable to Pharmacy)
  - 2 Hours Pharmacy Law
  - 2 Hours Safe and Appropriate Use of Opioids
  - CEs obtained for Immunization Certification, Smoking Cessation, Naloxone etc. are **in addition** to the 30 hour requirement (16.19.26 NMAC)

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10

ACPE UNIVERSAL ACTIVITY NUMBER



https://www.acpe-accredit.org/universal-activity-numbers/

Pharmacist Prescriptive Authority Renewal CPE Requirements (16.19.26 NMAC)

- **Continuing education shall be in addition to requirements in 16.19.4.10 NMAC.**

Emergency Contraception (EC):	2 hours ACPE approved EC drug therapy (DT) related
Hormonal Contraception (HC):	2 hours live ACPE approved HC DT related
Naloxone for opioid overdose:	2 hours live ACPE approved naloxone DT related
Tb Testing:	CE as specified by the Centers for Disease Control (CDC)
Tobacco Cessation (TC):	2 hours ACPE approved TC DT related
Vaccines:	2 hours live ACPE approved vaccine related, **and** current live BLS/CPR certification

https://www.srca.nm.gov/parts/title16/16.019.0026.html

NMAC 16.19.26

RPh Prescriptive Authority Not Needed to Dispense Opioid Antagonists

- Naloxone Standing Order For Registered Pharmacists Updated
- Includes other Opioid Antagonists for Rescue Use
- NMBOP website, FAQ tab to Naloxone Information

https://www.rld.nm.gov/boards-and-commissions/individual-boards-and-commissions/pharmacy/pharmacy-faqs/

NMBOP website FAQ's Naloxone or other Opioid Antagonists Information

- How to use the Statewide Standing Order for Registered Pharmacists to dispense Naloxone or other Opioid Antagonists
- Print the prescription template to dispense Opioid Antagonist
- Information on Opioid Safety and How to Use Naloxone

CPE Requirements Pharmacist Clinician

- Pharmacist Clinician (PhC) renewal
- In addition to 16.19.4.10
- 20 hours live CE – ACPE or ACCME
- A PhC with a controlled substance registration to prescribe Schedule II or III shall complete a minimum of 2 contact hours per renewal period in the subject area of responsible opioid prescribing practices.

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.17

CPE Requirements

- Pharmacist
  - Allows CPE programs that are approved by other state boards of pharmacy to count toward your New Mexico pharmacist renewal

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10A

CPE Requirements

- Pharmacists and pharmacist clinicians without sufficient documentation of completion of CPE requirements shall:
- Be subject to a fine of not less than $1,000
- Be required to complete the deficient CPE in a satisfactory time period as determined by the board

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.10F

Pharmacist Clinician

- Prohibit prescribing for themselves or immediate family members, except under emergency situations.
- Does not apply to meds under 16.19.26 (Vaccines, tobacco cessation, naloxone, TB testing)
- Removal of the restriction on Pharmacist Clinician writing a recommendation for use of medical cannabis.

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.17D

Pharmacist Clinician: PMP

(With Prescriptive Authority for CS)

- Shall register with the PMP
- May authorize delegate(s) but is solely responsible for reviewing PMP and documentation of medical record
- 1st rx written for over a 4 day supply for a CII, III, IV require PMP review OR if there is a gap in prescribing the CS for 30 days or more.
- Other regulations for utilizing PMP reports for continuous use of CS

NMAC 16.19.4.17F

Pharmacy Technicians

- Non-Certified Technician
  - Registration expires after 1 year
  - Cannot be renewed
  - Exception: Technician that is enrolled in a board recognized technician training program.

https://www.srca.nm.gov/parts/title16/16.019.0022.html

NMAC 16.19.22.9 E

Pharmacy Technicians

- MUST be registered PRIOR to working as a pharmacy technician
- Pharmacy Techs that are being allowed to work after their registration has expired may result in disciplinary action against the supervising pharmacist as well as the pharmacist-in-charge, and the pharmacy

NMAC 16.19.22.7 C (2) & NMAC 16.19.22.11 A

Pharmacy Technician Certification Board Renewal Changes

- Any CE hours earned by a CPhT will need to be pharmacy technician specific in order to qualify toward recertification
- PTCB requires 20 CE hours
- PTCB beginning January 1, 2018, PTCB no longer accepts in-service CE hours.
- PTCE and ExCPT are examinations that are accepted by PTCB to become a CPhT
- https://www.ptcb.org/credentials/certified-pharmacy-technician#take-the-exam
- https://www.nhanow.com/certification/nha-certifications/certified-pharmacy-technician-(cpht)

https://www.ptcb.org/continuing-education

https://www.nhanow.com/certifications/pharmacy-technician

Pharmacy Technicians

- The permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the Pharmacist-In-Charge

NMAC 16.19.22.10

Improper Activities of Pharmacy Technicians

- Perform the RPH final check and supervise
- Receipt of all new verbal prescription orders and reduction to writing;
- Professional judgment
- Consult a patient or his agent regarding a prescription or over-the-counter
- Patient Counseling
- Professional consultation with the prescriber

https://www.srca.nm.gov/parts/title16/16.019.0022.html

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.9(C15) & NMAC 16.19.22.11

Support Personnel

- Support personnel (who are not pharmacy technicians) may NOT:
- Process and fill prescriptions
- Stock prescription drugs in sites that do not utilize barcode verification or similar electronic verification process to ensure correct selection of medication
- Perform duties restricted to a pharmacist, intern or technician

https://www.srca.nm.gov/parts/title16/16.019.0022.html

NMAC 16.19.22.7H

Prescription Monitoring Program (PMP)

- CS prescriptions must be reported within one business day of a prescription being filled

https://www.srca.nm.gov/parts/title16/16.019.0029.html

NMAC 16.19.29.8C

Dispensers – Required PMP **Reporting**

- All **non-pharmacy dispensers** (clinics, urgent care or emergency care, dispensing practitioners) must report within one business day if more than **12 doses or 72 hour supply was dispensed (whichever is less)**
- If a **pharmacy** did not dispense any controlled substances during an operating business day, a "**zero report**" must be submitted within one business day.
- If a dispenser becomes aware of an data entry error, the **correction** must be submitted to the PMP within **five** (5) business **days**.

https://www.srca.nm.gov/parts/title16/16.019.0029.html

NMAC 16.19.29.7 & 16.19.29.8

Board of Pharmacy Newsletter

- Published quarterly by the NABP
- Electronically available
- To subscribe to receive email alerts for the NMBOP Newsletter and/or to obtain a current copy visit:

  https://nabp.pharmacy/bop_members/new-mexico/

HB47 Elizabeth Whitefield End-of-Life Options Act

- An MD, DO, Advanced practice nurse or PA
- May provide a prescription for medical aide in dying to a terminally ill adult who is mentally competent after meeting certain requirements.
- A prescription for medical aid in dying cannot be filled until 48 hours after the prescription is written unless the prescribing healthcare provider medically confirms that the individual may die before the expiration of the aforementioned time period.
- The prescription must include the time and date written as well as the time and date when it may be filled

https://www.nmlegis.gov/Sessions/21%20Regular/bills/house/HB0047.pdf

HB47 Elizabeth Whitefield End-of-Life Options Act

- Healthcare providers who object, for reasons of conscience, to participating in the provision of medical aid of dying are not required to do so and will not be subject to criminal liability, licensing sanctions, or professional disciplinary action.

- However healthcare providers must inform the individual of their decision and refer them to a provider who is able and willing to carry out the individual's request, or to another individual or entity to assist the requesting individual in seeking medical aid in dying.

NMBOP issued E-Alerts

- Contact the Board to receive E-Alerts
- E-Alerts provide important information including:
  - Changes to a prescriber's prescriptive authority and license status
  - Safety issues
  - Time sensitive information

Pharmacy Act 61-11-2 NMSA

- **Senate Bill 92 Section 1-** amended 61-11-2CC, definition of "practice of pharmacy" to include:
  - the administering or prescribing of dangerous drug therapy, devices or supplies for prescribed drug therapy for health conditions, including diabetes
    - for example: retail pharmacist can prescribe for a nebulizer and diabetic supplies
  - the ordering, performing and interpreting of tests authorized by the FDA and also CLIA waived tests under test and treat allowance.

https://www.nmlegis.gov/Sessions/23%20Regular/final/SB0092.pdf

Pharmacy Act 61-11-30 NMSA

Pursuant to a board-approved protocol approved by the New Mexico medical board, a pharmacist may order, test, screen, treat and provide preventative services for health conditions or situations that include:

- Influenza
- Group A streptococcus pharyngitis
- SARS-COV-2
- Uncomplicated UTI
- HIV pre and post-exposure prophylaxis
- and other emerging and existing public health threats during civil or public health emergencies

61-11-30A NMSA

Pharmacy Act 61-11-30 NMSA

Testing, Screening and Treatment of Health Conditions Pursuant to board approved protocol

- A pharmacist who orders, tests, screens or treats for health conditions or situations pursuant to this section may use any test that may guide clinical decision making, including CLIA waived tests, the federal rules adopted thereunder or any established screening procedure that can safely be performed by a pharmacist.
- A pharmacist may delegate the administrative and technical tasks of performing a CLIA waived test to a pharmacist intern or pharmacy technician acting under the supervision of the pharmacist.
  - For example: Perform an oral swab

https://www.nmlegis.gov/Sessions/23%20Regular/final/SB0092.pdf

Pharmacist Prescribing In Conjunction With POCT

- Board approved protocol available for Influenza, Strep and COVID-19

- Pharmacist must successfully complete a course of training accredited by ACPE, for ***each category*** of POCT for which the pharmacist exercises prescriptive authority, provided by:
  - the NMPhA
  - a similar health authority or professional body approved by the Board

NMAC 16.19.26.14

RPh Prescriptive Authority protocol HIV PEP (Post-Exposure Prophylaxis) with POCT (Point of Care Testing)

- For patients potentially exposed to HIV within the past 72 hours
- Complete Board approved training
- Notify the patient's primary care provider of the Rx and POCT results, with patient consent
- Maintain documentation/records
- Proper notification to the NM Department of Health, if required (e.g. positive HIV test results)
- RPh referral to a doctor or NMDOH under certain circumstances
- Complete 2 hours live ACPE CE per RPh license renewal period

https://api.realfile.rtsclients.com/PublicFiles/1ee897135beb4b1c82715d36398de4c5/167cd20d-6bf9-4fba-8388-661253283c6f/Protocol%20for%20Pharmacist%20Prescribing%20of%20HIV%20Post-Exposure%20Prophylaxis%20(PEP).pdf

NMAC 16.19.26.14

Required Reporting
Pseudoephedrine & Ephedrine OTC Sales
-NPLEx Reporting via Apriss

- Register at:

https://nplex.appriss.com/retail/pharmacy/loginRegister.do

- Training link :

https://videobred.app.box.com/s/1rtua3cvcgxxw1qtl2v84hu138fy4ijn/file/312452439879

- Support e-mail NPLexSupport@appriss.com
- Questions phone 883-755-2126

NMAC 16.19.20(53B)

Updated NMAC 16.19.4
Naloxone stocked in custodial care facilities

- Added an allowance for custodial care facilities to stock naloxone

https://www.srca.nm.gov/parts/title16/16.019.0004.html

NMAC 16.19.4.11 D (8) (c)

Updated NMAC 16.19.12
U.S. Military registration
and initial renewal fees waived

- Updated section 9 waiving registration fees and initial renewal fees for U.S. military service members, spouses, dependent children and veterans applying for pharmacist licensure by reciprocity.

https://www.srca.nm.gov/parts/title16/16.019.0012.html

NMAC 16.19.12.9EF and 16.19.12.12K

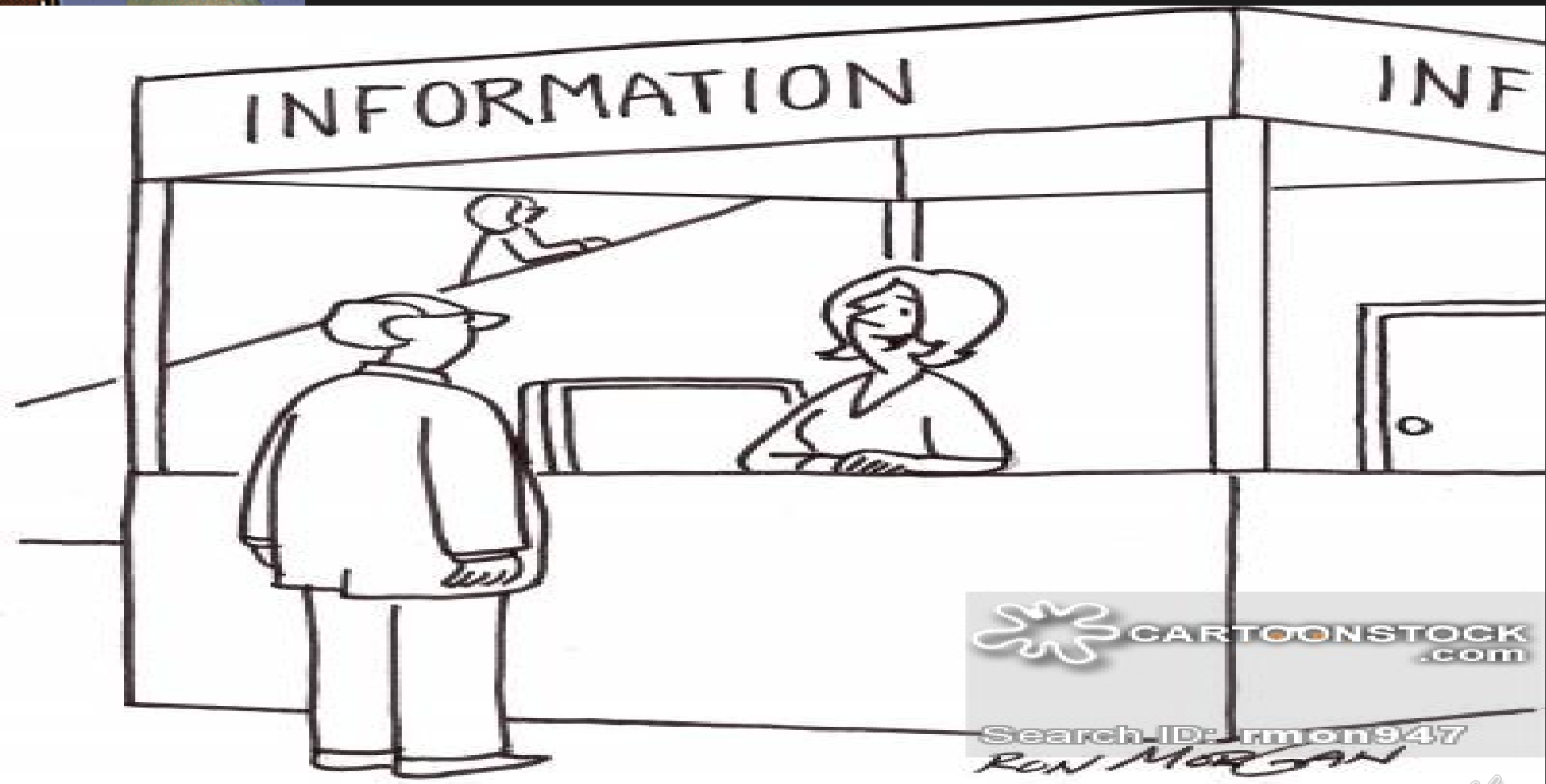
Updated NMAC 16.19.22
Support Personnel and Pharmacy Technicians

- Allowing for pharmacy technician administration of vaccines

https://www.srca.nm.gov/parts/title16/16.019.0022.html

NMAC 16.19.22.16

QUESTIONS?


INFORMATION
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CARTOONSTOCK .com
Search ID: rmon947
"Have you tried Googling that?"