Pharmacy Law Update
Presented by
New Mexico Board of Pharmacy

September 12, 2020
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September 2020

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FEDERAL LAW
Current Drug Disposal Information

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

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


Controlled Substance Public Disposal Locations

https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s3

APD Disposal Locations

https://www.cabq.gov/police/programs/pharmaceuticals

Drug Disposal

- Began September 2010.
- The DEA has sponsored 18 total take-back events
- On October 26, 2019
  - Collected 441.5 tons (882,919 pounds)
  - Record setting amount of 474.5 tons previously collected in April 2018
- Total collection of 6,349.7 tons (12,699,456 pounds)

https://takebackday.dea.gov/

DEA Drug Take-Back Events
Next National Take-Back

National Prescription Drug Take Back Day is October 24

The next National Take-Back Day will be October 24, 2020. This event is a safe, convenient, and responsible way to dispose of unwanted or expired prescription drugs at locations in communities throughout the country.

This year’s 2020 Take-Back Day brought in 382,919 pounds (almost 442 tons) of unwanted or expired prescription medication and vape devices.

This brings the total amount of prescription drugs collected by DEA since the fall of 2010 to nearly 17.7 million pounds. Read more about the most recent Take Back Day totals here.

Check the official Take Back Day website for more information and to find year-round collection sites near you.

Take Back Collection Sites

Take Back Collection Sites

 enraged US DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION

National Take-Back Initiative Collection Site Search

Take Back Drug Take Back Day National Prescription Drug Take Back Day

Get additional information on our Collection Sites now, at:

https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

Drug Disposal: Dispose "Non-Flush List" Medicine in Trash

Follow these simple steps before tossing medicines that are not on the flush list at home:

1. For medicines (liquid or pills) do not count tablets or capsules with an unaccepting substance such as cit, cut tablets, or used coffee grounds.
2. Place the medicine in a container such as a sealed plastic bag.
3. Throw the container in your trash at home.
4. Delete all personal information on the prescription label of empty medicine bottles or medication packaging. These should or recycle the empty bottles or packaging.

Other technologies which provide additional options for disposing of medicines have been developed.

https://www.fda.gov/drug/disposal-unused-medicines-what-you-should-know/drug-disposal-non-flush-list-medicine-trash
FDA Flush List: Medicines recommended for disposal by flushing only when take back options are not readily available.

Medicines on this flush list may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom they were prescribed. An example of such a drug is the fentanyl patch, which is an opioid.

Immediately flushing these types of medicines down the toilet helps keep children, pets, and other individuals safe by making sure these powerful and potentially dangerous drugs are not accidentally ingested, touched, or misused.

The FDA flush list tells you which old, unwanted, expired, or unused medicines to immediately flush easily when take back options are not readily available.

Links in the flush list direct you to specific disposal instructions in each medicine's label.

List Recommended for Disposal by Flushing

[Image of a table listing recommended drugs for disposal by flushing]

https://www.fda.gov/drugs/disposal-unused-medicines/what-you-should-know/drug-disposal-flush-potentially-dangerous-medicines#FlushList

Syringe Disposal

[Image of a map showing how to dispose of used sharps]

https://safeneedledisposal.org/

CONTACT INFO

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

[Location map and contact information for DEA Office for Northern NM]
CONTACT INFO

• DEA Office for Southern NM
• 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.”


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

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/OD/ET, etc.)
  - D/R – Manufacturer/Distributor/Researcher/Analytical Lab/Importer/Exporter/Reverse Distributor/Narcotic Treatment Program
  - S – Buprenorphine (Suboxone) physician, PA, NP

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

E-PRESCRIBING UPDATE

• Controlled substances in schedules II – V can be electronically prescribed.
• Please do not reject a C-II Rx because it is an E-prescription

https://www.deadiversion.usdoj.gov/faq/epcs_faq.htm
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.

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.

CFR 1306.03

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.

CFR 1306.25

CIII-V Rx Transferring for refill purposes

- Once the original Rx is filled, the transfer must be communicated directly between two licensed pharmacists
- Document pursuant to 1306.25 (b) (3) (4)

CFR 1306.25A

Unfilled Electronically Prescribed controlled substance (EPCS)

- An unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances (73 FR 36722).
- Addressed in a guidance letter by Loren Miller (DEA), available from the BOP website (FAQ—transfer of controlled substance prescriptions)
- For questions about system requirements to electronically transfer an EPCS, please contact the DEA.

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.

CFR 1301.76
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).

November 2013

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.

Outsourcing Facility

- Current FDA registration as an Outsourcing Facility
- Licensed by NMBOP as an outsourcing facility
- Providers may purchase non patient-specific compounded sterile product, for administration, from an outsourcing facility.

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.

**FDA Guidance for Compounding**

“Essentially a copy” of a commercially available drug product if:

- 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 can be used by the same route of administration
- Combination of more than one commercially available drug is still a copy, even if the combination is not commercially available.

[https://www.fda.gov/media/98964/download](https://www.fda.gov/media/98964/download)

**Essentially a copy**

- Documented prescriber determination:
  - No particular format needed but must be a clear change and significant difference for the patient for example
    - “No Dye X, patient allergy”
    - “Liquid form, patient can’t swallow tablet”
    - “6mg, patient needs higher dose”

[https://www.fda.gov/media/98964/download](https://www.fda.gov/media/98964/download)

**503A**

- FDA does not intend to take action if the:
  - Compounder fills 4 or fewer Rxs for the relevant compounded drug product in a calendar month (intended for emergencies);
  - Documented prescriber determination (significant difference for an individual patient);
  - Drug product is currently in shortage under 506E

[https://www.fda.gov/media/98964/download](https://www.fda.gov/media/98964/download)

**Unprofessional Conduct**

- If compounded regularly or in an inordinate amount of any drug products that are essentially copies of commercial products.

[https://www.fda.gov/media/98964/download](https://www.fda.gov/media/98964/download)

**New Mexico Law & Board Activity**

- 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.

A pharmacy may compound a **patient-specific** sterile preparation pursuant to a prescription or order for an individual patient.

Preparation of non-patient specific compounded sterile product for sale is considered manufacturing, and requires registration with the FDA and the NM Board of Pharmacy as an outsourcing facility.

**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

**Non-Sterile Compounding**
- The wording allowing for office use compounding was removed from the regulation.
- A pharmacy may no longer compound for a prescriber’s office use.

**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

**Automated Drug Distribution Systems (Pyxis type)**
- 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

**Emergency drug supply for a licensed custodial care facility**
- “E-Kit” - emergency drug supply
- 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 not used for routine dosing)
Prescription Synchronization

- Prescription drug or device benefit shall allow an insured to fill or refill a prescription for less than a thirty-day supply of the prescription drug, AND apply a prorated daily copayment or coinsurance for the fill or refill, if
  - Prescribing practitioner or the pharmacist determines it to be in the best interest of the insured
  - The insured requests or agrees to receive less than a thirty-day supply of the prescription drug; and
  - The reduced fill or refill is made for the purpose of synchronizing the insured’s prescription drug fills.


2015 HB 274 Legislature

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.

24-7A-7 NMSA

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.

Electronic Prescribed Controlled Substances by January 1, 2021

- 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, 2021.

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.samhsa.gov/about-us/who-we-are/laws-regulations

https://www.asam.org/advocacy/the-support-for-patients-and-communities-act-(h.r.-6)
**CARA 2016**

- **Summary of Provisions of CARA**
  - Prevention and Educational
  - Expand the availability of naloxone
  - Treat incarcerated individuals
  - Expand disposal sites for unwanted prescription medications
  - Expand evidence-based opioid and heroin treatment and intervention program
  - Strengthen prescription drug monitoring programs

**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.


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**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.

**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.

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**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
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://www.nmmb.state.nm.us/docs/statutes/PainReliefAct.pdf

24-2D-7, 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)

24-2D-7, 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

16.19.20.43A,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 govt. issued photo identification required, and the documentation of:
  - Name
  - Number
  - Identification Type (DL, ID card, passport)
  - State (If applicable)

16.19.20.42G

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

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.

(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.

Controlled Substance Refills

• Document date, time, and open or close of business
• 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

Annual CS Inventory

• Annual controlled substance inventory shall include in the count the separate expired or unusable controlled substances and documented as such

NMAC Update - Solicitation

• Language was added to New Mexico Administrative Code (NMAC) prohibiting the 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.

• This means that a pharmacy, or other entity providing prescription medications, cannot make a specific request for a new medication by preselecting a drug. Such requests must come from the patient or the provider.
NMAC Update - Solicitation

This falls under the regulations for both unprofessional conduct and dishonorable conduct. Licensed individuals and/or facilities not in compliance with the new regulations may be subject to disciplinary actions.

16.19.4.9 C (11), (12) and 16.19.27.7 A (9), (10), (11)

NMAC Update - Solicitation

- **16.19.27.7 NMAC – Dishonorable Conduct:** Amendment was added to protect the health and safety of patients in New Mexico by prohibiting the solicitation of prescription business via preselected medications on prescription blanks or via prescription requests not initiated by the patient or practitioner.
- **Statutory Authority:** Paragraphs 1 and 12 of Subsection A of Section 61-11-6 NMSA 1978

Update - Hospital Pharmacy Dispensing

16.19.7.16 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
- Prescriptions or orders may not be refillable or transferred

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

Cannabidiol (CBD) Epidiolex

- Manufactured by GW Pharmaceuticals
  - Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
- 1st CBD product approved by FDA
  - In September of 2018- DEA classified Epidiolex as a Schedule 5 controlled substance
  - FDA approval (June 2018) & no more than 0.1% THC


Naturopathic Doctors

Licensed by NM Medical Board
Have limited prescriptive scope of practice

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

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.

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

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.

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

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
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.

ACPE UNIVERSAL ACTIVITY NUMBER

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)

Pharmacist Prescriptive Authority Renewal CPE Requirements (16.19.26 NMAC)

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

Naloxone DOH Standing Order

- 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.
CPE Requirements
Pharmacist Clinician
- Educational programs approved by the New Mexico Medical Board in the subject area of opioid prescribing shall meet the requirements of this section.

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

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

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)
- Prohibited from referring a patient for the use of medical cannabis

Pharmacist Clinician: PMP
- 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
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.

- **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

Professional Judgment only by a RPh

- Pharmacy technician cannot perform tasks that require professional judgment.
- “Professional judgment” means a cognitive process, by a licensed professional, that takes education, experience, current primary literature and current standards of practice into consideration when drawing conclusions and reaching decisions.

Professional Judgment

- “Professional judgment” means a cognitive process, by a licensed professional, that takes education, experience, current primary literature and current standards of practice into consideration when drawing conclusions and reaching decisions.

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

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.alanow.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

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

Pseudoephedrine and Ephedrine OTC Sales

- Submit sales information reports electronically every seven (7) days
- New Mexico Methamphetamine Special Information System (NMMSIS-Brian Sallee)
  - NMMSIS is the Board-authorized contract for collection of data in a Board-defined format
- Pharmacies may petition the executive director of the board for an alternative method for the submission

NMMSIS REPORTING

- USER REQUEST FORM ON BOARD WEB SITE
  - NMMSIS USER REQUEST FORM
  - IN “FORMS” SECTION
  - http://www.rld.state.nm.us/uploads/FileLinks/bde0e0d28ef545cba3d8cd27c3974d/NMMSIS_Request_Form_081315.pdf

Prescription Monitoring Program (PMP)

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

Pharmacist

Prospective Drug Review: Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(a) clinical abuse/misuse;
(b) therapeutic duplication;
(c) drug-disease contraindications;
(d) drug-drug interactions;
(e) incorrect drug dosage;
(f) incorrect duration of drug treatment;
(g) drug-allergy interactions;
(h) appropriate medication indication
Pharmacist

- Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance Prescription Monitoring report or another state’s report if applicable and available, and/or consulting with the prescriber and/or counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

PMP Facts 16.19.29 NMAC

- Only an authorized account holder can access the NM PMP.
- Sharing login information is a violation of both federal and state regulations.
- Pharmacist delegate must be a certified pharmacy technician or a registered intern.
- Only for pharmacist dispensing or providing pharmaceutical care as defined by law.
- Pharmacist is responsible for reviewing and documenting.
- Consultant Pharmacists check the PMP to do reconciliation and oversight of the facility receiving controlled substances.

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 a data entry error, the correction must be submitted to the PMP within five (5) business days.

Board of Pharmacy Newsletter

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Protected Health Information

- PHI items must be shredded or otherwise altered so that confidential patient information does not end up discarded unaltered.

DRUG STORAGE

- ALL LICENSED FACILITIES STORING PRESCRIPTION DRUGS MUST MAINTAIN DRUG STORAGE TEMPERATURE MONITORING EQUIPMENT AND/OR LOGS
  - High/Low thermometers and daily logs
  - Automated recording devices
**DRUG STORAGE**

- Controlled Room Temp
  - 68 to 77 degrees F
- Cold
  - 36 to 46 degrees F
- Freezer
  - -13 to 14 degrees F


**Automated Filling Systems**

- Pharmacist shall inspect and verify accuracy of final contents, and label prior to dispensing the prescription unless:
  - AFS is maintained and operated according to policies and procedures, and verification criteria per regulation
  - Completed and sealed prescription ready to be dispensed to patient
  - Proper loading, quality assurance, and security are pharmacist’s responsibility
  - No CII
  - No hazardous drugs

18.19.6.28

**Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) is available**

The FDA’s goal is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of opioid analgesics, while maintaining patient access to pain medications.

Refer to “FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain.”

https://www.fda.gov/media/99496/download

**Health Care Workforce Data Collection, Analysis and Policy Act**

- 24-14C-5. HEALTH CARE WORKFORCE DATA COLLECTION BY BOARDS
  - A board shall not approve a subsequent application for a license or renewal of a license until the applicant provides the information.
  - The pharmacist survey is embedded in the on-line process