EVALUATION PROFILE FOR PDMP Data Use to Inform Clinical Practice and Improve Patient Safety





Centers for Disease Control and Prevention National Center for Injury Prevention and Control

Table of Contents

1.	Purpose of the Evaluation Profile		
2.	PDMP Data Use to Inform Clinical Practice and Improve Patient Safety		5
	÷	Logic Model	8
3.	Process Evaluations		9
	÷	Context	10
	÷	Reach	12
	÷	Dose Delivered or Received	14
	÷	Fidelity	15
	÷	Implementation	16
	÷	Individual-Level Change Outcomes	18
	÷	Community and System Change Outcomes	20
	÷	Unintended Outcomes	21
	÷	Morbidity and Mortality Outcomes	22
÷	Glossary23		
÷	Additional Resources		
÷	References25		
÷	Appendix26		
→	Endnotes47		

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Purpose of the Evaluation Profile

This evaluation profile **PROVIDES GUIDANCE** in designing evaluations of their Prescription Drug Monitoring Program (PDMP) data use to inform clinical practice and improve patient safety. This resource is meant to demonstrate how to conduct evaluations, in many cases using existing programmatic data, to produce actionable and timely findings. These findings will be used to inform program managers and stakeholders about how well initiatives are being implemented, and how effective they are at bringing about desired outcomes. This profile provides guidance on the types of evaluation questions, indicators, data sources, and data collection methods that may be used to evaluate PDMP data use to inform clinical practice and improve patient safety.

EVALUATION CONSIDERATIONS

CDC funded entities¹ are expected to tailor their evaluations to stakeholder needs and the stage of development for each activity. Evaluations should serve programmatic needs to ensure high-quality initiatives are developed, reach program goals, and are tested for effectiveness.

The evolving nature of drug overdose requires that programs strategically pivot to address emerging needs. Evaluators should remain vigilant to changing needs and look for ways to provide practical and actionable information to program implementers and decision makers.² Decisions surrounding the level of rigor needed for a given evaluation should be weighed and balanced by the evaluation standards of utility, feasibility, propriety, and accuracy.³ Examples are provided throughout the profiles to show where less rigorous, but potentially more accessible, data (e.g., discussions with stakeholders, program recipient logs, meeting notes) may be useful in evaluations.

CONTENT ORGANIZATION

The following items are included:

1. Evaluation Profile

The profile is organized by process and outcome evaluation subcategories to demonstrate aspects that stakeholders may want to explore at various stages of an initiative's life cycle. Evaluations often touch upon multiple subcategories; therefore, a glossary is included to provide detailed information on each subcategory.

2. Description and Logic Model

The description highlights core components of each activity, and the logic model shows expected outputs and outcomes. These may help implementers and evaluators see how their own activities or initiatives may be similar or differ from the ones presented.



PDMP Data Use to Inform Clinical Practice and Improve Patient Safety

PDMPs are **ELECTRONIC DATABASES** that contain information on controlled substance prescriptions dispensed by pharmacies and clinicians. PDMPs can provide clinicians, pharmacists, and authorities⁴ with timely and complete information about prescribing and patient behaviors to improve patient care and facilitate a targeted response.^B Health departments, in conjunction with the entity in which the PDMP is managed (if different), work to make the PDMP easier to use and a better tool for clinicians use in managing patient care. Such enhancements include making access to the PDMP easier (e.g., single sign-on, delegate access); encouraging clinicians to consult the PDMP before prescribing; making PDMP data easier to use to improve clinical practice through dissemination and alert systems; and integrating PDMPs with electronic health records (EHR).

PDMP data can be proactively used to enhance healthcare systems and improve patient care. Healthcare system enhancements that proactively use PDMP data include both integrating quality improvement (QI) measures into clinical practice and integrating evidencebased guidelines, like the CDC Guideline for Prescribing Opioids for Chronic Pain, and PDMP data into electronic clinical decision support (CDS) tools within the EHR.⁵ "CDS provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and healthcare. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools." In addition, integrating evidence-based clinical guidelines and PDMP data electronically into clinical workflow through CDS tools can help clinicians and/or pharmacists make informed decisions at the point of care. Integrating the guidelines or policies from either CDC, state/ territory, or health system⁶ into electronic CDS will equip clinicians with the tools and resources they need to quickly assess when it is appropriate to initiate opioid use for the treatment of chronic pain, and how to safely maintain or discontinue use in patients who are currently on long-term opioid therapy.



Implementation will vary depending on the local context and type of activity being implemented. However, this activity may include these core components:

1. Improve PDMP uptake and data utilization

- → Encourage universal use among pharmacists, clinicians, and/or their delegates (e.g., policy to consult the PDMP)
- Provide more timely or real-time data in the PDMP
- Actively manage the PDMP (e.g., creating proactive reports to inform prescribing, flagging clinicians prescribing outside the recommended guidance or policies, developing risk algorithms, etc.)
- → Ensure that the PDMP is easy to use and accessible by clinicians and pharmacists (e.g., user interface improvements, single sign-on, access delegation, EHR integration, etc.)
- 2. Increase clinician-level awareness of prescribing behavior and pharmacist awareness of patient safety
 - Initiate or enhance proactive reporting⁷
 (e.g., individual clinician reports, clinician comparison reports, medical director reports)
 - → Develop enhanced user interfaces (e.g., Morphine Milligram Equivalents [MME] calculators, patient risk scores, etc.)⁸
 - Strengthen education initiatives within a practice, health system, or payer (e.g., clinician education, academic detailing)

3. Deploy patient-level prescribing reports or alerts

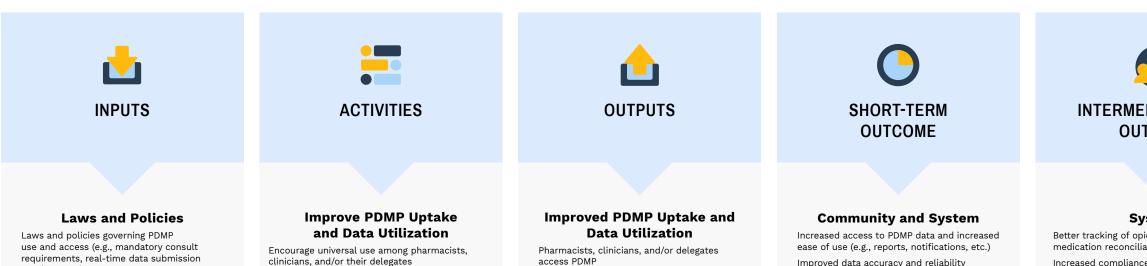
- Display past and present prescription history reports⁹
- → Develop and refine visualizations to enhance ease of use, and engage end users in this process to increase buy-in and use

→ Deploy notifications, alerts, or prompts to guide clinical care (e.g., for problematic prescribing, including overlapping prescriptions with other opioids, benzodiazepines, and other controlled substances, alerts that encourage the prescribing of naloxone, or other measures to ensure patient safety)¹⁰

4. Integrate PDMP/EHR interface, CDS tools, and QI measures

- ➔ Identify healthcare systems and EHR vendors operating in the jurisdiction
- → Establish links between the PDMP and EHR vendors
- → Design and deploy EHR CDS tools using computable PDMP and EHR data sources¹¹
- → Strengthen QI initiatives within a practice, health system, or payer (e.g., non-pharmacological pain management, medications for opioid use disorder [MOUD] referral, etc.)
- → Develop QI and care coordination resources to identify clinicians and patients to target for specific interventions (e.g., academic detailing or further training for clinicians and management and coordination of longterm opioid therapy for patients). These resources (e.g., health system patient registries) can also be used to generate QI measures and to monitor progress at the clinician and practice levels.

LOGIC MODEL **PDMP Data Use to Inform Clinical Practice and Improve Patient Safety**



requirements) Description of health system policy changes to align with CDC opioid prescribing guidelines, state/territory, or health system guidelines or policies

Partnership

Partnerships among and between state and local public health agencies, health payers/ insurers, health systems, healthcare licensing boards; EHR vendors, PDMP vendor, PDMP manager, and the entity in which the PDMP sits (if different)

Resources

PDMP funding to support software licenses, training, enhancements, and other activities

Data management plans^a

Knowledge and Attitudes

Knowledge and attitudes of clinicians and pharmacists toward PDMP, data quality, and use of data

Provide more timely or real-time data contained in the PDMP

Actively manage the PDMP^b Ensure that PDMPs are easy to use and accessible by clinicians and pharmacists

Increase Clinician-Level and Pharmacist Awareness

Initiate or enhance proactive reporting Enhance user interfaces and patient registries Strengthen education initiatives within a healthcare practice, system, or payer

Deploy Patient-Level Prescribing Reports and Alerts

Display prescription history reports Develop and refine visualizations to enhance ease of use

Deploy notifications, alerts, or prompts to guide clinical care^c

Integrate PDMP/EHR Interface

Identify health systems and EHR vendors operating in the jurisdiction Establish links between the PDMP and

EHR vendors Design and deploy EHR CDS tools using PDMP data

Strengthen QI initiatives within a practice, health system, or payer

Develop registries to identify patients to target for specific interventions

access PDMP

PDMP data is to up-to-date, complete, and accurate

PDMP system and software is routinely upgraded, and data are analyzed for use PDMP accessible via delegate, EHR, single sign-on, etc

Increased Clinician-Level and Pharmacist Awareness

PDMP proactive reports distributed to clinicians and pharmacists PDMP interfaces enhanced for users

Education initiatives strengthened for clinicians and pharmacists

Patient-Level Prescribing Reports and Alerts

Patient-level prescription history reports available in PDMP PDMP visuals are enhanced for ease of use

PDMP/EHR Interface

Health systems and EHR vendors identified Links established and integrated between PDMP and EHR vendors EHR is used with PDMP data to inform patient care

Improved data accuracy and reliability

of the PDMP system Increased application of data to drive prevention and response activities between state and local efforts

Individual-Level

Increased use of the PDMP by pharmacists. clinicians, and delegates

Increased knowledge of prescribing behavior and how to improve provision of healthcare

System^d

Better tracking of opioid prescriptions and medication reconciliation

Increased compliance with a jurisdiction's laws and/or health system/payer's policies surrounding the prescribing of controlled substances for improved, safer patient care and effective pain management

patient behaviors

or non-opioid treatment

Increased referral for Medications for Opioid Use Disorder (MOUD)

^a CDC requires recipients who collect or generate data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data. For more information please see CDC DMP policy.

^b PDMP data can be actively managed by initiating or enhancing proactive reporting (e.g., individual clinician reports, clinician comparison reports); developing enhanced user interfaces (e.g., MME calculators, patient risk scores, etc.); displaying past and present prescription history reports; developing and refining visualizations to enhance ease of use; and deploying notifications, alerts, or prompts to guide clinical care (e.g., for problematic prescribing including overlapping prescriptions with other opioids, benzodiazepines, and other controlled substances).

^c Notifications and alerts can be sent for problematic prescribing, including overlapping prescriptions with other opioids, benzodiazepines, and other controlled substances. For further information see pdmpassist.org

^d These outcomes are operationalized as indicators in the profile. For further details are provided here: CDC's Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain

OVERDOSE DATA 2 ACTION



INTERMEDIATE-TERM OUTCOME

Individual-Level

Identification of high-risk prescribing and

Decreased high-risk prescribing behaviors

Increased co-prescribing of naloxone

Increased referrals for non-pharmacologic



LONG-TERM OUTCOME

Morbidity

Decreased rate of opioid misuse, opioid use disorder, and non-fatal overdoses

Mortality

Decreased drug overdoses death rate, including prescription and illicit opioid overdose death rates



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Process Evaluations

Process evaluations DOCUMENT AND DESCRIBE HOW A PROGRAM IS IMPLEMENTED. They normally occur when programs or initiatives are early in their development and are based on stakeholders' needs.^N

Context

Evaluation Question

What factors facilitate and/or inhibit the use of PDMP data to inform clinicians' and pharmacists' clinical practice and improve patient safety?

What factors influence pharmacists' and clinicians' attitudes toward use of PDMP data in patient care settings? What factors influence attitudes toward CDS tools in EHRs?

Sample Indicators

Laws and Policies

- Description of laws and policies in your jurisdiction and/or health system related to the PDMP (e.g., mandatory consult requirements, real-time data submission requirements, interstate data sharing, etc.)
- Description of data use agreements in place between and among health systems, EHR vendors, PDMP, and state and local health departments
- → Description of health system or insurer policy changes to align with CDC opioid prescribing guidelines, state/territory, health system prescribing, or long-term opioid therapy guidelines or policies

Partnership

- Description of partnerships among and between state and local public health agencies; health payers/insurers; health systems; healthcare licensing boards; EHR vendors; PDMP vendor; PDMP manager; and the entity in which the PDMP sits (if different) and initiatives happening or planned to improve prescribing practices
- Description of PDMP/EHR landscape in jurisdiction including vendors, stages of EHR integration implementation, use of CDS, state/territory, and/or health system tools in EHR and methods for streamlining complementary work among partners
- Description of capacity within each partner organization to use PDMP data to inform clinical practice and patient safety

Resources

- Description of funding sources and resources available for PDMP licenses and support, training, enhancements, and other activities
- Description of non-monetary support available to the jurisdiction for PDMP data use implementation (e.g., technical assistance from vendors and health departments, published resources from the CDC and other government agencies, staffing within healthcare systems for PDMP and EHR support)

DATA SOURCES

- State policies
- Health systems policies
- Organizational policies
- PDMP
- Private data sources (e.g., hospital discharge/ billing)
- National EMS Information System (NEMSIS) and/or local EMS data
- Local syndromic surveillance systems
- State Unintentional Drug Overdose Reporting System (SUDORS)
- BioSense
- Funding mechanisms and fee structure

DATA COLLECTION METHODS

- Environmental scan, informal interviews, or surveys with stakeholders
- Policy search
- Interviews with stakeholders

- Description of existing health system QI initiatives and resources and use of CDS tools to inform opioid prescribing and care in an EHR
- Description of how healthcare practices, pharmacies, and/or systems are using PDMP data to improve patient care

Knowledge and Attitudes

- → Description of attitudes and knowledge of clinicians and pharmacists regarding the PDMP and use of PDMP data (e.g., clinician perceptions around timeliness of data, completeness, EHR integration availability, etc.)
- Description of health systems/insurers attitudes, knowledge, and familiarity with integrating CDS tools into an EHR
- Description of other activities influencing pharmacist and clinician knowledge of and attitudes toward use of PDMP data to affect patient care (e.g., academic detailing, PDMP vendor interventions)
- Description of training/education provided to clinicians and pharmacists



Reach

Evaluation Question

How many clinicians are being reached by the activities to improve clinician-level awareness of prescribing behavior?

How many pharmacists are being reached by activities to improve patient care and safety?

How many pharmacies, health systems, and/or health information exchanges (HIE) are using an integrated PDMP-pharmacy dispensing software system, PDMP/EHR, CDS, and/or QI measures?

Sample Indicators

Improve PDMP Uptake and Data Utilization

- Number and percentage of clinicians, pharmacists, and delegates registered with the PDMP
- → Number of PDMP patient queries

Increase clinician-level awareness of prescribing behavior

 Number and percentage of clinicians receiving proactive reports on prescribing behavior¹²

Increase pharmacist-level awareness of patient safety

Number and percentage of pharmacists receiving proactive reports on patient prescription history

DATA SOURCES

- PDMP data
- EHR vendor data
- Health systems policies

DATA COLLECTION METHODS

- Interviews with stakeholders
- Policy review

Integrate PDMP/EHR interface

- Number of connected healthcare systems and pharmacies with integrated PDMP connections via HIEs (e.g., state or regional)
- Number and percentage of pharmacies and health systems actively using PDMP data to improve clinical practice and patient care¹³
- Number and percentage of health systems in the jurisdiction using PDMP data in patient care settings¹⁴
- Number and percentage of health systems and/or EHRs displaying patient-level prescribing alerts and/or reports
- Number and percentage of EHR vendors operating in the jurisdiction that have integrated PDMP into the EHR
- Number and percentage of health systems and/or EHRs using an integrated PDMP/EHR interface
- Number and percentage of pharmacies and pharmacy dispensing software systems (PDS) with integrated PDMP interface
- Number and percentage of health systems and/or EHRs deploying CDS tools
- Number and percentage of health systems and/or EHRs implementing QI measures



Dose Delivered or Received

Evaluation Question

To what extent are healthcare systems/clinicians/pharmacists interfacing with PDMP data in clinical care settings?

Sample Indicators

Overall

- → Number of end user¹⁵ reports delivered
- → Number and percentage of clinicians/pharmacists/health systems/EHRs in the jurisdiction with the following functionality: patient prescription history; data feeding into clinician report cards; PDMP data integration with EHR for improved patient care; and, data on QI measures is being collected to monitor progress

DATA SOURCES

- PDMP data
- EHR vendors
- Health systems data

DATA COLLECTION METHODS

 Interviews with stakeholders

Fidelity

There may be circumstances in which strict fidelity to the original plan may actually work against an intended outcome. In this case, adaptation is necessary and expected. Tracking fidelity and purposeful/data-informed deviations are important for understanding implementation; however, strict fidelity should not supersede necessary adaptations that will facilitate outcomes.

Evaluation Questions

To what extent have PDMP data been used to inform clinical practice and improve patient safety as originally planned?

Sample Indicators

Overall

- Description of adaptations made to improve PDMP data use to inform clinical practice and improve patient safety (e.g., integrated PDMP/EHR interface, integrated pharmacy dispensing software system/EHR, and/or QI initiatives,)
- ➔ Description of adaptations made within CDS (e.g., Best Practice Alerts¹⁶)

DATA SOURCES

- Program implementation data
- PDMP data
- Policy documents
- EHR vendors
- Health systems data

DATA COLLECTION METHODS

- Interviews or meeting notes from stakeholders
- Interviews with users of the PDMP
- Environmental scan

Implementation

Evaluation Questions

To what extent has PDMP data been used to improve clinical practice and improve patient safety?

To what extent do clinicians, pharmacies, health systems and/or EHRs have integrated PDMP/EHR interface, integrated pharmacy dispensing software system/EHR, CDS, and/or QI measures?

What factors facilitated and/or hindered implementation?

What lessons were learned from implementation that can inform current and future efforts?

Sample Indicators

Overall

- → Description of barriers and facilitators to improve PDMP uptake and data utilization; clinician-level awareness of prescribing behavior; improving patient-level prescribing reports and alerts; and/or integrating PDMP/EHR interface; pharmacist-level awareness of patient safety
- → Description of lessons learned from implementation

Improve PDMP Uptake and Data Utilization

- Description of measures taken to encourage universal use of the PDMP among clinicians and/or their delegates
- Description of measures taken to encourage universal use of the PDMP among pharmacists
- Description of measures taken to encourage use of PDMP data by professional licensing boards
- → Description of activities completed to actively manage¹⁷ the PDMP
- Description of improvements made to PDMP user experience and PDMP accessibility (e.g., single sign-on, access delegation)
- Description of improvements made to PDMP navigation and enhanced ease of use
- Description of changes to timeliness of PDMP data (e.g., movement toward real-time data)

DATA SOURCES

- Stakeholders
- PDMP data
- Program implementation data
- Health systems data
- Policy documents
- EHR vendor data

DATA COLLECTION METHODS

- Interviews with key informants
- Survey of clinicians, PDMP administrators, and other stakeholders

- Description of improvements made to PDMP and/or EHR (e.g., Surescripts) data for increased accuracy, reliability, and completeness (e.g., change in data elements used in or design/ approach used for clustering/matching patient records)
- Percentage change in PDMP user feedback surveys that indicate positive user experience (e.g., usability)

Increase clinicians' awareness of prescribing behavior and pharmacists' awareness of patient safety

- Description of improvements/enhancements made to proactive reporting (e.g., individual clinician reports, clinician comparison reports)
- Percentage of PDMP users who are satisfied with the PDMP
- Descriptions of enhancements made to user interfaces (e.g., MME calculators, patient risk scores)

Deploy patient-level prescribing reports and alerts

 Description of improvements made to patientlevel prescribing reports, alerts, and prompts to guide clinical care

Integrated PDMP/EHR interface, CDS tools, and QI measures

- Description of implementation of links between the PDMP and various EHR systems
- ➔ Description of EHR CDS tool(s) deployed
- Description of QI initiatives being implemented in the jurisdiction and changes over time to these
- Description of clinician receptivity to including PDMP data in the EHR to improve patient safety



Individual-Level Change Outcomes

Evaluation Question

For whom, and in what ways, did individual-level changes occur based on using PDMP data to inform clinical practice and improve patient safety?

Sample Indicators

Short-term

- → Clinician/pharmacist (see appendix)
 - Percentage change in use of the PDMP by clinicians, pharmacists, and/or delegates (e.g., queries, reviewing PDMP data)
 - Percentage change in clinicians' knowledge of their prescribing behavior
 - Percentage change in clinicians' knowledge of guideline concordant prescribing practice
 - Percentage change in pharmacists' knowledge of best practices for patient safety
 - Percentage change in clinician's knowledge and attitudes toward PDMP, data quality, and use of data
 - Description of changes to communication between pharmacists and clinicians (e.g., increase in communication via telephone or PDMP messaging)
 - Percentage change in clinicians'/pharmacists' knowledge of PDMP
 - Percentage change in clinicians'/pharmacists' attitudes toward PDMP

Intermediate-term

- → State-level¹⁸ (see appendix)
 - Percentage change in patients prescribed any opioid
 - Percentage change in patients prescribed long-term opioid therapy
 - Percentage change in patients prescribed high-dose chronic opioid therapy
 - Percentage change in patients prescribed chronic concurrent opioids and sedatives
 - Percentage change in new opioid patients' days' supply of first opioid prescription

DATA SOURCES

- PDMP data
- Survey of clinicians and pharmacists
- Opioid Use Disorder (OUD) treatment center data
- EHR data

DATA COLLECTION METHODS

- Database queries to PDMP
- Survey sent out through the PDMP to clinicians and pharmacists
- Data requests to OUD treatment centers

- Percentage change in new opioid patients subsequently prescribed chronic opioids
- Percentage change in non-fatal overdose involving prescription opioids
- Percentage change in patients prescribed chronic opioids who receive a diagnosis of opioid use disorder

Health system¹⁹

Clinician (see appendix)

- → New opioid prescriptions:
 - Percentage of patients with a new opioid prescription for an immediate-release opioid
 - Percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing
 - Percentage of patients with a new opioid prescription for chronic pain with documentation that a urine drug test was performed prior to prescribing
 - Percentage of patients with a follow-up visit within four weeks of starting opioids for chronic pain
 - Percentage of patients with a new opioid prescription for acute pain for a three days' supply or less
- ➔ Long-term Opioid Therapy
 - Percentage of patients on long-term opioid therapy who are taking 50 MMEs or more per day
 - Percentage of patients on long-term opioid therapy who are taking 90 MMEs or more per day
 - Percentage of patients on long-term opioid therapy who received a prescription for a benzodiazepine
 - Percentage of patients on long-term opioid therapy who had a follow-up visit at least quarterly
 - Percentage of patients on long-term opioid therapy who had at least quarterly pain and functional assessments
 - Percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly
 - Percentage of patients on long-term opioid therapy who the clinician counseled on the

risks and benefits of opioids at least annually

- Percentage of patients on long-term opioid therapy with documentation that a urine drug test was performed at least annually
- Percentage of patients with chronic pain who had at least one referral or visit for nonpharmacologic therapy as a treatment for pain
- Percentage of patients on long-term opioid therapy who were counseled on the purpose and use of naloxone and either prescribed or referred to obtain naloxone
- Percentage of patients with an OUD who were referred to or prescribed MOUD



Community and System Change Outcomes

Evaluation Question

To what extent did greater use of PDMP data and integration contribute to community and system outcomes?

Sample Indicators

Short-Term

- → Percentage change in number of queries to the PDMP
- Percentage change in daily/weekly/monthly active users of the PDMP
- → Percentage change in clinicians receiving proactive reports through the PDMP

Intermediate-Term

- Description of changes in opioid prescription tracking and medication reconciliation (e.g., how was the system changed to improve the provision of real-time data of opioid prescriptions?)
- Description of changes made to increase compliance with a jurisdiction's laws and/or health system/payer policies surrounding the prescribing of controlled substances
- ➔ Percentage change in registration with the PDMP
- → Percentage change in use of the PDMP
- → Percentage change in EHRs using PDMP data to inform clinical practice
- Percentage change in practices, health systems, or payers implementing QI initiatives
- Description of changes to how healthcare practices and/or systems are using PDMP data to improve patient care
- Description of changes to how professional licensing boards are using PDMP data to improve patient care and safety

DATA SOURCES

- PDMP data
- Survey of clinicians and pharmacists
- EHR data

DATA COLLECTION METHODS

- Database queries to PDMP
- Survey sent out through the PDMP to clinicians and pharmacists
- Data requests to OUD
 treatment centers
- Key informant interviews with PDMP, EHR system administrators, and healthcare systems administrators

Unintended Outcomes

Evaluation Question

What unintended outcomes (positive or negative) were produced as a result of using PDMP data to inform clinical practice and improve patient safety?

Sample Indicators

Overall

→ Description of unintended outcomes of using PDMP data to inform clinical practice and improve patient safety, either positive (e.g., increased partnerships across public and private sectors resulting in improvements outside public health) or negative (e.g., changes made to PDMP resulting in incomplete or confusing information that leads to less use among healthcare clinicians, patients' undertreated pain or rapid tapering)

DATA SOURCES

- Program implementation data
- Program implementation partners

DATA COLLECTION METHODS

- Focus group discussion with program implementers
- Semi-structured interviews with clinicians, pharmacists, and PDMP/ EHR administrators



Morbidity and Mortality Outcomes

Evaluation Question

What were the changes in opioid-related morbidity and mortality when comparing before and after greater PDMP data use and integration?

Long-Term Sample Indicators

Number and percentage changes in morbidity and mortality indicators

Morbidity

- Patients receiving multiple naloxone administrations (MNAs) from emergency medical services (EMS)
- Patients transported to the emergency department (ED) for overdose by EMS where primary impression recorded in NEMSIS is *drug* overdose
- Patients refusing transport by EMS where primary impression recorded in NEMSIS is drug overdose
- ➔ EMS calls where naloxone was administered
- → All-drug non-fatal overdose emergency department visits
- Emergency department visits involving non-fatal opioid overdose, excluding heroin
- Emergency department visits involving non-fatal heroin overdose with or without other opioids
- → All-drug non-fatal overdose hospitalizations
- Hospitalizations involving non-fatal opioid overdose, excluding heroin
- Hospitalizations involving non-fatal heroin overdose with or without other opioids

Mortality

All drug overdose deaths

- ➔ Drug overdose deaths involving opioids
- → Drug overdose deaths involving prescription opioids
- ➔ Drug overdose deaths involving heroin
- Drug overdose deaths involving synthetic opioids other than methadone

DATA SOURCES

- Jurisdictional mortality and morbidity data
- ED/health department morbidity and mortality data
- CDC WONDER
- National Emergency Medical Services Information System (NEMSIS) and/or local EMS data
- PDMP data
- Private data sources (e.g., IQVIA, hospital discharge/billing)
- Local syndromic surveillance systems
- SUDORS
- BioSense

DATA COLLECTION METHODS

- Policy search
- Interviews with stakeholders
- Database queries of various morbidity, mortality, and other overdose data
- Reviews of jurisdictional reports (e.g., annual progress reports)
- Secondary data analysis
- Review of opioid-related morbidity and mortality data dashboards or reports

Glossary

Outcome evaluations assess progress on the sequence of outcomes (e.g., short-, intermediate-, and longterm) the intervention aims to achieve. Outcome evaluations normally occur when an intervention is established, and it is plausible to expect changes in a given timeframe. They should be planned from the beginning of an intervention, as they often rely on baseline data that need to be collected before the intervention starts.^M Outcome evaluations may examine the following areas:

- Individual-level Outcomes: The extent to which the intervention has affected changes in a given audience's knowledge, skills, attitudes, intentions, efficacy, and/or behaviors.
- Community and System Change Outcomes: The extent to which the intervention has affected changes in a community, organization, or system(s).
- Unintended Outcomes: The extent to which the intervention had unplanned or unanticipated effects—either positive or negative.
- Morbidity/Mortality Outcomes: The extent to which the intervention has affected changes in target audience's morbidity or mortality.

Process evaluations document and describe how a program is implemented. Process evaluations normally occur when programs or initiatives are early in their development, and are based on stakeholders' needs.^N Process evaluations may examine the following areas:

Context: Aspects of the larger social, political, and economic environment that may influence an activity's implementation.

Reach: The extent to which the intended target audience(s) is exposed to, or participates in an activity. If there are multiple interventions, then *reach* describes the proportion that participates in each intervention or component.

Doses delivered/received: The number (or amount) of intended units of each intervention, or each component that is delivered or provided.

- Dose delivered is a function of efforts of the people who deliver the intervention. The extent to which the intervention staff member (e.g., academic detailers, educators, etc.) actively engaged with, interacted with, were receptive to, and/or delivered intervention materials and resources to the target audience(s).
- Dose received is a characteristic of the target audience(s), and it assesses the extent of engagement of participants with the intervention.

Fidelity: The extent to which the intervention is delivered as planned. It represents the quality and integrity of the intervention as conceived by the developers. (Note: In some circumstances, strict fidelity to the original plan may actually work against an intended outcome. In these cases, adaptation is necessary and expected. Tracking fidelity and purposeful/datainformed deviations is important to understand implementation; however, strict fidelity should not supersede necessary adaptations that will facilitate outcomes.)

Implementation: The extent to which the intervention is feasible to implement and sustain, is acceptable to stakeholders, and is done with quality. Examination of these dimensions may also result in noted lessons learned, barriers, and facilitators that can help others when replicating similar initiatives.

Universal Use refers to efforts that require pharmacists, clinicians, and/or their delegates to check a state PDMP prior to prescribing certain controlled substances. The CDC Guideline Recommendation Nine states that "clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months". These policies have significant potential of ensuring that the utility and promise of PDMPs are maximized. For more information, see CDC's website on What States Need to Know about PDMPs.

Additional Resources

- ➔ Electronic Clinical Quality Improvement (eCQI)
- Integrating and Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States
- ➔ Health IT Clinical Decision Support
- ➔ Advancing Clinical Decision Support
- Agency for Healthcare Research and Quality Clinical Decision Support
- Driving Quality and Performance Measurement A Foundation for Clinical Decision
- ➔ Optimizing Strategies for Clinical Decision Support
- ➔ Adapting Clinical Guidelines for the Digital Age
- Kawamoto K, Houlihan CA, Balas EA. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success, BMJ. 2005;330:765. Available at: https://www.bmj.com/ content/330/7494/765.full. Accessed 18 October 2019.
- → Change Management in EHR Implementation
- Simonian AI, Lam JH. Informatics Interchange: Implementation of clinical decision support rules, Am J Health-Syst Pharm. April 1, 2016. 73(7):436-439. Available at: https://doi.org/10.2146/ajhp150122 Accessed 18 October 2019.
- Wright A, Sittig DF, Ash JS, et. al. Governance for clinical decision support: case studies and recommended practices from leading institutions, Journal of the American Medical Informatics Association. 2011;18(2):187-194. Available at: https:// academic.oup.com/jamia/article/18/2/187/802701. Accessed 18 October 2019.
- Quality Improvement Quality Measures
- Centers for Medicare and Medicaid Services. Clinical Decision Support: More Than Just 'Alerts' Tipsheet. undated; https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ Downloads/ClinicalDecisionSupport_Tipsheet-.pdf. Accessed 18 October 2019.



References

- ^A Agency for Healthcare Research and Quality. (2016, June 1). Factors to Consider in Managing Chronic Pain: A
 Pain Management Summary. Retrieved August 15, 2019, from
- ^B Centers for Disease Control and Prevention. (2017a, October 3). What States Need to Know about PDMPs. Retrieved August 15, 2019, from
- ^c Centers for Disease Control and Prevention. (2017b, February). Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States. Retrieved October 1, 2019, from
- Centers for Disease Control and Prevention. (2018) Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain. National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention, Atlanta, GA. Retrieved from https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf
- ^E Centers for Disease Control and Prevention. (2019b, September 24). Opioid Prescribing Support Implementation Guide.
 Retrieved October 1, 2019, from
- F Centers for Disease Control and Prevention. (2019c, July 29). Guideline Resources: CDC Opioid Guideline Mobile App. Retrieved August 15, 2019, from
- ^G Dowell, D., Haegerich, T., & Chou, R. (2019). No shortcuts to safer opioid prescribing. *New England Journal of Medicine*, 380(24), 2285-2287.
- ^H Dr. Robert Bree Collective. (2017). Opioid Prescribing Metrics. Retrieved from http://www.breecollaborative.org/wp-content/ uploads/Bree-Opioid-Prescribing-Metrics-Final-2017.pdf
- Flanigan, M., & White, G. (2019, September 27). Electronic Clinical Decision Support (CDS) Tools that Support the Implementation of the CDC Guideline for Prescribing Opioids for Chronic Pain. Retrieved October 1, 2019, from
- Prescription Drug Monitoring Program Center of Excellence at Brandeis (2016, May). Guidance on PDMP Best Practices: Options for Unsolicited Reporting. Retrieved August 15, 2019, from https://www.pdmpassist.org/pdf/PDMP_admin/ Update%20to%20%20Guidance%20on%20Unsolicited%20 Reporting%20final.pdf

- ^K Prescription Drug Monitoring Program Training and Technical Assistance Center. (2017, February 17). Prescriber Report Cards. Retrieved August 15, 2019, from
- Prescription Drug Monitoring Program Training and Technical Assistance Center. (n.d.). PDMP Enhancements. Retrieved August 15, 2019, from https://www.pdmpassist.org/content/ pdmp-enhancements
- M Rossi, PH., Lipsey, MW., & Freeman, HE. Measuring and Monitoring Program Outcomes. In: Rossi, PH., Lipsey, MW., & Freeman, HE. Evaluation a Systematic Approach. 7. Thousand Oaks, CA: Sage Publications; 2004.
- N Steckler, A., & Linnan, L. Process evaluation for public health interventions and research: An overview. In: A. Steckler & L. Linnan (Eds.), *Process Evaluation for Public Health Interventions and Research*. San Francisco, CA: Jossey-Bass; 2002.
- Sroujieh, L. S., Monroy, D., & Warren, E. (2016). Using Electronic Health Record (EHR) Best Practice Alert (BPA) to Improve RBC Transfusion Practices and Adherence to the Guidelines. Chest, 150(4), 599A.
- ^P Tcheng, J. E., S. Bakken, D. W. Bates, H. Bonner III, T. K. Gandhi, M. Josephs, K. Kawamoto, E. A. Lomotan, E. Mackay, B. Middleton, J. M. Teich, S. Weingarten, and M. Hamilton Lopez, editors. 2017. Optimizing Strategies for Clinical Decision Support: Summary of a Meeting Series. Washington, DC: National Academy of Medicine.
- ^Q Substance Abuse and Mental Health Services Administration. (2020) Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from: https://store.samhsa. gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-006_508.pdf

Appendix

The following Sample Indicators for Intermediate-term State-level (pg. 18-19) for Individual-Level Change Outcomes come from Dr. Robert Bree Collective's Opioid Prescribing Metrics document (2017).

- → Percentage change in patients prescribed any opioid
 - Metric: Patients prescribed any opioid. Percent of the population prescribed opioids, overall and by age group. Primary: All ages. Secondary: Age-specific (≤11, 11-20, 21-34, 35-64, ≥65 years old).
 - Rationale:
 - To track trends in opioid prescribing overall and by age group. Age is defined as the age on the first day of the quarter of analysis.
 - AMDG 2015 Guideline: Reserve opioids for acute pain resulting from severe injury or medical conditions, surgical
 procedures, or when alternatives are ineffective or contraindicated. (Page 22). The goal of opioid therapy is to
 prescribe the briefest, least invasive and lowest dose regimen that minimizes pain and avoids dangerous side
 effects. (Page 26).
 - CDC 2016 Guideline: Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4). (Page 24).
 - Number of Quarters of Data Needed: One calendar quarter (e.g., current (Oct-Dec)).
 - **Numerator:** Number of patients in the population with at least one opioid prescription prescribed in the calendar quarter.
 - **Denominator:** Number of patients in the population in the calendar quarter (e.g., health plan population, Washington State population). If total population denominator data is not available, report the number of patients with at least one opioid prescription filled in the quarter.
 - Frequency: Quarterly.
 - Level of Analysis: State/Region, System/Health Plan, Clinic/Provider.
 - **Inclusions:** Opioid prescription data for all patients in the population pulled the calendar quarter (e.g., Oct-Dec). See Appendix C for a full list of included and excluded opioids (Page 21).
 - Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioid not typically used in outpatient settings or when used as part of cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.

- → Percentage change in patients prescribed long-term opioid therapy
 - **Metric:** Patients prescribed chronic opioids. Metric 2A: Percent of patients prescribed chronic opioids among patients with at least one opioid prescription prescribed in the quarter. Metric 2B: Prevalence of patients prescribed chronic opioids (optional).

Rationale:

- To track trends in long-term (chronic) prescriptions of opioids among all patients using prescribed opioids and among the population (state population, county, health plan, etc.).
- AMDG 2015 Guideline: The overall data on effectiveness of opioids for longer term use, especially for improved function, and for routine conditions, such as non-specific low back pain, headaches, and fibromyalgia is weak, and the evidence of potential harm is strong. (Page 24). Prescribe chronic opioid analgesic therapy only if there is sustained clinically meaningful improvement in function and no serious adverse outcomes or contraindications. (Page 32).
- CDC 2016 Guideline: Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate. (recommendation category: A, evidence type: 3). (Page 17).
- Number of Quarters of Data Needed: One calendar quarter (e.g., current (Oct-Dec)).
- Numerator: Number of patients in the population prescribed ≥60 days supply of opioids in the calendar quarter.
- Denominator:
 - A: Number of patients in the population with at least one opioid prescription in the calendar quarter.
 - B: Number of patients in the population in the calendar quarter (e.g., health plan population, Washington State population).
- **Days, Supply:** The total days, supply is the sum of the days, supply from all opioid prescriptions prescribed during the calendar quarter, including overlapping prescriptions (and includes days that may extend into the next calendar quarter). Divide the number of units (e.g., tablets, capsules, patches) dispensed by the maximum number of units to be used in one day.
- Frequency: Quarterly.
- Level of Analysis: State/Region, System/Health Plan, Clinic/Provider.
- **Inclusions:** Opioid prescription data for all patients in the population pulled the calendar quarter (e.g., Oct-Dec). See Appendix C for full list of included and excluded opioids (Page 21).
- Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioids not typically used in outpatient settings or when used as part of cough and cold formulations, including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants

- → Percentage change in patients prescribed high-dose chronic opioid therapy
 - Metric: Patients prescribed high-dose chronic opioid therapy. Metric 3A: Percent of patients at high doses among
 patients prescribed chronic opioids. Metric 3B: Prevalence of patients prescribed opioids at high doses (optional).
 - Rationale:
 - To track trends in high-dose opioid prescribing (e.g., ≥50 mg/day MED, ≥90 mg/day MED) among those being prescribed chronic opioid therapy and among the population (state, county, health plan, etc.).
 - AMDG 2016 Guideline: There is no completely safe opioid dose. Chronic opioid analgesic therapy patients should be routinely assessed for risk as medical conditions and life circumstances may change during treatment. (Page 12) Prescribe opioids at the lowest possible effective dose. If the dose is increased but does not result in clinically meaningful improvement in function, then significant tolerance or adverse effects to opioids may be developing and opioids should be tapered back to the previous dose or possibly discontinued. (Page 32).
 - CDC 2016 Guideline: When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3). (Page 22).
 - Number of Quarters of Data Needed: One calendar quarter (e.g., current (Oct-Dec)).

Numerator:

- Number of patients in the population prescribed ≥60 days, supply of opioids at ≥50 mg/day MED in the calendar quarter.
- Number of patients in the population prescribed ≥60 days, supply of opioids at ≥90 mg/day MED in the calendar quarter.

Denominator:

- A: Number of patients in the population with at least one opioid prescription in the calendar quarter.
- B: Number of patients in the population in the calendar quarter (e.g., health plan population, Washington State population).
- **Days, Supply:** The total days, supply is the sum of the days, supply from all opioid prescriptions prescribed during the calendar quarter, including overlapping prescriptions (and includes days that may extend into the next calendar quarter). Divide the number of units (e.g., tablets, capsules, patches) dispensed by the maximum number of units to be used in one day.
- Frequency: Quarterly.
- Level of Analysis: State/Region, System/Health Plan, Clinic/Provider.
- Inclusions: Opioid prescription data for all patients in the population pulled the calendar quarter (e.g., Oct-Dec). See Appendix C for full list of included and excluded opioids (Page. 21).
- Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioids not typically used in outpatient settings or when used as part of cough and cold formulations, including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.
- Conversion Factors for Commonly Prescribed Opioids: Codeine- 0.15; Dihydrocodeine- 0.25; Fentanyl buccal, sublingual or lozenge/- 0.13; Fentanyl film or oral spray- 0.18; Fentanyl nasal spray- 0.16; Fentanyl transdermal- 2.4; Hydrocodone- 1; Hydromorphone- 4; Levorphanol tartrate- 11; Meperidine hydrochloride- 0.1; Methadone- (1-20 mg/ day- 4; 21-40 mg/day- 8; 41-60 mg/day- 10; ≥61-80 mg/day- 12); Morphine- 1; Oxycodone- 1.5; Oxymorphone- 3; Pentazocine- 0.37; Propoxyphene- 0.23; Tapentadol- 0.4; Tramadol- 0.1
- **Calculation of Average MED per Day:** The MED for each prescription is calculated by multiplying the number of units prescribed by the strength per unit and then multiplying by the conversion factor. The total MED is the sum of the MED from all opioid prescriptions prescribed during the calendar quarter, including overlapping prescriptions (and includes MED that may extend into the next calendar quarter). The total MED of all opioids is divided by 90 days. Note: Some guidelines refer to MED as morphine milligram equivalent or MME.

- Morphine Equivalent Dose Calculation: For example, if a patient filled 180 tablets of hydrocodone 5 mg / acetaminophen 500 mg and 180 tablets of oxycodone extended release 20mg during the calendar quarter, the average MED per day is calculated as follows:
 - 1. Find hydrocodone dose for prescription: Hydrocodone 5 mg x 180 tablets = 900 mg
 - 2. Convert hydrocodone dose to MED: 900 mg hydrocodone x 1 (conversion factor in Metric 3) = 900 mg MED
 - 3. Find oxycodone dose for prescription: Oxycodone 20 mg x 180 tablets = 3600 mg
 - 4. Convert oxycodone dose to MED: 3600 mg oxycodone x 1.5 (conversion factor in Metric 3) = 5400 mg MED
 - 5. Add MEDs from all prescriptions: 900 mg + 5400 mg = 6300 mg total MED
 - 6. Calculate average MED per day: 6300 mg MED ÷ 90 days = 70 mg per day MED

- → Percentage change in patients prescribed chronic concurrent opioids and sedatives
 - **Metric:** Patients prescribed chronic concurrent opioids and sedatives. Metric 4A: Percent of patients with concurrent chronic opioid and sedative prescriptions, among patients prescribed chronic opioids. Metric 4B: Prevalence of patients with concurrent chronic opioid and sedative prescriptions (optional).
 - Rationale:
 - To track concurrent chronic opioid and sedative prescriptions in those with chronic opioid use and among the population (state, county, health plan, etc.).
 - AMDG 2015 Guideline: High-risk chronic opioid analgesic therapy prescribing practices (high opioid dose, extended chronic opioid analgesic therapy duration, concurrent use of sedatives/hypnotics) are associated with increased risks of opioid overdose and serious fractures. Acute: "Avoid new prescriptions of benzodiazepines and sedative-hypnotics. Consider tapering or discontinuing benzodiazepines and/or sedative-hypnotics." Chronic: "Do not combine opioids with benzodiazepines, sedative-hypnotics or barbiturates." (Pages 24-5, 26, 27, 28, 32, 33).
 - CDC 2016 Guideline: Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently.
 - Number of Quarters of Data Needed: One calendar quarter (e.g., current (Oct-Dec)).
 - **Numerator:** Number of patients in the population prescribed ≥60 days, supply of opioids and prescribed ≥60 days, supply of sedative hypnotics, benzodiazepines, carisoprodol, and/or barbiturates in the same calendar quarter.
 - Denominator:
 - A: Number of patients in the population prescribed ≥60 days, supply of opioids in the calendar quarter.
 - B: Number of patients in the population in the calendar quarter (e.g., health plan population, Washington State population).
 - **Days, Supply:** The total days, supply is the sum of the days, supply from all opioid prescriptions prescribed during the calendar quarter, including overlapping prescriptions (and includes days that may extend into the next calendar quarter). Divide the number of units (e.g., tablets, capsules, patches) dispensed by the maximum number of units to be used in one day.
 - Frequency: Quarterly
 - Level of Analysis: State/Region, System/Health Plan, Clinic/Provider.
 - Codes to identify sedatives: Generic Names-
 - Benzodiazepines- Alprazolam; Chlordiazepoxide; Clonazepam; Clorazepate; Diazepam; Estazolam; Flurazepam; Lorazepam; Midazolam; Oxazepam; Quazepam; Temazepam; Triazolam
 - Barbiturates- Butabarbital; Butalbital; Mephobarbital; Phenobarbital; Secobarbital
 - Skeletal muscle relaxants- Carisoprodol
 - Non-benzodiazepine hypnotics- Chloral Hydrate; Eszopiclone; Meprobamate; Suvorexant; Zaleplon; Zolpidem
 - Inclusions: Opioid prescription data for all patients in the population pulled the calendar quarter (e.g., Oct-Dec). See Appendix C for a full list of included and excluded opioids (Page. 21). See Appendix D for list of included benzodiazepines, sedative-hypnotics, and anxiolytics. (Page 22).

• Exclusions:

- All patients with a cancer diagnosis or those who are on hospice, if possible.
- All prescriptions for buprenorphine.
- Prescriptions for opioid not typically used in outpatient settings or when used as part of cough and cold formulations, including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.

- → Percentage change in new opioid patients' days' supply of first opioid prescription
 - **Metric:** New opioid patients days, supply of first opioid prescription. Among new opioid patients, distribution of days, supply on first prescription.
 - Rationale:
 - CDC guidelines recommend initial opioid prescriptions should generally be for three days or less. Among new
 opioid patients in a quarter, this metric tracks the percent of first prescriptions with days, supply of ≤3, 4-7, 8-13,
 and ≥14.
 - AMDG 2015 Guideline: If opioids are prescribed, it should be at the lowest necessary dose and for the shortest duration (usually less than 14 days). (Page 22).
 - CDC 2016 Guideline: Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4). (Page 24).
 - Number of Quarters of Data Needed: Two subsequent calendar quarters (e.g., current (Oct-Dec) and previous (July-Sep)).
 - Numerator: Number of patients with at least one opioid prescription in the current quarter (e.g., Oct-Dec), who have
 no opioids prescribed in the prior quarter (e.g., July-Sep) among patients in the population during both quarters by
 days supply (i.e., ≤3, 4-7, 8-13, and ≥14) in the current quarter.
 - **Denominator:** Patients with at least one opioid prescription in the current quarter (e.g., Oct-Dec), who have no opioids prescribed in the prior quarter (e.g., July-Sep) in the population during both quarters.
 - Frequency: Quarterly.
 - Level of Analysis: State/Region, System/Health Plan, Clinic/Provider.
 - **Definition of new opioid patient:** Patients with at least one opioid prescription in the current quarter (e.g., Oct-Dec), who have no opioids prescribed in the prior quarter (e.g., July-Sep) among patients in the population during both quarters.
 - **Inclusions:** Opioid prescription data for all patients in the population pulled in two subsequent calendar quarters (e.g., Jul-Sep, Oct-Dec). See Appendix C for full list of included and excluded opioids. (Page 21).
 - Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioid not typically used in outpatient settings or when used as part of cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.

- → Percentage change in new opioid patients subsequently prescribed chronic opioids
 - **Metric:** New opioid patients subsequently prescribed chronic opioids. Metric 6A: Among new opioid patients, percent who then transition to chronic opioids in the next quarter. Metric 6B: Rate of new opioid users transitioning to chronic opioid use in the current quarter (optional).

Rationale:

- To track the transition from new to chronic opioid prescription.
- AMDG 2015 Guideline: Because there is little evidence to support long term efficacy of chronic opioid analgesic therapy in improving function and pain, and there is ample evidence of its risk for harm, prescribers should proceed with caution when considering whether to initiate opioids or transition to chronic opioid analgesic therapy. (Page 7) Patients who used opioids for at least 90 days were greater than 60% more likely to still be on chronic opioids in five years. (Page 11) Do not discharge the patient with more than a two week supply of opioids, and many surgeries may require less. Continued opioid therapy will require appropriate reevaluation by the surgeon. (Page 28).
- CDC 2016 Guideline: Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4). (Page 24).
- Number of Quarters of Data Needed: Three subsequent quarters (e.g., current calendar quarter (Oct-Dec) and the two subsequent previous calendar quarters (April-June, July-Sep)).
- Numerator: Number of patients who are prescribed ≥60 days, supply of opioids in the current calendar quarter (e.g., Oct-Dec) with at least one opioid prescription in the previous quarter (e.g., Jul-Sep) and no opioid prescription in the prior quarter (e.g., Apr-June).
- Denominator:
 - A: Number of patients with at least one opioid prescription in the previous quarter (e.g., July-Sep), who have no opioids prescribed in the prior quarter (e.g., April-June)
 - B: Number of patients in the population in the calendar quarter (e.g., health plan population, Washington State population)
- Frequency: Quarterly
- Level of Analysis: State/Region, System/Health Plan, Clinic/Provider
- **Definition of new opioid patient:** Patients with at least one opioid prescription in the current quarter (e.g., Oct-Dec), who have no opioids prescribed in the prior quarter (e.g., July-Sep) among patients in the population during both quarters.
- **Inclusions:** Opioid prescription data for all patients in the population pulled in three subsequent calendar quarters (e.g., Apr-June, Jul-Sep, Oct-Dec). See Appendix C for a full list of included and excluded opioids. (Page. 21).
- Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioids not typically used in outpatient settings or when used as part of cough and cold formulations, including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.

- → Percentage change in non-fatal overdose involving prescription opioids
 - **Metric:** Non-fatal overdose involving prescription opioids. Primary: All ages. Secondary: Age-specific: ≤11, 11-20, 21-34, 35-64, ≥65
 - Rationale: To track the non-fatal overdoses from prescription opioids.
 - Number of Quarters of Data Needed: One calendar quarter (e.g., current (Oct-Dec)).
 - Numerator:
 - Number of non-fatal overdoses involving prescription opioids presenting to the Emergency Department
 - Number of non-fatal overdoses involving prescription opioids resulting in hospitalization
 - Denominator: Total number of people in the population (e.g., health plan population, Washington State population)
 - Frequency: Quarterly
 - Level of Analysis: State/Region, System/Health Plan
 - **Definitions:** Rate of non-fatal overdoses in at least one quarter in the year with any of the following codes from hospitalization and emergency department (ED) by age:
 - ED visits or hospitalizations for all opioid overdose excluding heroin (ICD-9)- 965.00 Poisoning by Opium; 965.02
 Poisoning by Methadone; 965.09 Poisoning by Other Opiates and Related Narcotics; E850.1 Accidental Poisoning
 by Methadone; E850.2 Accidental Poisoning by Other Opiates and Related Narcotics.
 - ED visits or hospitalizations for all opioid overdose excluding heroin (ICD-10)- T40.0 (T40.0X T40.0X4): Opium; T40.2 (T40.2X – T40.2X4): Natural and semisynthetic opioids; T40.3 (T40.3X – T40.3X4): Methadone; T40.4 (T40.4X – T40.4X4): Synthetic opioids, other than methadone; T40.6 (T40.60 – T40.604): Other and unspecified narcotics.
 - Inclusions: Medical or billing record for all patients in the population pulled in the calendar quarter (e.g., Oct-Dec)

- → Percentage change in patients prescribed chronic opioids who receive a diagnosis of opioid use disorder
 - Metric: Patients prescribed chronic opioids who receive a diagnosis of opioid use disorder.
 - **Rationale:** To track the number of patients receiving opioids chronically who also receive a diagnosis of opioid use disorder.
 - Number of Quarters of Data Needed: Four subsequent quarters (e.g., current calendar quarter (Oct-Dec) and the three subsequent previous calendar quarters (Jan-Mar, April-June, July-Sep)).
 - Numerator: Number of patients diagnosed with an opioid use disorder and ≥60 days, supply of opioids in at least three of four quarters in a year.
 - **Denominator:** Number of patients in a population with ≥60 days, supply of opioids in at least three of four calendar quarters in a year.
 - Frequency: Annually.
 - Level of Analysis: State/Region, System/Health Plan.
 - **Definitions:** Rate of patients prescribed chronic opioids in at least three of four quarters in a year with any of the following codes in the same year:
 - ICD-9 diagnosis of an opioid use disorder- 304.00 304.03 Opioid type dependence; 304.7 Combinations of opioid type drug with any other; 305.50 – 305.53 Opioid abuse
 - DSM-IV for an opioid use disorder- 304.0 Opioid type dependence; 305.5 Opioid abuse
 - ICD-10 diagnosis of an opioid use disorder- F11 (F11.1 F11.99) Opioid related disorders
 - DSM5 for an opioid use disorder- 305.50 Opioid use disorder, mild; 304.00 Opioid use disorder, moderate; 304.00 Opioid use disorder, severe
 - **Inclusions:** Opioid prescription data and medical or billing record for all patients in the population pulled in four subsequent calendar quarters (e.g., three month intervals of Jan-Mar, Apr-June, Jul-Sep, Oct-Dec). See Appendix C for a full list of included and excluded opioids. (Page 21).
 - Exclusions:
 - All patients with a cancer diagnosis or those who are on hospice, if possible.
 - All prescriptions for buprenorphine.
 - Prescriptions for opioids not typically used in outpatient settings or when used as part of cough and cold formulations, including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants.

The following Sample Indicators for New Opioid Prescriptions (page 18-19) come from the CDC's Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain document (2018).

- Percentage of patients with a new opioid prescription who have documentation that a PDMP was checked prior to prescribing
 - **CDC Prescribing Guideline Recommendation 9:** Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. They should also assess whether the use of multiple prescribers and/or pharmacies suggests uncoordinated or insufficiently coordinated care. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
 - **Description:** The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.
 - **Numerator:** The number of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older prescribed an opioid for chronic pain (see Appendix D for ICD-10 codes) who had no opioid prescription in the previous 45 days.
 - Measurement period: One week (day of or within the week prior to prescribing).
 - Exclusions: Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - **Data sources:** Prescription data from the practice EHR; access to state PDMP data; a structured field in the EHR to capture that the PDMP was checked.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Not all clinicians may be registered with the PDMP and practices' access to the PDMP embedded within an EHR may not always work. While EHRs can sometimes have a hyperlink to the PDMP or a "single sign-on" access from the EHR, an indication that the PDMP was checked for a specific patient is not captured. Practices may need to create a structured field or checkbox for clinicians to indicate the PDMP was checked. Clinicians should remember to look for benzodiazepine prescriptions from other clinicians, as well as opioids.

- Percentage of patients with a new opioid prescription who have documentation that a urine drug test was performed prior to prescribing
 - **CDC Prescribing Guideline Recommendation 10:** When prescribing opioids for chronic pain, clinicians should administer urine drug tests before starting opioid therapy and at least annually to assess presence of prescribed opioids, as well as other controlled prescription drugs and illicit drugs.
 - **Description:** The percentage of patients with a new opioid prescription for chronic pain with documentation that a urine drug test was performed prior to prescribing.
 - **Numerator:** The number of patients with a new opioid prescription for chronic pain with documentation of a urine drug test.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older prescribed an opioid for chronic pain (see Appendix D for ICD-10 codes) who had no opioid prescription in the previous 45 days.
 - Measurement period: One week (day of or within the week prior to prescribing).
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids: https://www.cdc.gov/drugoverdose/ prescribing/guideline.html; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - Data sources: Prescription data from the practice EHR. Urine drug testing data in EHR and/or medical chart.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory. List of extended-release/long-acting opioids can be found here.
 - Some systems may not have access to laboratory services in house or the results in a structured field. It is not only important to determine whether a patient is taking other controlled or illicit substances; it is also important to determine whether the patient is taking the medication to help prevent opioid diversion. Practices should check with the labs they use, since mass spectrometry is usually required to test for the absence of a prescribed medication. A separate order may be required for this confirmation.

- → Percentage of patients who had a follow-up visit within four weeks of starting opioids for chronic pain
 - **CDC Prescribing Guideline Recommendation Seven:** Clinicians should evaluate benefits and harms to patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy to patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages, or to taper and discontinue opioids.
 - Description: The percentage of patients with a follow-up visit within four weeks of starting an opioid for chronic pain.
 - **Numerator:** The number of patients with a new opioid prescription for chronic pain with an in-person follow-up visit with the prescribing clinician within four weeks.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older prescribed an opioid for chronic pain (see Appendix C for ICD-10 codes) who had no opioid prescription in the previous 45 days.
 - Measurement period: Four weeks (within four weeks of starting opioids).
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - Data sources: Prescription data from the practice EHR. Patient follow-up visit data from the EHR or the medical chart.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - In-person follow-ups should be conducted by the prescribing clinician. However, if it is not feasible to require
 that patients would have their follow-up with the prescribing clinician because of staffing, they may consider
 revising the measure accordingly (to indicate any clinician).
 - Telemedicine or virtual visits are considered "in-person" visits when they are already considered a part of standard care in a practice.

The following indicators for Long-term Opioid Therapy Prescriptions (page 18-19) come from the CDC's Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain document (2018).

- → Percentage of patients on long-term opioid therapy who have a follow-up visit every 90 days
 - **CDC Prescribing Guideline Recommendation Seven:** Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages, or to taper and discontinue opioids.
 - Description: The percentage of patients on long-term opioid therapy who have a follow-up visit at least quarterly.
 - **Numerator:** The number of patients who had at least one in-person follow-up visit with the prescribing clinician at least quarterly.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter.
 - Measurement period: Ninety (90) days.
 - Exclusions: Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - Data sources: Prescription data from the practice EHR. Patient follow-up visit data from the EHR or the medical chart.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - It will be challenging to determine whether a visit was related to following-up on long-term opioid therapy without a chart. A practice should consider the best way to capture visits related to opioids (e.g., create a structured field, create a registry to track last visits).
 - If it is unreasonable to require that patients would have their follow-up with the prescribing clinician because of staffing, they may consider revising the measure accordingly (to indicate any clinician).
 - If there are challenges in securing these data, a practice may wish to look at a six-month interval, and limit the analyses to persons who were receiving long-term opioid therapy consistently over that time period. Then, one could count the number of visits to the prescribing physician. The simplest metric would be the percent of long-term opioid therapy patients who have at least one follow-up visit to the clinician in a six-month period.
 - Another option would be to report the percentage of long-term opioid therapy patients with at least two follow-up visits. However, it would then probably be necessary to extend the time period from six months to nine months to provide leeway for follow-up visits that fell slightly outside the one month time window.

- → Percentage of patients on long-term opioid therapy who have at least quarterly pain and functional assessments
 - **CDC Prescribing Guideline Recommendation Two:** Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
 - **Description:** The percentage of patients on long-term opioid therapy who had at least quarterly pain and functional assessments.
 - **Numerator:** The number of patients with documented pain and functional assessments using a validated clinical assessment tool (e.g., PEG) at least quarterly.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter.
 - Measurement period: Ninety (90) days.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - **Data sources:** Prescription data from the practice EHR. PEG assessment scale data captured outside and recorded in the EHR or a structured version of the PEG available in the EHR.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - Would need to create a structured field to capture when assessments were done and, optimally, the ratings
 on the PEG each time.

- Percentage of patients on long-term opioid therapy who have documentation that a PDMP was checked at least every 90 days
 - **CDC Prescribing Guideline Recommendation Nine:** Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
 - **Description:** The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.
 - Numerator: The number of patients who had documentation that a PDMP was checked at least quarterly.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter.
 - Measurement period: Ninety (90) days.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - **Data sources:** Prescription data from the practice EHR. Access to state PDMP data. A structured field in the EHR to capture that the PDMP was checked.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - Not all clinicians may be registered with the PDMP and practices' access to the PDMP embedded within an EHR may not always work. While EHRs can sometimes have a hyperlink to the PDMP or a "single sign-on" access from the EHR, an indication that the PDMP was checked for a specific patient is not captured. Practices may need to create a structured field or checkbox for clinicians to indicate the PDMP was checked. Clinicians should remember to look for benzodiazepine prescriptions from other clinicians, as well as opioids.

- Percentage of patients on long-term opioid therapy for whom the clinician counseled the patient on the risks and benefits of opioids at least annually
 - **CDC Prescribing Guideline Recommendation Three:** Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
 - **Description:** The percentage of patients on long-term opioid therapy for whom the clinician counseled the patient on the risks and benefits of opioids at least annually.
 - Numerator: The number of patients the clinician counseled on the risks and benefits of opioids at least annually.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter.
 - Measurement period: One year.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - **Data sources:** Prescription data from the practice EHR. Structured field indicating that counseling was provided or a signed treatment agreement housed in the EHR or the medical chart.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - Data that indicate that counseling was provided would potentially be captured in a clinical note, from which data is challenging to pull for measurement purposes. A practice may want to create a structured field or note template to allow this information to be readily queried from an EHR.
 - If a practice uses treatment agreements that address risks and benefits and instructs clinicians to counsel, a practice may wish to use a treatment agreement as an indicator that the patient was counseled on risks and benefits.

- Percentage of patients on long-term opioid therapy who have documentation that a urine drug test was performed at least annually
 - **CDC Prescribing Guideline Recommendation 10:** When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
 - **Description:** The percentage of patients on long-term opioid therapy with documentation that a urine drug test was performed at least annually.
 - Numerator: The number of patients with documentation of a urine drug test.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter.
 - Measurement period: One year.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - Data sources: Prescription data from the practice EHR. Urine drug testing data in EHR and/or medical chart.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - Some systems may not have access to laboratory services in house or the results in a structured field. It is not only important to determine whether a patient is taking other controlled or illicit substances; it is also important to determine whether the patient is taking the medication to help prevent opioid diversion. Practices should check with the labs they use, since mass spectrometry is usually required to test for the absence of a prescribed medication. A separate order may be required for this confirmation.

- Percentage of patients with chronic pain who had at least one referral to non-pharmacologic therapy as a treatment for pain
 - **CDC Prescribing Guideline Recommendation One:** Nonpharmacological therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacological therapy and non-opioid pharmacologic therapy, as appropriate.
 - **Description:** The percentage of patients with chronic pain who had at least one referral or visit to nonpharmacologic therapy as a treatment for pain.
 - **Numerator:** The number of patients who had at least one referral to nonpharmacologic therapy (e.g., physical therapy, exercise therapy, cognitive behavioral therapy, weight loss).
 - Current Procedural Terminology (CPT) codes cover procedures. Therapies are procedures, so the Z51.89 ICD-10 code is under a broad code for "Encounter for other specified aftercare." All outpatient clinicians use CPT codes to bill insurance along with ICD diagnoses codes. CPT codes were added for the therapies below when appropriate codes could be determined. The Healthcare Common Procedure Coding System (HCPCS) is a set of healthcare procedure codes based on the American Medical Association's (AMA) Current Procedural Terminology. Level I codes consist of the AMA CPT code and are numeric. Level II codes are alphanumeric and primarily include non-physician services such as ambulance services and prosthetic devices, and represent items and supplies and non-physician services, not covered by CPT-4 codes (Level I).
 - Some of these non-physician services may use HCPCS codes. Some of these codes include:
 - physical therapy (ICD-10: Z51.89); CPT: 97001-97039, but could also include areas noted in interventional procedure codes below),
 - > exercise therapy (ICD-10: Z51.89) (CPT: 97110 = therapeutic exercises, but could add aquatic therapy, etc.),
 - cognitive behavioral therapy,
 - weight loss HCPCS/CPT Codes G0447— face-to-face behavioral counseling for obesity, 15 minutes G0473 face-to-face behavioral counseling for obesity, group (2–10), 30 minutes. The related diagnoses are: ICD-10 Codes Z68.30, Z68.31, Z68.32, Z68.33, Z68.34, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.41, Z68.42, Z68.43, Z68.44, or Z68.45, and
 - non-invasive therapies could include CPT: Therapeutic Procedures 97110 -97546, or more broadly to include Medical Nutritional Therapy, Wound Care, Acupuncture, Osteopathic Manipulations and Chiropractic care, through 98943, and more.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with chronic pain (see Appendix C for ICD-10 codes).
 - Measurement period: Practice may determine the period of time.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure.
 - **Data sources:** Prescription data from the practice EHR. Diagnosis code data from the practice EHR and procedural code data for the non-pharmacological therapy.
 - Guidance for producing the measure and potential challenges:
 - Capturing referrals: There can be challenges measuring referrals in EHRs. Some EHRs may capture in a
 structured field whether a patient has been referred within the same healthcare system. However, if a patient
 is referred to a professional outside of the system, it may not be captured as a structured field. Some types of
 referrals may not be captured via anything other than a recommendation in the clinical note.
 - A practice should consider focusing on a specific chronic condition to make it easier to operationalize this
 measure, such as the percentage of patients with chronic low back pain who had at least one referral to physical
 therapy. Alternatively, focus on osteoarthritis, given how common it is.
 - Another challenge may be that patients who have had a chronic condition for several years may have been referred to nonpharmacological therapy years ago, which would be difficult to capture.

- If there are challenges in securing these data, a practice may wish to focus on patients on long-term opioid therapy (as the denominator), although the measure could worsen over time if patients are being put on nonpharmacologic therapy instead of opioids.
 - > Or, a practice could calculate the percentage of patients with chronic low back pain who had at least one referral to physical therapy.
- If a practice wants to define appropriate nonpharmacologic pain treatments for a particular condition and develop an operational definition of the initiation of an episode of care, they could track the percent of patients who received an appropriate nonpharmacologic treatment.

- → Percent of patients on long-term opioid therapy who are prescribed naloxone
 - CDC Prescribing Guideline Recommendation Eight: Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50MME/d), or concurrent benzodiazepine use, are present.
 - **Description:** The percentage of patients on long-term opioid therapy who were counseled on the purpose and use of naloxone, and either prescribed or referred to obtain naloxone.
 - **Numerator:** The number of patients counseled on the purpose and use of naloxone, and either prescribed or referred to obtain naloxone.
 - Denominator: The number of patients in an outpatient panel of patients 18 years of age or older with ≥ 60 days' supply of opioids within a quarter AND on ≥ 50 MMEs per day, OR diagnosis of opioid use disorder (OUD), OR diagnosis of substance abuse, OR taking benzodiazepines concurrently, OR a diagnosis of restrictive or obstructive lung disease, and/or sleep apnea.
 - Measurement period: Practice may determine the period of time.
 - **Exclusions:** Exclusion criteria include cancer patients (ICD-10 codes C00-D09 are "cancers," malignant neoplasms; ICD-10 codes D10-D3A are benign neoplasms; ICD-10 codes D37-D48 are neoplasms of uncertain behavior; and ICD-10 code D49 is a neoplasm of unspecified behavior—could be malignant, but not known [Appendix D]), palliative care and end-of-life care. Palliative care is identified with a principal ICD-10 code of terminal condition with (Z51.5), and end-of-life care patients would be identified using a procedure or CPT code. Note: identifying end-of-life care patients may be difficult to systematically capture; palliative care may be a sufficient proxy for end-of-life care. Patients who transfer into the practice may be excluded from the measure. Additional exclusion criteria are: (1) drugs not typically used in outpatient settings, such as cough and cold formulations including elixirs, and combination products containing antitussives, decongestants, antihistamines, and expectorants; (2) all other prescribed opioids not included on this list of commonly prescribed opioids; (3) buprenorphine products indicated as MOUD, identified by ICD-10 codes.
 - **Data sources:** Prescription data from the practice EHR. Naloxone counseling and referral data from the EHR or medical chart review.
 - Guidance for producing the measure and potential challenges:
 - Identifying opioid medications: EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Unknown days' supply in EHRs: Practices lacking information about days' supply could calculate the days' supply by dividing the prescription quantity by the maximum use per the sig and add up the MMEs of all opioid prescriptions.
 - Capturing referrals: There can be challenges measuring referrals in EHRs. Some EHRs may capture in a structured field whether a patient has been referred within the same healthcare system. If a patient is referred to a professional outside of the system, it may not be captured as a structured field. Some types of referrals may not be captured via anything other than a recommendation in the clinical note.
 - Counseling is not captured as a structured field in EHRs. Practices may have to create a field or check-box to indicate counseling was provided.
 - Alternatives for the Measure: If a practice is unable to identify patients in ALL risk categories, an alternative is to identify those in risk categories that are feasible (e.g., ≥ 50 MMEs or concurrent use of benzodiazepines). Practices may want to examine the percentage who received a naloxone prescription, separately from whether counseling was provided. The former may be more readily available in most practices' existing data, and separating these two may facilitate better clarity on what to target for improvement.

- ➔ Percentage of patients with OUD who are referred to MOUD
 - **CDC Prescribing Guideline Recommendation 12:** Clinicians should offer or arrange evidence-based treatment (usually medications for opioid use disorder, including naltrexone, buprenorphine, or methadone in combination with behavioral therapies) for patients with opioid use disorder.
 - **Description:** The percentage of patients with an opioid use disorder who were referred to or prescribed medications for opioid use disorder.
 - **Numerator:** The number of patients who were referred to a methadone treatment program, or were prescribed/ referred for treatment with naltrexone, buprenorphine, or buprenorphine/naloxone.
 - **Denominator:** The number of patients in an outpatient panel of patients 18 years of age or older with a diagnosis of opioid use disorder (OUD).
 - Measurement period: Practice may determine the period of time.
 - **Exclusions:** Some formulations of buprenorphine (e.g., belbuca, butrans) are prescribed for pain, so these would need to be excluded.
 - **Data sources:** Prescription data from the practice EHR. Diagnosis data for OUD in the EHR. Referral data in the EHR or medical chart for MOUD or prescription data for naltrexone or buprenorphine/naloxone.
 - Guidance for producing the measure and potential challenges:
 - EHRs may not be able to identify all opioid medications reliably. The associated National Drug Code (NDC), generic name, and product name, can be used to match with EHR records. See the FDA's National Drug Code Directory.
 - Capturing referrals: There can be challenges measuring referrals in EHRs. Some EHRs may capture in a structured field whether a patient has been referred within the same healthcare system. If a patient is referred to a professional outside of the system, it will not be captured as a structured field. Some types of referrals may not be captured via anything other than a recommendation in the clinical note.
 - Practices may need to create a field in the EHR to capture referrals for MOUD, since methadone clinics are often separate entities.

• Alternatives for the Measure:

- Practices could focus on measuring specific MOUD, based on what your patient panel has access to or where
 your practice is aiming to improve access.
- The simplest measure would be the percentage of the adult population (or the number per 1,000 population) using buprenorphine. Tracking this over time would be useful for tracking whether these drugs were being prescribed more frequently.
- In order to link prescribing of buprenorphine to patients who have received opioids for chronic pain, one option
 might be to measure the percentage of persons who received long-term opioid therapy at any time in a year who
 also received buprenorphine in the same year. This would provide a rough indication of the rate of transition from
 prescription opioids to MOUD.

Endnotes

- ¹ Recipients can be state, district, county, or city health departments, tribal health organizations, or other bona fide agents of the health department.
- ² See Improving the Use of Program Evaluation for Maximum Health Impact: Guidelines and Recommendations for more information on how large programs use evaluation findings to improve their interventions and inform strategic direction. Furthermore, evaluation approaches like developmental evaluation or rapid feedback evaluations may be helpful models for evaluators to use while working on overdose prevention efforts.
- ³ CDC Evaluation Standards: https://www.cdc.gov/eval/ standards/index.htm
- ⁴ Authorities may vary depending on where the PDMP is housed. It could include PDMP staff, board of pharmacy, department of health, etc.
- ⁵ (Centers for Disease Control and Prevention, 2019a; Centers for Disease Control and Prevention, 2019b) CDC developed 16 clinical QI measures that map to the 12 CDC Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) recommendation statements. These QI measures can be used to support safe and effective opioid prescribing and pain management. In addition, the CDC and the National Coordinator for Health Information Technology (ONC) have worked together to develop standardized and shareable electronic CDS tools to be used in EHRs.
- ⁶ These guidelines or policies may differ slightly from one another. Health departments and health systems should consult their current guidelines or policies to understand the differences. The establishment and operation of PDMPs vary given that each PDMP is subject to existing policies and management of its own respective state. While PDMPs may operate differently, there are system components that CDC promotes to improve PDMP functionality as a public health tool.
- ⁷ Health departments and health systems might consider publishing their scoring methodology to ensure validity and safety and increase user buy-in.
- ⁸ CDC's MME calculator: https://www.cdc.gov/drugoverdose/ prescribing/app.html (Centers for Disease Control and Prevention, 2019c)
- Prescription Drug Monitoring Program Training and Technical Assistance Center, 2017
- ¹⁰ Prescription Drug Monitoring Program Training and Technical Assistance Center, 2016
- "Flanigan & White, 2019; Agency for Healthcare Research and Quality, 2018

- ¹²See Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nice States (Centers for Disease Control and Prevention, 2017b)
- ¹³ PDMP data can be actively used by initiating or enhancing proactive reporting (e.g., individual clinician reports, clinician comparison reports); developing enhanced user interfaces (e.g., MME calculators, patient risk scores, etc.); displaying past and present prescription history reports; developing and refining visualizations to enhance ease of use; deploying notifications, alerts, or prompts to guide clinical care (e.g., for problematic prescribing including overlapping prescriptions with other opioids, benzodiazepines, and other controlled substances).
- ¹⁴Use of PDMP data in patient care settings can take various forms including consulting the PDMP to check for overlapping prescriptions of other opioids or benzodiazepines and implementing quality improvement and care coordination measures, among others.
- ¹⁵End users can be clinicians, physician assistants, clinician delegates, psychologists, licensed social workers, pharmacists, pharmacists' delegates, etc.
- ¹⁶Best Practice Alerts are generated by an EHR. They alert clinicians when certain thresholds or conditions are met and prompt interventions based on evidence-based guidelines.
- ¹⁷ PDMP data can be actively managed by initiating or enhancing proactive reporting (e.g., individual clinician reports, clinician comparison reports); developing enhanced user interfaces (e.g., MME calculators, patient risk scores, etc.); displaying past and present prescription history reports; developing and refining visualizations to enhance ease of use; and deploying notifications, alerts, or prompts to guide clinical care (e.g., for problematic prescribing including overlapping prescriptions with other opioids, benzodiazepines, and other controlled substances).
- ¹⁸ To see how these state-level indicators were operationalized and used in a state see Dr. Robert Bree Collaborative's Opioid Prescribing Metrics. How each state choses to define these may vary. Please be aware that some indicators used by the collaborative differ from CDC's guidelines. For example, the CDC guideline defines long-term opioid therapy as > 90 days while the collaborative defines chronic as >= 60 days.
- ¹⁹These indicators are operationalized in CDC's Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain and may be most applicable for use within health systems. See appendix for additional resources on improving clinical practice and patient care.