January 23, 2021

Jooyung Han
State Drug Inspector

Alejandro Amparan
State Drug Inspector
CURRENT BOARD MEMBERS

January 2021
- Chris Woodul RPh  Chairman SW
- Bill Lord RPh  Hospital
- Neal Dungan RPh  SE
- Dale McCleskey RPh  Central
- Teri Rolan RPh  NW
- Cathleen Wingert  Public
- Michael Garringer  Public
- Gwen Griscom  Public
Current Drug Disposal Information

https://www.deadiversion.usdoj.gov/
Drug Disposal Information

Home Disposal Methods
- DEA - Vaping and Marijuana Concentrates: What is Vaping?
- EPA - How to Dispose of Medicines Properly (PDF)
- EPA - Disposal of Medical Sharps
- FDA - How to Dispose of Unused Medicines
- FDA - Disposal of Unused Medicines
- Search for Year Round Pharmaceutical Disposal Locations
- National Prescription Drug Take Back Day

DEA Registrant Drug Disposal
- Title 21 Code of Federal Regulations; PART 1317 — DISPOSAL
- Disposal of Controlled Substances; Final Rule (PDF) (September
- Registration for Disposal of Controlled Substances
  - Modify eligible DEA registration to collect pharmaceutical controlled substances from ultimate users (e.g., patients)
  - Modify DEA registration to stop being a collector
  - Modify existing collector registration information

Drug Disposal - Rulemaking
- Secure & Responsible Drug Disposal Act of 2010 (PDF)
- Public Meeting on Drug Disposal
- Advance Notice of Proposed Rulemaking (ANPRM)

## Controlled Substance Public Disposal Locations

*U.S. Department of Justice ★ Drug Enforcement Administration*

**Diversion Control Division**

### Controlled Substance Public Disposal Locations - Search Utility

<table>
<thead>
<tr>
<th>Bus Name</th>
<th>Addr 1</th>
<th>Addr 2</th>
<th>City, State Zip</th>
<th>Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>WALGREEN CO.</td>
<td>5001 MONTGOMERY BLVD NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87109</td>
<td>2 miles</td>
</tr>
<tr>
<td>NCS HEALTHCARE OF NEW MEXICO, LLC</td>
<td>9019 WASHINGTON ST NE</td>
<td>SUITE B-1</td>
<td>ALBUQUERQUE, NM 87113</td>
<td>4 miles</td>
</tr>
<tr>
<td>KASEMAN POG ONCOLOGY INFUSION PHARMACY</td>
<td>8300 CONSTITUTION AVE NE BLDG D</td>
<td></td>
<td>ALBUQUERQUE, NM 87110</td>
<td>5 miles</td>
</tr>
<tr>
<td>KASEMAN PRESBYTERIAN HOSPITAL</td>
<td>ATTN: PHARMACY</td>
<td>8300 CONSTITUTION AVE NE</td>
<td>ALBUQUERQUE, NM 87110</td>
<td>5 miles</td>
</tr>
<tr>
<td>CVS PHARMACY, INC.</td>
<td>9640 MENAUL BLVD. NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87112</td>
<td>5 miles</td>
</tr>
<tr>
<td>WALGREEN CO.</td>
<td>9700 MENAUL BLVD. NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87112</td>
<td>5 miles</td>
</tr>
<tr>
<td>UNM MENTAL HEALTH CENTER OUTPATIENT PHARMACY</td>
<td>2600 MARBLE AVE NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87106</td>
<td>5 miles</td>
</tr>
<tr>
<td>PHS INDIAN HOSPITAL</td>
<td>801 VASSAR DR NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87106</td>
<td>7 miles</td>
</tr>
<tr>
<td>UNIVERSITY OF NEW MEXICO HOSP</td>
<td>2211 LOMAS BLVD NE</td>
<td>ATTN PHARMACY</td>
<td>ALBUQUERQUE, NM 87106</td>
<td>7 miles</td>
</tr>
<tr>
<td>WAL-MART PHARMACY 10-0835</td>
<td>400 EUBANK BLVD NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87123</td>
<td>7 miles</td>
</tr>
<tr>
<td>NORTH VALLEY CENTER FOR FAMILY AND COMMUNITY HEALTH</td>
<td>3401 4TH ST NW</td>
<td>STE 106</td>
<td>ALBUQUERQUE, NM 87107</td>
<td>6 miles</td>
</tr>
<tr>
<td>UNM HOSPITALS OUTPATIENT AND DISCHARGE PHARMACY</td>
<td>2211 LOMAS BLVD NE # 4ACC</td>
<td></td>
<td>ALBUQUERQUE, NM 87106</td>
<td>7 miles</td>
</tr>
<tr>
<td>UNIV HOSP OUTPATIENT PHARMACY</td>
<td>1209 UNIVERSITY BLVD NE</td>
<td>HEALTH SCIENCE CENTER</td>
<td>ALBUQUERQUE, NM 87102</td>
<td>7 miles</td>
</tr>
<tr>
<td>CANCER CENTER PHARMACY</td>
<td>1201 CAMINO DE SALUD NE</td>
<td></td>
<td>ALBUQUERQUE, NM 87102</td>
<td>7 miles</td>
</tr>
<tr>
<td>PRESBYTERIAN HOSPITAL</td>
<td>1100 CENTRAL AVE SE</td>
<td>ATTN INPATIENT PHARMACY</td>
<td>ALBUQUERQUE, NM 87106</td>
<td>8 miles</td>
</tr>
</tbody>
</table>

[https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s3](https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s3)
Disposal Locations

Medications may also be disposed at any of the six area command substations Monday through Friday from 8 a.m. to 5 p.m.

- Foothills Area Command
  12800 Lomas NE, (505) 332-5240
- Northeast Area Command
  8201 Osuna NE, (505) 823-4455
- Southeast Area Command
  800 Louisiana SE, (505) 256-2050
- Valley Area Command
  5408 2nd NW, (505) 761-8800
- Southwest Area Command
  6404 Los Volcanes NW, (505) 831-4705
- Northwest Area Command
  10401 Cibola Loop NW, (505) 768-4850

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

DEA Drug Take-Back Events

- Began September 2010.
- The DEA has sponsored 19 total take-back events
- On October 24, 2020
  - Collected 492.7 tons (985,392 lbs)
  - Record setting amount
- Total collection of nearly 13.7 million lbs

https://takebackday.dea.gov/
National Take Back Day Results

Results: October 2020 19th National Take Back

- Total Law Enforcement Participation: **4,153**
- Total Collection Sites: **4,587**
- Total Weight Collected: **985,392 lbs. (492.7 Tons)**

Click here for additional details about the 19th National Take Back Day.

https://takebackday.dea.gov/
19th National Take Back Day: October 24, 2020
Total Collection Sites: 4,587

Drug Enforcement Administration
Diversion Control Division

*American Indian and Alaskan Native Communities: 33 sites

https://takebackday.dea.gov/sites/default/files/NTBI%202019%20Totals_1.pdf
19th National Take Back Day: October 24, 2020
Total Weight Collected: 985,392 lbs. (492.7 Tons)

Drug Enforcement Administration
Diversion Control Division

*American Indian and Alaskan Native Communities: 1,208 lbs.

https://takebackday.dea.gov/sites/default/files/NTBI%202019%20Totals%201.pdf
Take Back Collection Sites

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

National Take Back Initiative Collection Site Search
The 19th National Prescription Drug Take Back Day
Saturday, October 24, 2020
10:00 am - 2:00 pm
Inquiries can also be made at 1-800-882-9539

Enter zip code or County/City/State to see Collection Sites near you.

<table>
<thead>
<tr>
<th>Zip Code</th>
<th>County</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
</table>

Search within ?: miles radius:
- 10  - 25  - 50  - 100+

Submit  Reset

Check back often; sites are added daily.

More information on the National Take Back Initiative

https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1
FDA – Disposal of Unused Medication (Link)

What You Should Know

Drug Disposal: Drug Take Back Locations
Drug Disposal: FDA’s Flush List for Certain Medicines
Drug Disposal: Dispose "Non-Flush List" Medicine in Trash
Drug Disposal: Questions and Answers

Video: How to Safely Dispose of Unused or Expired Medicine

Drug disposal options to consider and instructions for getting rid of unused or expired medicines

How to Safely Dispose of Unused or Expired Medicine

- The best way to dispose of most types* of unused or expired medicines (both prescription and over the counter) is to drop off the medicine at a drug take back site, location, or program immediately.
- If you cannot get to a drug take back location promptly, or there is none near you, and your medicine is
  - on the FDA flush list, your next best option is to immediately flush these potentially dangerous medicine down the toilet.

https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know
Drug Disposal: Dispose "Non-Flush List" Medicine in Trash

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

If no drug take back sites, locations, or programs are available in your area, and there are no specific disposal instructions (such as flushing) in the medication guide or package insert, you can follow these simple steps to dispose of most medicines in your trash at home:

1. Mix medicines (liquid or pills; do not crush tablets or capsules) with an unappealing substance such as dirt, cat litter, or used coffee grounds;
2. Place the mixture in a container such as a sealed plastic bag;
3. Throw away the container in your trash at home; and
4. Delete all personal information on the prescription label of empty medicine bottles or medicine packaging, then trash or recycle the empty bottle or packaging.

https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-non-flush-list-medicine-trash
Follow these simple steps to dispose of medicines in the household trash

MIX
Mix medicines (do not crush tablets or capsules) with an unpalatable substance such as dirt, cat litter, or used coffee grounds;

PLACE
Place the mixture in a container such as a sealed plastic bag;

THROW
Throw the container in your household trash;

SCRATCH OUT
Scratch out all personal information on the prescription label of your empty pill bottle or empty medicine packaging to make it unreadable, then dispose of the container.

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

https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-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 only when take back options are not readily available.

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

https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-flush-potentially-dangerous-medicine#FlushList
List Recommended for Disposal by Flushing

*Remember, don’t flush your medicine unless it is on the flush list.*

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Examples of Products on the Flush List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs That Contain Opioids</td>
<td></td>
</tr>
<tr>
<td>Any drug that contains the word “buprenorphine”</td>
<td>BELBUCA, BUAVAIL, BUTRANS, SUBOXONE, SUBUTEX, ZUBSOLV</td>
</tr>
<tr>
<td>Any drug that contains the word “fentanyl”</td>
<td>ABSTRAL, ACTIQ, DURAGESIC, FENTORA, ONSOLIS</td>
</tr>
<tr>
<td>Any drug that contains the word “hydrocodone” or “benzhydrocodone”</td>
<td>APADAZ, HYSINGLA ER, NORCO, REPREXAN, VICODIN, VICODIN ES, VICODIN HP, VICOPROFEN, ZOHYDRO ER</td>
</tr>
<tr>
<td>Any drug that contains the word “hydromorphone”</td>
<td>EXALGO</td>
</tr>
<tr>
<td>Any drug that contains the word “meperidine”</td>
<td>DEMEROL</td>
</tr>
<tr>
<td>Any drug that contains the word “methadone”</td>
<td>DOLOPHINE, METHADOSE</td>
</tr>
<tr>
<td>Any drug that contains the word “morphine”</td>
<td>ARYMO ER, AVINZA, EMBEDA, KADIAN, MORPHABOND ER, MS CONTIN, ORAMORPH SR</td>
</tr>
<tr>
<td>Any drug that contains the word “oxydode”</td>
<td>CODOXY, COMBUNOX, OXADYDD (formerly OXECTA), OXYCET, OXYCONTIN, PERCOCET, PERCODAN, ROXICET, ROXICODONE, RXILOX, ROXYBOND, TARGINIq ER, TROXYCA ER, TYLOX, XARTEMIS XR, XTAMPZA ER</td>
</tr>
<tr>
<td>Any drug that contains the word “oxymorphone”</td>
<td>OPA, OPA ER</td>
</tr>
<tr>
<td>Any drug that contains the word “tapentadol”</td>
<td>NUCYNTA, NUCYNTA ER</td>
</tr>
<tr>
<td>Drugs That Do Not Contain Opioids</td>
<td></td>
</tr>
<tr>
<td>Any drug that contains the term “sodium oxybate” or “sodium oxybates”</td>
<td>XYREM, XYWAV</td>
</tr>
<tr>
<td>Diazepam rectal gel</td>
<td>DIASTAT, DIASTAT ACUDIAL</td>
</tr>
<tr>
<td>Methylphenidate transdermal system</td>
<td>DAYTRANA</td>
</tr>
</tbody>
</table>

Syringe Disposal

How to Dispose of Used Sharps

Disposal rules and regulations vary across states and localities. Click on a state to see the guidance or regulations for safely disposing of used sharps in your area.

https://safeneedledisposal.org/
We found some disposal locations near you...

Click on the Location Name to view collection details. Please note that SafeNeedleDisposal.org is not affiliated with these facilities or programs. Contact the individual facility to confirm hours of operation and requirements. Business or commercial waste is not accepted.

<table>
<thead>
<tr>
<th>Location Name</th>
<th>Address</th>
<th>Contact Phone</th>
<th>Service Area</th>
<th>Residency Restriction</th>
<th>Provide Containers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuquerque Police Department - Northeast Area Command</td>
<td>8201 Osuna Rd NE, Albuquerque, NM 87103</td>
<td>505-823-4455</td>
<td>Albuquerque</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Midtown Public Health Office</td>
<td>2400 Wellesley Dr NE, Albuquerque, NM 87107</td>
<td>505-841-4100</td>
<td>Bernalillo County</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Northwest Valley Public Health Office</td>
<td>7704 2nd St NW, Albuquerque, NM 87107</td>
<td>505-897-5700</td>
<td>Bernalillo County</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Albuquerque Police Department - Valley Area Command</td>
<td>6338 5th St NW, Albuquerque, NM 87107</td>
<td>505-761-6800</td>
<td>Albuquerque</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuquerque Police Department - Foothills Area Command</td>
<td>12300 Lomas Blvd NE, Albuquerque, NM 87111</td>
<td>505-332-5240</td>
<td>Albuquerque</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuquerque Police Department - Northwest Area Command</td>
<td>10401 Cibola Loop NW, Albuquerque, NM 87111</td>
<td>505-700-4800</td>
<td>Albuquerque</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuquerque Police Department - Southwest Area Command</td>
<td>6404 Los Vacios Rd NW, Albuquerque, NM 87105</td>
<td>505-831-4705</td>
<td>Albuquerque</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Midtown Public Health Office

2400 Wellesley Dr NE
Albuquerque, NM 87107
Service Area: Bernalillo County

505-841-4100

Notes: Hours: Monday-Friday, 8am-4pm. Sharps must be in a sharps container or rigid, plastic container such as an empty laundry detergent or bleach bottle. Seal with duct tape and label container "SHARPS." Do not use glass or coffee cans.

https://safeneedledisposal.org/single-listing/?id=2237
CONTACT INFO

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

• 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.
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.)
  - **P/R** – Manufacturer/Distributor/Researcher/Analytical Lab/Importer/Exporter/Reverse Distributor/Narcotic Treatment Program
  - **X** – 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
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.
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.

1306.25A
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)

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.

[http://www.rld.state.nm.us/uploads/FileLinks/ad6770c244f74bdaaeaa53842023b4c7/Transfer_of_Controlled_Substance_Prescriptions.pdf](http://www.rld.state.nm.us/uploads/FileLinks/ad6770c244f74bdaaeaa53842023b4c7/Transfer_of_Controlled_Substance_Prescriptions.pdf)
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
This web application gives access to New Mexico District Court, Magistrate Court and Municipal Court data. Municipal court data is limited to criminal Domestic Violence and DWI historic convictions from September 1, 1991 onwards. Bernalillo County Metropolitan Court DWI data is available on this website; however, to search other Metropolitan Court case data click here.

District and Magistrate case information is updated every day. It is, therefore, current to within 24 hours of the time data is entered into a court's database. Cases filed prior to the completion of the statewide court automation project in June 1997, may exist in a database, depending on the individual court. If you are looking for cases filed prior to 1997 and do not find information on the web page, you should call the court directly.

If you have questions about the validity or accuracy of any data or if you have comments about the use of this web application or technical questions please E-mail them to helpdesk@nmcourts.gov.

Effective July 1, 2007 the New Mexico Judiciary will no longer display juvenile criminal cases on its Case Lookup website. Effective July 1, 2008, the New Mexico Judiciary will no longer display Family Violence Protection Act Order of Protection cases on its Case Lookup Website. To access juvenile or order of protection information, please contact the court in which the case was filed. Contact information for all district courts is available at http://www.nmcourts.gov/find-a-court.aspx.

Click here for Instructions  Click here for Court Locations  Make a Magistrate/Metro Court credit card payment for fines and fees.

Name Search  Case Number Search  DWI Search

Search by any combination of Name, Driver License Information, and Date of Birth

NAME: ____________________________ (Last First Middle)

DRIVER LIC. #: ________________ DRIVER LIC. STATE: 

DATE OF BIRTH: ___________ (mm/dd/yyyy) ~OR~ YEAR OF BIRTH: ________

☐ LIMIT SEARCH TO CASE NUMBERS WITH:

COURT TYPE: 

COURT LOCATION: 

CASE CATEGORY: 

☐ LIMIT SEARCH TO DATES IN RANGE: ☐ FILING DATE ☐ HEARING DATE

DATE FROM: January 1  

DATE TO: January 1  

RESULTS PER PAGE: 20
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).
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.

NMAC 16.19.37.8
http://164.64.110.134/parts/title16/16.019.0037.html
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.

http://164.64.110.134/parts/title16/16.019.0037.html
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 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
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
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.

New Applications/Remodel or Relocation of Pharmacies or Clinics

16.19.6.19 (Pharmacy)
16.19.10 (Clinic)
Compounding of Non-Sterile Pharmaceuticals

- A licensed pharmacy may compound non-sterile, non-controlled substance 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

16.19.30.9A(4)
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
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.
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.

NMAC 16.19.36.12
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 repack 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

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.

16.19.6.27
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)

16.19.11.8(A.9)
http://164.64.110.134/parts/title16/16.019.0011.html
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.

Prescription Synchronization

- The insurer **shall allow** a pharmacy to override any denial indicating that a prescription is being refilled too soon **for the purposes of medication synchronization; and** prorate a dispensing fee to a pharmacy that fills a prescription with less than a thirty-day supply.
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.
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.

[Links]
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)
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
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

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.
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.
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.
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
24-2D-1 et seq
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.nmlegis.gov/Sessions/19%20Regular/final/SB0221.pdf
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
• 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

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

• Expiration Dates
  – All CS prescriptions expire 6 months from the date written
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)
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.
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.
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.
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
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.

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.

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
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
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**

16.19.4.10B(1)
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.

16.19.4.7 O (Definitions)
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

16.19.4.10 B(2)
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.
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

  16.19.4.10

  CEs obtained for Immunization Certification, Smoking Cessation, Naloxone etc. are in addition to the 30 hour requirement (16.19.26 NMAC)
ACPE UNIVERSAL ACTIVITY NUMBER

197 – 000 – 11 – 001 – L05 – P

Provider ID (001-998)
Cosponsor Designator
000: no cosponsor
999: cosponsor
Sequential Activity Number
Format Designator
L: Live offering
H: Home study
B: Both
Development/Release Year

Intended Audience
P: Pharmacist
T: Pharmacy technician

Topic Designator
01: Disease State/Drug Therapy
02: HIV/AIDS
03: Law (pharmacy practice)
04: General Pharmacy
05: Patient Safety
06- Immunizations
07- Compounding
08- Pain Management/Opioids
Pharmacist Prescriptive Authority Renewal
CPE Requirements (16.19.26 NMAC)

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Contraception (EC)</td>
<td>2 hours ACPE approved EC drug therapy (DT) related</td>
</tr>
<tr>
<td>Hormonal Contraception (HC)</td>
<td>2 hours live ACPE approved HC DT related</td>
</tr>
<tr>
<td>Naloxone for opioid overdose</td>
<td>2 hours live ACPE approved naloxone DT related</td>
</tr>
<tr>
<td>Tb Testing:</td>
<td>CE as specified by the Centers for Disease Control (CDC)</td>
</tr>
<tr>
<td>Tobacco Cessation (TC)</td>
<td>2 hours ACPE approved TC DT related</td>
</tr>
<tr>
<td>Vaccines</td>
<td>2 hours live ACPE approved vaccine related, <strong>and</strong> current live BLS/CPR certification</td>
</tr>
</tbody>
</table>
Naloxone
DOH Standing Order

NEW MEXICO DEPARTMENT OF HEALTH
Statewide Standing Order for Naloxone

Name: ___________________________ DOB: _____________ Date: _____________
Address: __________________________

Dispense one of the three following products based on product availability and preference.

- Naloxone HCl Solution 1 mg/mL; 2 mL pre-filled Luer-Lok Syringe
  Qty: 2 x 2 mL syringes (4 mL total) with two nasal mucosal atomization devices.
  Sig: Spray 1 mL (one-half of prefilled syringe) in each nostril. Repeat after 3 minutes if no response.

- Narcan® Nasal Spray (naloxone HCl) 4 mg/0.1 mL Nasal Spray
  Qty: 1 box containing two 4 mg/0.1 mL doses of naloxone
  Sig: Administer a single spray of Narcan® Nasal Spray in one nostril. Open second dose and repeat after 3 minutes if no response.

- Evzio® (naloxone HCl) 2 mg auto-injector
  Qty: 1 box containing two auto-injectors
  Sig: Follow audio instructions from device. Place on thigh and use one injection. Repeat with second injector after 3 minutes if no response.

Refills: PRN
Prescriber: Chris Novak, MD
Address: 1190 S St. Francis Dr. Ste. S-1057
Santa Fe, NM 87505
NPI: 1508834110

For questions please contact NMDOH Prescription Drug Overdose Prevention Program at 505.476.1440

https://www.nmpharmacy.org/resources/Documents/Pharmacy%20Naloxone%20Rx%20Hardcopy%20June%202020.pdf
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.

16.19.4.17 (B) (3) (d)
CPE Requirements

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

• Pharmacists and pharmacist clinicians *without sufficient documentation* of completion of CPE requirements shall:
CPE Requirements

- 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

(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
- 1\textsuperscript{st} 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.
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
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.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
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

16.19.4.9(C15)
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

16.19.22.7H
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

16.19.20(53B)
NMMSIS REPORTING

- USER REQUEST FORM ON BOARD WEB SITE
  - NMMSIS USER REQUEST FORM
  - IN “FORMS” SECTION

http://www.rld.state.nm.us/uploads/FileLinks/bde0e0d28ef545cba3d8cd277c39749d/NMMSIS_Request_Form_081315.pdf
Prescription Monitoring Program (PMP)

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

http://nmpmp.org/Default.aspx
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.
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/
QUESTIONS?

- Alejandro.Amparan@state.nm.us