Pharmacists are from Mars and Prescribers are from Venus

Once upon a time Pharmacists and Providers met, fell in love, and had happy relationships together because they respected and accepted their differences. Then they came to Earth and amnesia set in: they forgot they were from different planets.

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NO financial disclosures.

Objectives

- To recognize both Federal and State laws that govern the dispensing buprenorphine products.
- To identify at least three dispensing barriers pharmacies are responsible that reduce access to buprenorphine.
- After participating in the session, attendees should be able to describe three approaches to creating a positive pharmacy/provider relationship.
- To describe two areas Montana pharmacists are working on decreasing the stigma to dispensing buprenorphine.

Good Cop . . . . . Bad Cop

- Buprenorphine is a Schedule III controlled substance defined by the Controlled Substance Act (CSA).
  - CSA-Federal Law that contains rules governing the issuance, filling and filing of prescriptions of controlled substances.
  - Highlights
    - Must be written for a person. No 'office use only'.
    - Provider must have a DEA license
    - Schedule III controlled substance prescriptions may be transmitted to the pharmacy in Montana by Fax, Phone, Written and electronic.
    - Buprenorphine prescriptions must be written for legitimate medical purposes—Meaning FDA Indication
      - Butrans-Pain Suboxone-OUD

CSA Highlights continue-yes that last slide was just the first page!

- Prescriptions must contain ALL items:
  - Must be dated on the date of issuance
  - Signed by provider
  - Patients Full Name
  - Patients Address
  - Drug Name
  - Dosage Form
  - Quantity Prescribed
  - Directions of Use
  - Providers Name, Address and DEA license number

CSA Transfer of Buprenorphine Prescription

- Transfer of Buprenorphine is allowed HOWEVER:
  - One-Time basis-Once the transfer to another pharmacy is made it may not be moved again. If refills remain, on the Rx it may not be moved again.
  - Electronic Rx must be transferred with its original electronic form.
  - Transfer may only be communicated between two pharmacists.

CSA-Yep still going

- Controlled Rx's are good for 6 months from the date of issuance
- Schedule III controlled substances may only be refilled 5 times in 6 months
  - #30 RF5 total quantity 180. The first fill plus 5 more. Patient may fill partial fills in between. Example: Patient only has enough money to fill #15 at a time. Patient still has access to 180 in 6 months.

Drug Addiction Treatment Act of 2000 (DATA)

- Required X waiver for prescribing buprenorphine products.
- **Consolidated Appropriations Act of 2023** removed Federal requirements of practitioners to obtain and X waiver.
- Providers with valid DEA may prescribe buprenorphine products for Opioid Use Disorder (OUD).
- New requirements for renewing or new DEA registrants
  - 8 hours of opioid and substance use disorder training
  - Board certification in addiction medicine
  - Graduation within 5 years from medical, advanced practice nursing or physician assistant school in the United States.

Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act

- Required Medicaid programs to cover the three FDA-approved medications for OUD-Buprenorphine, naloxone and methadone.
- Charges ‘Wholesalers’ to monitor “suspicious ordering”
  - Order for controlled substances of unusual size.
  - An order of controlled substances deviating substantially from a normal pattern.
  - Orders of controlled substances of unusual frequency.
  - Suspicious Orders Report System (SORS) is used to report orders deemed to be suspicious.

SUPPORT Act Cont

- Does NOT
  - Require DEA to monitor pharmacies ordering
  - Restrict pharmacies from ordering controlled substances
    - ***Only Wholesalers are restricting***
- DOES
  - SORS notifies DEA of suspicious ordering. DEA has a legal obligation to investigate the ordering.

Montana State Controlled Substance Laws

- Montana adopts Federal controlled Substance Laws.
  - Montana Board of Pharmacy has not imposed other restrictions like other states.

Dispensing Barriers Restricting Buprenorphine access

- **Wholesalers and Pharmacies have inadvertently created barriers in dispensing buprenorphine**

- To comply with Federal and State Laws.
- Reduce potential liabilities for opioid divergence.
- Reduce risk of revocation of DEA licenses.
- Lack of education in MOUD
- Stigma

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Delayed or Suspended Buprenorphine shipments

- Large orders will be held and not delivered by wholesalers
- Wholesalers will state the aggregated pharmacy orders exceed an unknown limit
  - Limits are made by wholesalers not DEA
  - Unknown to pharmacies
  - Determined off a rolling 30 day average
  - All morphine equivalent substances could be use to tally the limit even though buprenorphine is very different.
- Buprenorphine is not stocked in pharmacy
  - 70% of pharmacist believe opioid diversions could be curbed by declining to fill certain opioid prescriptions
  - If pharmacies don't stock it, then pharmacists don't have to lie about not being able to fill it.
  - Pharmacies sometimes fear DEA audits to the point that not stocking a medication reduces fears and anxiety of having a DEA investigation
- Buprenorphine Prescriptions Declined or not filled
  - Red Flag Protocols such as profiles with opioids only may restrict filling. Buprenorphine will flag in pharmacy software and not allow movement further if that is the only drug filled.
  - Non-local buprenorphine patients will often get declined because of a pharmacies history with patients traveling great distances to see providers and fill opioids.
  - Pharmacist comfort level with OUD may restrict dispensing.

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Subst Abuse Rehabil. 2022; 13: 127–138.

Let's Fall in Love All Over Again

- 90% of Americans live within 2 miles of a community pharmacy
  - Bonding pharmacies to prescribers treating patients for OUD is crucial to improving access.
  - Pharmacist have a positive attitude towards dispensing naloxone.
  - Pharmacist would like to carry a larger role in the opioid epidemic
    - Collaborative practice agreements.
    - Opioid misuse risk identification tool.
    - Only 50% of pharmacists feel calling a prescriber about a potential misuse or patient who could benefit MOUD therapy feel heard or valued.
    - 100% of pharmacist have been told “you will do as I say, I am the prescriber!”

Subst Abuse Rehabil. 2022; 13: 127–138.

Venus needs to speak Mars

- CSA has amended DATA for prescribers but the same buprenorphine dispensing laws have not been loosened for pharmacies
  - Understanding the complexity and layers of multiple laws helps understand a pharmacist perspective.
  - Often the quickest response to not filling is “we don’t have that drug”. The pharmacy might have had restrictions placed which put ordering all controlled substances in jeopardy.
  - It takes time to increase volume in ordering thus planning will be required. Communication with local pharmacy will help align efforts. Pharmacist need to know the anticipated amounts of patients and drug quantities that would be needed.
  - Offering back line or immediate assistance on buprenorphine prescriptions help alleviate issues seen such as changes in directions, quantity changes or early fills. Mars really hates being read the prescription in question back over the phone as if we can not read!

Communication begins before the patient arrives at the pharmacy

- Initiating a line of communication of intention to send MOUD patients to a pharmacy and work through concerns.
- Share anecdotal stories of success. I have become aware that most pharmacist don't see the success because of being in the role of dispensing medications.
- Invite a pharmacist from the pharmacy to be part of a weekly provider meeting if applicable.
- Increase the role of the pharmacist in the treatment team.
  - Pharmacist are public health experts but are viewed to count by 5's.
  - Pharmacist are medication experts that can be allowed to help bridge the gap in care for withdrawal symptoms. Counseling on symptom relief to administering assessment tools such as COWS to alert prescribers are all within the wheelhouse of pharmcists.

Education to pharmacist

- Montana pharmacist self report to be reserved and undereducated in MOUD treatments.
  - Montana Pharmacy Association has adopted a resolution decrease barriers in buprenorphine access
- **Support for the Reduction of Pharmacy Related Buprenorphine Access Barriers**
- WHEREAS, Montana pharmacies and pharmacists play a significant role in reducing access barriers to buprenorphine; and,
- WHEREAS, Buprenorphine is approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid use disorder (OUD) and can diminish the effects of opioid dependency, such as withdrawal symptoms and cravings; increase safety in cases of overdose; and lower the potential for opioid misuse, when taken as prescribed; and,
- WHEREAS, Patients face barriers to accessing buprenorphine caused by societal stigmatization, inadequate or inaccurate education regarding the benefits and risks of buprenorphine among healthcare workers and pharmacy staff, supply restriction from pharmacy wholesalers (who do not acknowledge the differences between partial and complete opioid agonists in their controlled substance policies and procedures), and pharmacy hesitancy due to fear of violating rules and low reimbursement.
- THEREFORE, BE IT RESOLVED, that MPA urges Montana pharmacies and pharmacist to review barriers being inadvertently imposed; and,
- FURTHER BE IT RESOLVED, that MPA advocates engagement in buprenorphine education activities as the usage of buprenorphine products continues to change and evolve.

Montana Medicaid Changes to Reduce Barriers

- **All Providers**
- **Changes Regarding Opioid Prior Authorization and Medication for Opioid Use Disorder**
- Montana Healthcare Programs no longer requires prior authorization (PA) for opioids, beyond universal opioid edits, for members with a history of Medication for Opioid Use Disorder (MOUD). Please continue to verify medication history using the Montana Prescription Drug Registry (MPDR).
- Furthermore, the one-time-per-NPI provider attestation to prescribe Suboxone films has been simplified, with several requirements removed, but the provider enrollment requirement remains. A copy of the form is on the Forms page on the Provider Information website.
- The Centers for Medicare & Medicaid Services prohibits state Medicaid programs from paying for prescriptions written by providers **not** enrolled with Medicaid. This requirement will be enforced for **all** prescriptions for **all** provider types at a future date. We encourage providers to be proactive and enroll as a Medicaid provider to prevent treatment interruption when this is implemented. Providers need to only enroll as an ordering/referring/prescribing provider to meet this requirement. They do not need to enroll as a pay-to provider.

Buprenorphine to Reverse Respiratory Depression

1. Current Narcan usage for reversal of opioid overdose often needs multiple 2-12 nasal sprays. Often the patient will fall back into overdose with the Narcan wears off.
2. 85 patients were randomized to receive buprenorphine or naloxone for reversal of respiratory depression due to opioid overdose.
    a. 55/56 patients given buprenorphine had rapid reversal which lasted >12hours
    b. 28/29 patients given naloxone had reversal but need high titrated doses and prolonged infusions.

Buprenorphine appears to be a safe effective substitute for naloxone in overdosed opioid dependent patients.

Crit Care **24**, 44 (2020). https://doi.org/10.1186/s13054-020-2740-y