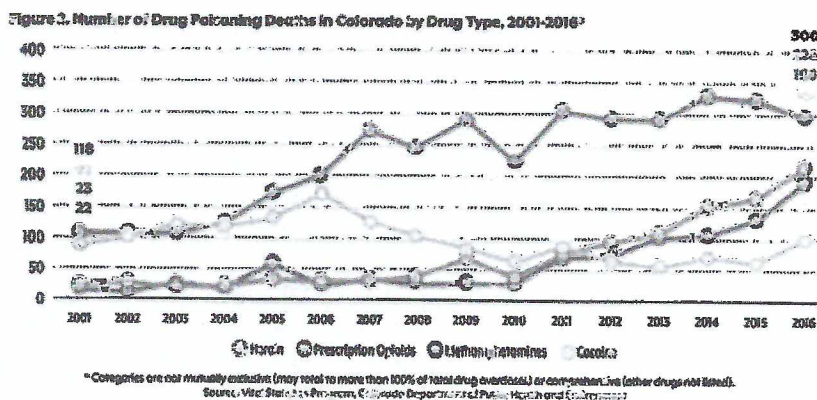# Program narrative

1. Statement of the problem

1.1 The opioid epidemic continues. The opioid crisis is a public health emergency that threatens the wellbeing of individuals who abuse drugs and impacts the safety of our communities. Despite decreased opioid prescribing[1], 11.4 million US citizens still suffer from opioid misuse[2] and opioid deaths continue to rise in the US.[3] Opioid abuse and deaths represent a significant cost to the US economy, with an estimated $78.5 billion spent annually.[4]

Colorado suffered from 1,010 drug-related deaths in 2017, a 9% increase from the prior year and the most ever.[5] Prescription opioid deaths reached 357 in 2017.[6] In the 2016-2017 National Survey on Drug Use and Health Colorado ranked

Figure 2. Number of Drug Poisoning Deaths in Colorado by Drug Type, 2001-2016[?]

* Categories are not mutually exclusive (may total to more than 100% of total drug overdoses) or comparison ive (other drugs not listed). Source: Vital Statistics Program, Colorado Department of Public Health and Environment

7th in number of individuals $\geq$12 years old reporting past year non-medical opioid use (5.03%).[7]

1.2 Colorado is actively working to improve opioid safety through PDMP improvements. The Colorado Consortium for Prescription Drug Abuse Prevention[8] was created to provide a statewide, interagency network to identify, respond to, treat, and support those impacted by the opioid epidemic. <u>One of their specific aims is to increase provider use of the prescription drug monitoring program (PDMP).</u>[9] The Department of Regulatory Agencies (DORA) operates Colorado's PDMP and works closely with the Consortium's PDMP work group to: spearhead the implementation of PDMP best practices, generate usage reports, recruit stakeholders, perform strategic planning and collaborate with local researcher experts.

This collaborative effort has created a systematic infrastructure to implement and evaluate interventions to align Colorado's PDMP with best practice strategies outlined in the Brandeis University PDMP Center for Excellence report.[10] PDMP specific interventions to date include: mandatory registration, delegated PDMP access, interstate data sharing, daily uploading, unsolicited reporting, provider report cards, electronic health record (EHR) PDMP integrations, using PDMP as a public health tool and most recently SB18-022 which limits the initial days supply and a mandates a PDMP search before a second opioid prescription for acute pain.[11] We now have 493 facilities (including pharmacies) with EHR PDMP integration, which has increased pharmacist PDMP utilization, but failed to meaningfully improve prescriber utilization. (See table from DORA annual report, rate=PDMP reviews/opioid prescriptions)

	Prescriber Utilization Rate	Overall Pharmacist Utilization Rate	Integrated Pharmacist Utilization Rate	Non-Integrated Pharmacist Utilization Rate
10/18	26%	41%	99%	21%
11/18	25%	42%	103%	21%
12/18	28%	41%	101%	20%
1/19	34%	34%	**47%	**30%
2/19	27%	41%	95%	21%
3/19	27%	42%	101%	19%

**One pharmacy chain experienced integrated access issues during this month

1.3 The University of Colorado-Denver (UCD) is an Ideal Research Partner/Prior Work

UCD, the subrecipient, and DORA, the recipient, have a shared goal to improve the efficiency and delivery of information to improve the quality and safety of prescriber decision-making and the efficacy of treatment. UCHealth, the clinical affiliation for UCD, supports the implementation, enhancement, and proactive use of PDMPs. UCHealth/UCD is the ideal evaluation setting due to their track record of innovation, technical skill and the research

expertise.[12-16] A centralized electronic health record (EHR) that is used in all clinical settings across 10 hospital systems accounting for 131,826 admissions and 3,453,952 outpatient visits in 2018 allows for rapid process changes and evaluation of impact. This integrated organization includes academic and community sites and serves urban, suburban and rural populations with a total population of this region 4,800,000 (85% of the state); this makes findings generalizable across many care settings.

The UCHealth clinical informatics team has experience integrating and evaluating clinical decision support into the Epic EHR system (which is a common system nationally with 28% EHR market share).[17] UCHealth was the first health system in the country to successfully integrate the Appriss PDMP connection into Epic. The integration was then freely made available for other health systems. Importantly, UCHealth is committed to paying for continued PDMP integration via the state's vendor (see letter of support from system CIO Steve Hess).

UCD has collaborated with DORA on PDMP research for the past 7 years including 3 publications and a BJA grant.[18-20] Our prior collaboration on a Harold Rogers BJA Grant established an integrated shared data system that is ideal to be leveraged to answer questions and improve PDMP integrations and patient outcomes. This includes: standing collaborative agreements between UCD/DORA and UCD/Colorado Department of Public Health &
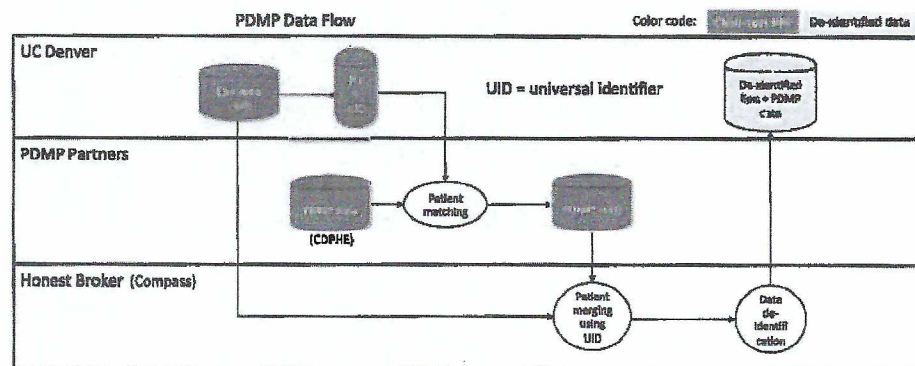

Environment (CDPHE), established PDMP statistical expertise and the development of a unique

"Honest Broker" system (Compass) that safely link clinical and PDMP data for research while protecting personal health information (PHI). (Flow chart)

UCD is in the process of completing the analysis for our prior BJA grant (2015) having recently received the final dataset. That grant is in a no cost extension due to delays in getting agreements in place and data from PDMP vendor (Appriss). To avoid these delays going forward we will extend existing agreements and avoid using the vendor for PDMP data; instead we will collaborate with CDPHE (granted access to PDMP data after prior grant started). Without the federal assistance applied for in this current opportunity, though, further work would not be possible, due to the State not allocating any funds for the proposed program. Our preliminary data in 5 emergency departments (ED) suggests PDMP integration and mandated use decrease opioid prescribing (figure) but generated several new questions to be addressed:

Pct of Patients Prescribed an Opioid at the ED Visit
by Hospital Group and Phase
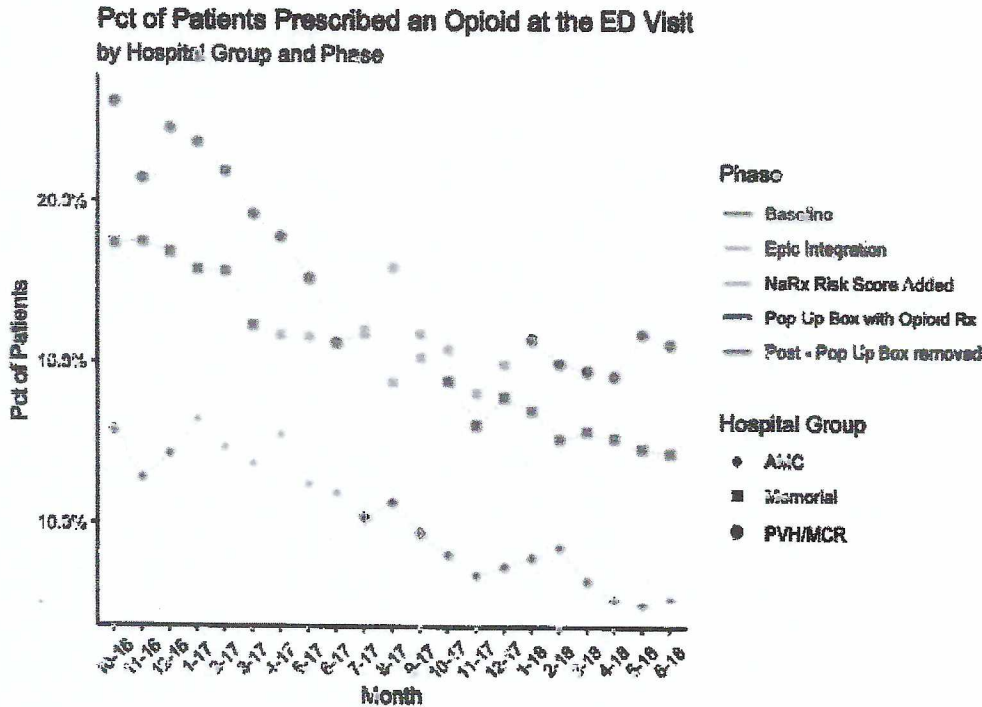
Why so much variability across practice sites? Nationally, the impact of PDMP interventions has been variable.[21-24] Our project found this as well; PDMP one-click integration (orange),

addition of interpretation score (green: "Narx score") and mandated use (blue: "pop-up box") all decreased prescribing and increased PDMP utilization, but there is significant variability in the magnitude of impact between sites, with community sites (Memorial, PVH/ MCR) seeing significantly less utilization vs. our academic center (AMC) despite identical EHR interventions.

Pct of Patients Searched in the PDMP by Hospital Group, Phase, and Prescription
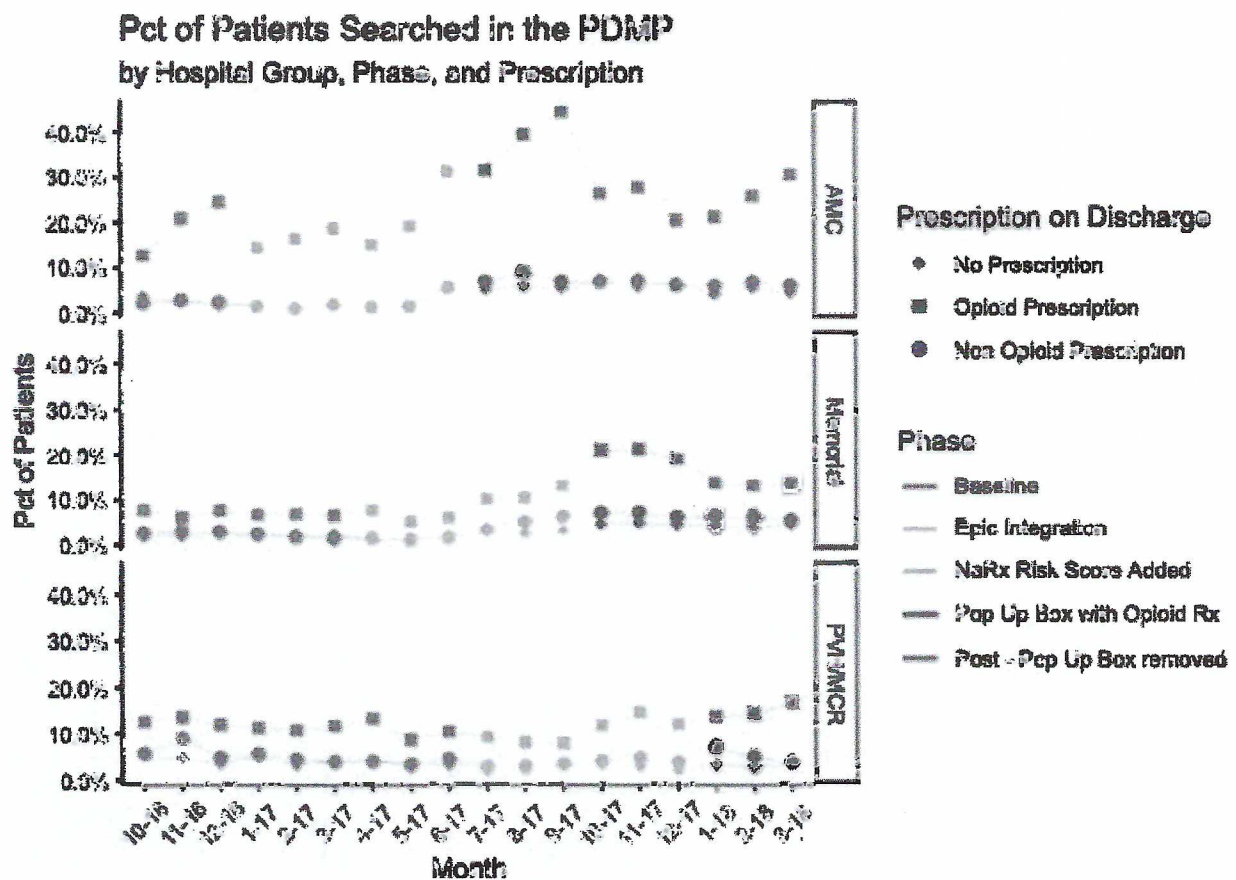
Why didn't mandated use increase PDMP utilization more? The maximum impact of mandated use was less than expected, with the highest reaching 40% of opioid prescriptions.

What happens to patients after PDMP use and integrations? UCD has recently successfully merged PDMP and EHR data sets for the 5 EDs with >200,000 visits. The evaluation of patient center outcomes of future opioid use (chronic and aberrant opioid use) is in progress.

1.4 Next steps: PDMP Integration helps but barriers to use need to be addressed. As PDMP availability and integration increases nationally, interventions to increase widespread clinical adoption need to be implemented and studied.[25, 26]

Variability in provider decisions to access the PDMP prior to prescribing limits the impact of PDMP integration. Being outside the typical flow of patient care, creates a disincentive for use. If PDMP access is a burden or not perceived as improving care, providers will not add it to their workflow.[27] Our preliminary work suggests EHR integration can facilitate PDMP use by including the search in the prescription writing workflow; unfortunately, the impact was still low and variable across sites. **Mandated PDMP use** removes provider discretion and should decrease variability in use, but it has the potential to increase work without clear gains in patient safety and it is difficult to measure the true impact because mandated use is hard to track and enforce.[28-30] Our prior project found mandated use (as a Best Practice Alert pop-up box) increased PMDP use; evaluation of the impact on prescribing and future opioid use is in process. System generated, automated unsolicited PDMP alerts for prescribers to identify high-risk patients can offload provider work to improve PDMP use and patient outcomes by addressing variability of access and use of PDMPs.[31-32]

Variability in the interpretation and lack of actionable recommendation also limits the impact of PDMPs. [33-35] Providers do not have real-time aids to interpret the information or suggest alternative therapies when the PMDP is concerning. Our pilot data has demonstrated that integration of an interpretation tool facilitates PDMP utilization when compared to visualization of the raw prescription data. This interpretation tool only considers PDMP data; it is likely that prescribing decisions can be improved with the addition of patient specific clinical data (e.g., overdose history, positive drug or alcohol screen, etc.) which are readily available in the EHR.[36]
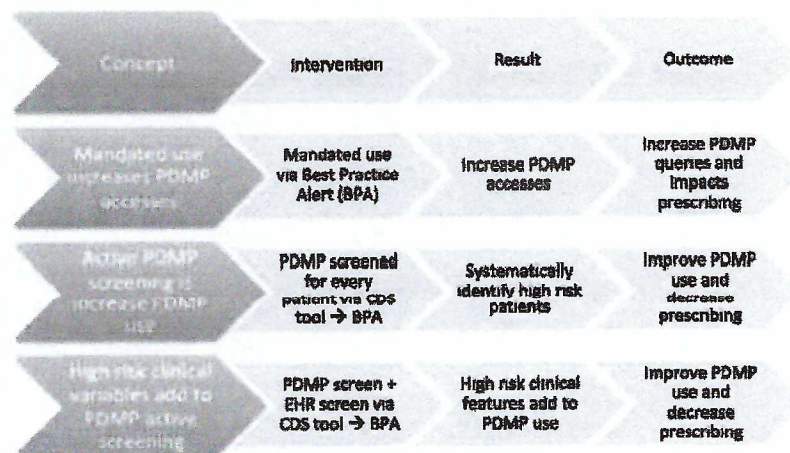
Our pilots have also re-demonstrated that **changing provider behavior is not easy.** Physicians have strong habits and beliefs about medications resulting in strong resistance to changes in workflow and practice. **To maximize PDMP utilization and make safe prescribing easy for provider we must provide technical solutions to offload providers, automate PDMP screening with clinical alerts, and offer alternatives to controlled medications.**[36-39]

Integrated health systems have significant opportunities to develop workflow solutions to support providers in guideline-concordant care by improving the utilization of PDMPs through EHR Clinical Decision Support (CDS) tools.[40,41] CDS enhances decision-making in clinician workflow by providing knowledge and patient-specific information, intelligently filtered and presenting alerts at appropriate times (and not interrupting when the information is irrelevant), to enhance health and health care.[42] Especially when combined with an EHR, CDS is one of the most potent ways to change physician behavior by strengthening information access, efficiency and appropriate interpretation of information.[43]

1.7 Objectives: This study will address the following knowledge gaps:

1.7(a) Does mandated PDMP use through EHR interventions improve the frequency of PDMP use and patient outcomes vs. integration alone? We will compare PDMP use, controlled medication

Conceptual Model

Concept	Intervention	Result	Outcome
Mandated use increases PDMP accesses	Mandated use via Best Practice Alert (BPA)	Increase PDMP accesses	Increase PDMP queries and impacts prescribing
Active PDMP screening increases PDMP use	PDMP screened for every patient via CDS tool → BPA	Systematically identify high risk patients	Improve PDMP use and decrease prescribing
High risk clinical variables add to PDMP active screening	PDMP screen + EHR screen via CDS tool → BPA	High risk clinical features add to PDMP use	Improve PDMP use and decrease prescribing

prescribing, and future opioid use before and after starting an EHR PDMP mandated used via a CDS generated "best practice alert."

1.7(b) Can using CDS to actively screen PDMP profiles improve PDMP use, prescribing and patient outcomes vs. integration and mandated use? We will examine the rates of PDMP use, controlled medication prescribing, and future opioid use before and after activating a CDS tool which will screen all patients' PDMP but is only is presented when patients are high-risk based on the PDMP profile.

1.7(c) Does adding key EHR clinical variables to our active CDS screening tool improve PDMP use, prescribing behavior and patient outcomes? We will examine the rates of PDMP use, controlled medication prescribing and future opioid use before and after activating a CDS tool, which will screen all patients' PDMP (as in 1.7b) with the addition of screening the EHR for high-risk clinical variables (e.g., prior overdose, + urine drug screens). This alert is only presented to providers when patients are high risk per the PDMP profile and/or clinical variables.

2. Project Design and Implementation

Guidance on when to access or how to use PDMP information to identify patients at risk is lacking, which has limited their impact. Inconsistent provider use and interpretation of PDMP calls for standardized CDS tools to facilitate use.[33] Passive EHR PDMP integration-PDMP is only seen when a provider decides to access the record- doesn't fix variable use and interpretation. **We propose an automated, evidence-based approach to PDMP interpretation, to allow for the application of this objective data in a consistent and unbiased way while decreasing work for providers.** We will develop an active CDS tool that automatically retrieves patient specific information from the PDMP when the patient is

admitted/discharged/transferred and then delivers a synthesized, digestible report to providers only when indicated. The benefit of these systems is that they are <u>universally applied to all patients via automated searches with decision rules to help push information forward to provider only when patient is identified as being at risk</u>. We hypothesize that this will increase sensitivity, with minimal impact on provider workflow. Further, since changing direction is easier than stopping, it is important to promote alternative actions rather then inaction. For high-risk patients a reasonable evidence-based alternative treatment option will be suggested.

2.2 Setting/subjects: DORA will partner with the UCD to evaluate PDMP interventions in 10 hospital systems under the larger UCHealth enterprise, including inpatient and outpatient clinics and EDs. The geographically diverse sites share the same EHR system (Epic: Verona, WI) and will be included in all interventions and outcome measurements. The counties served account for approximately 85% of the state's population. Children and prisoners will be excluded.

2.3 Approach:

2.3(a) CDS Development: Our experienced CDS team will leverage our existing connection to Colorado's PDMP vendor (Appriss) to screen for high-risk patients using existing information: (1) commercially available NARxCHECK score and (2) presence of active controlled medication prescriptions. The score has not been externally validated, but it provides a rapid, structured summary of patient's prescription history that can standardize risk assessment across patients.

Using clinical champions, we will iteratively develop a CDS PDMP tool that is optimized for end users, contains relevant information, is easily navigated and is presented at the correct time in workflow. In the first 6 months we will develop and test the tools through simulation and real-time clinical pilot work engaging users to test the interface for user acceptability, utility and process outcomes which can be used to modify the tool to maximize user preference.

2.3(b) CDS Monitoring: We aim to balance ideal research design with an acceptable intervention by monitoring the impact on PDMP utilization and patient care. **We will do so by tracking how often: alerts are being presented to providers, PDMP data is being reviewed and care prompts are being followed.** This is important for generalizability and scalability.

2.4 Staggered rollout of intervention. This project will utilize a quasi-experimental staged approach to EHR interventions across the care spectrum. It will proceed in all 10 hospitals in three 3-month stages with comparison to baseline using a stepped wedge design. In this approach the stages start in a staggered fashion across the 3 geographically clustered sites. Controlled medication prescribing can be highly influenced by secular trends and this method allows for both historical and contemporaneous controls. The order in which the hospitals receive the intervention will be randomized. We anticipate that the same clinicians will be providing care before and after the intervention. (See Figure below)

Site	Baseline	Month														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Central		1	1	1				3	3	3	3	3	3	3	3	3
North					1	1	1	2	2	2	3	3	3	3	3	3
South								1	1	1	2	2	2	3	3	3

2.5 Interventions

Phase 0 (Baseline: "one-click" PDMP integration): Based on our prior BJA project and the commitment by the UCHealth Epic; all UCHealth locations currently have "one-click," single sign-on EHR PDMP integration which links to the Appriss NARxCHECK product providing both raw prescription data and a standardized risk score. There is no mandated use at this time;

PDMP use is at the discretion of the providers, and providers can prescribe without accessing the PDMP. We are currently monitoring use so these data are immediately available.

Why? Our prior work in the UCHealth system emergency departments showed 10-20% utilization of PDMP one-click access prior to writing an opioid prescription, but little is known about use in our clinics or at hospital discharge. Further, there was significant variability in use between academic and community EDs. Phase 0 will determine the baseline rate of provider PDMP use, controlled medication prescribing, rates of controlled medication filling and opioid use during patient encounter across all prescribers in our healthcare system.

Education/dissemination before implementation: Nothing additional. This system has been in place for 6 months and was announced through system-wide announcements.

Phase specific integration measures: PDMP one-click access. On our prior BJA project, we were unable to reliably record each click and had to rely on a report from the PDMP vendor for PDMP access. Our EHR now records each click so this information can easily be abstracted. This will increase the reliability of our data collection.

Phase 1 (One-click EHR + mandated use with BPA): PDMP access via one-click button will remain. Additionally, if providers do not access the PDMP in EHR via one-click button before prescribing a controlled medication **they will be mandated to do so via a Best Practice Alert (BPA) window with the link to NARxCHECK PDMP product will open and mandate review before allowing an electronically signed prescription.** In order to complete the order, the provider will have to either (a) review the PDMP or (b) record a reason for not reviewing.
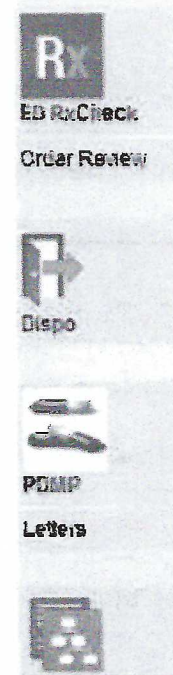
Notably: we do not force actions in EHR as our institution believes "hard-stops" in the clinical workflow are disruptive and associated with provider dissatisfaction. Below is an example of the BPA mandated use box used in prior work, this will be modified for the current project. The PDMP information provided will be the same as Phase 0. Alternative treatment options will be suggested instead of the high-risk medication.

Why? Phase 1 will allow us to measure the incremental impact of automated facilitated mandated PDMP review on prescribing decisions and future opioid use in the PDMP. In our prior work in 5 UCHealth EDs, mandated BPAs increased PDMP review before prescribing an opioid from 10-20% to 20-40%, again with variability between sites.

Education/dissemination before implementation: We will notify providers of the change (including the alternative therapies) through email and include video links demonstrating the use of the system. The number of providers who view the videos will be recorded and we will measure the perceived utility of the videos.

Phase specific integration measures: PDMP one click button use vs. BPA mandated button use or reason for not reviewing the PDMP when prompted by BPA.
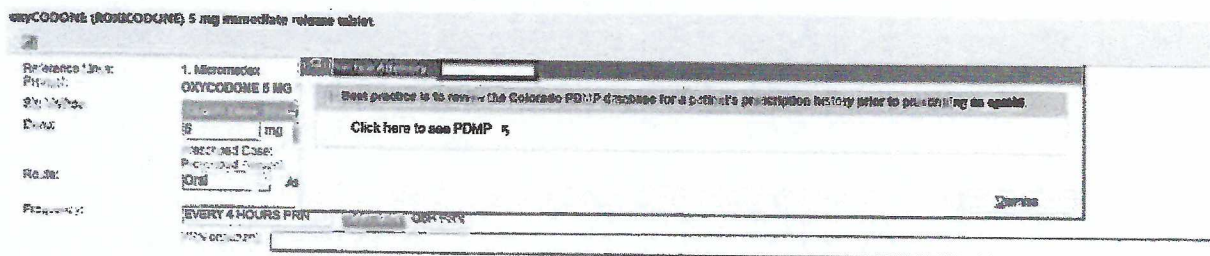

Figure: View of Best Practice Alert pop-up box from prior project

Phase 2 (automated PDMP screening → mandated use only when high-risk PDMP criteria present): PDMP access via one-click button will remain, the BPA will change. Using CDS, **all patients will automatically be searched in the PDMP** (when they are registered or the discharge process has begun), the information returned from the vendor will be screened by rules

set in our CDS inference engine. **If high-risk PDMP criteria are present, the rules will trigger the same BPA** window with the link to the PMDP NARxCHECK when the provider clicks to sign the prescription. Precise high-risk PDMP criteria will be determined by our informatics team during build up depending on how information from Appriss is presented to EHR. The preliminary plan is to use (1) a high NARxCHECK risk score (which considers total opioid dose, multiple prescriptions, and number of providers and pharmacies) and (2) the presence of an active opioid prescription. This phase differs from Phase 1 in the mandated use BPA will only show up in care of patients with a high-risk profile. Evidence-based alternative treatment options will be suggested.

Why? Phase 2 will allow us to measure if mandated use can be improved with CDS facilitated active screening of PDMP data.

Education/dissemination before implementation: We will notify providers of changes through email and include video links demonstrating the use of the system. The number of providers who view the videos will be recorded and we will measure the perceived utility of the videos.

Phase specific integration measures: PDMP one click button use; how often BPA appears; BPA mandated button use or reason for not reviewing; and controlled medication prescribing.

Phase 3 (PDMP + EHR patient risk factor information screened → mandated use only when high risk criteria met): Building on automated PDMP screening in phase 2, we will add an EHR search for high-risk clinical indicators (e.g., prior overdose, history of positive drugs of abuse screen).[36] If any of the high-risk PDMP and/or clinical risk factors are present, then mandated use BPA will appear when the provider attempts to sign a controlled medication in the EHR. Alternative treatment options will be offered to avoid the use of the high-risk medication.

Why? Phase 3 will allow us to measure the incremental impact of adding clinical high-risk indicators to CDS facilitated automated PDMP screening.

Education/dissemination before implementation: We will notify providers of the changes through email and include video links demonstrating the use of the system. The number of providers who view the videos will be recorded and we will measure the perceived utility of the videos.

Phase specific integration measures: PDMP one click button use, how often BPA appears, BPA mandated button use or reason for not reviewing, controlled medication prescribing.

2.6 Data collection plan: To accomplish our objectives UCD will use the Epic EHR reports to identify and collect clinical patient data as well as prescriber PDMP use and prescribing (all prescriptions are written using the EHR). Our honest broker (Compass) will then link these patients to the state PDMP via CDPHE to capture the PDMP data (controlled medication use 6 months before and after visit) for each visit during all stages of the study, as we have done in previous studies. This will result in a large de-identified dataset for analysis by research team that is free of protected health information and assures patient safety.

2.6(a) EHR via University of Colorado Health Compass: Clinical information from EHR including, but not limited to: patient demographics, provider, chief complaint, medical history, labs, medications, social history, discharge diagnosis, and prescription (name, strength, number of pills). PDMP access will by tracked by clicks on the EHR single sign-on tab. These variables are all captured by our EHR system and can be abstracted via computer algorithm.

2.6(b) Colorado PDMP: CDPHE will use their PDMP dataset which is provided quarterly by Appriss to determine prior and future opioid use (all controlled medications in 6 months before and 6 months after index visit, including any written at visit). Opioid use in 6 months prior to visit can be used to determine acute vs. chronic prescription opioid use and assess level of risk.

2.7 Analysis

Variable	Definition	Importance
Overall controlled medication prescribing rate	Total number of opioid/sedative/stimulant prescriptions divided by total number of visits at each site and the hospital system	Measures the overall impact for each intervention
Individual provider controlled medication prescribing rates	Total number of opioid/sedative/stimulant prescriptions divided by total number of encounters for each provider	Measures the behavior and practice variation of individual prescribers for each intervention
Overall rate of PDMP use	Total number of times PDMP is accessed when opioid/sedative/stimulant prescriptions are written	Measures how readily providers obtain information for each intervention
Provider specific rate of PDMP use	Total number PDMP searches for each provider, changes over time for each provider	Measures provider search behavior and variability changes for each intervention
Overall prescription rate after accessing PDMP	Number of times opioid/sedative/stimulant were prescribed after accessing the PDMP	Evaluate the impact of PDMP review on the decision to prescribe controlled mediations
Provider specific prescription rate after accessing PDMP	Total number of opioid/sedative/stimulant prescriptions divided by the number of times the provider accessed the PDMP for each provider	Evaluate provider variability in interpretation with and without decision support

2.7(a) Primary analysis: The primary analysis will be the change from baseline in the variables outlined in Table 2.7 for each intervention stage. The stepped wedge approach allows for historical and contemporaneous controls within and across sites to account for secular trends.

2.7(b) Secondary analyses: As planned secondary objectives, we will measure the impact of these interventions on future opioid use by patients. Future opioid use will be evaluated by abstracting all controlled medication prescriptions filled by the patient in the 6 months following the visit (number of prescriptions, pills, providers, pharmacies and milligram morphine

equivalents/day). This is important to assess impacts of these interventions on patient and the community.

It is likely each intervention will not impact our outcome variables for all patients equally. To assess this for the variables involving PDMP access and opioid prescribing, we will conduct sub-analysis to identify potential interactions between our interventions and numerous patient and condition characteristics. The analyses will be stratified by: patient demographics, chief complaints, diagnosis and patient opioid risk score at the time of visit. These will be considered exploratory, but may be used to enhance future decision support systems (e.g., mandated use could be waived in a clearly painful condition such as joint replacement surgery).

2.8 Collaboration: The PDMP work group is the framework for cooperation in this application. This group is designed to facilitate the collaboration and implementation strategic interventions.

co-chair the PDMP

workgroup together. They have worked extensively together and will leverage relationships with other participants to ensure the successful completion of the project objectives. This collaboration will also serve as a mechanism to disseminate the findings of our research and to make best practice recommendation to Colorado prescribers and healthcare systems.

2.9 Innovation: UCD and UCHealth are invested in maximizing the value of PDMPs, as part of their mission to generate novel ideas to improve the delivery of high quality care in their system and the community. They have the resources and expertise to develop EHR based solutions. This novel collaboration and strategy will implement and test several BJA priorities in a data driven manner. The stepped wedge methodology of staggered intervention roll out will provide a quantifiable response to differentiate the impact of each step on prescriber behavior and patients. This will empower DORA to work with our partners to implement evidence based health policy

interventions. The proposed project is innovative because: (1) it directly links patient outcomes (a controlled medication prescription) to PDMP use and (2) the methodology employs a targeted approach to measure the impact and effectiveness of 3 PDMP interventions across multiple practice settings: Mandated PDMP use, CDS with PDMP screening, and CDS with PDMP screening plus patient specific risk factors commonly found in EHRs.

The proposed body of innovative research has been identified as a core priority area for DORA, but could not be completed without a research partner. UCD is partnering with DORA because DORA is confident UCD can complete the interventions and analysis with information that will be critical to inform policy decision-making and improving patient safety.

2.10 Dissemination: DORA will submit all mandatory reports required by the grant. The findings of this research will be disseminated as scientific and policy resources. The findings will be submitted to national PDMP meetings (Harold Rogers, Rx Drug Abuse and Heroin Summit). The primary manuscript will be submitted to a high-impact medicine journal (NEJM, JAMA). The PDMP work group will disseminate any policy implications throughout the state.

2.11 Mandatory Project Components and Deliverables for Category 3: We agree to work closely with BJA's designated TTA provider(s). We will use technical solutions that are compliant with the PMIX National Architecture. We will ensure that the recipient's PDMP system has the capacity to exchange data with other PDMP systems via the PDMP hub. DORA is awaiting funds through a prior grant with CDPHE from the CDC to connect to RxCheck hub. DORA is working on a contract amendment and change order from Appriss. It is anticipated to begin prior to the start of this proposed project.

Mandatory Component for Data Collection, Aggregation, and Sharing: DORA guarantees that it owns the data and its approved designee(s) will retain unrestricted access to the

data, in accordance with all applicable laws, regulations, and BJA policy. This includes providing data (a) in an expeditious manner upon request by BJA; (b) in a clearly defined format that is open, user-friendly, and unfettered by unreasonable proprietary restrictions; and (c) at a minimal additional cost to the requestor.

3. Capabilities and competencies

3.1 DORA: DORA is excited at the prospects of this grant application. Prior BJA grants have successfully brought Colorado's PDMP in line with recognized best practices. We hope to leverage these building blocks and this grant to further our work. Locally we have had success facilitating necessary legislative changes and our representation on all of the Consortium workgroups will ensure the successful completion of the goals, objectives, and activities outlined in the work plan. As the grantee, DORA will establish interagency agreements with UC, prepare grant reports, oversee subcontracts and take responsibility for the grant.

3.2 Expertise: and UCD have an <u>extensive track record in contributing to the success of prescription drug abuse prevention efforts in the state and nationally.</u> He is currently the research partner on a funded BJA grant collaboration with DORA. In addition to publications on PDMP based research, he has also published on the importance of collaboration between stakeholders.[44] is the co-chair of Colorado's PDMP workgroup.

1 MD, PhD is an established researcher and methodological expert with a PhD in Clinical Sciences. He has expertise in clinical trials with over 120 peer-reviewed publications and has served as PI for multiple large clinical trials. He is Chief of Medical Pharmacology and Toxicology and can provide ! with the resources to complete this project.

have a track record of evaluating prescriber decision-making and

using the PDMP as a research tool. They have collaborated with the PDMP on 3 projects to date.[18-20] They have published on the association of ED prescribing and long-term opioid use in patients who were previously opioid naïve.[19] They also have extensive experience with searching the EHR and have published on opioid prescribing across a consortium of geographically diverse EDs.[44] They are currently finishing up their 2015 BJA Harold Rogers BJA grant with DORA.

, MD, an expert on clinical informatics and Senior Medical Director of Implementation and Informatics for the ED, will lead efforts to design and integrate automated Clinical Decision Support (CDS) tools in the Epic EHR and coordinate initiation at multiple UCHealth care sites. As part of UCHealth Information Technology, she will oversee design and roll out of CDS interventions and be a key resource for problem solving and effective design.

4. Plan for collecting data: This is a systematic investigations designed to develop or contribute to generalizable knowledge evaluating the following (see also data collection section: 2.4):
1) The impact of EHR facilitated PDMP mandated use alerts on PDMP use, controlled medication prescribing and future controlled medication use in multiple settings, and 2) The effect of automated screening using CDS solutions on PDMP review, prescribing and future opioid use. This investigation constitutes "research" for the purposes of applicable DOJ human subjects protection regulation and will require UC's institutional review board approval. DORA and UC have successfully completed similar IRB approved research using PDMP data in the past[19,25-26] and anticipate a similar approach to data sharing. Quarterly performance measures required by BJA will be abstracted and submitted by DORA through the BJA Performance Measurement Tool. Data abstraction will continue in the current manner in collaboration with the vendor Appriss.

5. Outcomes, Evaluation, Sustainment

5.1 Outcomes: The impact of PDMP solutions needs to be measured in patient outcomes. The PDMP provides critical information to providers, however, providers must access and use this information to inform treatment decisions and affect patient outcomes. Therefore, our study will measure both process outcomes (e.g., PDMP access, prescribing) and patient centered outcomes (e.g., future opioid use). The full list of outcomes is listed in section 2.7.

5.2 Evaluation: Our evaluation will include comparing the outcomes listed in section 2.7 between the baseline period and each intervention. To assure proper evaluation, our experienced analytic team has been closely involved in the design of the project, we use automated data collection for patient variables and outcome variables, and we propose a stepped-wedge approach across multiple clinical sites to account for regional and temporal variation.

5.3 Sustainability: The grant-funded activities will continue to strengthen the research partnership between DORA and UCD. Our collaboration allows patient level research by combing DORA's PDMP database in a way that is consistent with the law and maintains patient confidentiality. Our goal is to complete the analysis of our current BJA grant and use this new project to inform and support an application for external grant funding to further this collaboration. This project will provide substantial groundwork to develop a competitive proposal to further the evaluation of PDMP best practices and potentially a multicenter trial using external federal funding (e.g., NIDA's HEAL initiative).