All Payer All Claims Application for Limited Data File

APAC-3

OHA DRTS: 5551_CORE_Evaluate_CareOregon_PCPM

This application is used in conjunction with the APAC-2 submitted. If any corrections to information submitted on the APAC-2 are required, please note the changes below (as relevant) and in the email to which this application will be attached. If more space is needed, a separate file may be submitted with this application.

PROJECT INFORMATION

Project Title: Assessing the Direct and Indirect Effects of APMs in Primary Care

Principal Investigator: Hannah Cohen-Cline, PhD, MPH

Title of Principal Investigator: Program Director of Research and Evaluation

Organization: Center for Outcomes Research and Education

Address: 5251 NE Glisan Street, Bldg A

City: Portland State: OR Zip Code: 97213

Telephone:

Email: Hannah.Cohen-Cline@providence.org

Application Date: 2/4/21

SECTION 1: PROJECT STAFF

1.1 Project Staff: Please list any staff in addition to the principal investigator who will have direct access to the data. This must include any contractors or other third-parties with access to the data.

Name Megan Holtorf Role Analyst
Email Megan.Holtorf@providence.org

Name Lisa Angus Role Program Manager
Email Lisa.Angus@providence.org

Name Jennifer.Rountree Role Project Manager
Email Jennifer.Rountree@providence.org

Name	Natalie Kenton	Role	Research Scientist
Email	Natalie.Kenton@providence.org		
Name	Allison Ryan	Role	Research Associate
Email	Allison.Ryan2@providence.org		

Attach additional sheets as needed.

1.2 Technical Staff: Please 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.

Name	Taylor Doren	Role	Data Systems Analyst
Email	Taylor.Doren@providence.org		
Name		Role	
Email			

SECTION 2: PROJECT SUMMARY

2.1 Project Purpose: Briefly describe the purpose of the project and how it meets the APAC use as research, public health surveillance activities or health care operations. A more detailed project description including background, methodology and analytic plan that supports the APAC data options and data elements selected for your project may be submitted as a separate file with this application.

The purpose of this study is to evaluate CareOregon's Primary Care Payment Model (PCPM). We aim to answer the following research questions: 1) How has the PCPM affected health care cost and quality at participating clinics? and 2) To what extent has the PCPM had spillover impacts on cost and quality of care for clinic patients with sources of coverage other than CareOregon? We will use a comparative interrupted time series design, comparing change in prevention quality indicators, health care utilization, and costs of care over time between clinics that participated in the CareOregon APM and clinics that did not. To assess spillover, we will perform this analysis separately for patients with Medicaid and Medicare versus Commercial coverage; similar results in both analyses would indicate spillover effects. All measures will be derived from health care claims and enrollment data; we will assess this data for multiple years prior to PCPM implementation through the present.

2.2 Research Questions: What are the key research questions or hypotheses of the project? If this project is research and has been approved by an Institutional Review Board (IRB), the research questions must align with the IRB approval documentation. If needed, a more detailed response may be submitted as a separate file with this application.

We aim to answer the following research questions:
RQ 1) How has the PCPM affected health care cost and quality at participating clinics?
RQ 2) To what extent has the PCPM had spillover impacts on cost and quality of care for clinic patients with sources of coverage other than CareOregon?
The study population will be drawn from primary care clinics in Oregon. For RQ 1, all adults over 18 years of age enrolled in Medicaid, Medicare Advantage, or dually-enrolled in Medicaid and Medicare through CareOregon will be included; this is the target population for CareOregon's PCPM. RQ 2 will include all adults with commercial or non-CareOregon Medicaid coverage; this is the potential spillover population.

2.3 Products or Reports: Describe the intended product or report that will be derived from the requested data and how this product will be used. If needed, a more detailed response may be submitted as a separate file with this application.

The results of this study will be shared with CareOregon leadership, and will inform their decisions to make any changes to the PCPM program. CareOregon's external advisory groups, focused on VBPs and clinical strategy, will disseminate and use study findings. If the results indicate spillover effects on quality or costs for other payer groups, it will provide a strong argument for multi-payer collaboration to drive widespread improvements in health care value.

2.4 Project Timeline: What is the timeline for the project?

a. Anticipated Start Date: 4/1/21
b. Anticipated Publication/Release Date: 12/31/22
c. Anticipated End Date: 12/31/22

2.5 Data files may not be released or reused beyond the terms of the data use agreement resulting from this application regardless of funding source or other obligations of the Principal Investigator, organization or research team.

☒ I understand this limitation and agree that data files or work products will not be shared at less than an aggregated, de-identified level.

☐ I understand this limitation and request approval to share data files or work products at a potentially re-identifiable level as follows:

SECTION 3: DATA REQUEST

3.1 Purpose of the Data Request:

a. Listed below are the purposes for which OHA may share APAC data. Please choose the category in which your project falls (***choose only one***).

- [x] Research (refer to 45 CFR 164.501 for definition)
- [ ] Public health activities (refer to 45 CFR 164.512(b) for definition)
- [ ] Health care operations (refer to 45 CFR 164.501 for definition)

  Covered entity? [ ] Yes [ ] No

  (refer to 45 CFR 160.103 for definitions related to covered entities)
- [ ] Treatment of patient by health care provider (refer to 45 CFR 164.506 (c)(2) for definition)

  Covered entity? [ ] Yes [ ] No
- [ ] Payment activities performed by covered entity or health care provider (refer to 45 CFR 164.506 (c)(3) for definition)

  Covered entity? [ ] Yes [ ] No
- [ ] Work done on OHA's behalf by a Business Associate (refer to 45 CFR 160.103 for definition).

b. Describe how the project falls into the category chosen above.

The PSJH IRB has determined the project as exempt, identified in 45 CFR 46.104(d): CATEGORY 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFT 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

3.2 Direct identifiers. What level of data identifiers are you requesting (***choose only one***)? Reference the Data Elements Workbook for the categorization of data elements.

- [ ] De-identified (as outlined in 45 CFR 164.514(e)) protected health information
- [x] Limited, potentially re-identifiable data elements
- [ ] Restricted direct identifiers (member name, address, date of birth, etc.) *Please note:* Direct identifiers are only released under special circumstances that comply with HIPAA requirements, and will require specific approvals, such as Institutional Review Board (IRB) approval, patient consent and/or review by the Department of Justice.

3.3 Human Subjects Research: Institutional Review Board (IRB) protocol and approval are required for most research requests for limited data elements and are mandatory for research requests for restricted data elements. Not obtaining IRB approval or waiver in advance may delay approval of the data request. **Also, if the research questions reported in 2.2 of this application do not match the submission and IRB approval received, the application will be denied.**

The IRB application should indicate that APAC data contains sensitive personal health information and is subject to HIPAA regulations.

a. Does your project have IRB approval for human subjects research?

☒ Yes ☐ Not applicable (project is not research on human subjects)

If yes, include the IRB application and approval memo with the submission of the APAC-3 and complete parts b-e below.

☑ IRB application and approval memo are attached.

b. Describe how this application is within the authority of the approving IRB.

As CORE is aa department of Providence St. Joseph's Health (PSJH), PSJH has oversight over CORE research studies.

c. 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):

Collecting written consent and signed authorizations from each individual across more than 200 clinics throughout the state of Oregon would require significant staff resources that are unavailable. Significant staff time would be required to contact, train, and maintain oversight over staff that would be obtaining authorizations for the study, and significant clinical staff time would be redirected from patient care. As a result, the research would be impracticable without these waivers. Because the study will use measures of care quality that rely on individual service and diagnostic data, and intends to understand disparities by demographics as well as cost of care, the study would not be possible without use of individual level data (i.e., PHI).

d. On what date does the IRB approval expire? 3/31/22

SECTION 4: DATA ELEMENTS

Refer to the APAC Data Dictionary for detailed information about the data elements. OHA will only provide the minimum necessary data required for the project as represented in the research questions, protocol and IRB approval. In compliance with HIPAA regulations, you will only receive data elements that are adequately justified.

4.1 Data Element Workbook: Complete the Data Element Workbook. Complete the data request options and the data elements worksheets.

☑ Data Element Workbook completed and attached, including justifications for each element requested

4.2 Minimum Necessary Requirement: Please explain why the requested APAC options and data elements are the minimum necessary required for the project. The justification should be specific to this project and more than 'potential confounding variable'. Attach additional sheets as needed.

We have reviewed our list of requested data elements to ensure that they are the minimum necessary for the study, and where possible we are asking for constructed flags instead of identifiers (e.g. urban/rural flags instead of addresses). As outlined in our data elements table, claims data will be used to construct health care outcomes of interest, including: prevention quality indicators that assess quality of care for ambulatory sensitive conditions; utilization domains such as primary care, emergency department visits, inpatient stays, and outpatient mental health; and costs of health care, in total and by utilization category. Demographics will be included in the model as covariates. APAC data will be linked at the record level to program data at CareOregon for the purpose of categorizing APAC claims data into claims originating from clinics that participated in the CareOregon PCPM program versus claims coming from clinics that did not participate in this program. Data will be linked by billing and performing provider NPIs.

In addition to including demographics in our models, and in the context our research values and aims to achieve health equity, we will explore disparities in PCPM impact by demographic characteristics so that we don't inadvertently obscure or exacerbate existing disparities.

Detailed justification by field is outlined in the data elements table.

SECTION 5: DATA MANAGEMENT & SECURITY

5.1 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, generalization, or perturbation).

All results will be presented as aggregate findings. Given the anticipated size of the study population, we do not believe it is likely we will have many instances of data with small numbers. However, should we have any instances of small numbers, we will either aggregate to a larger group or suppress the cell (as well as any other cells that need to be suppressed in order to ensure the size of the cell in question cannot be calculated from the other visible numbers). Primary and secondary suppression will be applied to cell sizes smaller than 10.

5.2 Data Linkage: OHA seeks to ensure that APAC data cannot be re-identified if it is linked or combined with data from other sources. Requesters are strongly encouraged to consult with Health Analytics about linking APAC data with other data prior to submitting a data request. OHA prefers to conduct APAC data linking in-house and share only encrypted identifiers with data requesters

a. Does this project require linking to another data source?

☒ Yes ☐ No

If yes, please complete parts b-d below.

b. At what level will data be linked?

☐ Aggregate ☒ Facility ☐ Person

c. If required to link

☒ Authorized to provide data for linking at OHA

☐ Not authorized to provide data for linking at OHA

☐ Unknown

d. Describe and justify all necessary linkages, including the key fields in each data set, how they will be linked, the software proposed to perform the linkage and why it is necessary.

Data will be linked at the record level to program data at CareOregon for the purpose of categorizing APAC claims data into claims originating from clinics that participated in the CareOregon Primary Care Payment Model versus claims coming from clinics that did not participate in this program. Data will be linked by billing and performing provider NPIs. All linking of program data to APAC data will be performed using SQL Server Management Studio or Alteryx.

e. Describe in detail the steps will you take to prevent re-identification of linked data.

We will strip all individually identifiable information from the linked dataset, producing the de-identified dataset for analysis. The key that links the two data sources will be stored in a password-protected file on a secure PSJH network database, accessible only using password-protected computers. Only key project staff responsible for data management and analysis will be have access to this key. All results will be presented as aggregate findings.

5.3 Data Security:

☑ a. Attach a detailed description of your plans to manage access to the APAC data, personnel safeguards, technical and physical safeguards and administrative safeguards. Please describe and ensure the following:

- Designation of a single individual as the custodian of APAC data, either the Principal Investigator or staff listed in Section 1 of this

application, who is responsible for oversight of APAC data including reporting any breaches to OHA and ensuring the data are properly destroyed upon project completion

- A security risk management plan applicable to APAC data
- Compliance with HIPAA and the HITECH Act
- Ensure that all parties accessing APAC data are listed on the data use agreement and agree to the same terms and conditions for securing and protecting APAC data
- Procedures to restrict APAC data access to only those individuals listed on the data use agreement
- Ensure training for personnel on how to properly manage protected health information and electronic health information has occurred
- Signed agreements for organizational security and privacy policies
- User account controls i.e., password protections, maximum failed login attempts, lockout periods after idle time, user audit logs, etc.
- Electronic device protections i.e., anti-virus or anti-malware software, firewalls, and network encryption
- Procedures for restricting remote access to APAC data
- Procedures for storing hard copy data
- Protection of derivatives of APAC data at the identifiable level
- If applicable, procedures for handling direct identifiers, including storing identifiers separately from other APAC data
- Procedure for identifying, reporting and remedying any data breach

b. Record level or derivative data that can be reidentified must be destroyed within 30 days of the end of the data use agreement, in a manner that renders it unusable, unreadable or indecipherable. What are your plans for destruction of the dataset and any potentially identifiable elements of the data once the data use agreement has expired?

CORE implements a data destruction process at the end of each data use agreement; project staff compile a data destruction log that details process and timeline for data destruction in accordance with the data use agreement.

SECTION 6: COST OF DATA

APAC staff will review your request and estimate the number of hours required to produce and validate the data. The cost of the data set, at $63 per hour of staff time, will then be determined. Payment must be received before the data will be provided. An invoice is available to facilitate payment. OHA's W-9 is available on request.

SECTION 7: CHECKLIST AND SIGNATURE

7.1 Checklist: Please indicate that the following are completed:

- ☑ 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
- ☑ All questions are answered completely
- ☑ Data Element Workbook is attached to email or printed application (data options and data element worksheets completed)
- ☑ IRB approval memo is attached to email or printed application, if applicable
- ☑ Data privacy and security policies for the requesting organization, and any third-party organizations are attached to the email or printed application

7.2 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 Date 3/8/21

Printed name Jennifer Rountree

Title Project Manager

Return the completed form with required attachments to APAC.Admin@state.or.us.

Completed forms may also be printed and mailed to: 421 SW Oak St., Suite 850 – APAC
Portland, OR 97204

Assessing the Direct and Indirect Effects of APMs in Primary Care

Natalie Kenton, ~~Hannah Cohen-Cline, PhD~~MS, MPH
PSJH Center for Outcomes Research and Education
Natalie.Kenton@providence.org~~Hannah.Cohen-Cline@providence.org~~

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VERSION DATE:

Version 3 /2-12~~5~~-2021

Version Date	Summary of Changes	Consent Change?
2-5-2021	Added description of how data sources will be linked	No

Table of Contents

Study Summary

Study Design	Program records and health care enrollment and claims data review
Primary Objective	To understand how CareOregon's Primary Care Payment Model (PCPM) has impacted health care quality and costs for their members and other patients at participating clinics
Secondary Objective(s)	To determine if there have been spillover impacts for patients with non-CareOregon coverage
Research Intervention(s)	Non-interventional
Study Population	Oregon adults with Medicaid, Medicare Advantage, or dual Medicaid/Medicare coverage provided by CareOregon; adults with non-CareOregon Medicaid or commercial insurance coverage who receive services at clinics which also serve CareOregon patients.
Sample Size	We estimate this study will include approximately 260,000 records
Study Duration for individual participants	N/A
Study Specific Abbreviations/ Definitions	PCPM – Primary Care Payment Model – the name of the primary care APM designed by CareOregon

1.0 Objectives

The purpose of this study is to evaluate a primary care Value Based Payment model in Oregon, the Primary Care Payment Model (PCPM) offered by the non-profit insurance company CareOregon. We aim to answer the following research questions:
RQ 1) How has the PCPM affected health care cost and quality at participating clinics?
RQ 2) To what extent has the PCPM had spillover impacts on cost and quality of care for clinic patients with sources of coverage other than CareOregon?

2.0 Background

The United States continues to struggle with high and rising health care costs and unacceptable variations in quality of care across demographic groups and geographic areas, as well as between different providers and plans. One way that purchasers have attempted to address these issues is through the use of value-based payments (VBPs) that incentivize cost-effective and high quality health care. While they are more common for specialty or inpatient care, VBPs have also been used to reward or otherwise support value in primary care. Implemented at scale, VBPs have the potential to drastically alter how care is delivered, what outcomes are expected, and the cost of care.

Yet evidence for the impact of VBPs on quality and cost outcomes in primary care is mixed, and existing VBP models and the research studies examining them vary widely in terms of context and design (Lin et al. 2016, Rosenthal et al. 2016). A recent systematic review of primary care reform models found no statistically significant changes on Medicare expenditures, outpatient ED visits, hospital admissions, and 30-day readmissions (Cohen et al., 2018). But results varied across geographic settings and different models, and Medicare expenditures were better controlled for individuals with greater health care needs, or who originally qualified for Medicare because of a disability. Further, there are gaps in the evidence for payment reform, including for non-federal programs, interventions in Western states like Oregon, and payment innovations in Medicaid and safety-net settings (McClellan et al. 2017). Research that accounts for potential spillover of reforms from one payer or delivery system to another is particularly needed, given the pace of experimentation with VBP and the interconnected nature of the United States health care market (Pham et al. 2017).

This study will evaluate a primary care VBP model in Oregon that has been implemented at scale across approximately 130 clinics in different geographic regions of the state. The PCPM is offered by the non-profit insurance company CareOregon and is designed to incentivize quality and reduce overall costs for both Medicaid and Medicare enrollees, including dual eligibles. CareOregon has previously used a number of strategies to incentivize the provision of high quality care; the current PCPM began in 2018 and offers retrospective, performance-based, per-member-per-month (PMPM) payments to participating clinics, as well as technical assistance to help build capacity for future VBP arrangements. The PCPM has two tracks in order to provide both introductory and more advanced VBP options. Clinics select from a menu of quality measures; the two tracks differ on the number and type of measures on the menu, as well as the payment clinics

can receive depending on the number of targets achieved (up to $4 PMPM in Track 1 and $12 PMPM in Track 2).

The project will promote greater value in health care by providing evidence about how and for whom VBPs in primary care might slow health care spending growth while maintaining quality. It will likewise provide insight into which – if any – aspects of a VBP model can prompt system changes in clinics that alter outcomes for populations who are not part of the VBP. Finally, by evaluating a VBP model implemented in many clinics across different geographic regions, including urban and rural settings, this study has the potential to inform decisions by other payers and in other states about how to shape future primary care VBPs.

3.0 Inclusion and Exclusion Criteria

The study population will be drawn from primary care clinics in Oregon. For RQ 1, all adults over 18 years of age enrolled in Medicaid, Medicare Advantage, or dually-enrolled in Medicaid and Medicare through CareOregon will be included; this is the target population for CareOregon's PCPM. RQ 2 will include all adults with commercial or non-CareOregon Medicaid coverage; this is the potential spillover population (Exhibit 1). We will exclude individuals with less than 6 months of health care enrollment in the study window (2015 -2019) to ensure we can calculate stable utilization estimates.

Exhibit 1. Study Population for RQ 1 and RQ 2

Population	RQ 1	RQ 2
CareOregon Medicaid	X	
CareOregon Medicare Advantage	X	
CareOregon Medicaid/Medicare duals	X	
Non-CareOregon Medicaid		X
Commercial plan		X

We will divide clinics into those that participated in CareOregon's PCPM (intervention, n=130) and those that did not participate (control, anticipated n=130). Control clinics will be matched to intervention clinics on size, geography, and payer mix where possible. Individuals will be designated in the intervention or control based on their clinic assignment. Designation as intervention or control will be assessed monthly; individuals who switch clinics or health plans may contribute information to the intervention and control groups and/or to both RQ 1 and RQ 2.

For RQ 1, we know that the clinics participating in the PCPM serve approximately 130,000 CareOregon members, and we anticipate control clinics will serve a similar number. We expect a greater number of individuals – but the same number of clinics – for RQ 2. Given the size of the study population and the lack of interaction between study staff and study participants, we are will requesting a HIPAA waiver of authorization to preclude needing to formally recruit and consent patients (see Section 13.0).

4.0 Vulnerable Populations

The study will only include adult participants age 18 and older; participants may include individuals who are incarcerated, pregnant, or vulnerable due to cognitive or contextual (e.g. financial) situation, incidental inclusion of these participants is likely. Because the

study will not include contact information or primary data collection among these individuals, we believe sufficient protections are in place.

5.0 Study-Wide Number of Subjects

We estimate this study will include review of approximately 260,000 records.

6.0 Study Timelines

Following IRB approval, CORE will coordinate with CareOregon and OHA respectively on data sharing agreements to obtain CareOregon program data and OHA enrollment and claims data; we anticipate the study will be completed 18-24 months after access to data has been obtained.

7.0 Procedures Involved

This study is exclusively a secondary data analysis. We will combine program data from CareOregon with health care enrollment and claims data from CareOregon and OHA's All Payer All Claims (APAC) and Medicaid databases to assess how specific measures of health care quality changed before and after the implementation of the PCPM in 2018. We will use a comparative interrupted time series design to compare outcomes for clinics participating in the PCPM to those that did not; we will further explore variation by gender, race and ethnicity, and preferred language. RQ 1 will focus on outcomes among CareOregon members, while RQ 2 will explore if these impacts spillover to non-CareOregon members.

Data sources and example measures are provided below in Exhibit 2. Program data will be used to determine intervention status, and enrollment data will be used to determine study eligibility. Demographics will be included as covariates; we will also explore disparities in PCPM impact by demographics. Claims data will be used to construct health care outcomes of interest, including: prevention quality indicators that assess quality of care for ambulatory sensitive conditions; utilization domains such as primary care, emergency department visits, inpatient stays, and outpatient mental health; and costs of health care, in total and by utilization category. APAC data will be linked at the record level to program data at CareOregon for the purpose of categorizing APAC claims data into claims originating from clinics that participated in the CareOregon PCPM program versus claims coming from clinics that did not participate in this program. Data will be linked by billing and performing provider NPIs.

Exhibit 2. Data Sources and Example Measures

Data Type/Source	Topics	Example Measures
CareOregon Program Data	**Patient characteristics**	Age Gender Race/ethnicity Primary language

		Geography Coverage type
	Health	Presence of chronic conditions
	Clinic information	Clinic participation in PCPM PCPM payment
	Utilization measures	Primary care Emergency department visits Inpatient stays Outpatient mental health
OHA Medicaid/APAC Data	**Patient characteristics**	Age Gender Race/ethnicity Primary language Geography Coverage type
	Health	Presence of chronic conditions
	Prevention quality indicators – Ambulatory sensitive	Asthma Angina Gastroenteritis Congestive heart failure ENT infections
	Utilization measures	Primary care Emergency department visits Inpatient stays Outpatient mental health
	Cost	Medical claims

8.0 Data Management (Analysis)

The study will use a comparative interrupted time series (CITS) design to assess values of a specific outcome before and after an intervention in both an intervention and control group. For all analyses, we will explore variation in impact across race, ethnicity, preferred language, and gender using subgroup analyses. We will also explore variation in impact based on clinic performance with the PCPM, as measured by their PMPM payments, using subgroup analyses.

All analysis will be done using SAS/STAT software version 9.4 or R version 3.3.3.

9.0 Risks to Subjects (Protection of Confidentiality)

There is no more than a minimal risk to participants, and the principal risk is a breach of privacy. The study team and institution have a robust plan in place to protect patient identifying information from improper use and disclosure including analysis of data without identifiers, physical security measures such as password protected computers, and allowing only authorized personnel to access data. Study data will be stored on PSJH computers and servers that are secured, maintained, and accessed in accordance with

PSJH policies. Identifiable information will not be used or disclosed to a third party except as described above, required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. Published or presented results will not contain PHI and will use only de-identified data. Upon completion of the study, all documents containing PHI will be destroyed at the earliest opportunity in accordance with PSJH data destruction policies.

10.0 Potential Benefits to Subjects

This study does not present any direct benefit to participants. However the study does provide an opportunity to gain a better understanding of the potential impact of the PCPM and, by extension, similar value-based payment models on health care quality and costs, an indirect benefit to participants.

11.0 Dissemination

The results of this study will be shared with CareOregon leadership, and will inform their decisions to make any changes to the PCPM program. CareOregon's external advisory groups, focused on VBPs and clinical strategy, will disseminate and use study findings. If the results indicate spillover effects on quality or costs for other payer groups, it will provide a strong argument for multi-payer collaboration to drive widespread improvements in health care value. CareOregon, as a member of various state and national VBP and quality improvement bodies such as the Oregon Health Leadership Council and National Health Care Payment and Learning & Action Network, is positioned to disseminate and apply findings and implications of this study at a state and national level.

12.0 Recruitment and Consent Process

Not applicable.

13.0 Waiver or Alteration of Informed Consent and HIPAA Authorization

This protocol includes a request for a Waiver of Informed Consent and a Waiver of HIPAA Authorization to allow for review of patient records for research purposes. This waiver will not adversely affect the rights or welfare of the participants, as individual level data is being used to analyze cost and quality of care, as indicated by prevention quality indicators and utilization, and significant steps have been taken to protect privacy. Collecting written consent and signed authorizations from each individual across more than 200 clinics throughout the state of Oregon would require significant staff resources that are unavailable. Significant staff time would be required to contact, train, and maintain oversight over staff that would be obtaining authorizations for the study, and significant clinical staff time would be redirected from patient care. As a result, the research would be impracticable without these waivers. Because the study will use measures of care quality that rely on individual service and diagnostic data, and intends to understand disparities by demographics as well as cost of care, the study would not be possible without use of individual level data (i.e., PHI).

There is no more than a minimal risk to participants, and the principal risk is a breach of privacy. The study team and institution have a robust plan in place to protect patient identifying information from improper use and disclosure including analysis of data without identifiers, physical security measures such as password protected computers, and allowing only authorized personnel to access data. Study data will be stored on PSJH computers and servers that are secured, maintained, and accessed in accordance with PSJH policies. Identifiable information will not be used or disclosed to a third party except as described above, required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. Published or presented results will not contain PHI and will use only de-identified data. Upon completion of the study, all documents containing PHI will be destroyed at the earliest opportunity in accordance with PSJH data destruction policies.

Providence
1801 Lind Ave SW, Renton, WA 98057

EXEMPT DETERMINATION

February 12, 2021

Dear Natalie Kenton:

On February 11, 2021, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title of Study:	Assessing the Direct and Indirect Effects of APMs in Primary Care
Study ID:	STUDY2021000089
Investigator Name:	Natalie Kenton, MS, MPH
Sponsor:	CORE
IND, IDE, or HDE:	None
IRB of Record:	PSJH IRB
Documents Reviewed:	• CareOregon Primary Care APM version 2 dated 05FEB2021

This letter represents the IRB determination of **exempt** for your project, as the involvement of human subjects is limited to one or more of the Exempt Categories identified in 45 CFR 46.104(d):

***CATEGORY 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: **(iii)** The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).*

Exempt status research does not have an expiration date and does not require continuing review.

Approval of this study includes: A Waiver of HIPAA Authorization was approved in accordance with 45 CFR 164.512(i)(2)(ii) on February 11, 2021 under Exempt Review Procedures.

Waiver is limited to only information in a patient's medical record relevant to the research, not the entire record.

The IRB is satisfied that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(A) (1) An adequate plan to protect the identifiers from improper use and disclosure;
(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

Please note that this determination is based upon the information submitted.

Any future revisions to this protocol must be submitted to the IRB before they are implemented in order for the IRB to determine whether or not the revision affects the status of this project.

Should there be any questions, please contact the PSJH IRB at irbsharedservices@providence.org

Sincerely,

PSJH IRB

Data Privacy and Security Policy

Attach a detailed description of your plans to manage access to the APAC data, personnel safeguards, technical and physical safeguards and administrative safeguards. Please describe and ensure the following:

• Designation of a single individual as the custodian of APAC data, either the Principal Investigator or staff listed in Section 1 of this application, who is responsible for oversight of APAC data including reporting any breaches to OHA and ensuring the data are properly destroyed upon project completion
• A security risk management plan applicable to APAC data
• Compliance with HIPAA and the HITECH Act
• Ensure that all parties accessing APAC data are listed on the data use agreement and agree to the same terms and conditions for securing and protecting APAC data
• Procedures to restrict APAC data access to only those individuals listed on the data use agreement
• Ensure training for personnel on how to properly manage protected health information and electronic health information has occurred
▪Signed agreements for organizational security and privacy policies
•User account controls i.e., password protections, maximum failed login attempts, lockout periods after idle time, user audit logs, etc.
•Electronic device protections i.e., anti-virus or anti-malware software, firewalls, and network encryption
•Procedures for restricting remote access to APAC data
•Procedures for storing hard copy data
•Protection of derivatives of APAC data at the identifiable level
•If applicable, procedures for handling direct identifiers, including storing identifiers separately from other APAC data
•Procedure for identifying, reporting and remedying any data breach

APAC Data Oversight

Our Principal Investigator for this project, Hannah Cohen-Cline, PhD, MPH, is responsible for the oversight of APAC data, including reporting of data breaches to OHA and ensuring the data are properly destroyed upon project completion.

Security Risk Management

CORE maintains administrative processes and procedures to ensure data security. CORE's contracts and agreements are reviewed by a legal and regulatory team who specialize in privacy laws and regulations governing research. This team periodically reviews project activities to ensure compliance.

- All projects are required to develop project-specific data management plans. The data management plan is written to ensure compliance with agreement/s and IRB Research protocol.
- All project staff is required to read and understand the project-specific data management plan, data sharing agreement/s, and applicable research protocols for projects that they are assigned to.

Compliance with HIPPA and the HITECH Act

In order to ensure that client privacy is protected and meets OHA's Health Insurance Portability and Accountability Act Of 1996, (HIPAA) privacy policies, review and agree to abide by the OHA administrative policies including:

OHA 100-001 General Privacy Policy

OHA 100-002 Individual Privacy: Permissible and Prohibited Use and Disclosure of Information Policy

OHA 100-003 Accessing Individual Records Policy

OHA 100-004 Recording and Accounting for Disclosures of Individual Information Policy

OHA 100-005 Individual Privacy: Restricting Access to Individual Information Policy

OHA 100-006 Amending Individual Records Policy

OHA 100-007 Individual Privacy: Alternate Communications Policy

OHA 100-008 Using the Minimum Necessary Standard for Individual Information Policy

OHA 100-009 Administrative, Technical, and Physical Safeguards Policy

DHS|OHA 100-010 Release & Waivers for Use and Disclosure for Research and Reporting Policy

DHS|OHA 100-011 De-identification of Individual Information and Use of Limited Data Sets Policy

OHA 100-012 Enforcement, Sanctions, and Penalties for Violations of Individual Privacy Policy

OHA 100-013 OHA Business Associate Relationships Policy

(See https://www.oregon.gov/oha/FOD/OIS-ISPO/Pages/Policies.aspx). Ensure that the description meets Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996, 42USC 1320d et. seq, and, when applicable, the Substance Abuse and Mental Health confidentiality regulations outlined in Part II of the Department of Health and Human Services, Public Health Service, 42CFR Part 2; ORSs 179.505, 192.535, 192.547.

CORE will use the following procedures to ensure secure storage of the data set:

- Use agency-controlled (Providence Health & Services-approved) secure file transfer software (such as SFTP) to transfer data from state agency to the research team*
- Store data set on a secure network in password-protected files accessible only on a password-protected computer
- Limit access to data files from the data set containing personally identifiable information to only necessary CORE staff
- Hard drives and computers used to store data set are located in a locked and secure area, with access controlled via key or key card.
- Control access to the data set on portable devices and media with user ID and complex password, with devices set to automatically lock after a period of inactivity
- Report results only in aggregate form
- In order to protect subject identity during analysis, study participants will be assigned a separate ID number. Program data and the data set will be linked using the study ID in preparation for analysis. The link between the study ID and the data set will be stored on a secure Providence Health & Services network drive accessible only by CORE staff on password-protected computers.
- Subject confidentiality will be maintained through the destruction of personally identifiable information. Records containing personally identifiable information stored on the network, portable drive or disk, and/or computer hard drive will be erased using a software application or utility designed to remove or "wipe" data from storage. We do not anticipate paper records, but in the event that there are paper records, they will be shredded on site and/or disposed of by a contracted vendor certified for the secure destruction of confidential information

*Note: On previous Medicaid claims data requests CORE developed with OHA a process for CORE to perform data extracts from our in-house OHA Medicaid data system (maintained for Contract #145556 under Agreement #151436).

CORE has reviewed and agrees to abide by all policies listed above.

Procedures to Restrict APAC Data Access

All parties accessing APAC data will be listed on the data use agreement and will agree to the same terms and conditions for securing and protecting APAC data. Only those individuals listed on the Data Use Agreement will have access to APAC data.

CORE maintains separate databases, schemas, and/or network folders for each contract and its corresponding data use agreement(s). Data are partitioned by project and access is granted at the project level. Specific access to project data locations is granted based on one's role on a project (see SOP: File Folder Permissions Control). CORE administers its own role-based access control for electronic data locations (e.g., CORE-dedicated SQL Server, CORE-dedicated network drive, etc.).

Data Management Training

All CORE staff is required to complete enterprise-standard trainings through Providence St. Joseph Health (PSJH) that include the following topic areas:

- Data security and privacy protections
- Integrity and Compliance
- Research Ethics and Protection of Human Subjects
- Conflict of Interest in Research (COI) - as applicable

Additional CORE-specific trainings include:

- Annual department compliance training
- Ad-hoc project-specific training

Recurrent training ensures that CORE staff is aware of the legal protections in place for data (e.g. protected health information/HIPAA, Privacy Act, FERPA, 42 CFR Part 2, etc.), the obligations for compliance with state and federal regulations, relevant guidance issued by federal and state agencies (e.g., OHRP, FDA, SAMHSA), local and institutional systems in place to support data privacy, and our contractual obligations for data privacy on a project-specific basis (See CORE's internal guides on using HIPAA, FERPA, and Part 2 data).

CORE maintains signed agreements for organizational security and privacy policies.

Data Security Protections

Hardware. PSJH computers, laptops, and virtual machines are secured using multifactor authentication and hardened passwords. Password resets using two-factor authentication are required on all PSJH active directory user accounts (network logon accounts) annually and are required to meet minimum security criteria that conform to PSJH Enterprise Information Security standards. Computers used to access data are fully encrypted and password protected and automatically locks after a set idle period. Only encrypted USBs are permitted.

Per PSJH RIS 801.11 Acceptable Use policy, when accessing PSJH confidential information from an off-site location, users must use reasonable safeguards to ensure that the work session cannot be viewed by unauthorized individuals. Personally-owned devices may not store PSJH confidential information unless authorized by Information Services and may only be used to access PSJH confidential information through approved access methods (e.g., GlobalProtect, Citrix, or other approved remote desktop access).

Software. PSJH has controls in place to detect, prevent, report and respond to malicious software and malicious code. CORE employees may only use PSJH and CORE approved software applications. All files created using approved software and containing data will be stored on CORE's SQL Server database, the network drive, or approved cloud-based applications.

Procedures for Handling Direct Identifiers

CORE will strip all individually identifiable information from the linked dataset, producing the de-identified dataset for analysis. The key that links the two data sources will be stored in a password-protected file on a secure PSJH network database, accessible only using password-protected computers. Only key project staff responsible for data management and analysis will have access to this key.

Procedures in the Event of a Data Breach

CORE staff adhere to the PSJH Protected Health Information Breach Notification Policy, PROV-PSEC-814. CORE will provide notification of any Breaches of Unsecured protected health information (PHI) in accordance with the requirements of the federal HITECH Act or its implementing regulations and any other relevant laws.

Data Element Workbook

DATA TYPES	GENERAL CONTENT OUTLINE	JUSTIFICIATION
MEMBER DATA/ PATIENT CHARACTERISTICS	Medicaid or System ID	Links member information across data tables
	Year of Birth	Links claim information to other data sources and calculates member age for demographics
	~~RUCA~~ Zip code	~~Distinguishes rural-urban area codes~~
	Gender	Population and help link to other data sources demographics
	Race/ethnicity	Population demographics and help link to other data sources
	Preferred language	Population demographics and help link to other data sources
	Enrollment Start Date	Calculates length of eligibility for PMPM calculations
	Enrollment Term Date	Calculates length of eligibility for PMPM calculations
	Rate Category	Identify members' reason for eligibility
	~~Payor Name or~~ CareOregon CCO Flag	Identifies CCO~~ or Insurer~~
	Payor Type	Medicare, Medicaid, Commercial, Government, etc
	Primary Insurance Indicator	
MEDICAL CLAIMS DATA (physical, mental, dental)	Medicaid ID or System ID	Links member information across data tables
	Unique Encounter ID	Links member information across data tables
	Start date of service	Establishes unique EVENTS; Delineates PRE/POST claims

Commented [OJ1]: RUCA not available. Requester can crosswalk from zip code.

Commented [OJ2]: No payer names. We can set a flag for CareOregon enrollment.

	End date of service	Establishes unique EVENTS; Delineates PRE/POST claims
	Billing Provider ID	Identifies unique providers
	Service Provider ID	Identifies unique providers
	Service Provider Taxonomy	Identifies unique providers
	Service type/type of bill	Part of categorizing claims into types of care (ED, IP, etc.)
	Claim status (paid, denied, mgd care encounter)	Categorizes status of claim
	Place of service	Part of categorizing claims into types of care (ED, IP, etc.)
	Diagnosis Codes	Categorizes claims into types of care and identifies chronic conditions
	Modifier Codes	Provides supplementary information on procedures performed
	Revenue code	Part of categorizing claims into types of care (ED, IP, etc.)
	ICD Procedure codes	Part of categorizing claims into types of care (ED, IP, etc.)
	HCPCS/CPT Procedure Codes	Part of categorizing claims into types of care (ED, IP, etc.)
	~~Total~~ billed~~,~~ allowed and paid costs for claim	Calculates PMPM costs
	~~Coinsurance~~	~~Identifies~~ plans~~.~~
	Claim Line Number	Identifies unique claims
	Discharge Status	Categorizes discharge of claim
	CCO ID	Identifies CCO that paid the claim.
Pharmacy Claims Data	Claim ID number	Identifies unique claims
	Pharmacy NPI	Identifies unique providers
	Claim Status	Categorizes status of claim
	Prescriber ID	Identifies unique providers
	NDC	Identifies type of drug dispensed
	Date filled	Delineates PRE/POST claims
	Quantity dispensed	Determines dosage and proportion days covered.
	Payment	Calculates PMPM costs
	Ingredient cost	Calculates PMPM costs

Commented [OJ3]: No.

Commented [OJ4]: Wrong.

Commented [OJ5]: Recommend that requester add this field.

	Dispensing fees	Calculates PMPM costs
	Patient pay amount	Calculates PMPM costs
Provider Data	Provider ID	Link to Rendering/Billing provider IDs
	Provider NPI (if different than plan provider ID) or Participating Provider Flag	Link to Rendering/Billing provider IDs and identifies program participation
	Provider Taxonomy or specialty type	Part of categorizing claims into types of care (PCP, OPMH etc.)

New or Amended APAC Data Request Review (custom or OHA Business Associate)

Staff Reviewer: Oliver

DRTS Number: 5551

Date review completed: 4/9/2021

	Yes	No	N/A	Need more information
Is this a new APAC request?	X			
New APAC Request (skip to next section if amendment request):				
1.1 Project staff contact information provided	X			
1.2 Project technical staff information provided	X			
2.1 Project summary provided with adequate detail to identify a specific unambiguous project	X			
2.2 Research questions provided with adequate detail	X			Evaluation of APMs for CareOregon.
2.3 Described planned products and reports derived from requested data	X			Report to CareOregon.
2.4 Project begin and end date provided	X			4/1/2021 – 13/31/2022
2.5 Acknowledgement that APAC data cannot be reused beyond the DUA	X			
2.5 Acknowledgement that data cannot be shared beyond the DUA	X			
3.1ab Data request purpose box checked & description	X			Research
3.2 Checked box for level of data identifiers	X			
3.3 IRB application, approval memo, end date	X			
4.1 Completed data elements workbook			X	Submitted an alternate format.
4.2 Adequately described how the data elements requested are the minimum necessary	X			
5.1 Plan provided to prevent re-identification	X			
5.2ab Plan to link APAC data to other data source	X			Link providers by NPI.
5.2c Requests OHA to link APAC to other data			X	
5.2d Detailed data linking plan provided			X	
5.3 Provided adequate description of data management, security and data destruction plan	X			
Passes Minimum Necessary Review	X			
Recommend management approval	X			
Amendment request for previously approved APAC request (not needed for staff change only):				
Any new data elements requested				
Any new years of data requested				
Any new project purpose or research questions				
Description of new project purpose				
Completed data elements workbook				
IRB application and approval memo				
Passes Minimum Necessary Review				
Recommend management approval				