Maine Prescription Monitoring Program

Maine PMP Webinar Series

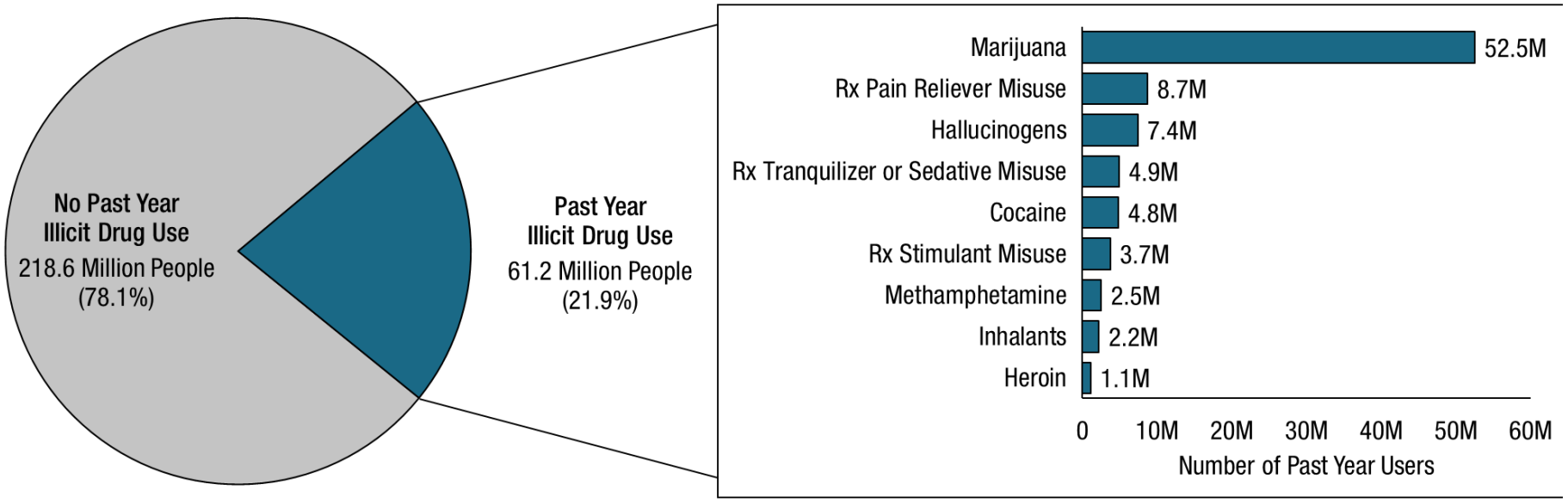
Current Issues in Controlled Substance Prescribing

Spring 2023-Spring 2024

Legal Issues and Controlled Substance Prescribing: How to Make It Work for ME

Elisabeth Fowlie Mock, MD | Ben Townsend, Esq. | Eric Haram, LADC

Past Year Illicit Drug Use: Among People Aged 12 or Older; 2021

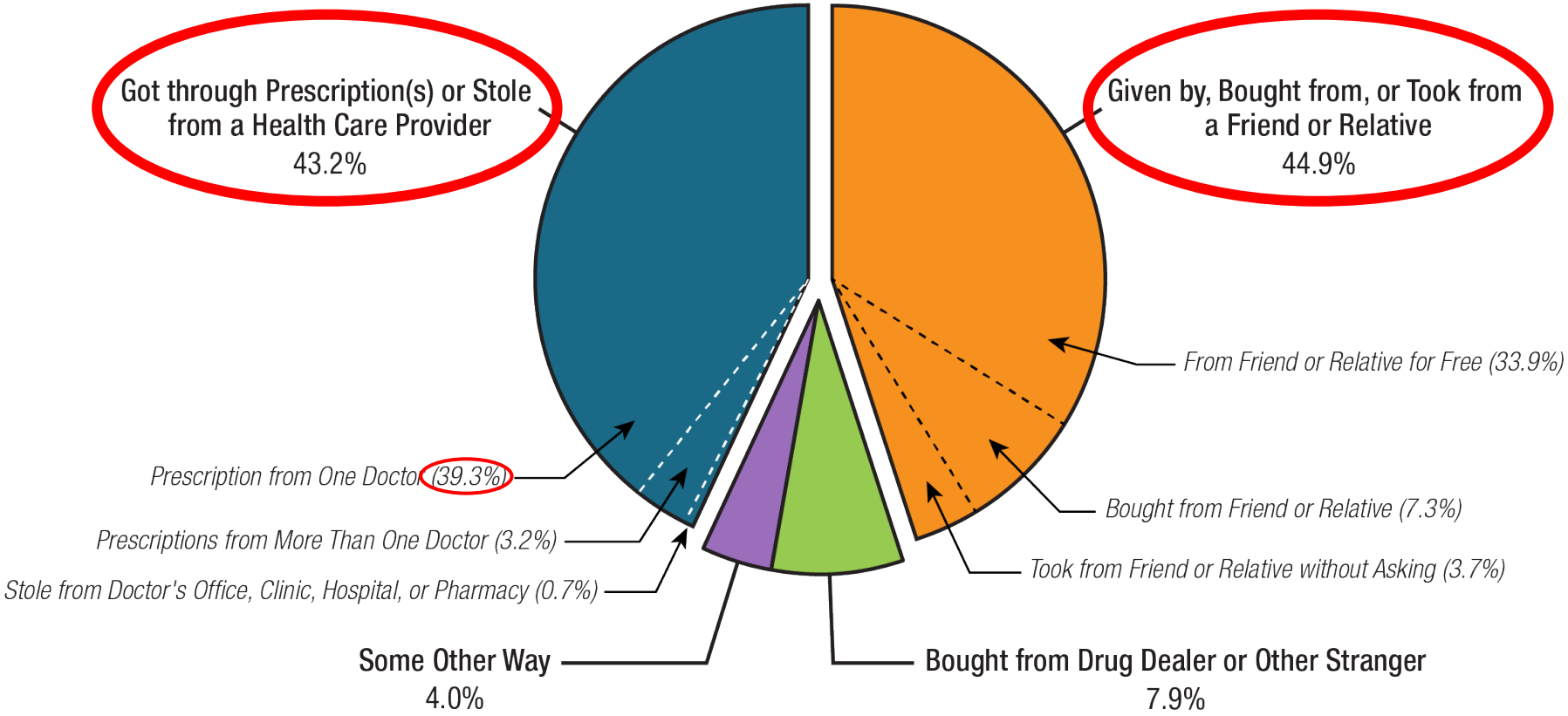


Rx = prescription.

Note: The estimated numbers of past year users of different illicit drugs are not mutually exclusive because people could have used more than one type of illicit drug in the past year.

SAMHSA
Substance Abuse and Mental Health Services Administration

Source Where Pain Relievers Were Obtained for Most Recent Misuse: Among People Aged 12 or Older Who Misused Pain Relievers in the Past Year; 2021



https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report

Mandatory Use-beta test

Maine

Mandatory Use Compliance

APPRISS HEALTH

Written Date (All)

Report Parameters:
- Search date less than or equal 90 days before written date
- Opioid and Sedative, and Buprenorphine Drug Categories
- Drug AHFS Desc excluding "Anxiolytics, Sedatives, and Hypnotics, misc"

View all

Patient Search Rate
0.00% 100.00%

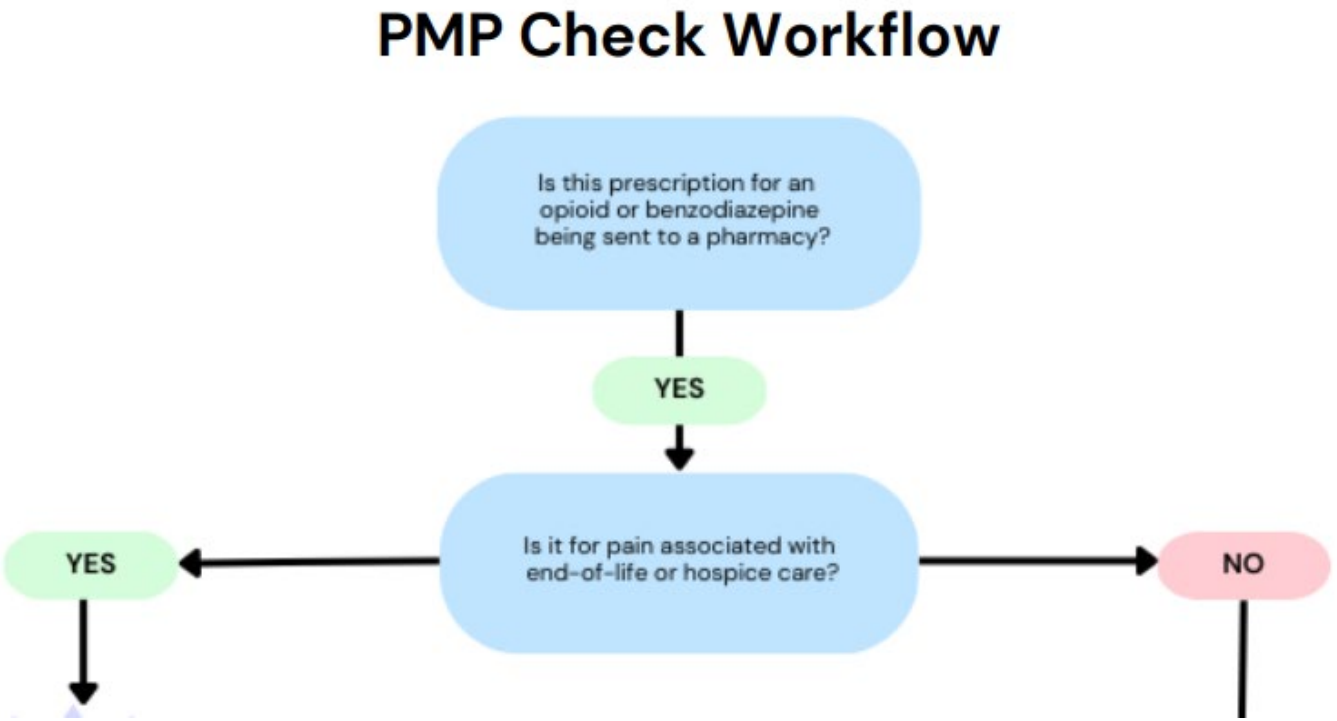
Overall Compliance Rate
93.33%

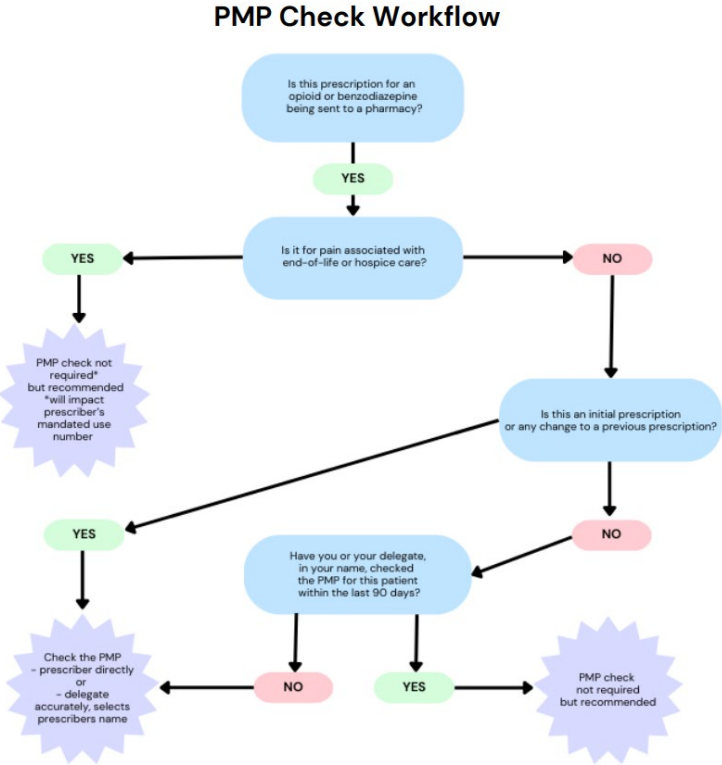
Prescriber Name	MOCK, MD, MPH, ELISABETH	
DEA #	[redacted]	
Specialty	ADDICTION ME..	ADDICTION ME..
Role	PHYSICIAN (MD..	PHYSICIAN (MD..
Address	489 STATE ST	489 STATE ST
City, State Zip	BANGOR, ME 04401	BANGOR, ME 04401

Provider Summary

Prescriber Name	DEA	Prescriber NPI	Dispensations	Search Count	Search Rate
MOCK, MD, MPH, ELISABETH	[redacted]	[redacted]	2	2	100.00%
			13	12	92.31%
Grand Total			15	14	93.33%

Mandatory Use Workflow





https://www.maine.gov/dhhs/sites/maine.gov.dhhs/files/inline-files/PMP%20check%20workflow.pdf

Workflow guidance

What gives a prescriber "credit" for checking the PMP?

- Prescriber checks in the PMP
- Prescriber checks through HealthInfoNet
- Prescriber uses integrated PMP "Gateway" in EHR's electronic prescribing of controlled substances (EPCS) platform to check as prescription is written
- Prescriber personally reviews (on paper or a screen) a PMP report that delegate pulled ***in that prescriber's name*** (if in doubt, double check under "RxSearch/Requests History"). Recommended to reference this type of review in the office/refill note.

What gives a prescriber "credit" for checking the PMP?

- Prescriber checks in the PMP
- Prescriber checks through HealthInfoNet
- Prescriber uses integrated PMP "Gateway" in EHR's electronic prescribing of controlled substances (EPCS) platform to check as prescription is written
- Prescriber personally reviews (on paper or a screen) a PMP report that delegate pulled ***in that prescriber's name*** (if in doubt, double check under "RxSearch/Requests History"). Recommended to reference this type of review in the office/refill note.

What does not give a prescriber "credit" for checking the PMP?

- Not checking
- Checking after the prescription is sent
- Delegate pulls report under a different prescriber's name
- Another prescriber checks (even if they are a group partner)
- Prescriber/delegate checked more than 90 days ago (for chronic, recurring scripts)

What does not register in the PMP compliance score but is still compliant with the checking law?

- Prescriber/delegate spells the patient's name incorrectly or differently than the PMP record (even though the incorrect spelling generated a report)
- Prescriber/delegate used the partial name search function to generate a report
- Prescriber uses the end-of-life/hospice pain exemption (this is legally allowed, however, the PMP compliance score does not know that the exemption was used)

If you prescribe an opioid…

- CO-PRESCRIBE NALOXONE

GetMaineNaloxone.org

Click here to request to be onboarded as a Tier 2 naloxone distributor

PMP Key Messages

- Check the PMP (score an A on Mandatory Use)
- Continue to talk to patients about alternatives to opioids for pain-both pharmalogical and nonpharmalogical
- Aim to lower risks of opioid use
  - lowest possible opioid dose
  - lowest possible number of pills
  - lowest possible number of days
  - lowest possible number of patients
  - avoid combining opioids and benzodiazepines
- Encourage safe storage and disposal of opioids
- Prescribe naloxone/opioid reversal agents liberally

Maine Opioid Prescribing Legal Summary 2023

Co-Occurring Collaborative Serving Maine

August 29, 2023

KOZAK & GAYER, P.A.

157 Capitol Street · Suite 1 · Augusta, Maine 04330

Disclaimer

- This presentation is for educational purposes and does not constitute legal advice.
- Nothing in this presentation, including questions and answers, creates an attorney-client relationship.
- If you need legal advice, please consult with your own legal counsel.

Legal Basis

- Statutes
- Rules
- Non-binding guidance
- Common law (duty of reasonable care)

Maine Opioid Prescribing Statute

- P.L. 2015, Chapter 488
- P.L. 2017, Chapter 213
- Substantially identical requirements inserted in licensure statutes for all prescriber categories:
  - NPs: 32 M.R.S. § 2210
  - DOs and PAs: 32 M.R.S. § 2600-C
  - MDs and PAs: 32 M.R.S. § 3300-F
  - Podiatrists: 32 M.R.S. § 3657
  - Veterinarians: 32 M.R.S. § 4878
  - Dentists: 32 M.R.S. § 18308

Maine Controlled Substances Prescription Monitoring Statute

- 22 M.R.S. §§ 7245-7254

Rules

- Maine DHHS, “Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications”

- “Use of Controlled Substances for Treatment of Pain”
  - Joint Rule of Board of Licensure in Medicine, State Board of Nursing, Board of Osteopathic Licensure, and Board of Licensure of Podiatric Medicine
  - Establishes “Principles of Proper Pain Management”

Non-Binding Guidance

- CDC *Clinical Practice Guideline for Prescribing Opioids for Pain* (2022)
  - Updates 2016 Guideline
  - More emphasis on flexibility and clinical judgment
  - Evidence of prevailing standard of care

Non-Binding Guidance (cont'd)

- DEA Practitioner's Manual (2023)
  - "An Informational Outline of the Controlled Substances Act"
  - Largely procedural (documentation and record-keeping)
- DEA Policy Statement (2006)
  - "Dispensing Controlled Substances for the Treatment of Pain"

“Universal Precautions”

- Evaluation and risk assessment
- Treatment plan
- Periodic review
- Consultation or referral when appropriate
- Coordination of care
- Informed consent

Basic Requirements

- Must prescribe opioid medications electronically
- Must include detailed information on prescriptions
- Must check Prescription Monitoring Program (PMP)
- Limits on opioid prescriptions unless an exemption applies:
  - Seven-day supply
  - 100 Milligram Morphine Equivalent (MME) daily
- Must have Opioid Medication Prescribing Policy

PMP Requirements

- Check PMP:
  - Upon initial prescription of opioids or benzodiazepines
  - Every 90 days thereafter as long as prescription continues
- Exceptions:
  - Directly ordering or administering in ED, inpatient hospital, long-term care, or residential care settings, or in connection with a surgical procedure
  - Directly ordering, prescribing, or administering to patient suffering pain associated with end-of-life or hospice care

Prescribing Limits

- 100 MME per day
- Seven-day limit for acute pain
- 30-day limit for chronic pain
- Subject to specified exemptions

Exemptions to Prescribing Limits

- Pain associated with active and aftercare cancer treatment
  - Prescriber must document that pain is directly related to patient's cancer or cancer treatment.

- Palliative care in conjunction with a serious illness.
  - Chronic pain can qualify as "serious illness"; treatment agreement required ("narcotics contract")

- End-of-life and hospice care.

- Medication-assisted treatment for substance use disorder.

Exemptions (cont'd)

- Pregnant individual with pre-existing prescription for opioid medications in excess of 100 MME aggregate daily limit (only during pregnancy).

- Acute pain for individual with existing opioid medication prescription for chronic pain. (Seven-day prescription.)

- Patients actively tapering off opioid medications. (Six-month maximum.)

- Patients prescribed second opioid medication after proving unable to tolerate first opioid medication, thus causing patient to exceed 100 MME daily limit for active prescriptions. (Individual prescriptions must not exceed 100 MME.)

Mandatory CME

- Prescribers must obtain 3 hours of CME every two years on opioid prescribing
  - Two-year cycle linked to prescriber's license renewal

Sanctions

- Licensing board discipline
- Consent agreements have included:
  - Physician Practice Monitor
    - Random chart review
  - Center for Personalized Education for Professionals ("CPEP")
    - Clinical competence assessment
    - CPEP also offers *Prescribing Controlled Drugs* course
  - Preceptor
    - Oversee implementation of CPEP recommendations
  - The Schmidt Institute
    - *Controlled Substances Stewardship Program*

Sanctions (cont'd)

- Criminal prosecution:
  - Controlled Substances Act, 21 U.S.C. § 841(a)(1):

    "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance[.]"
  - DEA Regulations, 21 C.F.R. § 1306.04(a):

    "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

What is a Crime?

- Government must prove all *elements* of a crime beyond a reasonable doubt
- Elements of crime involve *both*:
  - Actions or omissions, and
  - Culpable state of mind ("scienter" or "*mens rea*")

Scienter under the Controlled Substances Act

- *Ruan v. United States*, 597 U. S. ____ (2022)
  - Criminal cases under Controlled Substances Act
  - Charges: Dispensing controlled substances not "as authorized" (*i.e.*, not for legitimate medical purpose)
  - Supreme Court held:
    - Government must prove doctors acted "knowingly or intentionally"
    - Subjective state of mind, not objective reasonableness of actions

New England Prescription Opioid Strike Force

- Mission Statement: "primarily target criminal conduct by . . . medical professionals . . .."
- First arrest October 26, 2022:
  - Indictment alleged: "prescriptions . . . not issued for a legitimate medical purpose . . ." (Oxycodone, Adderall, Klonopin, Valium, Dilaudid, Methadone)
- Search warrant affidavit alleged:
  - Highest MME prescribing rate per patient in Maine (99th percentile nationwide)
  - Wal-Mart blocked prescriptions for "red flags"
  - Medical consultants alleged contraindications
  - Multiple patients died of overdoses

Example/Discussion

Controlled substances prescribing policy, procedure and controlled substances agreement

COPY

PURPOSE:

To provide a clear framework for the responsible management of prescribing ongoing or chronic controlled medications at YHPP.

POLICY:

Controlled drugs (Schedule 2, 3, 4, 5) will be prescribed and documented in compliance with Federal and State laws. Controlled drug prescribing will be monitored through the Maine Prescription Monitoring Program (ME PMP) AWARxE portal and eCW to minimize potential for diversion and misuse. Prescribers will not prescribe controlled medications to individuals who do not already have an established professional provider/relationship with ongoing monitoring and documentation.

RESPONSIBILITY:

Prescribers and all staff involved in the process shall be responsible for compliance with this policy.

PROCEDURE:

1. All orders for controlled substances will be e-prescribed using a secure PIN in eCW. Orders for all controlled medications will be reviewed for accuracy and for recent ME PMP query.
2. Prescribers will consider following the U.S. FDA recommendation for naloxone (Narcan) which includes conversations about naloxone with patients and caregivers of patients who are at increased risk for opioid overdose and strongly consider a concurrent naloxone prescription (U.S. FDA, 2020).

3. An Opioid Risk Tool should be administered prior to initiation of an opioid for pain management.
4. The prescriber or delegate will query the ME PMP AWARxE database prior to initiating therapy and at least every 90 days during an on-going treatment regimen.
5. The provider will review their own ME PMP dashboard at least every 90 days.
6. Prior to initiating controlled medication therapy and at least annually, the patient should be screened for substance misuse disorders and risk-factors by using Audit C, DAST or Craft for children.
7. If the patient is found to have a substance issue or is at greater risk, the treatment plan will be adjusted accordingly and counseling or referral to a treatment center should be initiated.
8. For chronic treatment regimens (greater than 6 weeks), the prescriber or delegate will review the Controlled Medication Treatment Agreement. The patient should initial all bullets and sign the agreement and retain a copy. **The agreement is to be introduced and activated at the time of the second refill, new patients accepted into the practice with existing chronic controlled substances as therapy and at initiation for any controlled medication therapy for adolescents.** The agreement will be reviewed, revised as needed and resigned at least annually by the patient and prescriber.
   Oncology, palliative, and end of life care are excluded from these requirements.
9. All communication regarding controlled medications will be documented in the patient's chart.
10. Chronic controlled medication prescriptions will be e-prescribed in increments that follow appointments with the prescriber.
11. All chronic controlled substance renewals will have refill dates in alignment with the prescriber's consistent availability and weekday office operations.
12. Patient follow-up will be ongoing with a face-to-face office visit at least every six months.

COPY

Controlled Medication Agreement

I am being prescribed the following Controlled Medication(s):

_____

The purpose of this agreement is to provide a clear framework for how controlled medications are to be responsibly managed. ***Please review each line and sign at the end to confirm your understanding of this agreement and to indicate your willingness to abide by it.***

- I understand that upholding this agreement is integral to the trust and confidence necessary in a provider/patient relationship. _____ pt initials
- I understand that if I break this agreement, my provider may stop prescribing **all** controlled medications and may elect to taper my controlled medication(s) over a period of several days to avoid withdrawal symptoms. An addiction program may be recommended._____ pt initials
- Should my provider want me to seek psychiatric treatment, psychotherapy, and/or psychological treatment, I will agree to do so. If I chose not to follow my treatment plan, my provider may elect to taper my controlled medication(s) over a period of several days to avoid withdrawal symptoms and discontinue prescribing these medications._____ pt initials
- I am aware of the risk of psychological and/or physical dependence and addiction associated with the use of certain controlled medication, such as what I am prescribed. _____pt initials

- If I am being prescribed an opioid for chronic pain, I will talk honestly and openly with my provider about the character and intensity of my pain, how the pain impacts my daily life, and how well or not the medication helps to relieve my pain. _____ pt initials
- I agree not to use any illegal substances. I will take my medications only as prescribed. I will not self-adjust medication schedules or doses or use medications not prescribed for me. _____ pt initials
- I agree to comply with unannounced urine drug screening and blood testing and that I may have an out-of-pocket cost for screening depending upon my insurance. If I am found to have used medications or drugs not prescribed to me by my provider or in amounts not prescribed to me by my provider may discontinue controlled medications. _____ pt initials
- I agree to bring my medications in their original pill container to the office for a random pill count at the discretion of my provider. _____ pt initials
- I will not share my medication with anyone under any circumstances. _____ pt initials
- If I receive care from a specialist's office, walk-in clinic, urgent care, or emergency room, I will inform the provider caring for me that a controlled substance agreement is in place with this provider, and I will notify my provider of any changes or additional prescribed controlled substances within two business days. _____ pt initials

- I understand that if I break this agreement my actions may result in the termination of the relationship with my provider including no longer being prescribed controlled medication(s). _____ pt initials
- I will safeguard my controlled medication from loss, theft, or unintentional use by others. ***Lost or stolen medication will not be replaced.*** _____ pt initials
- I will be ready to taper or discontinue the controlled medication for pain as my condition improves. If my condition does not improve, my provider may recommend additional conservative measures referral to other services. If my level of pain still does not allow me to taper and discontinue the controlled medication for pain, I may be referred to a pain management specialist for management of my pain medications. _____ pt initials
- I agree that refills of controlled medications will be made only during regular business hours with review by my primary care provider. No refills will be allowed after regular office hours, on weekends or at a practice-associated walk-in clinic. I understand a 48-hour processing time is to be required for refill requests. _____ pt initials
- I agree to schedule follow up face-to-face office visits at least every six months. _____ pt initials

I agree to only use the following pharmacy: _____

Located at: _____

- I authorize my provider and my pharmacy to cooperate fully with any city, state, or federal law-enforcement agency and the Maine Board of Pharmacy in the investigation of any possible misuse, sale, or other diversion of my controlled medication. I authorize my provider to provide a copy of this agreement to my pharmacy, primary care provider, and local emergency room. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations. _____ pt initials

- My provider will verify that I am receiving controlled medication from only one prescriber and only one pharmacy by using Maine's Prescription Monitoring Program website. _____ pt initials

All of my questions and concerns regarding treatment with controlled medication(s) have been answered and a signed copy of this document has been given to me for reference.

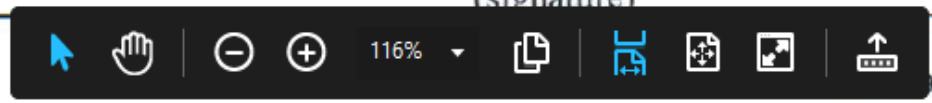
Date: _____

Patient (print name)_____(signature) _____

If patient is minor:

Parent/Guardian (print name)_____(signature)_____

Provider (print name)_____(signature)_____



Progress Note w/ PMP and Controlled Sub. integration

- History of Present Illness
- General:
- Controlled Substance RX Refills
- Number of Medication(s) refilled (document name(s) in note section): *00*
- Date of last office visit with PCP at which time controlled medication was reviewed:

01/01/2022

- Date of last refill: *01/01/2022*
- Schedule of refills:*[…]*

- Date of future appointment: *01/01/2022*
- Controlled Medication contract in chart signed on: *01/01/2022*
- Date of last PMP query (MUST be within 90 days of this RX): *01/01/2022*
- Total MME (per PMP)*[…]*
- Other type of pain control previously tried: *[…]*
- Last urine drug screen performed on: *01/01/2022*
- Result of last UDS: *[…]*
- **Electronically**

There are 2 things at play here--

1. The Maine Chapter 21 opiate prescribing regulation for pain management (attached here)-- in which (see Page 12-13) it references the follow up requirements specifically for opiate prescribing and the PMP Statute and rules 22 MRS Sub statutes 7245-7254

2. The controlled medication policy which names schedule 2,3,4,and 5 requiring QX mo visit and the application of the pt. controlled substance agreement.

Conclusion

- Use internal vetting processes for your organizational policy and procedure development. The crux, I think, revolves around your controlled medications agreement with pt. and when that gets applied.
- In the example of a health system's-controlled substances policy for primary care you can see it also includes all scheduled meds, and when they apply the controlled substances agreement which will state requirements for urine drug screening and face to face apts. Etc. This internal policy then becomes active with accrediting bodies, and regulators as you are in a position to evidence compliance with your own stated standards, Best practice standards often exceed rule, law or regulation as they are threshold safety standards
- Technically, this policy example could exempt some classes or specific medications (hormone, steroids, certain sedatives) and go further to state that the findings of annual risk assessment (including SBIRT) would dictate the application of a controlled medication agreement to further diffuse the application of urine drug screening and face to face requirements when non-opioid medications w/ low risk screening is evidenced.

REFERENCES:

Maine Legislature, (2020). Controlled substance prescription monitoring. Retrieved from: https://legislature.maine.gov/statutes/22/title22ch1603.pdf

State of Maine Behavioral Health, (2021). Prescription monitoring program. Retrieved from: https://www.maine.gov/dhhs/samhs/osa/data/pmp/index.htm.

State of Maine Behavioral Health, (2021). Adult mental health services. Retrieved from: https://www.maine.gov/dhhs/samhs/mentalhealth/

Substance Abuse and Mental Health Services Administration (SAMHSA), (2018). Opioid overdose prevention toolkit. Retrieved from: **https://store.samhsa.gov/sites/default/files/d7/priv/sma18–4742.pdf.**

United States Food & Drug Administration (U.S. FDA, (2020). New recommendations for naloxone. Retrieved from: https://www.fda.gov/drugs/drug-safety-and-availability/new-recommendations-naloxone

Maine Prescription Monitoring Program

QUESTIONS?