

Oregon All Payer All Claims (APAC) Program

Model APAC-3 Limited Dataset Application

The following pages show a real Oregon APAC-3 application (used by permission; names and contact info have been changed to protect the applicant's privacy). This data requester presents a very thorough, well-conceived research project with *detailed* research questions which clearly define which data elements will be needed to answer these questions.

Please review this application to understand the level of detail we are looking for when you are ready to fill out your application.

If you have any questions, please email them to apac.admin@odhsoha.oregon.gov



Oregon All Payer All Claims (APAC) Program

Application for Limited Data Files

APAC-3

This application is used to request limited data sets. Before submitting a completed application, please contact apac.admin@odhsoha.oregon.gov with a brief description of the project and your contact information. OHA will contact you to schedule a consultation meeting to determine if APAC data is appropriate for your project and, if so, which data elements may be needed.

Please provide all required information directly in this document. OHA will not review attachments or secondary documents other than the documents listed below.

Please review the Requesting APAC Data section of the APAC Data User Guide for additional guidance on the data request process. An example of a completed APAC-3 application is available for reference on the OHA website. A thoroughly completed and detailed application, including submission of the required documents below, will increase the likelihood of moving through the application process more quickly:

- 1. APAC-3 Application for Limited Data Files
- 2. Data Element Workbook
- 3. Data Security Plan
- 4. IRB Application
- 5. IRB Determination
- 6. IRB Approved Research Protocol (describing research methodology)
- 7. If applicable, a separate tab-delimited text file containing diagnosis codes, procedure codes, and/or clinical groupers of interest.

In compliance with HIPAA regulations, you must justify all data elements requested. APAC will provide only the minimum necessary data required for the project as represented in the research questions, protocol and IRB approval.

SECTION 1: PROJECT INFORMATION AND STAFF

1. Project Title: Impact of Community Pharmacy Closures among Patients with Serious Mental Illness & Addiction

2. Principal Investigator Information:

Name	John Smith, MD
Title	Professor
Organization	Major Oregon University, College of Pharmacy
Address	4856 N. Main St., Portland, OR, 97201
Telephone	555-555-1234
Email	Smith.John@University.edu

3. Additional Staff Information:

Please list all individuals in addition to the principal investigator who will have direct or indirect access to the data. This must include any contractors or other third parties with access to the data. Also list any additional staff who will be maintaining the data file(s) or otherwise assisting in the transfer or receipt of the data files. Files will not be transferred to anyone who is not listed on this application as either project staff or technical staff. If more than eight staff need access, please contact apac.admin@odhsoha.oregon.gov for a separate sheet.

Name	Email	Project Role
Joy Johnson	Johnson.Joy@University.edu	Research Analyst
Lee Michaels	Michaels.Lee@University.edu	Research Analyst
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
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SECTION 2: PROJECT SUMMARY

1.	Data Request Category: Listed below are the purposes for which OHA may share APAC data. Please choose the category that matches your project (choose only one).
	⊠ Research
	☐ Public health activities
	☐ Health care operations
	If you selected this option, are you a covered entity?
	☐ Yes
	□ No
	☐ Work performed on OHA's behalf by a Business Associate

2. **Project Purpose:** Describe the purpose of the project, the project's background, how APAC data are necessary for the project, and how the project fits into the category chosen above.

Community pharmacies are critical sources of pharmaceutical care and public health services for many communities, especially those that are medically underserved. Despite their vital role, pharmacies across the country are closing at an unprecedented rate. Nearly 30% of community pharmacies operating between 2010 and 2020 ceased operation by 2021. Although the risk of closure was highest among independent pharmacies, more than 1 in 5 chain pharmacies also closed during this period. Studies have determined that pharmacy closures are associated with reduced medication use across several therapeutic classes and demographic groups. Among older individuals using cardiovascular medications (beta-blockers, statins, anticoagulants) at a pharmacy that closed between 2011 and 2016, monthly adherence decreased by about 5 to 6 percentage points; the decline was greatest among patients receiving their medication from independent pharmacies, who mostly filled their prescriptions at one store, and in those who lived in neighborhoods with fewer pharmacies. Another study observed a similar pattern among patients using anticonvulsant medications in Colorado. When pharmacies close, patients not only lose access to a source of prescriptions, but also many public health services such as vaccinations, harm reduction resources, and other pharmacist-provided clinical services (e.g. contraception, HIV PrEP).

In November of 2021, 58 BiMart pharmacies in the state of Oregon ceased operation leaving many communities, especially in rural regions, without a conveniently located pharmacy (https://www.bimart.com/rxchange). This represents over 10% of all community pharmacies operating in the state. While Bi-Mart made efforts to transfer patient records to other pharmacies in the area, the impact of this potential care disruption has not been systematically characterized.

Patients with serious and persistent mental illness (SPMI) or substance use disorders may be uniquely vulnerable to such a disruption because of barriers they already face. Among patients with SPMI or OUD, declines in adherence have been associated with worsening health outcomes. Additionally, several studies have shown that in patients with opioid use disorder (OUD), access to buprenorphine is often constrained by pharmacies because of concerns about diversion and DEA scrutiny. 4,5

The objective of this study is to evaluate the impact of the BiMart closure on medication continuity and potential adverse health outcomes among patients who had previously received care at one of the affected BiMart pharmacies.

- 3. Research Question(s): What is the project's key research question or questions? An acceptable research question will include at minimum the following components:
 - a. Study population (e.g. people with specific diagnosis, procedure, or NDC (national drug codes), exclusion and inclusion criteria) and comparison group if applicable.
 - b. Independent, dependent, and control variables
 - Include diagnoses and/or procedures of interest (defined using procedure codes (HCPCS/CPT, ICD-10-PCS), diagnosis codes (ICD-9 or 10), or clinical groupers (e.g. CCSR, DRG, BETOS). As noted below in section 3, please provide any codes as an attachment in a separate tab-delimited text file.
 - c. Study timeframe: what years of data are needed for your study?
 - d. Any geographical components (e.g. zip codes, counties). These may need stronger justification due to privacy and trade secret considerations.

The research question(s) need to align with the IRB determination and must be entered below. It is not sufficient to only refer to the IRB determination.

APAC staff will use your response to this question to determine the minimum data elements necessary for this project, in accordance with the HIPAA minimum necessary standard. The research questions should be specific enough to justify the need for each data element beyond identifying it as a "potential confounding variable." General requests for data will not be approved. APAC staff will also use this information to discern whether APAC is an appropriate data source to answer the stated research question.

Question 1 Aim: Evaluate the impact of the BiMart pharmacy closures on medication use among patients with SPMI and OUD.

Question 1.1: How do patterns of medication use change among patients with SPMI receiving antipsychotics at an affected BiMart pharmacy compared to patients using non-affected pharmacies?

Question 1.2: How do patterns of medication use change among patients with OUD receiving buprenorphine at an affected BiMart pharmacy compared to patients using non-affected pharmacies?

Questioin1.3: How do BiMart pharmacy closure-related changes in medication use for patients with SPMI and OUD (A1HA, A1HB) differ across patient factors (race/ethnicity, age, sex, payor) or community (rurality, neighboring pharmacies) characteristics?

Question 2 Aim: Evaluate the impact of the BiMart pharmacy closures on health outcomes among patients with SPMI and OUD.

Question 2.1: How are ED/hospitalization rates for acute psychiatric events impacted among patients with SPMI receiving antipsychotics from an affected BiMart pharmacy? Question 2.2: How are ED/hospitalization rates for OUD-related events (e.g. overdose) impacted among patients with OUD receiving buprenorphine from an affected BiMart pharmacy?

Question 2.3: How do BiMart pharmacy closure-related changes in acute psychiatric events and OUD health outcomes differ across patient factors (race/ethnicity, age, sex, payor) or community (rurality, neighboring pharmacies) characteristics?

- **4. Project Methodology and Analytic Plan:** Describe the project's methodology and analytic plan in support of your request for APAC data elements. An acceptable methodology and analytic plan will include at minimum the following components:
 - a. Research design (e.g. descriptive, quasi-experimental)
 - b. Justification if multiple years are requested (i.e. whether there is a longitudinal component to your design)
 - c. Plans to link APAC data to another dataset. Include details on what data set would be linked, the key fields in each data set, how they would be linked, the software proposed to perform the linkage, why it is necessary, and the steps you will take to prevent re-identification.

We will evaluate the impact of the BiMart pharmacy closures on patients with SPMI or OUD using a retrospective, difference-in-differences (DD) design comparing individuals receiving medications at an affected BiMart pharmacy compared to those receiving medications from non-affected

pharmacies ("Control Pharmacy").

Our study period is November 2020 through November 2022 providing 12 months of observation time before (baseline period: November 2020 through October 2021) and after (closure period: December 2021 through November 2022) the BiMart closure period (November 2021). Our study cohort will include patients with one or more ICD10 diagnosis codes (any position) for either SPMI (schizophrenia or bipolar disorder) or OUD at any point during the study period, and at least one outpatient prescription for a relevant medication during the baseline period (November 2020 to October 2021). A summary of inclusion ICD10 diagnosis codes and relevant medications are summarized in attachment 1. Additionally, to ensure patients are 'observable,' patients will be required to have continuous insurance coverage during the study period.

Among patients identified using the codes in attachment 1, we will consider them a BiMart pharmacy patient if they have one or more fill from an affected BiMart Pharmacy in the baseline period (November 2020 to October 2021). BiMart pharmacy identifiers are included in Appendix A. Among the remaining study patients, we will assign them a control pharmacy using National Provider Identifiers (NPI) to determine, and assign them to, the most frequently used brick-and-mortar pharmacy in the baseline period.

Outcome measures for Aim 1 (hypothesis A and B) are derived from pharmacy claims data. For both hypotheses, our primary outcome measure will be medication adherence as measured by the monthly proportion of days covered (PDC). PDC is a commonly used measure of adherence that is defined as the percentage of days' supply for a specific class of drugs (e.g. antipsychotics) divided by a specific interval (e.g. 31 days in month). In this case, we compute PDC for each condition-drug cohort (schizophrenia – antipsychotics, bipolar – antipsychotic, OUDbuprenorphine) for 25 monthly intervals from November 2020 to October 2021. As a secondary outcome, we also evaluate monthly estimates in the number of prescriptions filled and total days supplied.

For A1HC, we examine if changes in medication adherence differ across patient factors and community characteristics. These factors and their data sources are summarized in Table 2. Patient demographic factors examined will include patient age, sex, and race/ethnicity. Other patient factors evaluated will include the number unique medications and the proportion of medications filled at each patient's assigned study pharmacy (BiMart or control pharmacy). Community factors examined include urbanicity of the patient's community and the number of other pharmacies in the area.

Outcomes measured for Aim 2 (Hypothesis A and B) are estimated from medical claims. For both hypotheses, we will determine if patients receiving medications from affected BiMart pharmacies experienced worsening in health outcomes as measured by inpatient admissions or ED encounters for acute psychiatric (A2HA) or an OUD-related events (A2HB).

We will estimate the monthly rates of inpatient admissions/ED encounters using the ICD-10 codes located in the primary position. Psychiatric events (Hypothesis A) are defined by the ICD-10 codes F01x to F69x (Mental and behavioral disorders). OUD-related events (Hypothesis B) are defined by ICD-10 codes T36-T50 (Poisoning by drugs, medicaments and biological substances).

For Hypothesis C (A2HC), we evaluate changes in these health outcomes across different subgroups. We explore the same subgroups described in A1HC and summarized in Table 2.

5. Project Timeline:

a. What is the anticipated start date for the project?

Note: projects using APAC data must be able to be completed within 1-2 years. If your project will take longer than this, you may discuss options for phasing the project with APAC staff.

6/30/2025

b. What is the anticipated end date for the project (defined by completing data destruction requirements)?

5/1/2027

SECTION 3: DATA REQUEST ELEMENTS AND FILTER CRITERIA

Refer to the <u>APAC Data Dictionary</u> for detailed information about the data elements.

1.	Study Timeframe: Select the years of data being requested.				
	 □ 2011 □ 2012 □ 2013 □ 2014 □ 2015 □ 2016 	 □ 2017 □ 2018 □ 2019 □ 2020 □ 2021 ⋈ 2022 	⊠ 2023 □ 2024 (No available ur 2026)		
2.	Payer Types: Select the paye	r types being reque	sted.		
	☑ Commercial☑ Medicaid☑ Medicare Advantage (commercial)	ommercial Medicare	Advantage and Part D only)		
3.	Data Files: Select the data file	es being requested.			
	☑ Medical claims☑ Pharmacy claims☑ Dental claims☑ Monthly enrollment☑ Provider				
4.	If you selected Pharmacy or D people and claims with no evid Note: This situation most frequency report medical coverage but of an entity that did report. It can ☐ Yes – Include data for in No	dence of medical co quently reflects ERI outsourced pharma n also reflect stand	verage in APAC? SA entities that elected not acy and/or dental coverage alone dental plans.	to	
5.	Study Population: Your resear population. Keeping minimum included in that population?		•		

	 ☑ Diagnoses – individuals who have been diagnosed we set of conditions. Describe the diagnosis here and pleased diagnosis codes to be used in a separate tab-delimited to Serious and persistent mental illness (SPMI) and opioid ☐ Procedures – individuals who have undergone certain procedures. Describe the procedure(s) here and pleased procedure codes to be used in a separate tab-delimited Click or tap here to enter text. 	se provide a list of ext file. use disorder (OUD) n services or provide a list of	
	☐ If you plan to link APAC data to <u>Oregon Center for Heath Certificate data and/or Birth Certificate data</u> , provand or death data variables that you plan to request from certificate data in a separate tab-delimited text file.	ide a list of the birth	
6.			
7.	7. What types of medical claim types are requested?		
		(e.g. APAC RX) Click or tap here to	

8.	Do you want to include out-of-state residents ? APAC has a small number of out-of-state residents included, most often through health plans from the Public Employees Benefits Board (PEBB) or Oregon Educators Benefits Board (OEBB). Note: This question applies only to Commercial and Medicare Advantage data. APAC considers people with Medicaid coverage to be Oregon residents regardless of address submitted in the data. □ Yes – Include out-of-state residents □ No
9.	Do you want orphan claims included (claims, but no coverage reported)? Orphan claims do not have any member information associated with them, such as age group and sex. ☐ Yes − Include orphan claims ☒ No
10	. Do you want denied claims included? (No reason is provided for denied medical or pharmacy claims. Claims can be denied then paid later.) ☐ Yes − Include denied claims ☒ No
11	. Do you want substance use disorder (SUD) claims included? SUD requests require detailed information about the purpose of SUD claims, hypotheses about SUD claims, and analyses involving SUD claims. OHA will give additional scrutiny to data security including data access, data destruction, and plans for linking to any external data source. Data use and release of information are restricted. Requires additional data security and other provisions in the Data Use Agreement. ☑ Yes − Include SUD claims ☐ No

SECTION 4: RESEARCH – IRB required

Complete this section if the Data Request Category is research.

If the Data Request Category is not research, skip to section 5 of this application.

The Institutional Review Board (IRB) application, research protocol and approval (or exemption) are required for all research requests. An exemption memo alone is not sufficient – APAC requires you to submit a full IRB application and share that application with your APAC application materials. Not obtaining IRB approval or exemption in advance may delay approval of the data request. The research questions reported in section 1 of this application must directly align with the information in the IRB application.

- 1. Confirm you will provide the following supplemental documents when you submit your application.
 - ☑ IRB application indicating that APAC data contains sensitive protected health information (PHI) and is subject to HIPAA regulations.
 - \boxtimes IRB approval or exemption memo.
 - ☑ IRB approved research protocol.
- 2. Describe how this application is within the authority of the approving IRB.

All project investigators and staff have appointments at OHSU where the project was reviewed

 Describe why the project could not be practicably conducted without a waiver of individual authorization (a waiver of individual authorization is provided by the IRB in cases in which the researcher does not need written authorization from participants to use their PHI).

Obtaining authorization from patients affected by the BiMart closures is not feasible or advisable for several reasons. Contacting patients impacted by the BiMart closure would involve contacting several thousand patients, increase the risk of PHI disclosure, and potentially lead to adverse psychological effects of knowing that sensitive individual-level health information was being used for research.

4. \	What	date	does	the	IRB	approval	expire?	?
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12/31/2026		

SECTION 5: DATA PRODUCTS, REPORTS, AND PUBLICATIONS

Data files may not be released or reused beyond the terms of the data use agreement (DUA) resulting from this application regardless of funding source or other obligations of the principal investigator, organization or research team. Outside of the DUA requirements, products may only be shared at an aggregated, de-identified level.

 Summary: Describe the intended product or report that will be derived from the requested data and how this product will be used. Products include journal articles, conference presentations and posters, dissertations, theses, presentations at meetings and any other presentation of information available to the public at any time.

The primary goal of this project is to generate preliminary data for an NIH or AHRQ application to evaluate the impact of pharmacy closures on a national level. Additionally, we aim to publish findings from this study in a peer-reviewed journal such as JAMA, Health Affairs, or a similar health services/health policy journal. We also will submit our results for presentation at a scientific conference.

2. Data Reporting: APAC data or findings may not be disclosed in a way that can be used to re-identify an individual. Data with small numbers – defined as values of 30 or less (n≤30) or subpopulations of 50 or fewer individuals (n≤50) – cannot be displayed in findings or outputs derived from APAC data. Please describe the techniques you will use to prevent re-identification when findings or outputs result in small numbers or subgroups (e.g. aggregation, cell suppression).

Our public-facing communications (publications, presentations) will adhere to reporting guidelines described above. We will use a combination of aggregation and, if necessary, cell size suppression, to ensure that summary data cannot be used for re-identification. We will apply strategies summarized by CMS (https://resdac.org/articles/cms-cell-size-suppression-policy) to address potential reporting issues where numbers of individual counts of patients falls under APAC policy.

3.	Timeline: What is the anticipated publication/ product release date for the
	project? Note: this may extend beyond the date of data destruction/ project end
	date.

1/1/2026			

SECTION 6: CHECKLIST AND NEXT STEPS

Return the completed form with required attachments to

APAC.Admin@odhsoha.oregon.gov.

To ensure streamlined advancement through the application process, please indicate that the following are completed and included with the application submission:

- □ Data Element Workbook
- □ Data Security Plan
- ☑ IRB application (leave blank if not applicable).
- ☑ IRB determination (approval or exemption memo) (leave blank if not applicable).
- ☐ IRB approved research protocol (leave blank if not applicable).
- ☐ Tab-delimited text file with codes to be used for filtering (leave blank if not applicable).

☑ I acknowledge that payment will not be refunded if OHA fulfills the data request, but the receiving entity does not have the capability to import or analyze the data.

Next Steps:

- An APAC Research Analyst will review the documents you submitted and respond with any questions or modifications you must make. Once finalized, OHA will send this document for your signature (leave signature blank for initial submission).
- 2. If you plan to link APAC data to Oregon Center for Health Statistics (CHS) Death Certificate data and/or Birth Certificate data, you will need approval from both CHS and APAC. Please submit this request to APAC first. After APAC approval, submit your request to CHS. Once approved by CHS, you must provide APAC with a copy of the CHS approval notice.
- 3. The project will be posted on the Oregon Health Authority website for a 2-week public comment period.
- 4. The project will be reviewed by Data Review Committee (DRC).

If approved:

- 5. Sign data use agreement.
- 6. Pay invoice.
 - a. APAC requires reimbursement for the cost of file transfer (\$890 per request) and the total time spent by APAC staff on research and administrative activities (cost varies).
 - b. Payment must be received before the data is provided. APAC staff will provide an invoice to facilitate payment.
 - c. OHA's W-9 is available on request.

- 7. APAC staff builds dataset.
- 8. Data released to requester via secure download portal.

Signature:

The individual signing below has the authority to complete this application and sign on behalf of the organization identified in Section 1. By signing below, the individual attests that all information contained within this Data Request Application is true and correct.

Signature: /s/ John Smith, MD

Date: 06/01/2025

Printed Name: John Smith

Title: Professor of Pharmacology, Major Oregon University