

BUREAU OF NARCOTICS & DANGEROUS DRUGS



Michael R. Boeger, Administrator



Missouri BNDD

1. Controlled substance authority for the state of Missouri. Enforcing federal DEA laws and bringing them down to state statutes and regulations.
2. All persons conducting any activities with controlled substances must be registered.
3. BNDD has authority over registry, record keeping, security, and determining what is legal.
4. No authority over proper clinical and therapeutic complaints. Boards do that with peer review.
5. Enforcement since 1970 with federal act.
6. An administrative and regulatory healthcare agency. No powers of arrest or fines.



Missouri BNDD (Cont.)

- 31,731 registrants on 4/3/2019;
- Over 26,000 are individual prescribers;
- FY 18 = 543 random-unannounced inspections;
- FY 18 = 58 completed investigations
- FY 19 so far = 3 warnings (As of 3/31/19)
 - 9 censures
 - 25 probations
 - 1 immediate suspension
 - 1 revocation
 - 1 denial of a registration
- We average 15 educational presentations per year
- 15,000 calls to central office
- 600 emails per month with inquiries

Opiate Overdoses

- At one point, Missouri was recently ranked 7th in the nation in overdose deaths;
- Rx deaths exceed deaths from illegal street drugs;
- Rx deaths exceed car wreck fatalities;
- Missouri does not have a PDMP;
- Missouri does not have published opiate prescribing guidelines for practitioners;
- Missouri does not have specific regulations for pain clinics.

CDC Rates for Missouri

2012.....there were 95 opioid prescriptions for every 100 patients seen.

2016.....89,000 per 100,000



Missouri Opioid Deaths

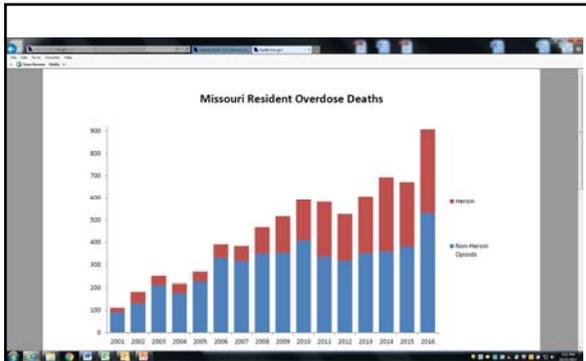
Deaths only—does not include all overdoses.

2015.....672 deaths

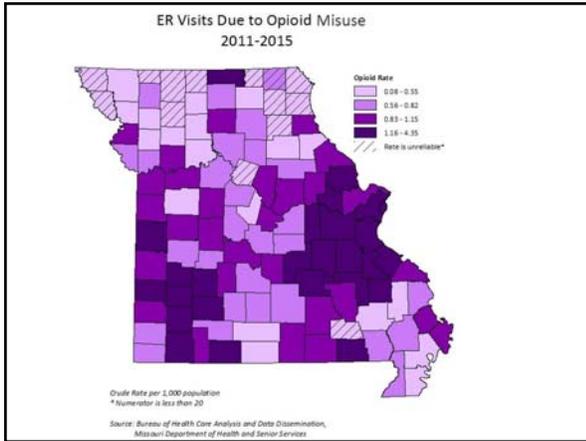
2016.....908 deaths (+35%)

2017.....951 deaths (+4%)

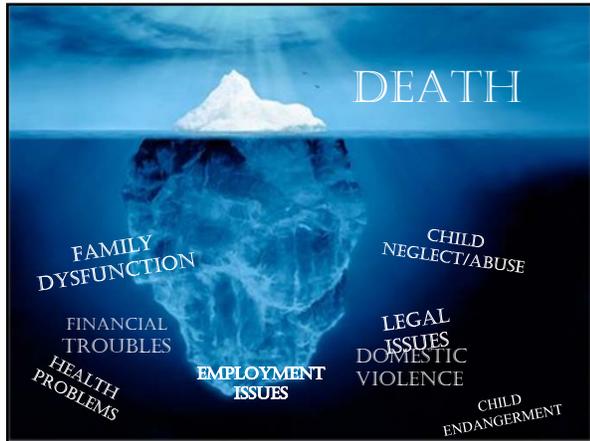
- 66% from illegal street drugs, heroin, fentanyl or carfentanil
- 33% from prescription opioids
- Of the 66% abusing street opioids, 80% of them started with prescription drug problems



Source: Bureau of Vital Statistics, Missouri Department of Health and Senior Services







Causes

- More patients/citizens than ever = 6.2 million
- Biggest segment are aging “Baby Boomers”
- More prescribers than ever = over 28,000
- More pharmacies than ever = 1,380
- Doctors were told they were undertreating pain
- Drug companies saying you can prescribe a lot more, without any risks = lawsuits
- Patients not taking medicine as directed
- Pain becomes a new vital sign
- CMMS not reimbursing at good rates if patients complain about pain medications

Addressing Opiates-1

- Support legislation for a PDMP;
- Publish prescribing guidelines as an educational tool;
- Increase Rx disposal boxes;
- Regulation of pain clinics, ownership, and required board certifications;
- Emergency responder access to naloxone.
- Educational brochures for patients on proper handling of medications.

Addressing Opioid Abuse-2

- Enhanced “Good Samaritan” law so people call 911;
- Dr. Randall Williams statewide standing order for naloxone (9/9/17);
- Increasing support for medication assisted therapy (MAT);
- 9 opioid summits around the state to share information and discuss locally;
- HB2280 expands Medicaid to treat new mothers and infants up to one year for NAS issues;
- State Board of Healing Arts planning opiate prescribing CME;
- Medicaid expanded to allow treatment with non-opiates and acupuncture.

Addressing Opioid Abuse-3

- MO HOPE (St. Louis)—Providing naloxone and training to first responders and law enforcement.
- St. Louis emergency response operations center for immediate “wrap-around” services after overdoses and homicides.
- MORE Project—MO Overdose Rescue & Education—Grant of \$800,000 per year to provide naloxone and training to all first responders in Missouri. (Police, Fire, EMS)
- Reversing CMMS reimbursement issue when patients don’t get medications they want.

Opioid Prescription Intervention (OPI)

Simultaneously, the BNDD can ask for and receive reports for information such as highest prescribers or the most MME per day. This allows the BNDD to more efficiently identify the prescribers for possible investigation without affecting compliant practitioners.

BNDD inspections include:

- Routine compliance with drug recordkeeping and security laws;
- Is the provider triggering quality indicators from MoHealthNet?; and
- Is there a **significant and repetitive habit** of prescribing beyond the published CDC guidelines.



Opioid Prescription Intervention (OPI)

MoHealthNet established an OPI for their patients in 2012. As the payer, they can see the office visits, the prescriber and treatment information, and the pharmacy dispensing, all gathered through claims data.

Prescriptions are analyzed through a database to look for and determine certain Quality Indicators. Prescribers who trigger indicators with patients are automatically sent letters so that treatment may be adjusted or patients may be counseled.

Prescribers who repeatedly display the same indicators are asked to respond with explanations, that are reviewed by physicians. Prescribers are referred to BNDD for an inspection as appropriate.

Quality Indicators

Use of Buprenorphine with another Opioid (Prescribed by another Physician)
Use of Buprenorphine with a Benzodiazepine (Prescribed by another Physician)
Patient's Use of Four or More Pharmacies for Opioid Prescriptions
Patient's Use of Five or More Prescribers for Opioid Prescriptions
Patient's Use of Four or More Pharmacies for Opioid Prescriptions (Under 18 Years)
Patient's Use of Four or More Prescribers for Opioid Prescriptions (Under 18 Years)
Use of Opioids for 60 or More Days with a Diagnosis Suggesting Opioid, Alcohol, or Other Substance Abuse in the Last Year
Use of Opioids at a High Dose without a Malignant Cancer Diagnosis
Use of Opioids at a High Dose without a Malignant Cancer Diagnosis or Other Supporting Diagnosis (65 Years and Older)
Use of Opioids for 60 or More Days with Two or More Diagnoses of Malingering, Somatization, or Factitious Disorder
Use of Opioids for 60 or More Days in Absence of a Diagnosis Supporting Chronic Use
Use of Opioids for 60 or More Days in Absence of a Diagnosis Supporting Chronic Use (Under 18 Years)

P.D.M.P in Missouri

- A statewide PDMP authorized and funded by the legislature has not been established at this time.
- St. Louis County has established a PDMP among 57 local jurisdictions.
- DHSS signed an agreement with Express Scripts for prescribing data. BNDD is provided with prescription data such as date written, date dispensed, prescriber and address, drug names and quantities, days' supply and name of dispensing pharmacy. An open invitation for all PBMs or pharmacies is available on our website.(Executive Order)
- The data is analyzed to determine opiate and benzodiazepine prescribing levels, by provider's name, geographic areas and populations, and similar specialties to identify outliers who clearly stand out from their peers as **Red Flags.** 

Examples of Red Flags

- Dentist filled a cavity for an 8-year old girl. Gave her 30-day supply of oxycodone;
- #1 prescriber of all opiates in Missouri was a family practice doctor (not board certified) and was in a village of 728 people in rural Missouri.
- #1 dispensing pharmacy was in a third class county, in rural Missouri in a town of 2,700 people.

The data helps us identify who we may need to go see and allows us to leave the rest alone.

CDC Guidelines—Page 16

- ❖ Patients receiving opioids for acute care should not receive more than a 7 day supply;
- ❖ Prescribers should start with lowest doses possible;
- ❖ Patients receiving acute care should only receive immediate release (IR) formulations and not extended release (ER);
- ❖ Chronic pain is lingering pain that should only be treated 3 to 6 months;
- ❖ Patients should be seen at least every 30 days for evaluation;



CDC Guidelines—Page 16

- ❖ Prescribers and patients should discuss a pain management plan and develop a strategy so the prescribing does not last more than 6 months;
- ❖ Carefully assess benefits and risks when increasing to more than 50MME per day, and avoid increasing to 90MME per day, or carefully justify a decision; and
- ❖ Prescribers should avoid prescribing opioids and benzodiazepines concurrently whenever possible.



Missouri Drug Take Back Since 2010

Missouri.....	413,320.....	47.7 %
Kansas.....	148,298.....	17.1%
Iowa.....	113,447.....	13.1%
Nebraska.....	86,157.....	9.9%
Southern Illinois.....	83,256.....	9.6%
South Dakota.....	21,513.....	2.4%
Total.....	865,991	

New law expands disposal boxes in Missouri

Private Sector Actions

- Prescribers more aware, not using pain as a vital sign, and reviewing opiate levels.
- Treating acute pain differently than chronic pain.
- Pharmacies protecting liability by asking a **LOT MORE** questions. Some limited dispensing quantities by store policy.

Senate Bill 826

Effective August 28, 2018

An initial opioid prescription for the treatment of acute pain shall be limited to a seven (7) day supply.

- A thorough review of the new law was published in the August 2018 Missouri Board of Pharmacy Newsletter.
- Another review was published in the BNDD newsletter in October 2018.
- The new law applies to Missouri patients and not patients from out of state. Out of state prescribers must comply.
- The new law applies to opioids and not other drugs such as stimulants.

Acute Pain

Section 195.010(1), RSMo defines acute pain as pain, whether resulting from disease, accidental or intentional trauma, or other causes, that the practitioner reasonably expects to last only a short period of time. “Acute pain” shall not include chronic pain, pain associated with cancer care, hospice, or other end-of-life care, or medication-assisted treatment for substance abuse disorders.



Initial Prescription

- Initial prescription is defined as when the patient has not received this “drug” for the previous five (5) months.
- Please note the language says, “drug”. The patient may have already received another opioid, but the new initial prescription law applies when the drug changes and the patient has not received the same drug.
- The strength and dosage form can change, but this law applies when the drug changes.



Initial Prescription Scenarios

#1—A patient has not received any opioid for the past 5 months. Their initial prescription for acute pain is limited to 7 days or less.

#2—A patient has received hydromorphone for 2 months. The doctor reduces them to hydrocodone. This is a new drug the patient has not received for 5 months, so the 7-day limit applies.

#3—A patient received oxycodone while admitted in the hospital. Upon discharge, the doctor may prescribe more than a 7-day supply since the patient just had the same drug in the hospital.

Initial Prescription Scenarios

#4—Patient receives a 10-day supply of codeine or hydrocodone cough syrup to treat a cough. This is allowed. It is not acute pain.

#5—Patient receives a 10-day supply of diphenoxylate to treat diarrhea. This is allowed and not for acute pain.

#6—A patient is on hydrocodone for two months. The doctor wants to increase the drug to oxycodone. This is a new drug so a 7-day limit is authorized.

How Do You Know?

Checking Patient History

Registrants are expected to make good-faith efforts to verify their activities are legal. This may include:

- Talking with the patient or caregivers;
- Contacting other prescribers;
- Contacting other pharmacies;
- Consulting a PDMP;
- Checking a patient's medical record;
- Checking Missouri's cyber-access MoHealthnet data;
- Other actions you deem appropriate in your professional judgement, and document.

A Quick Review To This Point

- Missouri patients only;
- Opioids only;
- In the treatment of acute pain;
- The initial prescription when the patient has not received the drug for 5 months prior.



Exceptions To The Law

- Patients undergoing treatment for cancer;
- Patients enrolled in hospice or receiving palliative care;
- Patients residing in a long-term care facility;
- Patients receiving buprenorphine for the treatment of substance abuse disorder;
- The seven day limit does not apply to veterinarians treating animals within their scope of practice;
- **AND.....**

Prescriber's Professional Judgement

If in the professional medical judgment of the practitioner, they determine that more than a seven day supply is required to treat the patient's acute pain, the practitioner may issue a prescription for the greater quantity needed to treat the patient's acute pain; provided that the practitioner shall document in the patient's medical record the condition triggering necessity for more than a seven day supply and that a non-opioid alternative was not appropriate to address the patient's condition. **In these cases, it is extremely important that the prescribers document similar information on the prescription so that a pharmacy would know and understand the reason for the greater supply.**

Questions Being Asked

The doctor issues a new initial opioid prescription for a 30-day supply. What should the pharmacy do?

Fill the initial 7 days allowed by law. The remainder of the prescription is void. Contact the prescriber and let them know that 7 days were dispensed and the remainder was void. The new law states that after the initial 7 days, if the prescriber wants to provide more, they can prescribe more AFTER a second consultation.

Questions Being Asked

Patient appears at pharmacy counter with two separate prescriptions. The first prescription is for 7 days. The second prescription is for 23 days.

The first prescription is valid. The second prescription is not valid because there has to be a second and subsequent consultation before the second prescription.



Pharmacy Good Faith Immunity

Section 195.080.3, RSMo—

A pharmacist or pharmacy shall not be subject to disciplinary action or other civil or criminal liability for dispensing or refusing to dispense medication in good faith pursuant to an otherwise valid prescription that exceeds the prescribing limits established by subsection 2 of this section.



Patient Education Required

Section 195.080.2, RSMo--Prior to issuing an initial prescription for an opioid controlled substance, a practitioner shall consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity and shall inform the patient of the risks associated with the opioid prescribed.

It has been suggested that prescribers also document this consultation in the medical chart.

BNDD Contact

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QUESTIONS