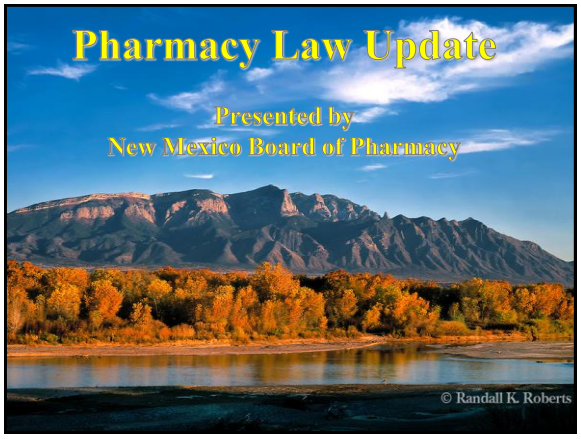
Pharmacy Law Update
Presented by
New Mexico Board of Pharmacy
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1


June 26-27, 2021
Bobby Padilla
State Drug Inspector
Kris Mossberg
State Drug Inspector

2


CURRENT BOARD MEMBERS
January 2021

3


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

4

5


FEDERAL LAW

6

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

7

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

8

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

9

Controlled Substance Public Disposal Locations

https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1

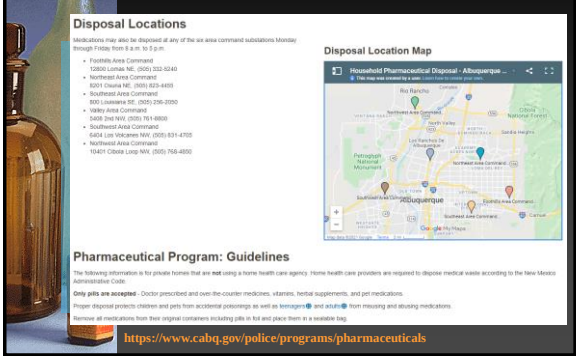
10

Controlled Substance Public Disposal Locations

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

11

APD Disposal Locations



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

12

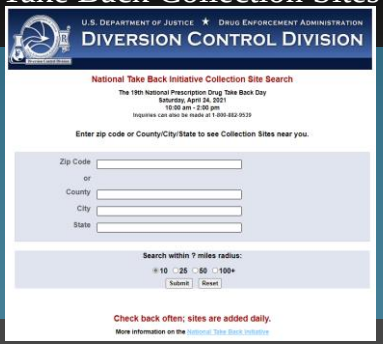
DEA Drug Take-Back Events

- Began September 2010.
- The DEA has sponsored 20 total take-back events
- Largest amount collected:
  - October 24, 2020
  - Collected 492.7 tons (985,392 lbs)
- Total collection of 7,262 tons (14.5 million pounds)

https://takebackday.dea.gov/

13

Take Back Collection Sites



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

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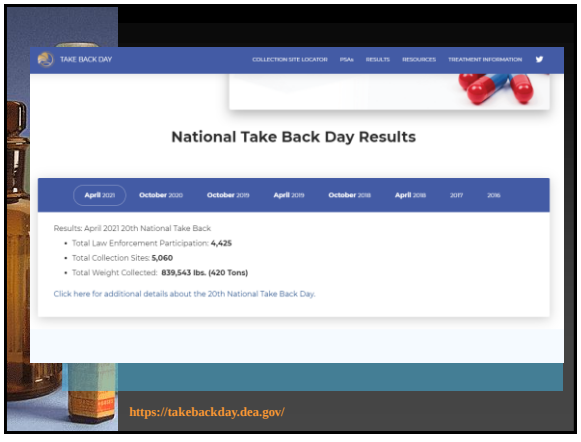

https://takebackday.dea.gov/

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https://takebackday.dea.gov/sites/default/files/NTBI20%20Totals.pdf

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https://takebackday.dea.gov/sites/default/files/NTBI20%20Totals.pdf

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https://takebackday.dea.gov/sites/default/files/NTBI20%20Totals.pdf

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https://takebackday.dea.gov/sites/default/files/NTBI20%20Totals.pdf

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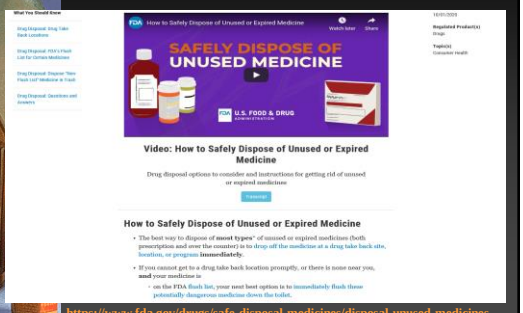
FDA – Disposal of Unused Medication (Link)



https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know

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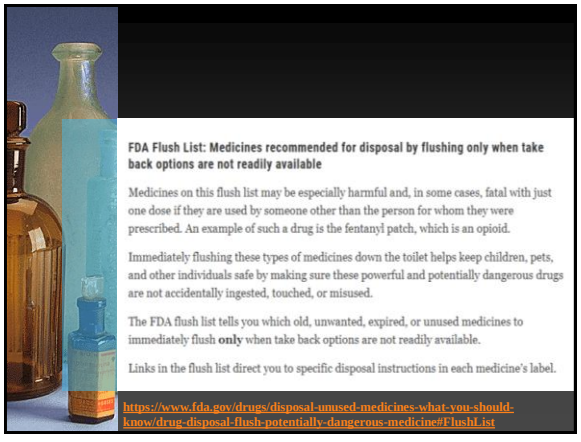


https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-flush-potentially-dangerous-medicine#FlushList

21

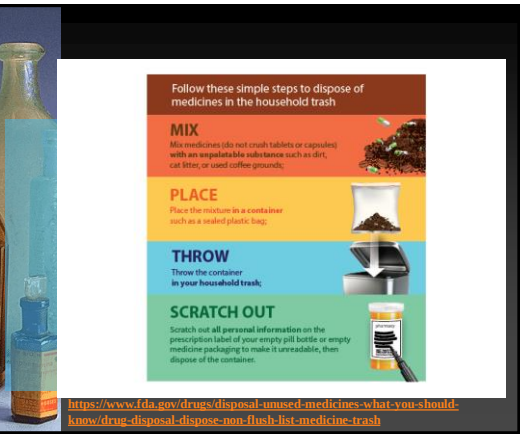
List Recommended for Disposal by Flushing

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

22

https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-non-flush-list-medicine-trash

23



https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-non-flush-list-medicine-trash

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Syringe Disposal

https://safeneedledisposal.org/

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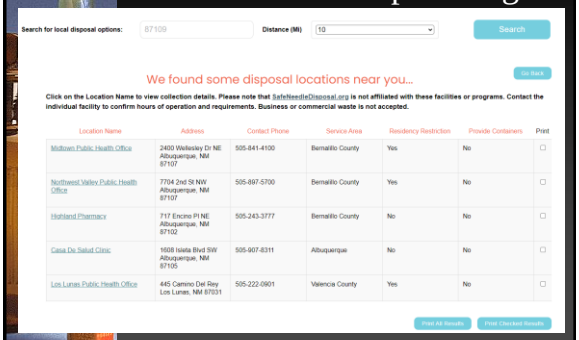
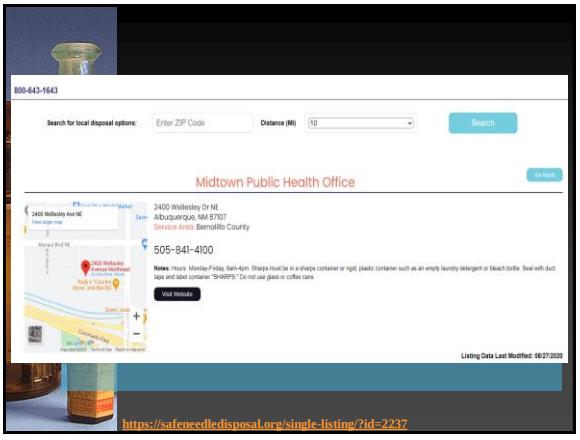
SafeNeedleDisposal.org



https://safeneedledisposal.org/search-results/

26



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

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CONTACT INFO

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

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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

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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

30

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

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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

32

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

33

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

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

34

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

35

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

https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_25.htm

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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)

https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_25.htm

37

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.

http://www.rld.state.nm.us/uploads/FileLinks/ad6770c244f74bdaaeaa53842023b4c7/Transfer_of_Controlled_Substance_Prescriptions.pdf

38

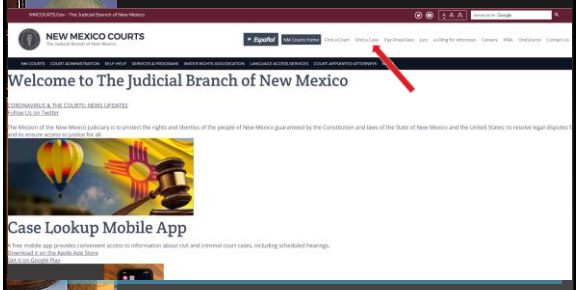
Employment Screening

- 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

39

NMCourts.gov



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

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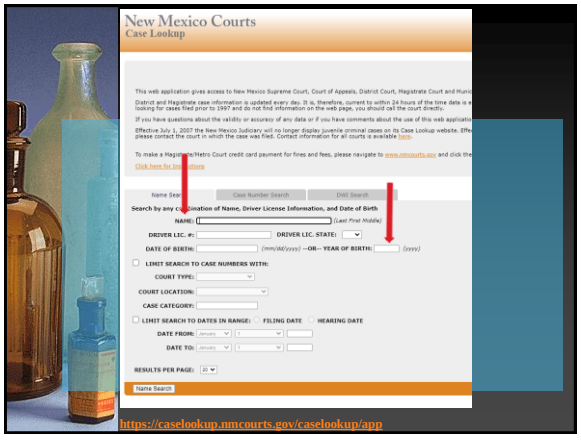

https://caselookup.nmcourts.gov/caselookup/app

41

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

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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 addition***: 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/114/plaws/publ198/PLAW-114publ198.pdf

43

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

44

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

45

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

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New Mexico Law & Board Activity

47

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.

16.19.6.19 (Pharmacy)
16.19.10 (Clinic)

http://www.rld.state.nm.us/uploads/files/Remodel%20or%20Relocation.pdf

48

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)

49

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

16.19.6.23I

50

Controlled Substances

16.19.20.42 NMAC Effective April 1, 2021 all controlled substance prescriptions must be 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;
- (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;

16.19.20.42B

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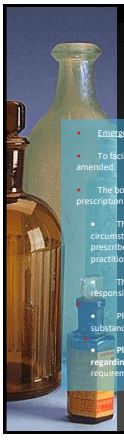

Controlled Substances

- Emergency Dispensing Declaration non-Electronic Prescriptions for Controlled Substances March 31, 2021
- To facilitate a successful and timely transition to EPCS: Beginning April 1, 2021 until June 30, 2021, unless otherwise amended:
- The board does not intend to take action against a pharmacist who fills a non-electronic controlled substance prescription that is not otherwise subject to an exception for required EPCS under 16.19.20.42 NMAC.
- The pharmacist is to communicate directly with the prescriber as appropriate to establish the current circumstance. For example, a pharmacist who has communicated directly with the prescriber and is aware that the prescriber's EPCS will not be implemented for a period of three weeks is not required to communicate with the practitioner for every non-EPCS received during that time period.
- The duties and responsibilities of the pharmacist are otherwise unchanged, including corresponding responsibility.
- Pharmacists are to exercise sound professional judgment when making a determination of whether a controlled substance prescription is legitimate.
- **Please communicate with prescribers who are submitting non-EPCS (not otherwise subject to an exception) regarding the EPCS requirement.** The board-issued communication to practitioners and pharmacists regarding the requirement is available via: Electronic Prescribing of Controlled Substances (EPCS)

52

PHARMACY COMPOUNDING

- 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

53

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

16.19.36.9

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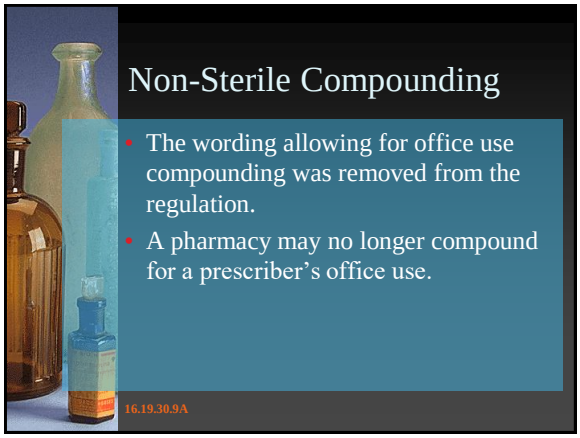

Non-Sterile Compounding

- The wording allowing for office use compounding was removed from the regulation.
- A pharmacy may no longer compound for a prescriber's office use.

16.19.30.9A

55

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.

26-1-16J

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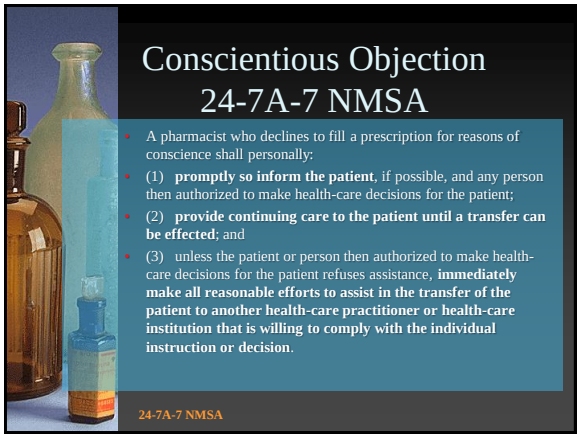

Conscientious Objection 24-7A-7 NMSA

- 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**.

24-7A-7 NMSA

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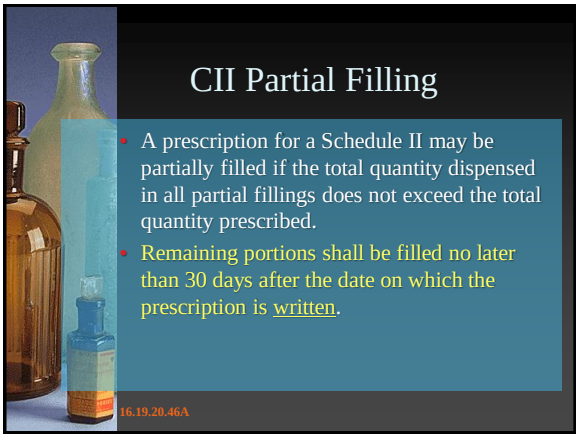

CII Partial Filling

- 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.

16.19.20.46A

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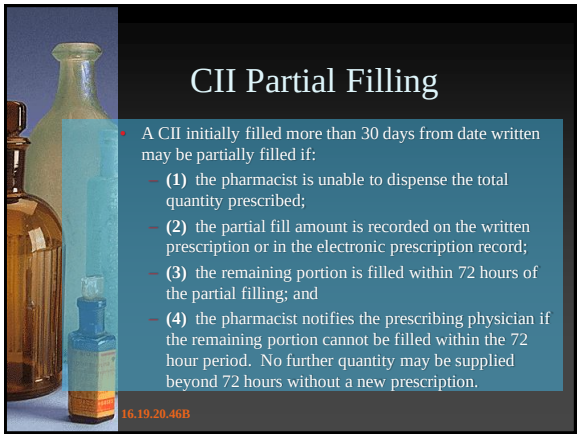

CII Partial Filling

- 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.

16.19.20.46B

59

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 D

60

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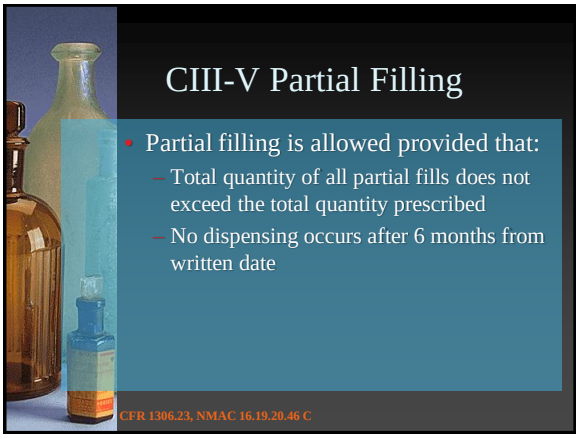

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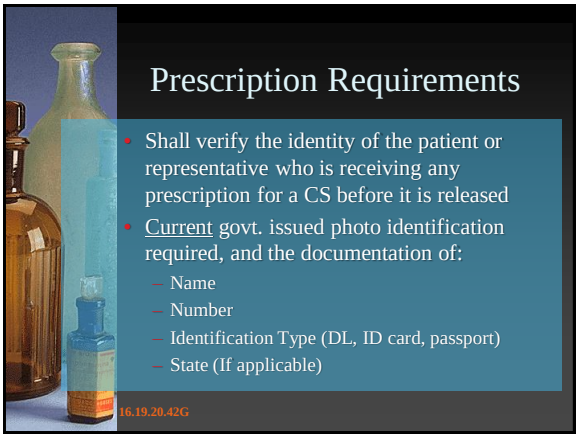

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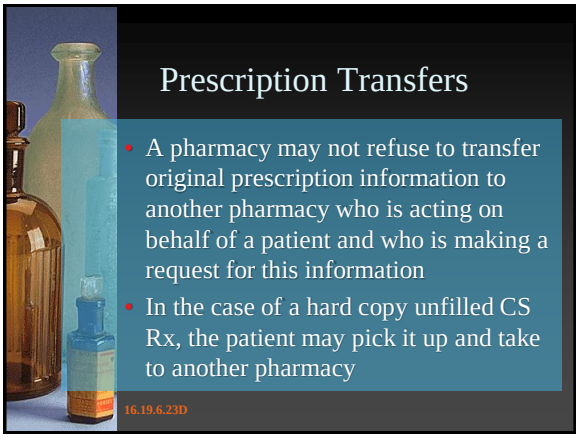

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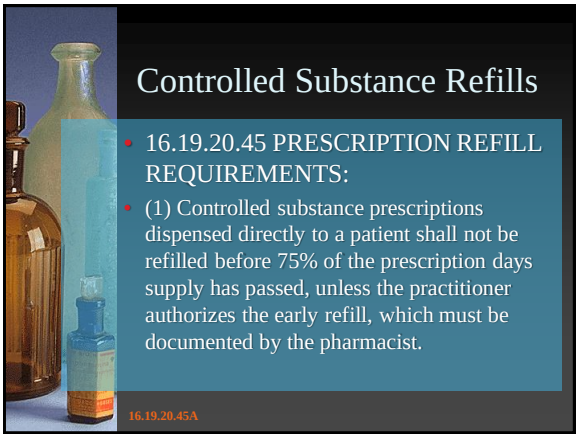

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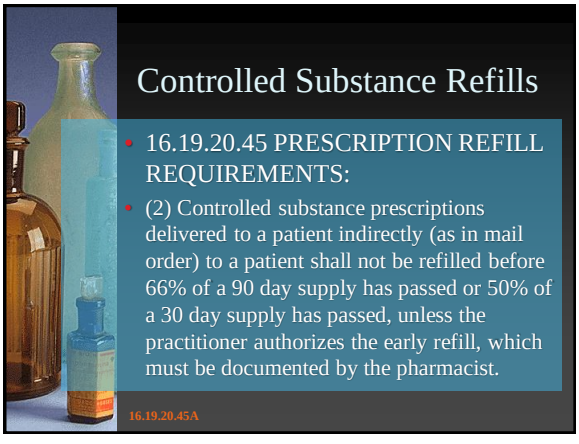

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Controlled Substance Inventory Records

- 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
- 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

16.19.20.20

67

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

16.19.7.17

68

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.

16.19.2.9

69

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.

16.19.4.14

70

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)

71

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)

72

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)

73

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

16.19.4.10 B(3)

74

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.

16.19.4.10 B(4)

75

CPE Requirements

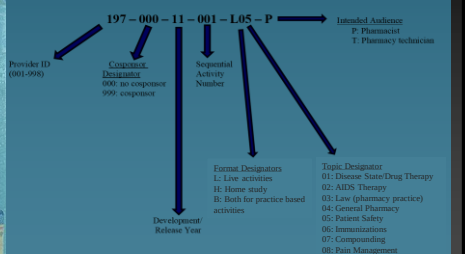
- 30 Total Hours Required
  - 10 Hours of Live Programs
  - 2 Hours Patient Safety (Applicable to Pharmacy)
  - 2 Hours Pharmacy Law
  - 2 Hours Safe and Appropriate Use of Opioids

  - CEs obtained for Immunization Certification, Smoking Cessation, Naloxone etc. are **in addition** to the 30 hour requirement (16.19.26 NMAC)

16.19.4.10

76

ACPE UNIVERSAL ACTIVITY NUMBER



77

CPE Requirements

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

16.19.4.10A

78

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)

79

CPE Requirements

- Pharmacists and pharmacist clinicians without sufficient documentation of completion of CPE requirements shall:

16.19.4.10F

80

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

16.19.4.10F

81

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

16.19.4.17D

82

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

16.19.4.17F

83

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/

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

84

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.

16.19.22.9 E

85

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

16.19.22.11 A

86

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://ptcb.zendesk.com/hc/en-us/articles/115000809531
https://www.nhanow.com/certifications/pharmacy-technician

87

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)

88

Pharmacy Technicians

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

16.19.22.10

89

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

90

Prescription Monitoring Program (PMP)

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

16.19.29.8C

91

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

92

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

93

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

16.19.29

94

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.

https://law.justia.com/codes/new-mexico/2017/chapter-27/article-2/section-27-2-12.21/

95

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

2015 HB 274 Legislature

96

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

16.16.7.9

97

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

16.10.22.11

98

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)

99

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

16.19.26

100

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 **NPI:** 1508834110
Address: 1190 S St. Francis Dr. Ste. S-1057
Santa Fe, NM 87505

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

101

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

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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://dea.ntis.gov/recordlayout.pdf
https://www.deadiversion.usdoj.gov/drugreg/index.html

103

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

104

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.

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

105

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.

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

106

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

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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

108

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

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

109

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.

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)

110

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

111

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

112

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

16.19.6.30

113

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

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