
WY Controlled Substances Act/Rules 2017 & WOR_x

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Conflict of Interest

- I have no actual or potential conflict of interest to declare regarding this presentation



WY Controlled Substances Act and Rules: Changes 2017: Objectives

- Understand the statute changes W.S. 35-7-1001 through 1101
- Understand the rules changes
- Tools for Naloxone prescribing/dispensing
- Future Plans



Legislation 2017 affecting pharmacy

- Introduced in Senate or House, discussed in committees, passed after 3 readings
- Sent to other chamber, then committee, then passed after 3 readings
- Joint group of legislators work out differences



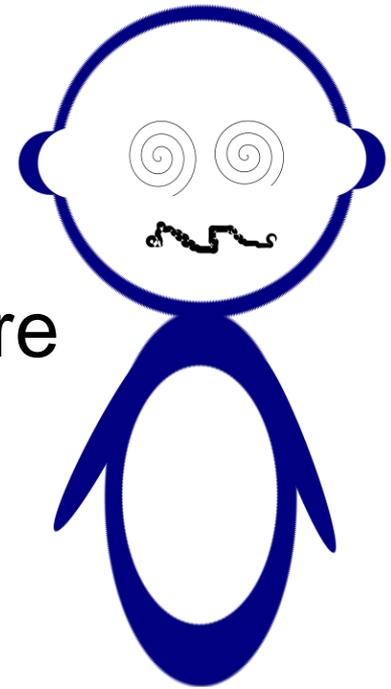
SF0042 Opiate Overdose Emergency Treatment

- W.S. 33-24-158 (new) Pharmacist prescribing, rules promulgated with BOM
- W.S. 35-4-901 (new) Definitions
- Practitioner or Pharmacist may prescribe without a prescriber-patient relationship to:
 - a person at risk of an opiate overdose
 - a person in a position to assist
 - a person who may encounter a person experiencing an opiate overdose



SF 42 cont (opiate overdose)

- Educate regarding how to:
 - recognize and respond
 - administer naloxone
 - ensure additional medical care



Immunity for prescribing opiate antagonist

- Personally immune from civil or criminal liability for any act or omission resulting in damage or injury (prescribe or administer)
- Prescribing an opiate antagonist shall not constitute unprofessional conduct
- Administration of an opiate antagonist :
“act in good faith if appears to be experiencing an opiate related drug overdose”



What is Naloxone Rescue



- Real Stories from Real People:
- <https://www.narcan.com/>



<http://www.empr.com/narcan-nasal-spray/drug/34524/>

<http://www.chaindrugreview.com/cvs-to-provide-narcan-spray-at-discount/>

https://www.nytimes.com/2014/06/13/nyregion/anti-overdose-drug-becoming-an-everyday-part-of-police-work.html?_r=0



Impact of Opiate Overdose Emergency Treatment to Pharmacists

- Who may benefit from this?
 - ❑ Opiate naïve patients prescribed opiates for the first time
 - ❑ Surgery patients who are prescribed high MME's of opiates
 - ❑ Persons who provide care for individuals who self administer opiates (first responders, family member, ...)
 - ❑ Any persons at risk for an opiate related over dosage
 - ❑ Employee risk of exposure



Continued...



“Ohio SWAT member also needed a trip to the local ER recently while entering a house where the suspect was trying to destroy a large amount of heroin/fentanyl in the toilet.

This has prompted drug units to carry nasal naloxone as this is not an isolated problem. Fentanyl is bad enough, but some agencies are experiencing carfentanil, the elephant tranquilizer, mixed in with heroin and/or fentanyl.”

<https://www.statnews.com/2017/05/16/overdose-officer-fentanyl-east-liverpool/>



Continued...

- Pharmacists education:

- Recognize and respond
- Administer naloxone
- Ensure additional medical care



- Training:

- 90% of licensed pharmacy staff have already completed opiate/naloxone CE, per BOP CE audit



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Tools regarding naloxone

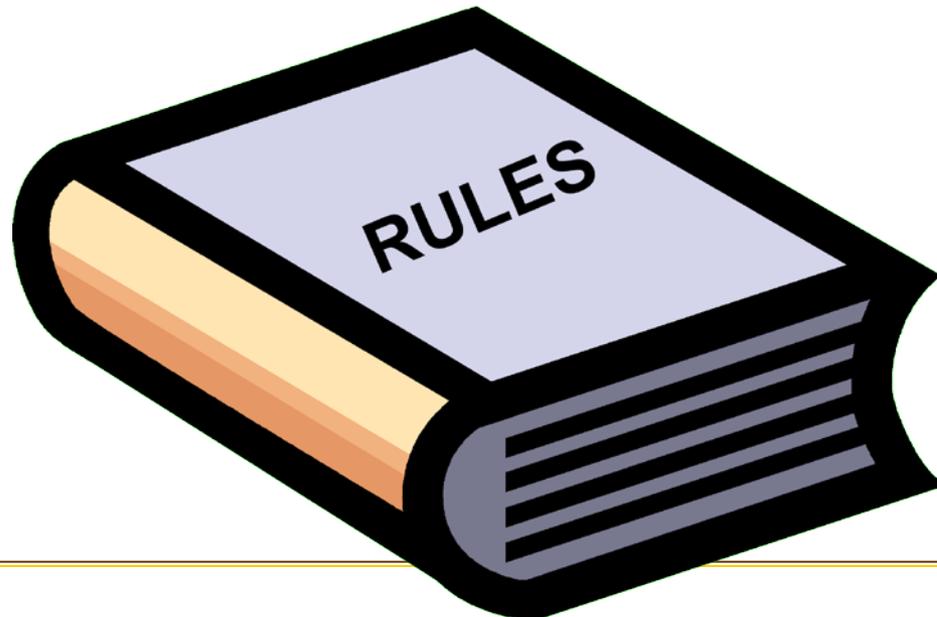
- Brochure
- Sample prescription format
- Summary for pharmacists

- Thank You to Amy Thompson, PharmD candidate



New Chapter 18: Prescribing by Pharmacists re naloxone

- Emergency rules in effect for 120 days
- Lists the counseling points
- Report dispensed naloxone to WORx



Continued...

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Other CSA changes: Hemp

- W.S. 35-7-1063: the penalties of this chapter shall not apply to:
 - the medical use of hemp extract 35-7-1901
 - Persons in possession of any controlled substances for purposes of disposal
 - Industrial hemp farming or grown for research purposes 35-7-2101



Hemp, continued 35-7-1901

- Dept of Health issues registration cards
- Neurologist statement re: intractable epilepsy or seizure disorders
- Hemp extract means...cannabis plant material that is composed of less than 0.3% tetrahydrocannabinol by weight, is composed of at least 5% cannabidiol by weight.
- Where to buy?? Internet? Montana?



What is WOR_x?



- Monitoring tool
- No diagnostic information
- Protected patient information/limited access:
 - Patient's practitioners & pharmacists
 - Law enforcement only with open investigations.
- Dispensing data (data in, data out),
 - Pharmacy's must report data by COB on the business day immediately following the day the controlled substance was dispensed (24 hours depending on business hours)
 - Rx not picked up by patient/Returned to stock
 - Reporting errors, incorrect practitioner "dr. shopper", etc...
- WOR_x is not an official record of what occurred!



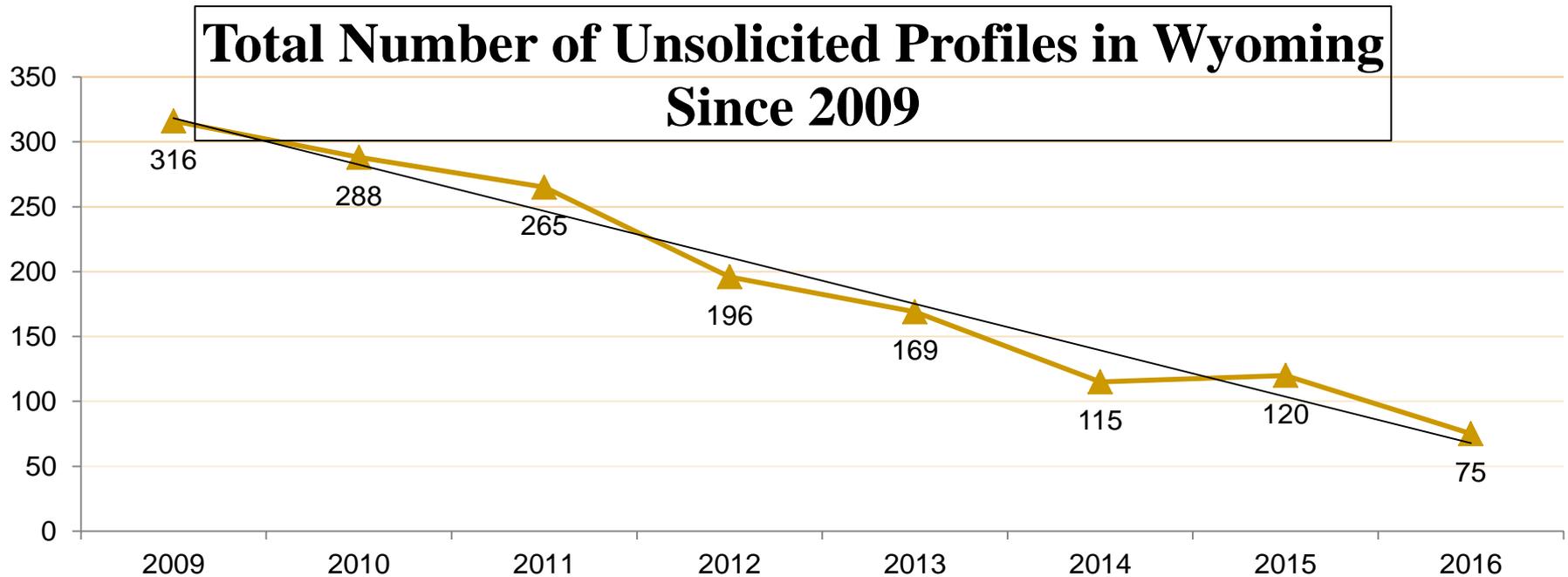
PDMP tools like WORx:

- 21 states require reports prior to prescribing opioids in some form (1st time) - 18 do not
- Kentucky mandated use in 2012 and there was a 25% reduction in deaths due to opioid overdose
- Pharmacists and practitioners can use reports to help:
 - identify patients obtaining CS from multiple providers, &
 - calculate the possible MME per day
 - may identify concurrent use of benzodiazepines or other drugs that can potentiate or impact opiate effect



- Number of Searches
 - 2016: 53,388
 - 2017 to date: 60,395

75% drop in suspected “doctor shopping” since 2009



W.S. 35-7-1033 “doctor shopping”



- “[U]nlawful for any person...[to:]
- ...**obtain a prescription** for, any controlled substance by misrepresentation, ...includes but is not limited to:
- (A) **Failing to disclose** to a practitioner that the person has received...[a] prescription for a controlled substance from another source within the **prior thirty (30) days**;
- (B) Alteration or forgery...
- (C) The use of a false name or address



Education:



- BOP Staff: Mary K. Walker, Executive Director
 - ❑ Example report reviews
 - ❑ CDC Opiate Prescribing Guidelines, MME's
 - ❑ Importance of patients education on:
 - ❑ opiate risks
 - ❑ dangers of mixing medications
 - ❑ need to keep all providers informed of medications & history
 - ❑ proper storage and disposal

BOP Education

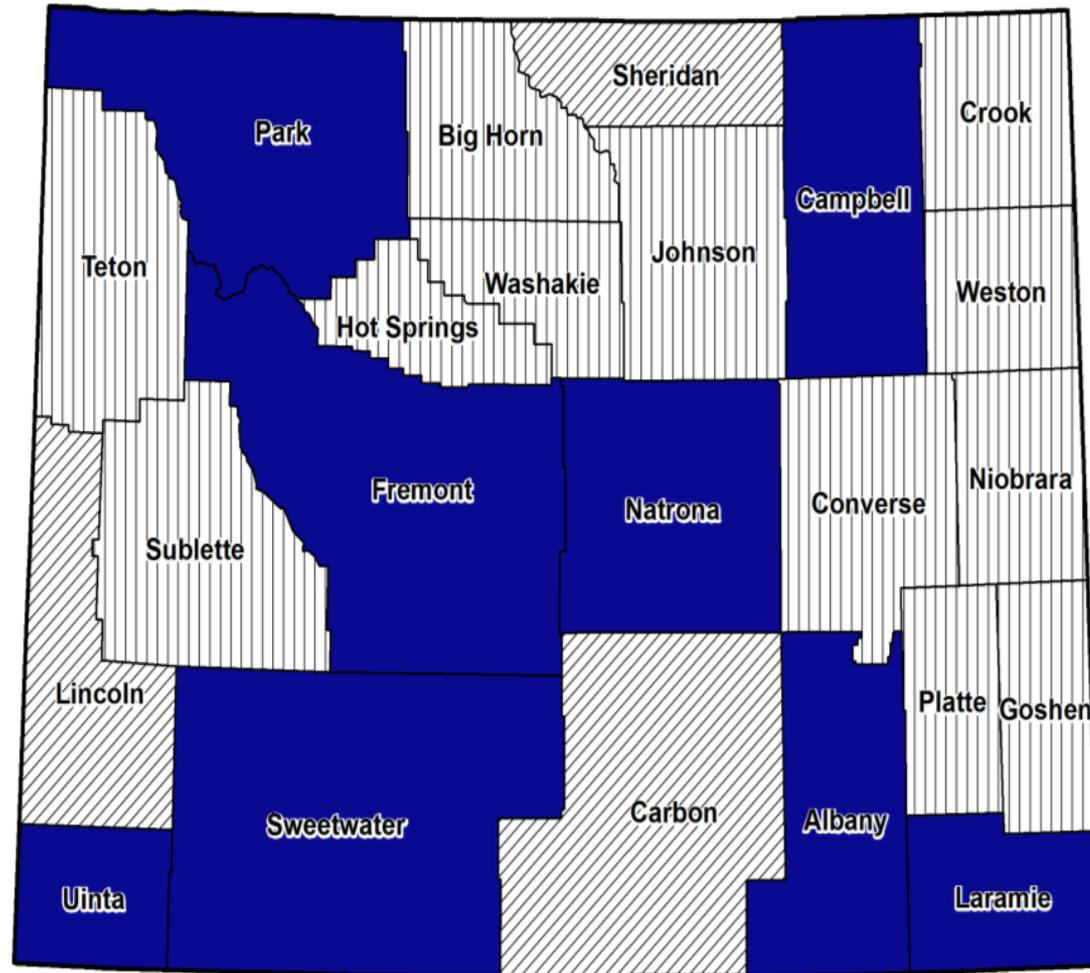


#	Name	Professions	Date	Location	Number Attended
1	LECC	Law Enforcement	06/02/16	Cheyenne	135
2	WY Medical Society	MD, DO, PA	06/03/16	Jackson	43
3	WPHA	RPh, RPT	06/24/16	Casper	55
4	VA Hospital Pharmacy	RPH, RPT, Interns, P4	07/14/16	Sheridan	22
5	WAPA Conference	PA	07/16/16	Sheridan	32
6	VA Hospital Staff	NP, PA, MD, RPh	07/17/16	Sheridan	28
7	WRAS	RPh, Atty, DOH	08/03/16	Cheyenne	15
8	Technitian Conference	RPT	10/01/16	Casper	23
9	WCAPN	NP	10/14/16	Casper	85
10	LCPHA	RPh, RPT	10/26/16	Cheyenne	32
11	Nurse Day @ Letilature	RN, Students	02/09/17	Cheyenne	280
12	Meth Conference	Law, Therapists, Health	04/19/17	Casper	283
				Total	1033



Drug Poisoning Death Rate per 100,000, by County, 2010-2014

Wyoming



Dr. Kahn and Wife Indicted in Casper

- A federal judge issued arrest warrants for a Casper doctor and his wife charged with illegally selling prescription painkillers after the couple allegedly violated conditions of their bond by contacting former patients who are potential witnesses in the case.
- DEA agents in WY began investigating Kahn in April 2016 after the Wyoming Board of Pharmacy sent a complaint that said Kahn was prescribing large amounts of controlled substances.



Why pharmacists? 21 CFR 1306.04(a)

- **Pharmacist is not obligated to fill a prescription**
 - just because a prescription is presented by a patient or demanded to be filled for a patient by a practitioner does not mean the pharmacist has to fill it.
- “A prescription for a controlled substance...must be issued for:
 - **a legitimate medical purpose** ...by [a] practitioner acting in the **usual course of his professional practice.**
 - The responsibility...for...prescribing...[CS]...is upon the...practitioner, but a **corresponding responsibility** rests with the **pharmacist** who fills the prescription.”



Corresponding Responsibility

Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!

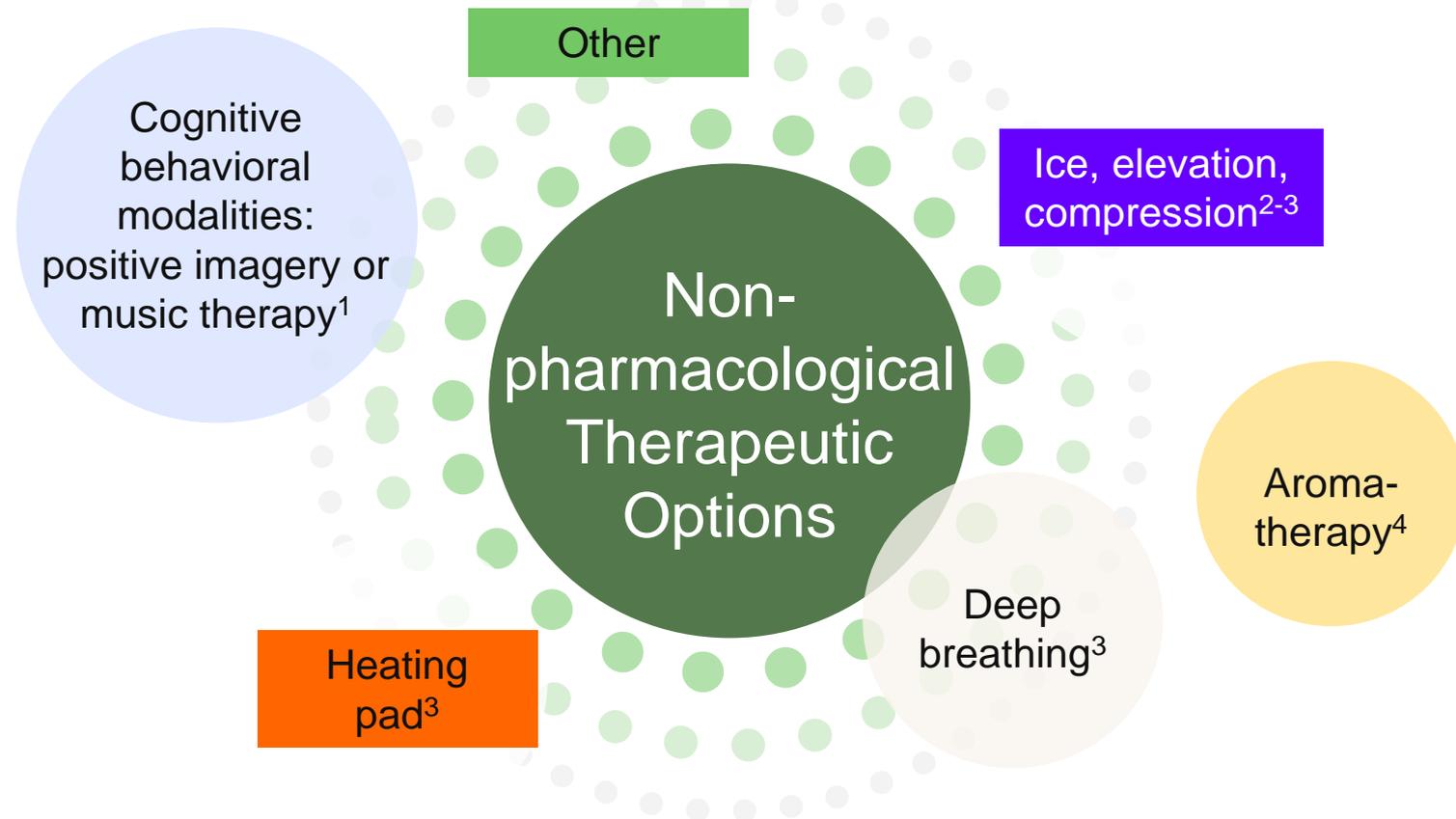


Counseling by pharmacists

- Realistic benefits, pain reduction expectations
- Primary goal in chronic treatment is improvement in function
- Serious effects can include fatal respiratory depression, lifelong opioid use disorder if used > 3 months
- Common side effects: constipation, dry mouth, N&V, drowsiness, confusion, tolerance, withdrawal symptoms
- Assess motor vehicle injury, risk of overdose
- Proper storage and security
- Concern for patient and family safety requires monitoring



Non-pharmacological Therapeutic Options Complement Traditional Analgesic Options



Patient education is the biggest thing we can do to help!

1. Palmer T and Toombs JD. *J Am Board Fam Practice*. 2004;17:S32-S42. 2. Zacharoff KL et al. *PainEDU.org Manual: A Pocket Guide to Pain Management*. 4th ed. 2010. 3. Rombolà L et al. *Mini Rev Med Chem*. 2016;16:721-728. 4. Chou R et al. *J Pain*. 2016;17:131-157.

2. Adapted from COMPAS slide 2017 Rx Abuse & Heroin Summit



How to discuss WORx reports with the patient

- Are you having side effects?
- What is your pain level right now?
- “I am concerned about your health and safety”
- How many doses are you taking per day?
- You are asking for early refills: pain level?, traveling?,
- Are you on a pain contract, lock-in, other program?





Changes to WORx

- Method of payment (Ins/cash) reported – may be an indicator of need for drug interaction screens
- Report/monitoring three non-scheduled drugs:
 - gabapentin i.e. Neurontin^R ,
 - cyclobenzaprine i.e. Flexeril^R, and
 - **naloxone** i.e. Narcan^R prescriptions dispensed
- Implementing delegate registration:
 - when notified health care professionals can register/manage their delegates and each will have their own user name and password.
- Implementing interstate data sharing:
 - Not immediate/will need the entire legal name of the patient but will be able to get reports from surrounding states.
- Updating website



Revised Rules WY CSA Chapters 4, 6, 7, 8

- Reduce the length and complexity
- Correct spelling, grammar, format
- Incorporate by reference to other documents
- 2015 WY legislature statute changes



Chapter 4 Records and Inventories

- Electronic or written files of controlled substance prescriptions can be kept in consecutive numbers or by date



CSA Ch 4 cont

- Written or electronic invoices shall be dated and signed when received
- Invoices shall be maintained with order forms
- Perpetual inventories must be reconciled (and the reconciliation must show in the record)
- Records kept for two years



Chapter 6 Issuing, Filing and Filling

- Electronic records
- Clarification of partial filling for Schedule II for long term care or terminally ill



Partial Fills for C II in long term care

- Partial filling for long term care: Section 16
- Pt has LTCF or “terminal illness”
- Record the date, quantity dispensed, remaining quantity, pharmacist
- Cannot exceed total quantity prescribed
- Valid for 60 days from issue date



Partial Filling from CARA

- Partial filling for Schedule II medications now allows for periods of longer than 72 hours (CARA of 2016)
 - Reduces amount of drugs in home or on hand
 - Allows for less doses without voiding the Rx & requiring a new office visit
 - WY rules in the future but CARA can be followed as a federal law



Combat Meth Act of 2005

- Specific lists of identification sources
- Some tribal cards do not have a picture but contain the rest of the identification elements



Identification of patients W.S. 31-7-111 and W.S. 8-7-101

- An identification card issued by the governing body of the Eastern Shoshone tribe of Wyoming or Northern Arapahoe tribe of Wyoming that substantially conforms to the requirements of W.S. 31-8-102(a)(i) through (vi) shall be considered a valid form of identification for all purposes for which an identification card issued under W.S. 31-8-101 may be used.



Section 7 Stickers

- Under no circumstances may stickers be utilized for information relating to ~~patient name~~, drug, strength, quantity or directions.
- 21 CFR 1306.05 “all prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner...”



Chapter 7 Administrative Inspections

- Incorporate by Reference to 21 CFR 1316
- Notice of Inspection



Clarification: eRx not filled but transferred C-III, IV, V

Yes: a pharmacy is allowed to transfer an original unfilled eRx to another pharmacy if the first is unable to or chooses not to fill.

- A pharmacy is allowed to transfer an eRx with remaining refills to another pharmacy if communicated between two RPh
- 1306.25(a)



- “Pharmacist must check with other pharmacy to determine whether the Rx was received and dispensed. Original pharmacy must mark the electronic version as void or canceled.”



Transfer of unfilled C-II eRx

- No guidance found for an unfilled C-II eRx. eRx cannot be printed as a hard copy and C-II cannot be transferred via phone
- Leaves patient/pharmacist/prescriber in a dilemma.
- New Rx is the best option



Chapter 8 Prescription Drug Monitoring Program (WORx)

- Pharmacies report the method of payment
- Pharmacies report within 24 hours
- Delegates appointed by RPh to access WORx
- Records kept by the board
- Adding reporting of gabapentin, cyclobenzaprine, naloxone dispensed prescriptions



Questions

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- David.wills@wyo.gov

- WORXPDMP.com
- Pharmacyboard.state.wy.us

