For Multiple-Use Case Projects



Project Tracking		
Client Organization (legal name):	Institute for Health Research, Kaiser Permanente Colorado	
CIVHC Project Number:	25.07	
Project Title:	APCD Master Agreement – KPCO IHR	
Deliverable Type:	Limited Extract	

Navigation

Supplement Revision History	2
Use Case Details	3
Protected Health Information (PHI)	8

Supplement Instructions

To help clients get the most use of Colorado All Payer Claims Database (CO APCD) data, the Center for Improving Value in Health Care (CIVHC) may approve multiple use cases for a particular data extract. This form defines either of the following:

- 1. A new use case of a previously delivered extract
- 2. One of multiple planned use cases of and upcoming data delivery

The use case defined in this document may be for use of all data in the original extract or a further filtered subset of that data.

Use Case Conditions

This document serves only to define a single use case and does not represent the addition of data elements or changes to filtering from those components specified in the final version of Data Element Selection Form (DESF) approved for production and identified in the final version of the Data Release Application (DRA) of the project number above. All conditions of the Data Use Agreement (DUA) executed for the project number above apply to the use case defined in this document.

For Multiple-Use Case Projects



Supplement Revision History

The following reflects the history of changes made to this document prior to its final approval by CIVHC.

To be completed by CIVHC staff				
Date	New Version Number	Description of Change(s)	CIVHC Change Author (full name, complete title)	
3/21/2025	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager	
4/21/2025	V.02	Added Data Sourcing/Use of APCD data information to Question #3	Heather Tavel, Sr. Manager of Research Operations	
	V.03			
	V.04			
	V.05			
	V.06			
	V.07			
	V.08			
	V.09			
	V.10			

For Multiple-Use Case Projects



Use Case Details

Use Case No.:	003	
Use Case Title:	Health and Mortality Risks of Health Plan Disenrollment Following Opioid Tapering	
Use Case Start Date:	4/1/2025	

1. Explain the purpose of this specific use case. If the use case is related to a previous project, also explain how this use case is related and whether the data or results of both projects will be combined.

Opioid analgesics continue to be commonly prescribed pain medications with 143 million prescriptions dispensed in 2020. While an important treatment for pain, opioid analgesics are associated with serious adverse events, including opioid overdose, opioid use disorder, and death. More than 80,000 fatal opioid overdoses were reported in 2021, an all-time high. In response to the unprecedented number of overdose fatalities attributed to the opioid epidemic in the United States, the Centers for Disease Control and Prevention issued in 2016 and updated in 2022 its clinical guideline for safer opioid management, recommending a reduction or discontinuation (taper) of opioids for patients on long-term opioid therapy (LTOT) when benefits of continued therapy do not outweigh risks. However, tapering opioid doses is clinically challenging, and growing evidence suggests that tapering itself can be clinically destabilizing and lead to significant risks, including heroin use, substance use disorders, mental health crises, and overdose or suicide. Tapers may lead to patient dissatisfaction, diminished trust, and health complications that interfere with employment, resulting in health plan disenrollment. Disruptions to health care services associated with health plan disenrollment could exacerbate serious outcomes following tapers.

The purpose of this use case is to investigate potential health and mortality consequences following tapers of long-term opioid therapy (reduction or discontinuation of opioid therapy).

This project falls under the master subscription agreement, related to the following research aims presented there:

(i) Full capture of outcomes and exposures for all members, mitigating research bias, for KP members that utilize external providers, as well as evaluation of processes of care, outcomes and value of care for KPCO patients with chronic health conditions. This is foundation in accurate and valid research and operational questions.

(ii) Disenrollment and Consequences for Health, Healthcare, and Health Coverage

(iv) Benchmarking KPCO outcomes, measures, and membership to other plans and health systems

(x) Understand prior utilization of services to better identify patients that will benefit from more intesnxive medical management

For Multiple-Use Case Projects



(xii) Understand comparative utilization and clinical outcomes for complex homebound members within KPCO and those who disenroll

- 2. Detail the specific project aims, research question(s) you are trying to answer, or problem(s) you are trying to solve with this use case.
 - i. Aim 1. Assess the association of opioid tapering, patient characteristics, and social factors with health plan disenrollment in a large cohort of patients prescribed long-term opioid therapy.
 - ii. Aim 2. Examine the association between health plan disenrollment with emergency care and death among patients prescribed long-term opioid therapy using linked electronic health records (EHR) data, National Death Index (NDI), and Colorado All-Payer Claims Database (CO APCD).
- 3. Describe your methodology or how you will be using data from the Colorado All Payer Claims Database (CO APCD) to answer your research questions.

We describe our methodology below. Specifically, we will draw on Colorado APCD data to capture key outcomes (emergency department visits and in-patient stays [ED/IP] and coverage after disenrollment) to investigate the relationship between disenrollment from KPCO and adverse events.

Data Sourcing/Use of APCD data: The cohort for this use case will be selected from patients enrolled in the KPCO health plan at the time of study entry, using the KPCO research data warehouse. APCD data will be provided according to our data management plan, where a small data coordinating team will provide APCD data for these cohort members for the specified follow-up timeframe.

Study Design

We will assess risk of adverse events following health plan disenrollment in a retrospective cohort study of patients prescribed long-term opioid therapy. To capture patient outcomes, we will conduct linkage of KPCO EHR, NDI, and CO APCD data. These data will allow us to identify health care utilization and health insurance coverage after disenrollment from KPCO. We hypothesize that disenrollment will increase risk of adverse events among patients with opioid dose tapers.

Study Population

For Multiple-Use Case Projects



We will focus on patients prescribed long-term opioid therapy and those who experienced opioid tapers. For patients with disenrollment (exposed group), the date of disenrollment will represent the index date. For the patients without disenrollment (unexposed group), individuals will be randomly assigned an index date based on the distribution of index dates in the exposed group, after matching on patient age, sex, race, and ethnicity. Follow-up for subjects in both groups will start 1 day after the index date and continue until the outcome is observed, death, 1 year after the index date, or end of the study on December 31, 2024, whichever occurs first. We limit follow-up to 1 year to focus on outcomes proximal to disenrollment.

Outcomes and Measures

Exposure. The exposure will be health plan disenrollment. We will allow multiple disenrollments per subject during follow-up.

Outcomes. We will assess (a) all-cause mortality, (b) any ED/IP encounter, (c) drug- or alcoholrelated overdose from an ED/IP encounter, and (d) mental health crisis (depression, anxiety, or attempted suicide) ED/IP encounter. We will use ICD codes to identify (c) and (d), following prior work. For each outcome we will create a dichotomous measure and assess time to the first instance.

Covariates. We will consider patient characteristics that may be associated with health plan disenrollment and outcomes based on prior work. Key covariates will include demographics, insurance type, chronic health conditions, mental health disorders, substance use disorders, prescription medications, and prior history of ED/IP encounters. Demographic characteristics and insurance type will be measured on the index date, and all other measures will be assessed in the 12 months before the index date.

Statistical Analysis

Outcome rates. We will first calculate unadjusted rates of each outcome, defined as the number of outcomes divided by years of person-time. Rates will be calculated for the study cohort overall and by the exposure.

Propensity score analysis. To address imbalance in characteristics between patients who experience disenrollment and those who do not, we will employ propensity score analysis and apply stabilized weighting in survival analysis. Stabilized weighting reduces the impact of extreme propensity scores and represents an advantage over conventional inverse probability of treatment weighting, and we have used this approach in our prior work. We will generate propensity scores and stabilized weights by estimating a multivariable logistic regression model with health plan disenrollment as the outcome. We will include covariates that are associated with disenrollment and any outcome. To determine covariates to be included, we will conduct separate univariate regression analyses with disenrollment and each outcome as the dependent variable. Covariates with p<0.10 will be included in the propensity score model. To assess covariate balance, we will calculate population standardized mean differences (PSD) before and after stabilized weights are applied to the cohort. A PSD of <0.10 will be considered adequate balance.

For Multiple-Use Case Projects



Survival analysis with stabilized weighting. We will fit separate Cox PH models on the propensityweighted cohort to assess the association of health plan disenrollment and each outcome. To allow for multiple disenrollments per patient, we will use frailty models that incorporate random effects. To address residual confounding, we will adjust for covariates that do not demonstrate adequate balance. We will assess the proportional hazards assumption via a global test and graphically. To test for clustering of events from the time of disenrollment, we will evaluate models with the observation period after the index date set at 1, 3, and 6 months.

Sensitivity analyses. The reason for health plan disenrollment (i.e., planned or unplanned) may affect the level of risk. We will repeat analyses above for commercially insured patients with the exposure separated into year-end and within-year disenrollment. Disenrollment on December 31 of any given year will be considered year-end, which we assume to represent "planned" withdrawal following open enrollment. Disenrollment on all other days will be considered within-year or "unplanned." We expect year-end disenrollment to incur lower risk compared to within-year disenrollment. Estimates from the propensity-score weighted analysis may be subject to unmeasured confounding. To determine the minimum strength of an unmeasured confounder needed to fully explain away the observed association between disenrollment and mortality, we will calculate the E-value. A large E-value (relative to observed estimates) would indicate that substantial unmeasured confounding would be needed to explain away observed results.

Finally, we will use CO APCD data to distinguish patients who lose insurance coverage following disenrollment from those who transition to coverage by another insurance provider.

- 4. Explain how this use case will benefit Colorado and its residents.¹
 - 1. This use case will allow us to study the health needs of patients who experience transitions in care following health plan disenrollment and will inform development of clinical standards for managing patients receiving opioid therapy that may be tested and implemented within Kaiser Permanante Colorado, which serves more than 500,000 Colorado residents directly.
 - 2. The opioid epidemic continues to impact residents of Colorado. Our proposed research will contribute to efforts to address the ongoing epidemic by identifying potential risks, including overdose, following disenrollment among patients who experience changes in their opioid therapy treatment.

¹ It is a statutory requirement for all non-public releases of CO APCD data to benefit Colorado or its residents. Contributions to generalizable knowledge alone are not sufficient to satisfy this requirement.

For Multiple-Use Case Projects



- 5. Describe how this use case will improve health care quality, increase health care value, or improve health outcomes for Colorado residents.²
 - 1. This project will improve the quality of care for patients in Colorado who experience changes in their opioid treatment by identifying potential high-risk transitions in care associated with health plan disenrollment.
 - 2. This project will improve the health of Colorado residents and reduce health costs by investigating health plan disenrollment and its consequences following tapers or changes in opioid therapy, which will directly inform interventions to decrease critical and high-cost care in emergency departments and hospitals as well as to reduce mortality.

For Multiple-Use Case Projects



Protected Health Information (PHI)

If <u>Protected Health Information</u> data elements will be used, indicate what elements are available in the original CO APCD data extract and which of those are needed for this use case:

Available in the Extract	Use Case Need	Data Element	
\boxtimes		Member 5-Digit Zip Code	
		Member County	
		Member City	
\boxtimes	\boxtimes	Member Dates of Service	
\boxtimes	\boxtimes	Member Eligibility Dates	
		Claim Paid Dates	
		Employer Name	
\boxtimes	\boxtimes	Member <u>Census Tract</u>	
\boxtimes		Member <u>Census Block</u>	
\boxtimes		Member <u>Census Block Group</u>	
		Member Name	
		Member Date of Birth (if requesting more than year only)	
		Member Street Address	
		Member Latitude and Longitude	
		Employer Tax ID	
Provide detailed justification for the inclusion of all PHI data selected above to carry out this use case, and explain how its inclusion meets the Minimum Necessary Requirement. ²			

Dates of service and eligibility dates are needed to establish enrollment dates and to identify the timing of care utilization (e.g., in emergency departments) following health plan disenrollment.

Census tract information is necessary to link to census-based socioeconomic measures (e.g. ACS or ADI) used as covariates in models.

² Limited and Identifiable extracts must adhere to the <u>Minimum Necessary Requirement</u> under the <u>HIPAA Privacy</u> <u>Rule</u>; only that data required to answer the project purpose can be included in the request.